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WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, November 18, 2008
9:00 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 294, 359, 362, 451, 530, 531, 532, 534, 536, 550, 591, 630, 831, and 842

RIN 3206–AK88

Changes in Pay Administration Rules for General Schedule Employees

AGENCY: U.S. Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The U.S. Office of Personnel Management is issuing final regulations on pay setting rules for General Schedule employees. The final regulations revise the interim regulations by making a number of technical modifications, corrections, and clarifications.

DATES: The regulations are effective on December 8, 2008.

FOR FURTHER INFORMATION CONTACT: Carey Johnston by telephone at (202) 606–2858; by fax at (202) 606–0824; or by e-mail at *pay-performance-policy@opm.gov.*

SUPPLEMENTARY INFORMATION: On May 31, 2005, the U.S. Office of Personnel Management (OPM) published interim regulations (70 FR 31278) to implement section 301 of the Federal Workforce Flexibility Act of 2004 (Pub. L. 108–411, October 30, 2004), hereafter referred to as ''the Act.'' On December 19, 2005, OPM corrected minor errors in the interim regulations (70 FR 74995). Section 301 of the Act amended provisions in 5 U.S.C. chapter 53 relating to the administration of special rates, locality rates, and retained rates. The statutory and regulatory changes were designed to correct a variety of pay administration anomalies that resulted in unfair pay reductions or unwarranted pay increases, to allow locality rates and special rates to be treated in similar ways, and to improve the operation of the special rates program.

The 60-day comment period ended on August 1, 2005. We received comments from eight agencies, one union, and several individuals. This **Federal Register** notice addresses the comments we received on the interim regulations and makes a number of technical revisions and clarifications, which are summarized below. In addition, we issued guidance, including examples, to address many of the questions we received about the interim regulations. We encourage agencies and employees to review these materials on OPM's Web site at *http://www.opm.gov/oca/pay/HTML/factindx.asp.* We will continue to provide additional guidance on pay administration, as necessary.

Comment Applicable to the Effective Date

One commenter objected to the effective date of the interim regulations. The commenter stated he was a manager who had to redo personnel actions because of the retroactive implementation of the rules. The commenter stated OPM should have published the rules before they became effective.

Section 301(d) of the Act provided that section 301 would take effect the first day of the first pay period beginning on or after the 180th day of enactment of the Act. The 180th day after enactment was April 28, 2005, and the first day of the first pay period following that date was May 1, 2005. On November 1, 2004, OPM issued a memorandum to agencies notifying them of changes resulting from the Federal Workforce Flexibility Act of 2004. (See *http://www.opm.gov/oca/compmemo/2004/2004-22.asp.*) On April 25, 2005, OPM issued an additional memorandum to agencies notifying them of changes to special rate schedules and special rate entitlements resulting from the Act. (See *http://www.opm.gov/oca/compmemo/2005/2005-06.asp.*) While OPM did not publish interim regulations until May 31, 2005, the regulations became effective on May 1, 2005, in order to implement the statutory changes mandated by the Act. The regulations must be applied prospectively from that date. OPM has no authority to waive or change this statutory effective date.

Comments Applicable to Senior Executive Service Saved Rates

An agency recommended that OPM revise § 359.705, which provides the rules on establishing, adjusting, and terminating saved rates for former members of the Senior Executive Service (SES) who are guaranteed placement in a position covered by another pay system. The agency suggested that OPM clarify that an employee who is placed under 5 CFR part 359, subpart G, in a General Schedule (GS) position is not subject to the limitation on GS basic pay in 5 U.S.C. 5303(f) of the rate for level V of the Executive Schedule (EX). This statement was included in former § 359.705(c) as in effect prior to May 1, 2005. In addition, a commenter requested that OPM clarify what pay limitations apply to SES saved rates.

Under § 359.705(a), an appointee placed under subpart G in a position outside the SES is entitled to receive basic pay at the highest of (1) the rate of basic pay in effect for the position in which the appointee is being placed; (2) the rate of basic pay currently in effect for the position the appointee held immediately before being appointed to the SES; or (3) the rate of basic pay in effect for the appointee immediately before removal from the SES. Under 5 U.S.C. 5382, the maximum SES rate for an agency with a certified performance appraisal system is the rate for EX–II, and the maximum SES rate for an agency without a certified performance appraisal system is the rate for EX–III. Consistent with the purpose of the SES saved pay provision, we are revising § 359.705(c) to clarify that an employee placed under subpart G in a position outside of the SES pay system is subject to the limitation on SES pay in 5 U.S.C. 5382 of the rate for level II of the Executive Schedule.

Comments Applicable to General Schedule Basic Pay Setting

Definitions of Demotion and Promotion (§ 531.203)

A commenter recommended that OPM revise the definitions of *promotion* and *demotion* in § 531.203 to cover situations involving movements between pay systems. Specifically, the commenter would like the definitions to be the same as or similar to the definitions of *promotion* and *change to*

lower grade in the Guide to Processing Personnel Actions (GPPA).

We are not adopting this recommendation. The same or similar terms may be used and defined in different ways in the GPPA and the CFR, depending on the purpose of the term and statutory requirements. In the GPPA, a *promotion* is an employee's movement to a position at a higher grade level within the same job classification system and pay schedule, or to a position with a higher rate of basic pay in a different job classification system and pay schedule. In § 531.203, a *promotion* is a GS employee's movement from one GS grade to a higher GS grade while continuously employed. It is necessary for the definition of *promotion* in § 531.203 to be more narrow than the definition of *promotion* in the GPPA because the two-step promotion rule in 5 U.S.C. 5334(b) and 5 CFR 531.214 applies only to GS employees who are promoted to a higher grade under the General Schedule without a break in service. Similarly, the demotion rules in § 531.215 apply only to employees who move from one GS grade to a lower GS grade while continuously employed. As a result, we cannot revise the definitions of *promotion* and *demotion* in § 531.203 to be consistent with the GPPA definitions. Agencies need to be aware of these different definitions. For example, an employee who moves from a non-GS pay system to the GS pay system may receive an increase in basic pay, and the nature of action may be documented as a *promotion* as that term is defined in the GPPA. However, for GS pay-setting purposes, the movement would be considered a *transfer* or *reassignment* as those terms are defined in § 531.203, depending on whether the movement occurs within the same agency or between agencies.

Superior Qualifications and Special Needs Pay-Setting Authority (§ 531.212)

An agency recommended that OPM clarify what constitutes a candidate's existing salary in § 531.212(c)(2). Section 531.212(c) provides the factors an agency may consider, as applicable in the case at hand, to determine the step at which to set an employee's rate of basic pay using the superior qualifications and special needs pay-setting authority. The agency stated it would be helpful to clarify whether bonuses or overtime premium pay should or could be a factor in the candidate's existing salary.

We are not adopting this recommendation. Bonuses or overtime pay could be a factor in determining the step at which to set an employee's payable rate of basic pay, since those payments could be considered ''other relevant factors'' under § 531.212(c)(10). However, this is a matter that must be decided at the agency level.

Setting Pay Upon Promotion (§ 531.214)

A commenter requested clarification on why the locality pay associated with his previous worksite was not considered in setting his pay upon promotion at his new worksite. He stated that the interim regulations provide that locality rates are considered basic pay in applying GS pay administration provisions (e.g., GS promotion provisions).

When an employee's official worksite is changed to a new location where different pay schedules apply, the agency must convert the employee to the applicable pay schedule(s) and rate(s) of basic pay for the new official worksite based on the employee's position of record before the promotion, as provided in § 531.205, before processing a simultaneous promotion action. See § 531.214(b) and 5 U.S.C. 5334(g). Therefore, the geographic conversion rule must be applied before the use of any applicable locality rates in applying the GS pay-setting rules. A major objective of the geographic conversion rule is to provide the same pay result that would have occurred if the employee in question had moved laterally without a change in position (such as grade) to the new geographic location and then underwent a position change.

An agency recommended OPM revise § 531.214(b) to state that the rate resulting from the geographic conversion rule must be used as the existing rate in processing a promotion. While the converted rate is used as the *existing rate*, we are not adopting the recommendation because the geographic conversion rule is adequately stated in §§ 531.205, 531.206, and 531.214(d)(1). We also note that the definition of *existing rate* in § 531.203, which is a term used in § 531.214, includes ''For example, the *existing rate* immediately before a promotion action must reflect any geographic conversion under § 531.205 and any simultaneous within-grade increase or quality step increase.''

Three commenters, who were apparently entitled to special rates prior to May 1, 2005, expressed concerns that their basic pay had decreased upon promotion. In the past, special rates were viewed as a rate of basic pay replacing the corresponding GS base rates of pay. Under current law and regulations, a special rate is viewed as consisting of a base rate (GS rate or law enforcement officer special base rate) and a special rate supplement—similar to the base-plus-supplement concept we have long used for locality rates. In other words, special rate employees have the same base rates as non-special rate employees, but have a different supplement. Changing the way special rates are documented is not a reduction in basic pay. Special rates are still considered basic pay for the purposes specified in § 530.308, including retirement contributions and benefits.

It appears the commenters were promoted either from or to positions where special rates had recently been terminated. Section 301 of the Act amended 5 U.S.C. 5305(h) so that an employee is not entitled to a special rate if he or she is entitled to a higher rate of basic pay under another authority (e.g., a locality rate or a retained rate). The termination of these special rates did not result in a loss in pay for any covered employees, since all affected employees continued to receive the higher locality rate to which they were otherwise entitled.

Furthermore, by law, OPM was required to issue regulations governing the extent to which special rates and locality rates would be used in applying the GS promotion rule. (See 5 U.S.C. 5334(b), as amended by section 301(a)(3) of the Act.) Under the law and regulations in effect before May 1, 2005, a special rate employee promoted to a grade with underlying special rates (where locality rates were higher at all steps of the grade) would have received a higher pay increase than the normal GS promotion increase. Section 301 of the Act was designed to correct this anomaly and restore fairness by ensuring that locality rates would be considered in applying the promotion rule. This intent was documented in the legislative history of the Act:

> Section 301(a)(3)(A) would amend Sec. 5334(b), which covers employee entitlement to basic pay rates upon promotion * * *. OPM would prescribe regulations on the circumstances under which and the extent to which special rates or locality-adjusted rates would be considered to be basic pay in applying this subsection. This amendment would authorize OPM to determine how special rates and locality rates should be used in applying the two-step promotion rule (upon promotion to a higher General Schedule grade, an employee is generally eligible for a pay increase at least equal to two steps in the grade from which he or she is promoted) in order to remedy existing pay administration problems arising in situations involving promotions, special rates, and retained pay when locality pay is not considered to be basic pay. This amendment would also allow OPM to prescribe regulations to avoid current windfalls resulting from employees receiving a two-step promotion (based on the higher special

rate schedule) and then receiving locality pay on top of the adjusted rate.

H.R. Rep. No. 108–733 (2004), 2005 U.S.C.C.A.N. 2289, 2298–2299.

The promotion rules in § 531.214 meet the statutory requirements and the Congressional intent of the Act and further changes are unnecessary.

One of the commenters requested to be ''grandfathered in,'' stating that changes should apply to new personnel entering the workforce. OPM is not able to accommodate any requests to be grandfathered in because the Act contained no special grandfathering provisions. Pay actions must be processed using the law and regulations that are in effect at the time of the pay action.

Using a Highest Previous Rate Under the Maximum Payable Rate Rule (§ 531.221–223)

An individual objected to the revised rule in § 531.221 of the interim regulations for determining an employee's maximum payable rate when the employee's highest previous rate is a rate under the Federal Wage System (FWS). The individual stated that the revised rule is neither consistent with the President's intention for locality pay nor legal. The individual also stated that even though he received an increase in total pay (i.e., basic pay and locality pay), his basic pay was reduced.

We do not agree that the current maximum payable rate rule is inconsistent with Presidential or Congressional intent. In applying the former maximum payable rate rule in cases where an employee was moving from an FWS position to a GS position, a highest previous rate based on an FWS rate of pay was compared to the underlying GS base rate range for the employee's grade, excluding locality pay. The maximum payable rate was set at the lowest step rate in the underlying GS base rate range that equaled or exceeded the highest previous rate, not to exceed the rate for step 10 of the GS grade. This process of comparing a locality-based FWS rate to a GS rate range that did not include a locality adjustment resulted in substantial pay increases for affected employees—an anomalous result not intended by the maximum payable rate rule. At the same time, in cases where an employee was moving from a GS position to an FWS position, the employee's highest previous rate was based on the GS base rate, excluding locality pay, and was compared to the locality-based FWS rate range. This process resulted in an FWS rate that was significantly lower than the employee's former GS locality rate, which also was an anomalous result not intended by the FWS highest previous rate rule. Both types of anomalies have been corrected under the current OPM regulations, which require that GS locality rates be considered in applying these pay-setting rules.

Under the current GS maximum payable rate rule, when an employee moves from an FWS position to a GS position, his or her highest previous rate is compared to the GS rate range for the employee's grade, including locality pay. The maximum payable rate is set at the lowest rate in the locality rate range that equals or exceeds the highest previous rate. The current rule more logically compares a locality-based FWS rate of pay to a GS locality rate range to determine the employee's maximum payable rate and avoids substantial pay increases not intended by the maximum payable rate rule.

A commenter requested clarification regarding how the maximum payable rate rule applies to employees in the GM pay plan. (A GM employee is a GS employee who was formerly covered by the Performance Management and Recognition System under 5 U.S.C chapter 54 on October 1, 1993, and became covered on November 1, 1993, by section 4 of Public Law 103–89, the Performance Management and Recognition System Termination Act of 1993.) As noted in § 531.221(a)(1), special rules for GM employees are provided in § 531.247.

In the Supplementary Information for the interim regulations published May 31, 2005, we invited comments on a proposal to establish a regulatory time limit on the period of time from which an employee's highest previous rate may be drawn. The purpose of the proposed time limit was to reduce the administrative burden associated with identifying an employee's highest previous rate over an entire career and comparing the highest previous rate with pay schedules in effect many years ago.

We received mixed reactions regarding establishing a regulatory time limit. Two agencies supported this proposal and three agencies did not support the proposal. Two agencies stated it would be better if the time limit was discretionary. One agency did not think a time limit was necessary, but stated, if a time limit is established, OPM should mandate a time limit rather than allowing each agency to establish its own policy. The agencies also expressed different views regarding the length of the time limit.

We have decided not to establish a regulatory time limit. We note that each agency continues to have discretion to set an employee's pay at any rate equal to or less than the maximum payable rate; thus, an agency could take into account the recentness of an employee's highest previous rate in exercising that discretion.

An agency suggested that OPM specify that a rate of pay earned during military service may not be used as an employee's highest previous rate. We agree. While § 531.222(a)(1)(i) already provides that a highest previous rate must be a ''rate of basic pay previously received * * * while employed in a civilian position * * *'', we have added a new paragraph § 531.223(i) to expressly exclude a rate of pay received as a member of the uniformed services from rates of pay that may be used as the highest previous rate. ''Uniformed services'' is defined in 5 U.S.C. 2101.

A commenter requested clarification on determining an employee's maximum payable rate when the employee has a retained rate under part 536. We have added a new paragraph § 531.223(j) excluding retained rates from rates of pay that may be used as the highest previous rate. Under part 536 of the interim regulations, a retained rate is based on an employee's highest applicable rate, including any applicable locality rate after any geographic conversion. This clarification is consistent with the policy in effect before May 1, 2005, that a locality-adjusted retained rate could not be used as a highest previous rate. The agency may use the rate of pay the employee received immediately before his or her entitlement to pay retention as the employee's highest previous rate.

Comment Applicable to Removal of Special Pay Adjustments for Law Enforcement Officers

The interim regulations removed subpart C of part 531, which dealt with special geographic adjustments for law enforcement officers (LEOs) under section 404 of the Federal Employees Pay Comparability Act of 1990, because all of the special geographic adjustments for LEOs have been surpassed by regular locality payments under 5 U.S.C. 5304. One commenter asked hypothetically whether an employee would become entitled to special geographic adjustments for LEOs if locality payments were to decrease and fall below the LEO special geographic adjustments. Although such a scenario seems unlikely under current circumstances, OPM would address such a situation by regulation if it were to occur.

Comment Applicable to General Schedule Within-Grade Increases

One agency asked if an increase in pay an employee receives when moving from a non-GS pay system to the GS pay system would be an equivalent increase, as determined under the rules in § 531.407. Section 531.407 provides a list of personnel actions that are considered equivalent increases for the purpose of determining when GS employees are entitled to their next within-grade increase. The within-grade increase rules take into account personnel actions that occur within the GS pay system and within a non-GS pay system (for the purpose of determining when an employee is eligible to receive a within-grade increase after movement from a non-GS to a GS position). Personnel actions that occur within the GS pay system are listed in § 531.407(a). Personnel actions that occur within a non-GS system are listed in § 531.407(b).

We have revised § 531.407(b) to clarify that the personnel actions listed in paragraph (b) must have occurred in the non-GS pay system. If an employee receives an increase in pay as a result of moving between non-GS pay systems, from a non-GS to the GS pay system, or from the GS pay system to a non-GS pay system, such personnel actions are not considered equivalent increases.

However, when certain personnel actions occur simultaneously with a pay system change under authority of the non-GS pay system and those personnel actions are within-level or within-range increases that result in forward movement in the rate range that applies to the employee's new position, such actions are considered equivalent increases. This would include, for example, a pay increase that is paid simultaneously with a pay system change to account for the value of accrued within-grade increases under the former system or to provide a promotion-equivalent increase. We have revised § 531.407(b)(2) to clarify that such a simultaneous personnel action is considered an equivalent increase. We also have revised § 531.407(b)(2)(ii) to clarify that placement under a new basic pay schedule within the same pay system is not an equivalent increase when such placement results in a nondiscretionary basic pay increase to account for occupational pay differences.

Comments Applicable to Locality Rates

Determining an Employee's Official Worksite (§ 531.605)

In the Supplementary Information for the interim regulations published on May 31, 2005, we invited comments on a proposal to revise the regulations so that, in cases involving a temporary promotion or reassignment, the official worksite for the employee's permanent position of record would be considered to be the official worksite of the temporary position of record for pay-setting purposes (unless the employee receives relocation benefits under 5 U.S.C. 5737).

One agency supported the proposal. Another agency suggested revising the proposal to provide agencies with the flexibility to determine whether or not the official worksite should be changed, depending on which location would provide the employee with the greatest pay entitlement. Revising the proposal as suggested would not be equitable to an employee who is permanently reassigned or promoted to a different location and cannot receive the same benefit due to the geographic conversion rule in § 531.205. A third agency summarized conflicting comments it received from its subcomponents on this issue.

We will consider these comments further as we review the need for changes in OPM requirements related to documentation of personnel actions. Accordingly, we have not included the proposed changes in these final regulations.

The interim regulations implemented changes in determining an employee's official worksite that OPM proposed on January 5, 2005, as part of a larger notice of proposed rulemaking (70 FR 1068). Under § 531.605(a), the official worksite generally is the place where the employee regularly performs his or her duties. We are making clarifying revisions in § 531.605(a) to provide that, when an employee's work involves recurring travel or the work location varies on a recurring basis, the official worksite is the location where the work activities for his or her position of record are based, as determined by the employing agency, subject to the requirement that the official worksite must be in a locality pay area in which the employee regularly performs work.

Under § 531.605(d) (as issued in the May 2005 interim regulations), a teleworker must report to the regular worksite at least once a week on a regular and recurring basis in order for the regular worksite to be the employee's official worksite. One agency recommended removing this portion of the regulations because of the ''potentially adverse impact that the interim regulations will have on employees who are currently teleworking from outside their locality pay area.''

We do not agree. It is not consistent with the law (5 U.S.C. 5304) to pay locality payments based on an employee's regular worksite if the employee generally does not perform his or her duties in that locality pay area. We do not see any reason to remove the requirements in § 531.605(d). The public had an opportunity to comment on the proposed regulations issued in January 2005, and we addressed the comments we received on those proposed regulations in the Supplementary Information accompanying the interim regulations issued in May 2005.

Another agency suggested that OPM delete ''at least once a week'' from the regulation and allow the agency to determine what constitutes having an employee report to the official worksite on a regular and recurring basis. We do not agree that the determination of an employee's official worksite should be made by individual agencies without criteria or parameters. Providing certain specific criteria in regulations is essential to ensure that agencies pay employees fairly and consistently, especially in situations such as telework arrangements. However, we have revised § 531.605 to replace the once-a-week standard with a twice-a-pay-period standard. Revised § 531.605 allows an agency to treat the regular worksite for a telework employee's position of record as the employee's official worksite if the employee works at the regular worksite for the employee's position of record at least twice each biweekly pay period on a regular and recurring basis. We are identifying additional examples of temporary situations in which an agency may make an exception to the twice-a-pay-period standard: (1) An extended period of approved absence from work, (2) a period during which the employee is in temporary duty travel status away from the official worksite, or (3) a period during which an employee is temporarily detailed to work at a location other than a location covered by a telework agreement. These changes will provide agencies some additional flexibility in determining official worksites for teleworkers while continuing to ensure such determinations are made consistently and meet the intent of the locality pay law.

Relationship of Locality Rates to Other Pay Rates (§ 531.608)

A union and an agency requested that OPM waive § 531.608 for certain Department of Defense civilian engineers until implementation of the National Security Personnel System

(NSPS) in October 2006. The agency noted that an employee's entitlement to a special rate is terminated when an employee's locality rate exceeds a corresponding special rate; the agency was concerned how this loss of entitlement to the special rate would affect the employee's promotion entitlement. The agency also expressed concerns about possible recruitment and retention problems.

OPM has no authority to delay the effective date of this regulation until implementation of NSPS. The provisions regulated under § 531.608(b) are required by law at 5 U.S.C. 5305(c). See the discussion in the ''Comment Applicable to the Effective Date'' section within this Supplementary Information. Also see the discussion of promotions involving special rates under ''Comments Applicable to General Schedule Basic Pay Setting'' within this Supplementary Information. To address any existing or likely staffing problems, an agency may request that OPM establish or increase special rates under § 530.305 or use other tools such as recruitment and retention incentives under 5 CFR part 575.

Treatment of Locality Rates as Basic Pay (§ 531.610)

In the Supplementary Information for the interim regulations published May 31, 2005, we invited comments on whether the final regulations should make a change in the treatment of locality rates in computing danger pay allowances and post differentials. Since August 2004, OPM regulations have provided that locality rates are considered basic pay in computing danger pay allowances and post differentials in foreign areas for which the State Department has authorized danger pay allowances, as long as the employee's official worksite is located in a locality pay area (i.e., within the 48 contiguous States or the District of Columbia). (See 69 FR 47353, August 5, 2004.) Employees receiving locality rates are eligible for post differentials only when they are temporarily detailed (including a work assignment while in temporary duty travel status) to a post differential area for at least 42 consecutive days.

OPM received comments on the August 2004 interim regulations from three agencies that a locality rate should be considered basic pay for the purpose of computing danger pay and post differentials for all employees on temporary duty assignments at overseas posts designated for post differentials as well as for those posts designed for danger pay.

OPM solicited comments in the May 2005 interim regulations on whether it is appropriate to continue the current rules and consider special rates as basic pay in computing post differentials where danger pay allowances do not apply, while locality rates are not considered rates of basic pay in this same situation. Two agencies responded that the difference in treatment is not appropriate because it is not consistent with the intent of the new pay administration regulations, which is to treat both locality rates and special rates as supplements to the General Schedule. OPM also solicited comments on whether we should maintain the existing policy of using detailed employees' locality rates in computing danger pay allowances and post differentials only in danger pay areas or establish a new policy requiring the use of detailed employees' locality rates to compute post differentials authorized in any area (regardless of whether danger pay applies). Three agencies clearly supported extending the policy to other post differential areas. No commenters opposed the proposals.

We agree with the commenters. We are revising § 531.610(f) to treat locality pay as basic pay for the purpose of computing danger pay under 5 U.S.C. 5928, post differentials for foreign areas under 5 U.S.C. 5925(a), and post differentials for nonforeign areas under 5 U.S.C. 5941 when an employee's official worksite is in a locality pay area.

Miscellaneous Provisions (§ 531.611)

Section 531.611(a) of the interim regulations provides that a locality rate may be paid only for those hours for which an employee is in a pay status. An agency requested that OPM clarify the situations where an employee is in a pay status.

An employee is in a pay status during the hours for which an employee receives pay, such as when the employee works or uses paid time off. This provision was in the former § 531.606(d). Under 5 U.S.C. 5304(c)(2)(B), a locality-based comparability payment must ''be paid in the same manner and at the same time as the basic pay payable to such employee pursuant to any provision of law outside of this section.''

Comments Applicable to Grade and Pay Retention

Definitions of Management Action, Position of Record, and Temporary Reassignment (§ 536.103)

An agency requested that OPM clarify an employee's entitlement to grade or pay retention in situations in which an employee is reduced in grade or pay for inability to perform the duties of his or her position because of a medical or physical condition beyond the employee's control. The agency noted that the definition of *reduced in grade or pay for personal cause* states that such a reduction is not considered to be for personal cause. However, the agency requested that OPM clarify whether such a reduction is caused or influenced by a management action or if the employee is reduced in grade or pay at the employee's request. The agency recommended that OPM revise the regulations to provide that a determination to grant or not to grant grade or pay retention in demotions based on physical or mental inability to perform should be based on the individual circumstances of each case and should be left to the discretion of the agency.

We do not believe it is necessary to revise the regulations. An employee who is reduced in grade or pay for inability to perform the duties of his or her position because of a medical or physical condition beyond the employee's control would not be entitled to mandatory or optional grade retention because that is not a basis for grade retention. However, such an employee normally will be eligible for optional pay retention under § 536.302 if the reduction in grade or pay is the result of a management action, unless the employee's reduction satisfies one of the conditions for mandatory pay retention in § 536.301.

Another agency requested clarification regarding the definition of *position of record* in § 536.103. The definition in the interim regulations stated that it excludes ''any position to which an employee is temporarily detailed.'' The agency asked OPM to clarify whether the exclusion of any position to which an employee is temporarily detailed includes any temporary action (including temporary promotion). The exclusion refers only to situations when the employee is temporarily detailed. We are revising the definition of *position of record* in §§ 530.302, 531.203, 531.602, and 536.103 to clarify that a position to which an employee is temporarily detailed is not documented as a *position of record*. An employee who is on detail is considered for pay and strength count purposes to be permanently occupying his or her regular position. Unless the agency chooses to use a Standard Form 50 (Notification of Personnel Action), a detail is generally documented with a Standard Form 52 (Request for Personnel Action).

The same agency also asked whether there is a Nature of Action Code for a *temporary reassignment*. The agency stated that previously temporary reassignments have not been processed by the GPPA.

Section 536.102(c) provides that a temporary reassignment is not a basis for grade or pay retention. A *reassignment* is defined in § 210.102(b)(12) as a change of an employee, while serving continuously within the same agency, from one position to another without promotion or demotion. An agency may intend to reassign an employee to another position for a specified period of time, but the agency would still use the Nature of Action (NOA) Code 721 for reassignments. OPM staffing regulations make no distinction between permanent and temporary reassignments. However, certain OPM regulations recognize this distinction. For example, application of the pay retention regulation requires that the time-limited nature of a reassignment be documented in some way beyond a NOA code.

Mandatory Grade Retention or Optional Grade Retention (§§ 536.201 and 536.202)

An agency requested that OPM clarify whether a reclassification process, as that term is used in § 536.201(a)(2), includes the correction of an erroneous classification. It does. See 5 CFR part 511, subpart G.

Another agency requested that OPM clarify whether mandatory or optional grade retention applies when an employee moves without a break in service of more than 3 days from a position in a Department of Defense or Coast Guard nonappropriated fund instrumentality (NAFI) to a position under a covered pay system in the same agency. The agency stated that § 536.201(e) and § 536.202(d) of the interim regulations appeared to have the same wording.

We have determined that the regulations in effect prior to May 1, 2005, did not provide grade retention to a NAFI employee who moved to a position in a covered pay schedule. A NAFI employee would not have a reduction-in-force right to a competitive or excepted service position under OPM's 5 CFR part 351 regulations. In addition, OPM has previously determined that the movement from NAFI to another pay system would not be as a result of a reclassification process. (See discussion in 57 FR 182, September 18, 1992.) Therefore, neither mandatory nor optional grade retention applies when an employee moves without a break in service of more than 3 days from a position in a Department of Defense or Coast Guard NAFI to a position under a covered pay system in the same agency. Adding the NAFI-related provisions in §§ 536.201(e) and 536.202(d) in the interim regulations was an error. Accordingly, we are removing §§ 536.201(e) and 536.202(d). These changes bring the grade retention regulations in conformity with § 536.102(b)(8) and (d). If an agency provided grade retention to an employee moving from a NAFI position to a position under a covered pay system based on the erroneous provision in the interim regulations, that action should be corrected.

Loss of Eligibility for Grade Retention and Termination of Grade Retention (§§ 536.207 and 536.208)

An agency recommended that OPM clarify whether an employee who is eligible for optional grade retention would be ineligible for optional pay retention if he or she waives optional grade retention. The agency recognized that, under §§ 536.207(c) and 536.208(d) of the interim regulations, an employee is not eligible for pay retention if the employee elects to terminate mandatory eligibility for grade retention. The agency believed it was not clear that an employee is also ineligible to receive pay retention if he or she waives optional grade retention.

We agree that clarification is needed. Both § 536.207(a) and § 536.208(d) cross reference § 536.207(a)(5), which deals with loss of eligibility for mandatory grade retention. While the provision dealing with loss of eligibility for optional grade retention in § 536.207(b) refers to the conditions in § 536.207(a), we agree that the effect on optional grade retention is not clear. Accordingly, we have revised §§ 536.207(c) and 536.208(d) to clarify that an employee is not eligible for pay retention if the employee elects to terminate mandatory or optional eligibility for grade retention. This is consistent with the provision in § 536.207(b)(1) concerning loss of eligibility for optional grade retention.

Mandatory Pay Retention (§ 536.301)

A commenter requested clarification about whether an employee whose payable rate of basic pay otherwise would be reduced as a result of a management action that places the employee in a formal employee development program generally used Governmentwide is entitled to pay retention under § 536.301(a)(5) when the employee is moving from a non-covered pay system to a covered pay system. The commenter believed the employee would be entitled to pay retention.

We agree that mandatory pay retention under § 536.301(a)(5) can apply to an employee who is moving from a non-covered pay system to a covered pay system, but only if this movement is within the same agency so that it qualifies as a ''placement,'' as required by § 536.301(a)(5). If such a movement involves a ''transfer'' to a different agency, the gaining agency may provide optional pay retention as long as the employee is otherwise eligible. We have revised § 536.301(a) to clarify that, subject to the requirements in § 536.102 and § 536.301, an agency must provide pay retention to an employee who moves between positions under a covered pay system, or from a position not under a covered pay system to a position under a covered pay system, and whose payable rate of basic pay otherwise would be reduced (after application of any applicable geographic conversion under § 536.303(a)) as a result of one of the actions listed in paragraph (a). The actions listed in paragraph (a) include placement in a position under a formal employee development program generally used Governmentwide.

Another commenter suggested revising § 536.301(a)(6) to be consistent with the promotion rules in § 531.214. The commenter noted that, under § 536.301(a)(6), an agency must provide pay retention to an employee in a position under a covered pay system whose payable rate of basic pay otherwise would be reduced as a result of the application of the promotion rule for GS employees under 5 U.S.C. 5334(b) and 5 CFR 531.214 when the employee's payable rate of basic pay after promotion exceeds the maximum rate of the highest applicable rate range. The commenter requested clarification because step D of the promotion rules in § 531.214(d)(3)(i) and (4)(i) provides that, if the rate identified in step C exceeds the maximum of the rate range identified in step D, the employee's payable rate is (1) that maximum rate, or (2) if the employee's existing rate is higher than that maximum rate, a retained rate under 5 CFR part 536 equal to that existing rate. The commenter also requested that OPM clarify a similar provision under § 536.301(a)(7), which states that an agency must provide pay retention to an employee in a position under a covered pay system whose payable rate of basic pay otherwise would be reduced as a result of the application of the promotion rule for prevailing rate employees under 5 CFR 532.407 when the employee's payable rate of basic pay after

promotion exceeds the maximum scheduled rate of the grade, as described in 5 CFR 532.407(b).

We agree that a revision to § 536.301 is needed to clarify how a retained rate is created when application of a promotion increase rule for GS or prevailing rate employees results in a rate of basic pay that exceeds the maximum rate of the highest applicable rate range for the employee's new position. We are deleting former paragraphs (a)(6) and (a)(7) and inserting a new paragraph (b) in § 536.301 to address retained rates resulting from application of a promotion rule. We are adding a reference to the GS and prevailing rate promotion increase rules and noting that, under those rules, a retained rate is created only when an employee's existing rate before promotion exceeds the maximum rate of the grade to which promoted, and such retained rate is set to equal that existing rate. Retained rates created under the GS or prevailing rate system promotion rule are not created based on a finding that pay would otherwise be reduced, because the promotion rules themselves prevent such a reduction. These promotion-rule retained rates should be rare, since they should occur only when an employee is being promoted from the high steps of a high special rate range to a non-special rate range. Employees with an existing retained rate under 5 CFR part 536 who are promoted are excluded from this provision because they are covered by the rules in § 536.304(c)(3)–(5).

Determining an Employee's Pay Retention Entitlement (§ 536.304)

Two commenters requested that OPM allow their agencies to continue paying locality payments on top of retained rates.

OPM is not able to accommodate the commenters' request. Section 301(a)(1) of the Act amended the definition of ''scheduled rates of basic pay'' in 5 U.S.C. 5302 so that a retained rate was no longer considered a scheduled rate of basic pay. Locality pay under 5 U.S.C. 5304 is paid on top of a scheduled rate of basic pay (see 5 U.S.C. 5304(c)(1)(B)). Thus, locality pay ceased to be payable on top of a retained rate effective May 1, 2005. Instead, § 536.304 provides that an eligible employee is entitled to a retained rate if his or her rate of basic pay (including any locality payment or special rate, but after geographic conversion under § 536.303(a)) exceeds the maximum rate of the highest applicable rate range for the new position or geographic area. The retained rate will equal the employee's former rate of basic pay (including any locality payment or special rate supplement).

Comment Requesting Definition of ''One Year''

One agency recommended that OPM define what constitutes ''one year'' as provided in §§ 531.223(b), 531.407(a)(5), and 536.203(b). We did not change the use of the term ''one year'' in the interim regulations, and the clarification is not directly related to changes made by the Federal Workforce Flexibility Act of 2004. We will review the need to clarify ''one year'' in future regulations, and, if warranted, we will invite comments on the use of the term.

Additional Miscellaneous Changes

The final regulations also include additional miscellaneous changes to correct technical errors or omissions and to improve clarity. For example, in various places in parts 530, 531, and 536, we are clarifying that references to a ''rate'' being used in lieu of a ''step'' refer to the relative position in range of a GM employee's off-step rate. We also are revising the definition of special rate supplement in §§ 530.302, 531.203, and 531.602 to clarify that, when a special rate schedule covers both law enforcement officer positions and other positions, the value of the *special rate supplement* will be less for law enforcement officers because they have a higher base rate. Additional miscellaneous changes are described below.

In subpart G of part 359 (dealing with SES saved rates), we are making the following changes:

- Adding a parenthetical explanation in § 359.705(a)(1) to clarify that the rate of basic pay in effect for the position in which the appointee is being placed refers to a rate of basic pay within the normal rate range of that position, consistent with the rules of the pay system covering such position.
- Correcting an omission by adding a paragraph (c)(3) to § 359.705 to provide that an SES saved rate is considered to be an employee's rate of basic pay for the same purposes that apply to a retained rate under part 536. This is consistent with OPM's stated purpose for making changes to § 359.705, which was explained in the Supplementary Information for the interim regulations-namely, to ''make changes that are consistent with * * * the changes made in the pay retention provisions in part 536 * * * .'' (See 70 FR 31286.)

In subpart C of part 530 (dealing with special rates), we are making the following changes:

- Removing the words ''under 5 CFR 359.705 or 5 CFR part 536'' from the definition of *rate of basic pay* in § 530.302 because these references are included in the definition of *retained rate* in the same section.
- Revising the last sentence of § 530.304(a) to make the language regarding the limitation on special rates more consistent with the language in 5 U.S.C. 5305(a)(1).
- Revising § 530.309(d) to add a cross reference to § 530.308 and to update a reference to an action under § 930.214. OPM revised the administrative law judge program regulations in 5 CFR part 930, subpart B, in March 2007, which included renumbering § 930.214 as § 930.211.

In subpart B of part 531 (dealing with GS basic pay setting), we are making the following changes:

- Revising the definition of *rate of basic pay* in § 531.203 to clarify that, for the purpose of applying the maximum payable rate rule using a rate under a non-GS pay system as an employee's highest previous rate, the non-GS rate may not be a type of rate that is generally excluded under § 531.223. We are also adding references to 5 CFR 530.308, 531.610, and 536.307. Those regulations address the purposes for which a special rate is considered a rate of basic pay, a locality rate is considered a rate of basic pay, and a retained rate is considered a rate of basic pay, respectively.
- In § 531.205, replacing ''(or rate)'' with ''(or a GM employee's GS rate)'' in the second sentence.
- Revising § 531.212(a)(3) to clarify a ''non-permanent appointment'' excludes a Schedule C appointment under 5 CFR part 213. An agency may not use the superior qualifications and special needs pay-setting authority when an employee moves from a Schedule C appointment to a non-Schedule C appointment, unless the employee has a 90-day break in service. We are also listing non-permanent appointments and time-limited appointments separately to increase clarity.
- Adding employment under the Student Career Experience Program under 5 CFR 213.3202(b) as a new paragraph (3)(v) in § 531.212(a). A similar provision was included in the former superior qualifications and special needs pay-setting regulations, but it was inadvertently left out of the interim regulations.
- Revising § 531.215 to clarify an agency is not limited in pursuing action for misconduct or other problems and setting pay in accordance with such action when an employee is in a supervisory probationary period, consistent with 5 U.S.C. 3321(b)(2). Such an action, however, would have to

be taken in accordance with applicable laws and regulations.

• Revising § 531.221(a)(1) to clarify that the maximum payable rate rule may be used when an employee moves from a non-GS pay system to the GS pay system without a change in position. We are also clarifying that an agency may use the maximum payable rate rule upon termination of grade or pay retention.

• In § 531.244, replacing ''rate of basic pay'' in each place it appears with ''GS rate'' and replacing ''GM rate'' in paragraph (a)(2) with ''GS rate''.

• Replacing ''rate of basic pay'' in § 531.246 with ''GS rate''.

• Replacing steps 1–6 with steps A-F in § 531.247 to be consistent with other tables in the regulations.

In subpart D of part 531 (dealing with GS within-grade increases), we are making the following changes:

• Deleting the last sentence of § 531.406(b)(2). The sentence is not necessary because § 531.406(b)(3) sufficiently states that time in a nonpay status that is in excess of the allowable amount extends a waiting period for a within-grade increase by the excess amount, except as provided in § 531.406(c).

• Revising § 531.407(a)(2) to improve clarity.

In subpart F of part 531 (dealing with locality-based comparability payments), we are updating a reference in § 531.611(d) to the administrative law judge program regulations. OPM revised 5 CFR 930, subpart B, in March 2007, which included renumbering § 930.214 as § 930.211.

In 5 CFR part 536 (dealing with grade and pay retention), we are making the following changes:

• Replacing the term *representative rate* with *comparison rate* throughout part 536, including the definition of *representative rate* in § 536.103. OPM's regulations in 5 CFR 351.203 define the term representative rate for reduction-in-force purposes. Separate terms will help reduce any confusion since the terms are defined differently.

• Correcting an omission by clarifying in § 536.208 that termination of grade retention benefits takes effect at the end of the day before separation from service if termination is the result of a break in service. We are also adding in § 536.208 a necessary exception to the rule that the termination of grade retention benefits takes effect at the end of the last day of the pay period in which the employee elects to terminate grade retention benefits. The exception is that, if an employee's election specifically provides that the termination will take effect at the end of a later pay period, the election is considered to be made effective on the last day of that later pay period.

• Revising § 536.304(c)(3) and (c)(4) to add references to the terminating conditions in § 536.308.

• Adding, in § 536.307, an explicit reference to adverse action provisions in 5 CFR part 752 as a purpose for which a retained rate is considered a rate of basic pay, consistent with longstanding policies and OPM's interpretation of the interim regulations. We also are removing ''OPM'' from § 536.307(a)(11) to clarify that a retained rate is considered a rate of basic pay for the purpose of computing and applying other provisions as specified in regulations of OPM or other agencies.

• Revising the language in § 536.308(a)(2) to clarify that entitlement to an equal or higher rate of basic pay during a temporary promotion or temporary reassignment does not terminate an employee's preexisting entitlement to pay retention, but that the pay retention entitlement is held in abeyance.

• Correcting an omission in § 536.308 by clarifying that termination of pay retention benefits takes effect at the end of the day before separation from service if termination is the result of a break in service.

• Correcting an omission in § 536.308 by clarifying that termination of pay retention benefits takes effect at the end of the day before the employee becomes entitled to an equal or greater rate as described in § 536.308(a)(2).

In 5 CFR part 550 (dealing with miscellaneous pay administration matters), we are making the following changes:

• In §§ 550.202 and 550.703, adding the word ''supplement'' after ''special rate'' in paragraph (1) of the definition of *rate of basic pay.*

• Deleting a reference to a temporary appointment pending establishment of a register (TAPER) in the definition of *nonqualifying appointment* in § 550.703 because the TAPER authority is no longer used.

We are replacing the term *representative rate* with *comparison rate* in §§ 550.703, 831.503, and 842.206 and clarifying those definitions. Under 5 CFR 536.102(b)(6), an agency may not provide grade or pay retention under part 536 to an employee who moves between positions not under a covered pay system or from a position under a covered pay system to a position not under a covered pay system. However, the severance pay (§ 550.703) and discontinued service retirement provisions (§§ 831.503 and 842.206) do not have this same exclusion. Therefore, although paragraph (2) in the definition of new term *comparison rate* in § 536.103 of the grade and pay retention regulations refers to comparing grades or levels of work in making reasonable offer determinations when one of the grades or levels of work is not under a covered pay system, this comparison for making reasonable offer determinations for severance pay or discontinued service retirement purposes is not limited to whether the offered position is under a covered pay system.

Title 38 Market Pay

Since publication of the interim regulations in May 2005, OPM has used its authority under 5 U.S.C. 5371 to delegate to certain agencies authority to provide market pay to physicians and dentists under 38 U.S.C. 7431(c), consistent with the authority of the Department of Veterans Affairs. Under this OPM delegation, title 38 market pay may be paid on top of General Schedule base rates in lieu of locality payments under 5 U.S.C. 5304, special rate supplements under 5 U.S.C. 5305, or grade and pay retention under 5 U.S.C. 5361–5365. We decided it would not be necessary to amend the regulations related to locality payments, special rate supplements, and grade and pay retention to address the exclusion of physicians and dentists receiving title 38 market pay. Those exclusions are not effected under the authorities related to those payments, but are based on OPM's administrative authority under 5 U.S.C. 5371. Title 38 market pay is generally not considered basic pay for GS pay administration purposes; however, it may be used in establishing an employee's highest previous rate. (See revised definitions of *rate of basic pay* and *special rate* in § 531.203 and new paragraph (a)(5) in § 531.221.)

Pay Setting for NAFI Employees Who Move to GS Positions

This notice finalizes the rules in 5 CFR 531.216, as published in the May 2005 interim regulations, concerning pay setting for nonappropriated fund instrumentality (NAFI) employees who move to GS positions. However, section 1114 of the National Defense Authorization Act for Fiscal Year 2008 (Pub. L. 110–181, January 28, 2008) amended 5 U.S.C. 5334(f) to provide that a NAFI employee in the Department of Defense (DOD) or the United States Coast Guard (USCG) (as described in 5 U.S.C. 2105(c)) who moves voluntarily to a GS position in DOD or USCG, respectively, without a break in service of more than 3 days may (at the employing agency's discretion) have the GS rate of basic pay set at the lowest

step rate of the applicable GS grade that equals or exceeds the former NAFI rate. This amendment became effective on January 28, 2008. Under previous law, the employee's GS rate of basic pay could not exceed the formerly applicable NAFI rate in such voluntary movements; thus, setting the rate at a GS step for these former NAFI employees generally resulted in a reduction in pay. The amendment permits DOD and USCG to set pay at the next higher step rate, avoiding a pay reduction. OPM has issued proposed regulations to conform with this statutory change. (See 73 FR 50575, August 27, 2008.)

E.O. 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with E.O. 12866.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will apply only to Federal agencies and employees.

List of Subjects in 5 CFR 294, 359, 362, 451, 530, 531, 532, 534, 536, 550, 591, 630, 831, and 842

Administrative practice and procedure; Air traffic controllers; Alimony; Claims; Decorations, medals, awards; Disability benefits; Firefighters; Freedom of information; Government employees; Hospitals; Income taxes; Intergovernmental relations; Law enforcement officers; Pensions; Reporting and recordkeeping requirements; Research; Retirement; Students; Transportation and travel expenses; Wages.

Office of Personnel Management.

Michael W. Hager,

Acting Director.

■ The interim rule published May 31, 2005, at 70 FR 31278 and amended at 70 FR 74995 (December 19, 2005) is adopted as final with the changes set forth below, and OPM further amends 5 CFR chapter I as follows:

PART 359—REMOVAL FROM THE SENIOR EXECUTIVE SERVICE; GUARANTEED PLACEMENT IN OTHER PERSONNEL SYSTEMS

■ 1. The authority citation for part 359 is revised to read as follows:

Authority: 5 U.S.C. 1302, 3302, and 3596, unless otherwise noted.

Subpart G—Guaranteed Placement

■ 2. In § 359.705, revise paragraphs (a)(1) and (c) to read as follows:

§ 359.705 Pay.

(a) * * *

(1) The rate of basic pay in effect for the position in which the appointee is being placed (i.e., a rate of basic pay within the normal rate range of the position in which placed, consistent with the rules of the pay system covering such position);

* * * * *

(c)(1) For an employee placed in a General Schedule position, a saved rate established under this section may not be supplemented by a locality payment under 5 U.S.C. 5304, a special rate supplement under 5 U.S.C. 5305, or a similar payment under other legal authority.

(2) A saved rate established under this section is subject to the limitation on Senior Executive Service pay in 5 U.S.C. 5382 of the rate for level II of the Executive Schedule.

(3) A saved rate established under this section is considered an employee's rate of basic pay for the same purposes as a retained rate under 5 CFR part 536, as described in 5 CFR 536.307.

* * * * *

PART 530—PAY RATES AND SYSTEMS (GENERAL)

■ 3. The authority citation for part 530 continues to read as follows:

Authority: 5 U.S.C. 5305 and 5307; subpart C also issued under 5 U.S.C. 5338 and sec. 4 of the Performance Management and Recognition System Termination Act of 1993, Pub. L. 103–89), 107 Stat. 981.

Subpart C—Special Rate Schedules for Recruitment and Retention

■ 4. In § 530.302—

■ a. Revise the definition of *position of record*;

■ b. Amend the definition of *rate of basic pay* by removing the words ''under 5 CFR 359.705 or 5 CFR part 536''; and

■ c. Revise the definition of *special rate supplement.*

The revisions read as follows:

§ 530.302 Definitions.

* * * * *

Position of record means an employee's official position (defined by grade, occupational series, employing agency, LEO status, and any other condition that determines coverage under a pay schedule (other than official worksite)), as documented on the employee's most recent Notification of Personnel Action (Standard Form 50 or equivalent) and current position description. A position to which an employee is temporarily detailed is not documented as a position of record. For an employee whose change in official position is followed within 3 workdays by a reduction in force resulting in the employee's separation before he or she is required to report for duty in the new position, the position of record in effect immediately before the position change is deemed to remain the position of record through the date of separation.

* * * * *

Special rate supplement means the portion of a special rate paid above an employee's GS rate. However, for a law enforcement officer receiving an LEO special base rate who is also entitled to a special rate, the special rate supplement equals the portion of the special rate paid above the officer's LEO special base rate. When a special rate schedule covers both LEO positions and other positions, the value of the special rate supplement will be less for law enforcement officers receiving an LEO special base rate (since that rate is higher than the corresponding GS rate). The payable amount of a special rate supplement is subject to the Executive Schedule level IV limitation on special rates, as provided in § 530.304(a).

■ 5. In § 530.304, revise the last sentence of paragraph (a) to read as follows:

§ 530.304 Establishing or increasing special rates.

(a) * * * A special rate may not exceed the rate for level IV of the Executive Schedule.

* * * * *

■ 6. In § 530.309, revise paragraph (d) to read as follows:

§ 530.309 Miscellaneous provisions.

* * * * *

(d) Consistent with § 530.308, the reduction or termination of an employee's special rate supplement in accordance with the requirements of this subpart is not an adverse action under 5 CFR part 752, subpart D, or an action under 5 CFR 930.211.

■ 7. In § 530.322, revise the first sentence of paragraph (a) to read as follows:

§ 530.322 Setting pay when a special rate schedule is newly established or increased.

(a) *General rule.* When an employee holds a position that becomes covered by a newly established special rate schedule (including a schedule for which coverage is expanded) or increased special rate schedule (including an increased special rate range within a schedule), the agency must set the employee's special rate at the step (or relative position in range for

a GM employee) of the grade on the new special rate schedule that corresponds to the employee's existing numerical step (or relative position in range for a GM employee) as in effect immediately before the new special rate schedule takes effect, except as otherwise provided in this section. * * *

* * * * *

§ 530.323 [Amended]

■ 8. In § 530.323, remove the parenthetical clause ''(or rate)'' in both places in paragraph (c) and add ''(or relative position in range for a GM employee)'' in each place.

PART 531—PAY UNDER THE GENERAL SCHEDULE

■ 9. The authority citation for part 531 continues to read as follows:

Authority: 5 U.S.C. 5115, 5307, and 5338; sec. 4 of Pub. L. 103–89, 107 Stat. 981; and E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316; Subpart B also issued under 5 U.S.C. 5303(g), 5305, 5333, 5334(a) and (b), and 7701(b)(2); Subpart D also issued under 5 U.S.C. 5335(g) and 7701(b)(2); Subpart E also issued under 5 U.S.C. 5336; Subpart F also issued under 5 U.S.C. 5304, 5305, and 5338; and E.O. 12883, 58 FR 63281, 3 CFR, 1993 Comp., p. 682 and E.O. 13106, 63 FR 68151, 3 CFR, 1998 Comp., p. 224.

Subpart B—Determining Rate of Basic Pay

■ 10. In § 531.203, revise the definitions of *position of record, rate of basic pay* and *special rate supplement* to read as follows:

§ 531.203 Definitions.

* * * * *

Position of record means an employee's official position (defined by grade, occupational series, employing agency, LEO status, and any other condition that determines coverage under a pay schedule (other than official worksite)), as documented on the employee's most recent Notification of Personnel Action (Standard Form 50 or equivalent) and current position description. A position to which an employee is temporarily detailed is not documented as a position of record. For an employee whose change in official position is followed within 3 workdays by a reduction in force resulting in the employee's separation before he or she is required to report for duty in the new position, the position of record in effect immediately before the position change is deemed to remain the position of record through the date of separation.

* * * * *

Rate of basic pay means the rate of pay fixed by law or administrative action for the position held by a GS employee before any deductions, including a GS rate, an LEO special base rate, a special rate, a locality rate, and a retained rate, but exclusive of additional pay of any other kind. For the purpose of applying the maximum payable rate rules in §§ 531.216 and 531.221 using a rate under a non-GS pay system as an employee's highest previous rate, *rate of basic pay* means a rate of pay under other legal authority which is equivalent to a rate of basic pay for GS employees, as described in this definition, excluding a rate under § 531.223. (See also 5 CFR 530.308, 531.610, and 536.307.)

* * * * *

Special rate means a rate of pay within a special rate schedule established under 5 CFR part 530, subpart C, or a similar rate for GS employees established under other legal authority (e.g., 38 U.S.C. 7455). The term *special rate* does not include an LEO special base rate or an adjusted rate including market pay under 38 U.S.C. 7431(c).

* * * * *

Special rate supplement means the portion of a special rate paid above an employee's GS rate. However, for a law enforcement officer receiving an LEO special base rate who is also entitled to a special rate, the special rate supplement equals the portion of the special rate paid above the officer's LEO special base rate. When a special rate schedule covers both LEO positions and other positions, the value of the special rate supplement will be less for law enforcement officers receiving an LEO special base rate (since that rate is higher than the corresponding GS rate). The payable amount of a special rate supplement is subject to the Executive Schedule level IV limitation on special rates, as provided in 5 CFR 530.304(a).

* * * * *

§ 531.204 [Amended]

■ 11. In § 531.204, amend paragraph (c) by removing the parenthetical clause ''(or relative position)'' and adding in its place ''(or relative position in range for a GM employee)''.

■ 12. In § 531.205, revise the second sentence to read as follows:

§ 531.205 Converting pay upon change in location of employee's official worksite.

* * * The agency must first set the employee's rate(s) of basic pay in the applicable pay schedule(s) in the new location based on his or her position of record (including grade) and step (or a GM employee's GS rate) immediately before the change in the employee's official worksite. * * *

■ 13. In § 531.212—

■ a. Revise paragraph (a)(3)(i);

■ b. Remove ''or'' at the end of paragraph (a)(3)(ii);

■ c. Remove the period at the end of paragraph (a)(3)(iii) and insert a semicolon; and

■ d. Add paragraphs (a)(3)(iv) and (a)(3)(v).

The revision and additions read as follows:

§ 531.212 Superior qualifications and special needs pay-setting authority.

(a) * * *

(3) * * *

(i) Employment under a time-limited appointment in the competitive or excepted service;

* * * * *

(iv) Employment under a non-permanent appointment (excluding a Schedule C appointment under 5 CFR part 213) in the competitive or excepted service; or

(v) Employment under the Student Career Experience Program under 5 CFR 213.3202(b).

* * * * *

■ 14. In § 531.213, remove the parenthetical clause ''(or rate)'' and add in its place ''(or relative position in range for a GM employee)''.

■ 15. In § 531.215, revise the last sentence in paragraph (d) to read as follows:

§ 531.215 Setting pay upon demotion.

* * * * *

(d) * * * However, nothing in this paragraph prohibits an agency from taking action against an employee serving under a probationary period under 5 U.S.C. 3321(a)(2) for cause unrelated to supervisory or managerial performance and setting pay in accordance with such action.

* * * * *

■ 16. In § 531.221—

■ a. Revise the first sentence in paragraph (a)(1);

■ b. Revise paragraph (a)(4); and

■ c. Add a new paragraph (a)(5).

The revisions and addition read as follows:

§ 531.221 Maximum payable rate rule.

(a) *General.* (1) An agency may apply the maximum payable rate rule as described in this section to determine an employee's payable rate of basic pay under the GS pay system at a rate higher than the otherwise applicable rate upon reemployment, transfer, reassignment, promotion, demotion, change in type of

appointment, termination of a critical position pay authority under 5 CFR part 535, movement from a non-GS pay system, or termination of grade or pay retention under 5 CFR part 536. * * *

* * * * *

(4) In applying this section, an agency must treat a critical position pay rate under 5 CFR part 535 as if it were a rate under a non-GS pay system, as described in paragraph (d) of this section.

(5) In applying this section, an agency must treat an adjusted GS rate that includes market pay under 38 U.S.C. 7431(c) as if it were a rate under a non-GS pay system, as described in paragraph (d) of this section.

* * * * *

■ 17. In § 531.223—

■ a. Remove ''or'' at the end of paragraph (g);

■ b. Remove the period at the end of paragraph (h) and insert a semicolon; and

■ c. Add new paragraphs (i) and (j) to read as follows:

§ 531.223 Rates of basic pay that may not be used as the highest previous rate.

* * * * *

(i) A rate received as a member of the uniformed services; or

(j) A retained rate under 5 U.S.C. 5363 or a similar rate under another legal authority.

§ 531.244 [Amended]

■ 18. In § 531.244, remove ''rate of basic pay'' in each place it appears and add ''GS rate'' in each place, and remove ''GM rate'' in paragraph (a)(2) and add ''GS rate'' in its place.

■ 19. Revise § 531.246 to read as follows:

§ 531.246 Within-grade increases for GM employees.

GM employees are entitled to within-grade increases as provided under subpart D of this part. A within-grade increase may not cause a GM employee's GS rate to exceed the maximum GS rate of his or her grade. GM employees may receive quality step increases as provided in subpart E of this part.

■ 20. In § 531.247, revise the table in paragraph (c)(2) as follows:

§ 531.247 Maximum payable rate rule for GM employees.

* * * * *

(c) * * *

(2) * * *

Step A	Find the difference between the employee's highest previous rate and the minimum rate for the GS rate range (for the employee's current grade) in effect at the time the highest previous rate was earned.
Step B	Find the difference between the maximum rate and the minimum GS rate for the rate range identified in step A. (If the GS maximum rate was not payable because of the EX level V pay limitation, use the uncapped maximum rate.)
Step C	Divide the result from step A by the result from step B. Carry this result to the seventh decimal place and truncate, rather than round, the result. This decimal factor represents the employee's relative position in the rate range.
Step D	Using the current GS rate range (for the employee's current grade), find the difference between the maximum rate and the minimum rate. (If the maximum GS rate was not payable because of the EX level V pay limitation, use the uncapped maximum GS rate.)
Step E	Multiply the result from step D by the factor derived under step C.
Step F	Add the result from step E to the minimum rate for the employee's current GS rate range and round to the next higher whole dollar. This rate is the maximum payable GS rate the agency may pay the employee (subject to the EX level V pay limitation).

* * * * *

Subpart D—Within-Grade Increases

§ 531.406 [Amended]

■ 21. In § 531.406, remove the last sentence of paragraph (b)(2).

■ 22. In § 531.407, revise paragraphs (a)(2)(i) and (ii) and paragraph (b) to read as follows:

§ 531.407 Equivalent increase determinations.

(a) * * *

(2) * * *

(i) A temporary promotion if, at the end of the that temporary promotion, the employee is returned to the grade from which promoted; or

(ii) A promotion to a higher-graded supervisory or managerial position when the employee does not satisfactorily complete a probationary period established under 5 U.S.C. 3321(a)(2) and is returned to a position at the lower grade held before promotion;

* * * * *

(b) *Non-GS employees who move to the GS pay system.* When an employee performs service under a non-GS pay system for Federal employees and that service is potentially creditable towards a GS within-grade increase waiting period, an equivalent increase is considered to occur at the time of any of the following personnel actions in the non-GS pay system:

(1) A promotion to a higher grade or work level within the non-GS pay system (unless the promotion is cancelled and the employee's rate of basic pay is redetermined as if the promotion had not occurred); or

(2) An opportunity to receive a within-level or within-range increase that results in forward movement in the applicable range of rates of basic pay (including an increase granted immediately upon movement to the non-GS pay system from another pay system—e.g., to account for the value of accrued within-grade increases under the former pay system or to provide a promotion-equivalent increase), where ''forward movement in the applicable range'' means any kind of increase in the employee's rate of basic pay other than an increase that is directly and exclusively linked to—

(i) A general structural increase in the employee's basic pay schedule or rate range (including the adjustment of a range minimum or maximum); or

(ii) The employee's placement under a new basic pay schedule within the same pay system, when such placement results in a nondiscretionary basic pay increase to account for occupational pay differences.

* * * * *

Subpart F—Locality-Based Comparability Payments

■ 23. In § 531.602, revise the definitions of *position of record* and *special rate supplement* to read as follows:

§ 531.602 Definitions.

* * * * *

Position of record means an employee's official position (defined by grade, occupational series, employing agency, LEO status, and any other condition that determines coverage under a pay schedule (other than official worksite)), as documented on the employee's most recent Notification of Personnel Action (Standard Form 50 or equivalent) and current position description. A position to which an employee is temporarily detailed is not documented as a position of record. For an employee whose change in official position is followed within 3 workdays by a reduction in force resulting in the

employee's separation before he or she is required to report for duty in the new position, the position of record in effect immediately before the position change is deemed to remain the position of record through the date of separation.

* * * * *

Special rate supplement means the portion of a special rate paid above an employee's scheduled annual rate of pay. However, for a law enforcement officer receiving an LEO special base rate who is also entitled to a special rate, the special rate supplement equals the portion of the special rate paid above the officer's LEO special base rate. When a special rate schedule covers both LEO positions and other positions, the value of the special rate supplement will be less for law enforcement officers receiving an LEO special base rate (since that rate is higher than the corresponding GS rate). The payable amount of a special rate supplement is subject to the Executive Schedule level IV limitation on special rates, as provided in 5 CFR 530.304(a).

* * * * *

■ 24. Revise § 531.605 to read as follows:

§ 531.605 Determining an employee's official worksite.

(a)(1) Except as otherwise provided in this section, the official worksite is the location of an employee's position of record where the employee regularly performs his or her duties.

(2) If the employee's work involves recurring travel or the employee's work location varies on a recurring basis, the official worksite is the location where the work activities of the employee's position of record are based, as determined by the employing agency, subject to the requirement that the official worksite must be in a locality pay area in which the employee regularly performs work.

(3) An agency must document an employee's official worksite on an employee's Notification of Personnel Action (Standard Form 50 or equivalent).

(b) For an employee who is relocated and authorized to receive relocation expenses under 5 U.S.C. chapter 57, subchapter II (or similar authority), the official worksite is the established worksite for the position in the area to which the employee has been relocated. For an employee authorized to receive relocation expenses under 5 U.S.C. 5737 in connection with an extended assignment resulting in a temporary change of station, the worksite associated with the extended assignment is the official worksite. (See 41 CFR 302–1.1.)

(c) For an employee whose assignment to a new worksite is followed within 3 workdays by a reduction in force resulting in the employee's separation before he or she is required to report for duty at the new location, the official worksite in effect immediately before the assignment remains the official worksite through the date of separation.

(d) For an employee covered by a telework agreement, the following rules apply:

(1) If the employee is scheduled to work at least twice each biweekly pay period on a regular and recurring basis at the regular worksite for the employee's position of record, the regular worksite (where the employee's work activities are based) is the employee's official worksite. However, in the case of such an employee whose work location varies on a recurring basis, the employee need not work at least twice each biweekly pay period at the regular official worksite (where the employee's work activities are based) as long as the employee is regularly performing work within the locality pay area for that worksite.

(2) An authorized agency official may make an exception to the twice-in-a-pay-period standard in paragraph (d)(1) of this section in appropriate situations of a temporary nature, such as the following:

(i) An employee is recovering from an injury or medical condition;

(ii) An employee is affected by an emergency situation, which temporarily prevents the employee from commuting to his or her regular official worksite;

(iii) An employee has an extended approved absence from work (e.g., paid leave);

(iv) An employee is in temporary duty travel status away from the official worksite; or

(v) An employee is temporarily detailed to work at a location other than a location covered by a telework agreement.

(3) If an employee covered by a telework agreement does not meet the requirements of paragraphs (d)(1) or (d)(2) of this section, the employee's official worksite is the location of the employee's telework site.

(4) An agency must determine a telework employee's official worksite on a case-by-case basis. A determination made under this paragraph (d) is within the sole and exclusive discretion of the authorized agency official, subject only to OPM review and oversight.

(e) In applying paragraph (d) of this section for the purpose of other location-based pay entitlements under other regulations that refer to this section, the reference to a *locality pay area* is deemed to be a reference to the applicable geographic area associated with the given pay entitlement. For example, for the purpose of special rates under 5 CFR part 530, subpart C, the reference to a *locality pay area* is deemed to be a reference to the geographic area covered by a special rate schedule.

■ 25. In § 531.610—
■ a. Revise the introductory text;
■ b. Revise paragraph (f);
■ c. Redesignate paragraphs (g) through (n) as (h) through (o), respectively; and
■ d. Add a new paragraph (g).

The revisions and addition read as follows:

§ 531.610 Treatment of locality rate as basic pay.

A locality rate is considered to be an employee's rate of basic pay only for the purpose of computing or applying—

* * * * *

(f) Post differentials under 5 U.S.C. 5925(a) and danger pay allowances under 5 U.S.C. 5928 for an employee temporarily working in a foreign area when the employee's official worksite is located in a locality pay area;

(g) Post differentials under 5 U.S.C. 5941 and 5 CFR part 591, subpart B, for an employee temporarily working in a nonforeign area when the employee's official worksite is located in a locality pay area;

* * * * *

■ 26. In § 531.611, revise paragraph (d) to read as follows:

§ 531.611 Miscellaneous provisions.

* * * * *

(d) Consistent with § 531.610, a reduction or termination of a locality rate under § 531.609 is not an adverse action for the purpose of 5 CFR part 752, subpart D, or an action under 5 CFR 930.211.

PART 536—GRADE AND PAY RETENTION

■ 27. The authority citation for part 536 is revised to read as follows:

Authority: 5 U.S.C. 5361–5366; sec. 4 of the Performance Management and Recognition System Termination Act of 1993 (Pub. L. 103–89), 107 Stat. 981; § 536.301(b) also issued under 5 U.S.C. 5334(b); § 536.308 also issued under section 301(d)(2) of the Federal Workforce Flexibility Act of 2004 (Pub. L. 108–411), 118 Stat. 2305; § 536.405 also issued under 5 U.S.C. 552, Freedom of Information Act, Public Law 92–502.

Subpart A—General Provisions

■ 28. In § 536.103—

■ a. Revise the definition of *position of record*;

■ b. Amend the definition of *representative rate* by removing ''representative rate'' in each place it appears and adding in its place ''comparison rate''; and

■ c. Revise the definition of *reduced in grade or pay for personal cause*.

The revisions read as follows:

§ 536.103 Definitions.

* * * * *

Position of record means an employee's official position (defined by grade, occupational series, employing agency, LEO status, and any other condition that determines coverage under a pay schedule (other than official worksite)), as documented on the employee's most recent Notification of Personnel Action (Standard Form 50 or equivalent) and current position description. A position to which an employee is temporarily detailed is not documented as a position of record. For an employee whose change in official position is followed within 3 workdays by a reduction in force resulting in the employee's separation before he or she is required to report for duty in the new position, the position of record in effect immediately before the position change is deemed to remain the position of record through the date of separation.

* * * * *

Reduced in grade or pay for personal cause means a reduction in grade or rate of basic pay based on the conduct, character, or unacceptable performance of an employee. In situations in which an employee is reduced in grade or pay for inability to perform the duties of his or her position because of a medical or physical condition beyond the employee's control, the reduction in grade or pay is not considered to be for personal cause.

* * * * *

§ 536.105 [Amended]

■ 29. In § 536.105, amend paragraph (a) by removing ''representative rates'' and inserting ''comparison rates''; and amend paragraph (b) by removing ''representative rate'' and inserting ''comparison rate''.

Subpart B—Grade Retention

§ 536.201 [Amended]

■ 30. In § 536.201, remove paragraph (e).

§ 536.202 [Amended]

■ 31. In § 536.202, remove paragraph (d).

§ 536.206 [Amended]

■ 32. In § 536.206, amend paragraph (b) by removing ''(or rate)'' and adding in its place ''(or relative position in range for a GM employee)''.

■ 33. In § 536.207, revise paragraph (a)(2) by removing ''representative rates'' and inserting ''comparison rates''; and amend paragraph (c) by revising the second sentence to read as follows:

§ 536.207 Loss of eligibility for grade retention.

* * * * *

(c) * * * An employee is not eligible for pay retention under subpart C of this part based on an action that provided eligibility for grade retention if the employee elects to terminate eligibility for grade retention under paragraph (a)(5) or (b) of this section.

■ 34. In § 536.208, revise paragraphs (c) and (d) to read as follows:

§ 536.208 Termination of grade retention.

* * * * *

(c) Termination of grade retention benefits takes effect—

(1) At the end of the day before separation from service if termination is the result of a break in service;

(2) At the end of the day before placement if the termination is the result of the employee's placement in another position; or

(3) At the end of the last day of the pay period in which the employee—

(i) Declines a reasonable offer;

(ii) Elects to terminate grade retention benefits (except that, if an employee's election specifically provides that the termination will take effect at the end of a later pay period, the election is considered to be made effective on the last day of that later pay period for the purpose of applying this paragraph); or

(iii) Fails to enroll in, or comply with reasonable written requirements established to assure full consideration under, a program providing priority consideration for placement.

(d) If an employee's entitlement to grade retention terminates under this section, the employee's rate of basic pay must be set in accordance with the pay-setting rules and pay rates applicable to the employee's position of record (e.g., 5 CFR part 531, subpart B, for GS positions). An employee is not entitled to pay retention under subpart C of this part based on a reduction in basic pay resulting from waiver of the employee's grade retention entitlement under paragraph (a)(5) or (b) of § 536.207.

Subpart C—Pay Retention

■ 35. In § 536.301—

■ a. Revise the introductory text of paragraph (a);

■ b. Add ''or'' at the end of paragraph (a)(5);

■ c. Remove paragraphs (a)(6) and (a)(7);

■ d. Redesignate paragraph (a)(8) as paragraph (a)(6);

■ e. Redesignate paragraphs (b) through (d) as paragraphs (c) through (e), respectively; and

■ f. Add a new paragraph (b).

The revision and addition read as follows:

§ 536.301 Mandatory pay retention.

(a) Subject to the requirements in § 536.102 and this section, an agency must provide pay retention to an employee who moves between positions under a covered pay system or from a position not under a covered pay system to a position under a covered pay system and whose payable rate of basic pay otherwise would be reduced (after application of any applicable geographic conversion under § 536.303(a)) as a result of—

* * * * *

(b) An agency must establish a retained rate when application of a promotion increase rule for General Schedule or prevailing rate employees results in a payable rate of basic pay that exceeds the maximum rate of the highest applicable rate range for the employee's new position. (See the promotion increase rules in 5 U.S.C. 5334(b) and 5 CFR 531.214 for GS employees and in 5 CFR 532.407 for prevailing rate employees—in particular, the special provisions in these promotion increase rules on establishing a retained rate equal to an employee's existing rate when that existing rate exceeds the applicable range maximum.) Once established, such a retained rate is governed by the provisions of this subpart.

* * * * *

■ 36. In § 536.303, revise the second sentence after the heading of paragraph (a) as follows:

§ 536.303 Geographic conversion.

(a) *Geographic conversion at the time of action that may provide initial entitlement to pay retention.* * * * The agency must identify the highest applicable rate range that would apply to the employee's position of record before the pay action as if that position were stationed at the new official worksite and determine the employee's converted payable rate of basic pay based on the step (or relative position in range for a GM employee) in that range that corresponds to the employee's step (or relative position in range for a GM employee) before the pay action. * * *

* * * * *

■ 37. In § 536.304, revise paragraphs (c)(3) and (c)(4) to read as follows:

§ 536.304 Determining an employee's pay retention entitlement.

* * * * *

(c) * * *

(3) If the employee's pay system is not changing but the employee is being promoted to a higher-graded position, the agency must apply the applicable promotion rules to determine the employee's payable rate of basic pay (e.g., the rules in 5 CFR 531.214(d)(5) for GS positions and 5 CFR 532.407 for Federal Wage System positions). If the promotion action results in a terminating condition as described in § 536.308 (e.g., the resulting rate is equal to or greater than the existing retained rate), pay retention ceases to apply. Otherwise, the employee's existing retained rate continues.

(4) If the employee is moving to a position under a different covered pay system whose grade has a higher comparison rate, the agency must apply the applicable pay administration rules to determine the employee's payable rate of basic pay (e.g., part 531, subpart B, for GS positions and part 532 for Federal Wage System provisions). If the promotion action results in a terminating condition as described in § 536.308 (e.g., the resulting rate is equal to or greater than the existing retained rate), pay retention ceases to apply. Otherwise, the employee's existing retained rate continues.

* * * * *

■ 38. In § 536.307—

■ a. Redesignate paragraphs (a)(10) and (a)(11) as paragraphs (a)(11) and (a)(12), respectively;

■ b. Amend paragraph (a)(11), as redesignated, by removing ''OPM''; and

■ c. Add a new paragraph (a)(10).

The addition reads as follows:

§ 536.307 Treatment of a retained rate as basic pay for other purposes.

(a) * * *

(10) Adverse action provisions in 5 CFR part 752;

* * * * *

■ 39. In § 536.308—

■ a. Amend paragraph (a)(4) by removing ''representative rates'' and adding in its place ''comparison rates''; and

■ b. Revise paragraphs (a)(2) and (c).

The revisions read as follows:

§ 536.308 Loss of eligibility for or termination of pay retention.

(a) * * *

(2) The employee is entitled to a rate of basic pay under a covered pay system which is equal to or greater than the employee's retained rate (after applying any applicable geographic conversion under paragraph (b) of this section), except that entitlement to a retained rate will not be terminated based on entitlement to an equal or higher rate of basic pay during a temporary promotion or temporary reassignment but will be held in abeyance during that temporary period.

* * * * *

(c) Termination of pay retention benefits takes effect—

(1) At the end of the day before separation from service if termination is the result of a break in service;

(2) At the end of the day before the employee becomes entitled to an equal or greater rate as described in paragraph (a)(2) of this section;

(3) At the end of the day before placement or movement if the termination is the result of the employee's placement in or movement to another position; or

(4) At the end of the last day of the pay period in which the employee declines a reasonable offer.

* * * * *

PART 550—PAY ADMINISTRATION (GENERAL)

Subpart B—Advances in Pay

■ 40. The authority citation for subpart B of part 550 continues to read as follows:

Authority: 5 U.S.C. 5524a, 5545a(h)(2)(B); E.O. 12748, 3 CFR, 1992 Comp., p. 316.

■ 41. In § 550.202, amend the definition of *rate of basic pay* by adding the word ''supplement'' after ''special rate'' in paragraph (1) of the definition.

Subpart G—Severance Pay

■ 42. The authority citation for subpart G of part 550 continues to read as follows:

Authority: 5 U.S.C. 5595; E.O. 11257, 3 CFR, 1964–1965 Comp., p. 357.

■ 43. In § 550.703—

■ A. Add a definition of *comparison rate* in alphabetical order;

■ B. Amend the definition of *nonqualifying appointment* by removing paragraph (f)(2) and redesignating paragraphs (f)(3) through (f)(6) as paragraphs (f)(2) through (f)(5), respectively;

■ C. Amend the definition of *rate of basic* pay by adding the word ''supplement'' after ''special rate'' in paragraph (1) of the definition;

■ D. Amend the definition of *reasonable offer* by removing ''representative rate'' in both places in paragraph (c)(4) and by adding in its place ''comparison rate''; and

■ E. Remove the definition of *representative rate.*

The addition reads as follows:

§ 550.703 Definitions.

* * * * *

Comparison rate has the meaning given that term in § 536.103 of this chapter, except paragraph (2) of that definition should be used for the purpose of comparing grades or levels of work for all situations not covered by paragraph (1) of that definition.

* * * * *

PART 831—RETIREMENT

■ 44. The authority citation for part 831 continues to read as follows:

Authority: 5 U.S.C. 8347; Sec. 831.102 also issued under 5 U.S.C. 8334; Sec. 831.106 also issued under 5 U.S.C. 552a; Sec. 831.108 also issued under 5 U.S.C. 8336(d)(2); Sec. 831.114 also issued under 5 U.S.C. 8336(d)(2), and section 1313(b)(5) of Pub. L. 107–296, 116 Stat. 2135; Sec. 831.201(b)(1) also issued under 5 U.S.C. 8347(g); Sec. 831.201(b)(6) also issued under 5 U.S.C. 7701(b)(2); Sec. 831.201(g) also issued under sections 11202(f), 11232(e), and 11246(b) of Pub. L. 105–33, 111 Stat. 251; Sec. 831.201(g) also issued under section 7(b) and (e) of Pub. L. 105–274, 112 Stat. 2419; Sec. 831.201(i) also issued under sections 3 and 7(c) of Pub. L. 105–274, 112 Stat. 2419; Sec. 831.204 also issued under section 102(e) of Pub. L. 104–8, 109 Stat. 102, as amended by section 153 of Pub. L. 104–134, 110 Stat. 1321; Sec. 831.205 also issued under section 2207 of Pub. L. 106–265, 114 Stat. 784; Sec. 831.301 also issued under section 2203 of Pub. L. 106–265, 114 Stat. 780; Sec. 831.303 also issued under 5 U.S.C. 8334(d)(2) and section 2203 of Pub. L. 106–235, 114 Stat. 780; Sec. 831.502 also issued under 5 U.S.C. 8337; Sec. 831.502 also issued under section 1(3), E.O. 11228, 3 CFR 1964–1965 Comp. p. 317; Sec. 831.663 also issued under sections 8339(j) and (k)(2); Secs. 831.663 and 831.664 also issued under section 11004(c)(2) of Pub. L. 103–66, 107 Stat. 412; Sec. 831.682 also issued under section 201(d) of Pub. L. 99–251, 100 Stat. 23; Sec. 831.912 also issued under section 636 of Appendix C to Pub. L. 106–554, 114 Stat. 2763A–164; subpart V also issued under 5 U.S.C. 8343a and section 6001 of Pub. L. 100–203, 101 Stat. 1330–275; Sec. 831.2203 also issued under section 7001(a)(4) of Pub. L. 101–508, 104 Stat. 1388–328.

Subpart E—Eligibility for Retirement

■ 45. In § 831.503, revise paragraph (b)(3)(iv) to read as follows:

§ 831.503 Involuntary retirement.

* * * * *

(b) * * *

(3) * * *

(iv) Not lower than the equivalent of two grades or pay levels below the

employee's current grade or pay level, without consideration of the employee's eligibility to retain his or her current grade or pay under part 536 of this chapter or other authority. In movements between pay schedules or pay systems, the comparison rate of the grade or pay level that is two grades below that of the current position will be compared with the comparison rate of the grade or pay level of the offered position. For this purpose, ''comparison rate'' has the meaning given that term in § 536.103 of this chapter, except paragraph (2) of that definition should be used for the purpose of comparing grade or levels of work in making reasonable offer determinations in all situations not covered by paragraph (1) of that definition.

PART 842—FEDERAL EMPLOYEES RETIREMENT SYSTEM—BASIC ANNUITY

■ 46. The authority citation for part 842 continues to read as follows:

Authority: 5 U.S.C. 8461(g); Secs. 842.104 and 842.106 also issued under 5 U.S.C. 8461(n); Sec. 842.104 also issued under sections 3 and 7(c) of Pub. L. 105–274, 112 Stat. 2419; Sec. 842.105 also issued under 5 U.S.C. 8402(c)(1) and 7701(b)(2); Sec. 842.106 also issued under section 102(e) of Pub. L. 104–8, 109 Stat. 102, as amended by section 153 of Pub. L. 104–134, 110 Stat. 1321–102; Sec. 842.107 also issued under sections 11202(f), 11232(e), and 11246(b) of Pub. L. 105–33, 111 Stat. 251, and section 7(b) of Pub. L. 105–274, 112 Stat. 2419; Sec. 842.108 also issued under section 7(e) of Pub. L. 105–274, 112 Stat. 2419; Sec. 842.213 also issued under 5 U.S.C. 8414(b)(1)(B) and section 1313(b)(5) of Pub. L. 107–296, 116 Stat. 2135; Secs. 842.304 and 842.305 also issued under section 321(f) of Pub. L. 107–228, 116 Stat. 1383, Secs. 842.604 and 842.611 also issued under 5 U.S.C. 8417; Sec. 842.607 also issued under 5 U.S.C. 8416 and 8417; Sec. 842.614 also issued under 5 U.S.C. 8419; Sec. 842.615 also issued under 5 U.S.C. 8418; Sec. 842.703 also issued under section 7001(a)(4) of Pub. L. 101–508, 104 Stat. 1388; Sec. 842.707 also issued under section 6001 of Pub. L. 100–203, 101 Stat. 1300; Sec. 842.708 also issued under section 4005 of Pub. L. 101–239, 103 Stat. 2106 and section 7001 of Pub. L. 101–508, 104 Stat. 1388; subpart H also issued under 5 U.S.C. 1104; Sec. 842.810 also issued under section 636 of Appendix C to Pub. L. 106–554 at 114 Stat. 2763A–164; Sec. 842.811 also issued under section 226(c)(2) of Public Law 108–176, 117 Stat. 2529.

Subpart B—Eligibility

■ 47. In § 842.206, revise paragraph (c)(3)(iv) to read as follows:

§ 842.206 Involuntary retirement.

* * * * *

(c) * * *

(3) * * *

(iv) Not lower than the equivalent of two grades or pay levels below the employee's current grade or pay level, without consideration of the employee's eligibility to retain his or her current grade or pay under part 536 of this chapter or other authority. In movements between pay schedules or pay systems, the comparison rate of the grade or pay level that is two grades below that of the current position will be compared with the comparison rate of the grade or pay level of the offered position. For this purpose, ''comparison rate'' has the meaning given that term in § 536.103 of this chapter, except paragraph (2) of that definition should be used for the purpose of comparing grades or levels of work in making reasonable offer determinations in all situations not covered by paragraph (1) of that definition.

* * * * *

[FR Doc. E8–26562 Filed 11–6–08; 8:45 am]

BILLING CODE 6325–39–P

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 300

RIN 3206–AL18

Time-in-Grade Rule Eliminated

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is eliminating the time-in-grade restriction on advancement to competitive service positions in the General Schedule. The rule eliminates the 52-week time-in-grade requirement for promotions. Employees must continue to meet occupational qualification standard requirements and any additional job-related qualification requirements established for the position.

DATES: The rule is effective March 9, 2009.

FOR FURTHER INFORMATION CONTACT: Ms. Janice Warren by telephone (202) 606–0960; by FAX (202) 606–2329; by TTY (202) 418–3134; or by e-mail *janice.warren@opm.gov.*

SUPPLEMENTARY INFORMATION: On February 6, 2008, OPM published in the **Federal Register** at 73 FR 6857 a proposal to eliminate the time-in-grade (TIG) restriction found in 5 CFR part 300, subpart F. The restriction applies to Federal employees in competitive service General Schedule positions at grades 5 and above. These employees qualify for promotions to higher grades if they have: (1) At least one year of specialized experience equivalent in difficulty to the next lower grade level or (in some cases) the equivalent education; and (2) service of at least 52 weeks at their current grade (known as ''time in grade'').

The public comment period for the proposed regulation ended on April 7, 2008. We received comments from seven agencies, five unions, one national employee organization, and 33 individuals. We also received 61 form letters from individuals. We carefully considered the comments; as a result, we have decided to eliminate the time-in-grade restriction. The final regulation will become effective 120 days after the publication date of this notice in order to give agencies time to amend policies and communicate changes to their human resources staff and employees. Below is a discussion of the comments OPM received.

Comment Extension

The national employee organization and almost half of the form letter commenters suggested extending the comment period because the supplementary information accompanying the proposed rule provided incorrect dates for OPM's prior proposals to eliminate the time-in-grade restrictions. The February 6, 2008, proposal stated that OPM published its prior proposals on June 14, 1995, and January 10, 1996. In fact, they were published on June 15, 1994, and January 10, 1995. However, the February 6, 2008 proposal provided correct citations to the **Federal Register** notices for the prior proposals at 59 FR 30717 and 60 FR 2546, respectively.

We are not extending the comment period. OPM provided the dates and citations for its previously-published proposals as background information only. Potential commenters could adequately evaluate the February 6, 2008 proposal without reviewing the prior proposals. Moreover, the February 6, 2008 proposal supplied correct **Federal Register** citations for both of the previously-published proposals, thereby adequately facilitating their review by potential commenters.

Potential for Abuse and Favoritism

Many commenters stated that abolishing the time-in-grade requirement would lead to abuse of a manager's promotion authority, primarily because it would allow managers to promote their favorite employees. These commenters believe that eliminating the time-in-grade

requirement will subject agencies to charges of disparate treatment, and that the requirement ensures fairness and equity in promotions. One commenter also thinks too many individuals will reach their full performance levels in their positions too soon.

We disagree. The time-in-grade requirement is only one of the requirements for eligibility for promotion. Managers must still select only from those individuals who have at least one year of specialized experience equivalent in difficulty to the next lower grade level or (in some cases) the equivalent education. Moreover, individuals must meet occupational qualification standard requirements and any additional job-related qualification requirements established for the position.

Further, since the advent of the merit system, Federal managers always have possessed discretion to choose whom to promote. Managers are presumed to act in good faith in making employment decisions. In addition, there are safeguards in place to protect the merit system. Section 2302, which enumerates prohibited personnel practices, defines a personnel action as including a promotion, and enhances merit system protections that have existed in various forms since the Nineteenth Century.

When the time-in-grade restriction was first implemented, procedures for redressing prohibited personnel practices had not yet been enacted, and OPM's qualification standards did not exist. Eliminating the time-in-grade restriction does not alter management's responsibility to ensure that promotions are merit-based, and based on an individual's relative knowledge, skills, and abilities for a particular position.

In its oversight role, OPM will continue to review agency promotion actions for adherence to applicable requirements and identify necessary corrective actions.

The comment that the elimination of the time-in-grade requirement will result in individuals reaching their full performance levels too soon is merely speculative. The pace at which an employee advances to the full performance level of his or her position is a function of the employee's experience and/or knowledge, skills, and abilities relative to the qualification standard for the position. Even after the elimination of the time-in-grade restriction, qualification standards will provide the basis for managers to determine whether a particular employee is qualified for a promotion.

One individual commented that although safeguards against improper promotions exist, these systems have proven to be ineffective in responding to alleged violations and prescribing corrective or disciplinary actions. OPM is not responding to this comment because the efficacy of those safeguards is beyond the scope of these regulations.

Impact on Minorities and Veterans

Many commenters were concerned that eliminating the time-in-grade requirement would have a negative impact on minorities and veterans. There is no logical or factual basis for this concern. The time-in-grade restriction applied to all individuals seeking promotion above grade 5 to a competitive service position, without regard to whether employees are minorities or veterans. Accordingly, eliminating the restriction negates one of the requirements for advancement applicable to all individuals, including minorities and veterans. In making selections for promotions, managers and human resources staff continue to be bound by applicable civil service laws and the laws pertaining to equal employment opportunity.

Using Qualification Standards and Delegated Examining

A number of commenters questioned the use of qualification standards as the sole determination for promotion. They expressed concerns that qualification determinations will be subjective. Some commenters also felt that using qualification standards will lead to ''grade creep.''

Agencies use qualification standards to ensure candidates for promotion demonstrate at least one year or the appropriate level of education as outlined in the OPM Operating Manual Qualification Standards for General Schedule Positions (available on the OPM Web site (*http://www.opm.gov*)). An individual may demonstrate the required competencies (or knowledge, skills, and abilities) by paid or unpaid experience. This includes experience gained through school, volunteer work, military service, paid employment, or hobbies. Beyond the OPM qualification standards, agencies have discretion to establish additional requirements that employees must meet for promotions. Examples include a specified level of performance achieved; possession of specific job-related competencies (or knowledge, skills, and abilities); and evidence of ability to perform higher-level duties.

Qualification standards are minimum requirements intended to identify applicants who are likely to be able to perform successfully on the job, and to screen out those who are unlikely to do so. Qualification standards are only one element of a responsible human resources management program. They are not designed to substitute for a careful analysis of applicants' competencies (or knowledge, skills, and abilities).

Before qualification standards were implemented, agencies relied on time-in-grade to ensure that individuals were qualified for a higher-graded position. Now that qualification standards are in place, agencies are in a position to use the standards to determine which applicants will be able to perform at the higher grade levels.

With respect to the comment that the elimination of the time-in-grade restriction will lead to ''grade creep,'' as noted previously, managers are obligated to make promotion decisions based on an individual's experience and/or knowledge, skills, and abilities relative to the qualification standard for the position.

A number of commenters suggested that agencies should use delegated examining for identifying and promoting individuals who do not meet the time-in-grade requirement. This suggestion is based on a misunderstanding of examining procedures. An agency announces a vacancy using competitive examining procedures to allow candidates from outside the Federal workforce, current Federal employees without civil service status, and employees with civil service status in other positions to compete for the position. OPM has created ''delegated examining'' by entering into written agreements with most agencies authorizing them to conduct competitive examining. If a current Federal employee applies for a promotion under competitive examining procedures (typically through a vacancy announcement stating it is open to the general public), the employee does not need to meet a time-in-grade requirement.

In contrast, promotions filled under the merit promotion procedures in 5 CFR part 335, are open to current or former Federal employees who hold or did hold a career or career-conditional appointment in the competitive service. If an eligible current Federal employee applies for a position at a higher grade through a merit promotion announcement, the employee must meet the time-in-grade requirement.

The decision to fill a position using delegated examining or merit promotion procedures rests with the agency filling the position. If a current or former Federal employee who holds or did hold a career or career-conditional appointment in the competitive service wants to apply under both procedures,

the agency's own policy determines whether it will accept an application under both methods. If the agency allows the individual to apply only through merit promotion procedures, and the individual does not meet the time-in-grade requirement (but is otherwise qualified for the position), the agency will not consider the individual. Once the time-in-grade requirement is eliminated, the agency may consider otherwise qualified applicants who have less than 52 weeks in grade, regardless of the agency's chosen recruitment procedures.

One union commented that elimination of TIG will lead to agencies bidding against each other on the establishment of a time-in-grade requirement for promotion. Once TIG is eliminated, agencies are not required to implement their own TIG requirement. Agencies will use qualification standards for determining whether an employee has met the specified criteria needed for promotion to the next highest grade level.

Effect on Within-Grade Increases

Some commenters expressed concerns that elimination of the time-in-grade requirement would result in a reduction in the number of within-grade pay increases. Based on the descriptions of these concerns, we believe the commenters are referring to General Schedule (GS) within-grade increases (WGIs) authorized by 5 U.S.C. 5335 and 5 CFR part 531, subpart D. It appears there may be some confusion between the time-in-grade restriction for promotions and the waiting period for GS WGIs.

To clarify, the rate range for each GS grade has 10 step rates. WGIs or step increases are periodic increases in a GS employee's rate of basic pay from one step of the grade of his or her position to the next higher step of that grade. One of the requirements for earning a WGI is that the employee must have completed the required waiting period for advancement to the next higher step. For employees with a scheduled tour of duty, the required waiting period is 52 weeks, 104 weeks, or 156 weeks of creditable service, depending on the employee's current step. In contrast, time in grade is the amount of time one must stay at a particular grade (regardless of the step) in order to be eligible for promotion to the next higher grade level. Eliminating the time-in-grade requirement does not affect eligibility for WGIs.

Suggestions on OPM Actions

A number of commenters provided suggestions regarding what OPM can do to ensure fairness and equity in promotions. Suggestions included monitoring promotion rates for Government employees, requiring reports, and conducting random audits of agencies. As mentioned earlier, OPM will continue to monitor agency promotion actions through our normal oversight function. We do not believe additional reporting requirements are necessary.

One commenter suggested, as an alternative to time-in-grade elimination, that agencies give preference to individuals who are eligible for time in grade over those who are not eligible. We are not adopting this suggestion. Agency promotions are to be based on merit, using government-wide and agency-specific qualification standards. Therefore, OPM will no longer require that time in grade be considered in selecting individuals for promotions. Eliminating the time-in-grade restriction from the selection process reinforces the principle that promotions are based on an individual's ability to perform the requirements of the position, i.e. merit, and not the passage of time per se.

One commenter suggested, rather than eliminating time in grade, that agencies give incentives such as student loan repayments, performance awards, retention allowances, superior qualification appointments, retention allowances, flexiplace, and alternative work schedules to reward employees. We are not adopting this suggestion because it is based on the mistaken assumption that the items listed serve the same purpose as the time-in-grade requirement. TIG is an eligibility factor for a promotion. The items listed by the commenter, however, are recruitment and retention tools that do not define eligibility for promotion. Thus, use of the items mentioned would not be equivalent to eliminating the time-in-grade requirement.

Time in Grade as an Observation Period

One union suggested we keep the time-in-grade-restriction as a period for agencies to consider an employee's demonstrated ability to perform at the next highest grade level, and to provide supervisors with a time period during which they can motivate, develop, and prepare employees for promotion. As previously noted, after the requirement is eliminated, agencies will use qualification standards to ensure that candidates for promotion have demonstrated the ability to perform at the next highest grade level. In addition, agencies will utilize their performance management systems when considering individuals for promotion. Even after the elimination of the TIG requirement, supervisors will have some period of time to observe their employees' performance before recommending promotion. Supervisors are encouraged to motivate, develop, and prepare their employees for promotions, without regard to whether the employee is subject to a time in grade requirement.

Impact on Payroll Costs

One agency, a professional organization, several unions, and several individuals commented that elimination of the time-in-grade restriction would result in increased payroll costs for Federal agencies. This comment assumes that elimination of the time-in-grade requirement will correlate with an increase in the number promotions, thereby increasing payroll costs. Whether such a correlation will occur is merely speculative. Moreover, even if such a correlation were to occur, because the number of promotions is not the only factor that determines payroll costs, an increase in promotions may not lead to a rise in overall payroll costs. Payroll costs depend on a variety of other factors, including collective bargaining agreements and the agency's rate of attrition. Further, agencies are presumed to use sound management practices in making promotions, including consideration of the financial consequences of their decisions.

E.O. 12866, Regulatory Review

The Office of Management and Budget has reviewed the final rule in accordance with Executive Order 12866.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it affects only certain Federal employees.

List of Subjects in 5 CFR Part 300

Freedom of information, Government employees, Reporting and recordkeeping requirements, Selective service system.

Office of Personnel Management.

Michael W. Hager,

Acting Director.

■ Accordingly, OPM is revising 5 CFR part 300 to read as follows:

PART 300—EMPLOYMENT (GENERAL)

■ 1. Revise the authority citation for part 300 to read as follows:

Authority: 5 U.S.C. 552, 3301, 3302; E.O. 10577, 3 CFR, 1954–1958 Comp., page 218, unless otherwise noted.

Secs. 300.101 through 300.104 also issued under 5 U.S.C. 7201, 7204, 7701; E.O. 11478, 3 CFR, 1966–1970 Comp., page 803.

Sec. 300.301 also issued under 5 U.S.C. 1104 and 3341.

Secs. 300.401 through 300.408 also issued under 5 U.S.C. 1302(c), 2301, and 2302.

Secs. 300.501 through 300.507 also issued under 5 U.S.C. 1103(a)(5).

Subpart F—[Removed and Reserved]

■ 2. Remove and reserve subpart F, consisting of § 300.601 through § 300.606.

[FR Doc. E8–26559 Filed 11–6–08; 8:45 am]

BILLING CODE 6325–39–P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 370

RIN 3064–AD37

Temporary Liquidity Guarantee Program

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Amendment to the Interim Rule with request for comments.

SUMMARY: The FDIC is amending its Interim Rule with Request for Comment (Interim Rule) relating to implementation of its Temporary Liquidity Guarantee Program (TLG Program) by extending the opt out date for eligible entities until December 5, 2008; extending the deadline for complying with certain disclosure requirements related to the TLG Program until December 19, 2008; and establishing assessment procedures to accommodate the extended opt out period.

DATES: The Amended Interim Rule becomes effective on November 4, 2008. The effective date of § 370.5 paragraphs (h)(2) and (h)(3), added at 73 FR 64186, October 29, 2008, is delayed from December 1, 2008 until December 19, 2008. The FDIC seeks general and specific comments relating to questions raised in both the Amended Interim Rule and the Interim Rule. Comments regarding both the Amended Interim Rule and the Interim Rule must be received by November 13, 2008.

ADDRESSES: You may submit comments on the Amended Interim Rule by any of the following methods:

- *Agency Web Site: http://www.FDIC.gov/regulations/laws/federal/notices.html.* Follow instructions for submitting comments on the Agency Web Site.
- *E-mail: Comments@FDIC.gov.* Include RIN # 3064–AD37 on the subject line of the message.
- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m.

Instructions: All comments received will be posted generally without change to *http://www.fdic.gov/regulations/laws/federal/propose.html*, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: William V. Farrell, Manager, Assessment Operations Section, Division of Finance, (703) 562–6168 or *wfarrell@fdic.gov*; Donna Saulnier, Manager, Assessment Policy Section, Division of Finance, (703) 562–6167 or *dsaulnier@fdic.gov*; Richard Bogue, Counsel, Legal Division, (202) 898–3726 or *rbogue@fdic.gov*; Robert Fick, Counsel, Legal Division, (202) 898–8962 or *rfick@fdic.gov*; A. Ann Johnson, Counsel, Legal Division, (202) 898–3573 or *aajohnson@fdic.gov*; Gail Patelunas, Deputy Director, Division of Resolutions and Receiverships, (202) 898–6779 or *gpatelunas@fdic.gov*; John Corston, Associate Director (Large Bank Supervision), Division of Supervision and Consumer Protection, (202) 898–6548 or *jcorston@fdic.gov*; Serena L. Owens, Associate Director, Supervision and Applications Branch, Division of Supervision and Consumer Protection, (202) 898–8996 or *sowens@fdic.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The TLG Program was first announced by the FDIC on October 14, 2008, as an initiative to counter the current system-wide crisis in the nation's financial sector. It provided two limited guarantee programs: One, that guaranteed newly-issued senior unsecured debt of insured depository institutions and most U.S. holding companies of such insured depository institutions (the debt guarantee program), and another, that guaranteed certain noninterest-bearing transaction accounts at insured depository institutions (the transaction account guarantee program).

The FDIC's action in establishing the TLG Program was preceded by a determination of systemic risk by the Secretary of the Treasury (after consultation with the President), following receipt of the written recommendation of the Board on October 13, 2008, along with a similar written recommendation of the Board of Governors of the Federal Reserve System.

The recommendations and eventual determination of systemic risk were made in accordance with section 13(c)(4)(G) to the Federal Deposit Insurance Act (FDI Act), 12 U.S.C. 1823(c)(4)(G). The determination of systemic risk allowed the FDIC to take certain actions to avoid or mitigate serious adverse effects on economic conditions and financial stability. The FDIC believes that the TLG Program promotes financial stability by preserving confidence in the banking system and encouraging liquidity in order to ease lending to creditworthy businesses and consumers. As a result, on October 23, 2008, the FDIC's Board of Directors authorized publication in the **Federal Register** and requested comment regarding an Interim Rule designed to implement the TLG Program. The Interim Rule was published on October 29, 2008.[1] It became effective on October 23, 2008, with the exception of certain disclosure requirements for which a delayed effective date of December 1, 2008 was established.[2] The FDIC requested comments regarding the Interim Rule by November 13, 2008.

II. Opt Out Deadline in the Interim Rule

The Interim Rule provides that no later than 11:59 p.m. Eastern Standard Time (EST), on November 12, 2008, each eligible entity[3] must inform the FDIC if it desires to opt out of the debt guarantee component or the transaction account guarantee component (or both components) of the TLG Program.[4] If an eligible entity opts out of the TLG Program, coverage under the program ends on the earlier of the date of the opt out or on November 12, 2008.[5] According to the Interim Rule, failure to opt out by November 12, 2008 constitutes a decision on behalf of an eligible entity to remain in the

[1] 73 FR 64179 (Oct. 29, 2008).

[2] 12 CFR 370.5(h)(2) and (h)(3).

[3] 12 CFR 370.2(a) defines ''eligible entity'' as any of the following: (1) An insured depository institution; (2) a U.S. bank holding company, provided that it has at least one chartered and operating insured depository institution within its holding company structure; (3) a U.S. savings and loan holding company, provided that it has at least one chartered and operating insured depository institution within its holding company structure; or (4) other affiliates of insured depository institutions that the FDIC after consultation with the appropriate Federal banking agency, designate as eligible entities which affiliates, by seeking and obtaining such designation, will have opted in to the debt guarantee program.

[4] 12 CFR 370.5(c).

[5] 12 CFR 370.5(a).

program.[6] Prior to November 12, 2008, an eligible entity may also notify the FDIC that it will not opt out of (that is, that it will opt in to) either or both programs.[7] The choice to opt out or in, once made, is irrevocable.[8]

The opt out deadline of November 12, 2008 is referenced in several sections of the Interim Rule in describing the scope of the guarantees provided by the TLG Program. For example, the Interim Rule provides that funds held in noninterest-bearing transaction accounts at eligible entities will be guaranteed from October 14, 2008, through November 12, 2008,[9] and that eligible entities that do not opt out on or before November 12, 2008 will not be able to select which newly issued senior unsecured debt[10] is guaranteed debt under the Debt Guarantee Program.[11]

Significantly, in the Interim Rule calculations involving assessments charged to an eligible entity for its participation in the TLG Program are related to the November 12, 2008 opt out date. For example, the Interim Rule permits eligible entities to participate in both components of the TLG Program from October 14, 2008, through November 12, 2008, at no cost to the entities.[12]

With respect to the Debt Guarantee Program, the Interim Rule requires an eligible entity that does not opt out of the program by the opt out date of November 12, 2008, and that issues guaranteed debt during the period from October 14, 2008, through November 12, 2008 that was still outstanding on November 12, 2008, to notify the FDIC and certify that the issuances that it made did not exceed the guaranteed limit.[13] (An eligible entity that has not opted out of the Debt Guarantee Program and that issues debt after November 12, 2008, is subject to similar notification and certification requirements.) Beginning on November 13, 2008, if an eligible entity has not opted out, the Interim Rule provides for eligible entities to be charged assessments for their participation in the Debt Guarantee Program.[14]

With respect to the Transaction Account Guarantee Program, the Interim Rule provides that, beginning on November 13, 2008 and continuing through December 31, 2009, any eligible entity that has not opted out of this component of the TLG Program will be subject to an assessment for its participation in the Transaction Account Guarantee Program.

III. Opt Out and Disclosure Deadlines Extended in the Amended Interim Rule

The comment period for the Interim Rule will expire on November 13, 2008. Thus, the FDIC will not issue a final rule concerning its TLG Program before eligible entities are required to opt out on November 12, 2008, as prescribed in the Interim Rule. The FDIC anticipates issuing a final rule after the expiration of the comment period and after its consideration of comments related to the Interim Rule. In order to provide eligible entities an opportunity to review the final rule before they are required to decide whether or not to opt out, this Amended Interim Rule extends the opt out deadline for the TLG Program until December 5, 2008. For similar reasons, this Amended Interim Rule extends the deadline for compliance with certain disclosure requirements described in section 370.5(h) until December 19, 2008.

By establishing December 5, 2008 as the new opt out deadline, conforming modifications are required to provisions of part 370 that refer to or are based upon the previous opt out deadline of November 12, 2008. The changes that result from the extended opt out period are technical in nature, and are not discussed in further detail. Those changes that relate to assessments under the Debt Guarantee Program and the Transaction Guarantee Program are described further below.

Assessments under the Debt Guarantee Program are discussed in section 370.6. Under section 370.6(a), eligible entities are not required to pay any assessment associated with the Debt Guarantee Program for the period from October 14, 2008, through November 12, 2008. The amendments made to the Interim Rule retain this provision. In addition, section 370.6(a) of the Amended Interim Rule includes a provision to the effect that an eligible entity that opts out of the Debt Guarantee Program by the extended deadline of December 5, 2008 will not pay any assessment under the program.

Sections 370.6(b)(1) and (2) contain notice and certification requirements for eligible entities that issue guaranteed debt under the Debt Guarantee Program for the period from October 14, 2008 through November 12, 2008 and for the period after November 12, 2008, respectively. Although the notification and certification requirements have not changed, the references in those sections to the former opt out deadline of November 12, 2008, have been changed to reflect the new opt out deadline of December 5, 2008.

Section 370.6(c) governs the initiation of assessments for the Debt Guarantee Program. It originally provided that beginning on November 13, 2008, any eligible entity that has chosen not to opt out of this aspect of the TLG Program would be charged assessments as provided elsewhere in part 370. The section did not distinguish between overnight debt instruments and other types of newly issued senior secured debt. Although the manner of calculating assessments has not changed, the revisions to section 370.6(c) reflect two changes. The first change reflects the newly extended opt out deadline, and the second change differentiates between overnight debt instruments and other newly issued senior unsecured debt and explains how assessments are initiated for overnight debt instruments as compared with other newly issued senior unsecured debt.

Section 370.6(c), as amended, provides that assessments will accrue, with respect to each eligible entity that does not opt out of the debt guarantee program on or before December 5, 2008 (1) beginning on November 13, 2008, on all senior unsecured debt, other than overnight debt instruments, issued by it on or after October 14, 2008 that is still outstanding on November 13, 2008; (2) beginning on November 13, 2008, on all senior unsecured debt, other than overnight debt instruments, issued by it on or after November 13, 2008 and before December 6, 2008; and (3) beginning on December 6, 2008, on all senior unsecured debt issued by it on or after December 6, 2008. Calculations related to both overnight debt instruments and other newly issued unsecured debt will continue to be made in accordance with section 370.6(d). Section 370.6(d) remains unchanged.

Assessments under the Transaction Account Guarantee Program are discussed in section 370.7. Under section 370.7(a), eligible entities are not required to pay an assessment associated with the Transaction Account Guarantee Program from the

[6] 12 CFR 370.5(c).

[7] *Id.*

[8] 12 CFR 370.5(d).

[9] 12 CFR 370.5(j)(2).

[10] 12 CFR 370.2(f) defines ''newly issued senior unsecured debt'' as senior unsecured debt issued by a participating entity on or after October 14, 2008, and on or before: (1) The earlier of November 12, 2008 or the date an eligible entity opts out, for an eligible entity that opts out of the debt guarantee program; or (2) June 30, 2009, for an eligible entity that does not opt out of the debt guarantee program.

[11] 12 CFR 370.5(f). The limitations of this provision are subject to 12 CFR 370.3(f), describing the long term non-guaranteed debt option.

[12] 12 CFR 370.6(a) and 370.7(a).

[13] 12 CFR 370.6(b)(1) and (2).

[14] 12 CFR 370.6(c).

period October 14, 2008, through November 12, 2008. The Amended Interim Rule adds a new provision to section 370.7(a) to the effect that an eligible entity that opts out of the Transaction Account Guarantee Program by the extended opt out deadline of December 5, 2008 will not pay any assessment under the program.

Section 370.7(b) governs the initiation of assessments for the Transaction Account Guarantee Program. It originally provided that for the period beginning on November 13, 2008, and continuing through December 31, 2009, any eligible entity that failed to notify the FDIC that it had opted out of the Transaction Account Guarantee Program would be charged an assessment for its participation in the Transaction Account Guarantee Program. Section 370.7(b) of the Amended Interim Rule contains references to the newly extended opt out date. The amended section now provides that beginning on November 13, 2008, an eligible entity that does not opt out of the Transaction Account Guarantee Program on or before December 5, 2008 will be required to pay the FDIC assessments on all deposit amounts in noninterest-bearing transaction accounts. Calculations related to the amount of assessments for the Transaction Account Guarantee Program will continue to be made in accordance with section 370.7(c). Section 370.7(c) remains unchanged.

IV. Request for Comments

The FDIC requests comments on all aspects of the Amended Interim Rule. The FDIC specifically requests comments on the following questions:

1. Should the FDIC charge different premium rates for Fed Funds and/or other short-term borrowings versus longer term borrowings? If so, why, what should be the criteria for determining which borrowings qualify for which rates, and what should be the rate differential?

2. Should banks be allowed to issue guaranteed debt in an amount equal to the bank's cap plus its holding company's(ies') cap, so long as the total guaranteed debt issued by the bank and its holding company(ies) does not exceed their combined cap? If so, why, and how could this process be managed to assure, among other things, that the entities together do not exceed their combined cap?

3. Section 370.3(b) of the Interim Rule states, ''If a participating entity had no senior unsecured debt on September 30, 2008, the entity may seek to have some amount of debt covered by the debt guarantee program. The FDIC, after consultation with the appropriate Federal banking agency, will decide whether, and to what extent, such requests will be granted on a case-by-case basis.'' Should the FDIC establish an alternative guarantee cap, e.g., a percentage of total liabilities, or an average of outstanding senior unsecured debt over some period of time, for those eligible entities that had no or de minimis amounts of senior unsecured debt outstanding on September 30, 2008? If so, what should that alternative be, and why?

V. Regulatory Analysis and Procedure

A. Administrative Procedure Act

Pursuant to section 553(b)(B) of the Administrative Procedure Act (APA), notice and comment are not required prior to the issuance of a final rule if an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. In addition, section 553(d)(3) of the APA provides that an agency, for good cause found and published with the rule, does not have to comply with the requirements that a final rule be published not less than 30 days before its effective date. The FDIC invoked these good cause exceptions to make the Interim Rule effective on October 23, 2008, due to the severe financial conditions that threaten the stability of the nation's economy generally and the banking system in particular, the serious adverse effects on economic conditions and financial stability that would result from any delay of the effective date of the Interim Rule, and the fact that the Temporary Liquidity Guarantee Program became effective on October 14, 2008.

For the same reasons, and because comments regarding the Interim Rule may be submitted through November 13, 2008, and because the delay that would result from complying with notice and public procedure in connection with the Amended Interim Rule would frustrate the FDIC's objective of quickly restoring liquidity to the financial markets, the FDIC finds good cause to adopt the Amended Interim Rule without prior notice and comment and without the 30-day delayed effective date.

B. Community Development and Regulatory Improvement Act

The Riegle Community Development and Regulatory Improvement Act (RCDRIA) requires that any new rule prescribed by a Federal banking agency that imposes additional reporting, disclosures, or other new requirements on insured depository institutions take effect on the first day of a calendar quarter unless the agency determines, for good cause published with the rule, that the rule should become effective before such time.[15] The FDIC invoked the RCDRIA's good cause exception to make the Interim Rule effective on October 23, 2008 due to the severe financial conditions that threaten the stability of the nation's economy generally and the banking system in particular, the serious adverse effects on economic conditions and financial stability that would result from any delay of the effective date of the Interim Rule, and the fact that the Temporary Liquidity Guarantee Program has been in effect since October 14, 2008.

For the same reasons, the FDIC finds good cause to make the Amended Interim Rule effective immediately. In addition, the Amended Interim Rule does not impose any additional reporting, disclosures, or other new requirements on insured depository institutions that were not already imposed by the Interim Rule.

C. Small Business Regulatory Enforcement Fairness Act

The Office of Management and Budget has previously determined that the Interim Rule is not a ''major rule'' within the meaning of the relevant sections of the Small Business Regulatory Enforcement Act of 1996 (SBREFA), 5 U.S.C. 801 *et seq.* As required by SBREFA, the FDIC will file the appropriate reports with Congress and the General Accounting Office so that the Interim Rule and the Amended Interim Rule may be reviewed.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency that is issuing a proposed rule to prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities. Like the Interim Rule, this Amended Interim Rule does not involve the issuance of a notice of proposed rulemaking. As a result, the requirements of the RFA do not apply.

E. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the information collections contained in the Interim Rule issued by the Board on October 23, 2008, were submitted to and approved by the Office of Management and Budget (OMB) under emergency clearance procedures and assigned OMB Control No. 3064–0166 (expiring on April 30, 2009). The Amended Interim

[15] 12 U.S.C. 4802.

Rules does not affect the collections of information outlined in the Interim Rule nor does it affect the estimated burden set forth in the Interim Rule.

List of Subjects in 12 CFR Part 370

Banks, Banking, Bank deposit insurance, Holding companies, National banks, Reporting and recordkeeping requirements, Savings associations.

■ For the reasons stated above, The Board of Directors of the Federal Deposit Insurance Corporation amends 12 CFR part 370 as follows:

PART 370—TEMPORARY LIQUIDITY GUARANTEE PROGRAM

■ 1. The authority citation for part 370 continues to read as follows:

Authority: 12 U.S.C. 1813(l), 1813(m), 1817(i), 1818, 1819(a) (Tenth); 1820(f), 1821(a); 1821(c); 1821(d); 1823(c)(4).

§ 370.2 [Amended]

■ 2. Amend § 370.2 as follows:

■ A. In paragraph (f), remove ''November 12'' and replace it with ''December 5''.

■ B. In paragraph (g), remove ''November 12'' and replace it with ''December 5'' and remove ''November 13'' wherever it appears and replace it with ''December 6''.

§ 370.3 [Amended]

■ 3. Amend § 370.3 as follows:

■ In paragraphs (b) and (f), remove ''November 12'' wherever it appears and replace it with ''December 5''.

§ 370.5 [Amended]

■ 4. Amend § 370.5 as follows:

■ A. In paragraphs (a), (c), (f), and (j), remove ''November 12'' wherever it appears and replace it with ''December 5''.

■ B. In paragraph (h), remove ''December 1'' and replace it with ''December 19''.

■ 5. Amend § 370.6 by revising paragraphs (a), (b)(1), (b)(2), and (c) to read as follows:

§ 370.6 Assessments under the Debt Guarantee Program.

(a) *Waiver of assessment for certain initial periods.* No eligible entity shall pay any assessment associated with the debt guarantee program for the period from October 14, 2008 through November 12, 2008. An eligible entity that opts out of the program on or before December 5, 2008 will not pay any assessment under the program.

(b) * * *

(1) Any eligible entity that does not opt out of the Debt Guarantee Program on or before December 5, 2008, as provided in § 370.5, and that issues any guaranteed debt during the period from October 14, 2008 through December 5, 2008 which is still outstanding on December 5, 2008, shall notify the FDIC of that issuance via the FDIC's e-business Web site FDIC*connect* on or before December 19, 2008, and the eligible entity's Chief Financial Officer or equivalent shall certify that the issuances outstanding at each point of time did not exceed the guaranteed amount limit as set forth in § 370.3.

(2) Any eligible entity that does not opt out of the program and that issues guaranteed debt after December 5, 2008, shall notify the FDIC of that issuance via the FDIC's e-business Web site FDIC*connect* within the time period specified by the FDIC. The eligible entity's Chief Financial Officer or equivalent shall certify that the issuance of guaranteed debt does not exceed the guarantee limit as set forth in § 370.3.

* * * * *

(c) *Initiation of assessments.* Assessments, calculated in accordance with paragraph (d) of this section, will accrue, with respect to each eligible entity that does not opt out of the debt guarantee program on or before December 5, 2008.

(1) Beginning on November 13, 2008, on all senior unsecured debt, other than overnight debt instruments, issued by it on or after October 14, 2008 that is still outstanding on November 13, 2008;

(2) Beginning on November 13, 2008, on all senior unsecured debt, other than overnight debt instruments, issued by it on or after November 13, 2008 and before December 6, 2008; and

(3) Beginning on December 6, 2008, on all senior unsecured debt issued by it on or after December 6, 2008.

■ 6. Amend § 370.7 by revising paragraphs (a) and (b) to read as follows:

§ 370.7 Assessments under the Transaction Account Guarantee Program.

(a) *Waiver of assessment for certain initial periods.* No eligible entity shall pay any assessment associated with the transaction account guarantee program for the period from October 14, 2008, through November 12, 2008. An eligible entity that opts out of the program on or before December 5, 2008 will not pay any assessment under the program

(b) *Initiation of assessments.* Beginning on November 13, 2008 each eligible entity that does not opt out of the transaction account guarantee program on or before December 5, 2008 will be required to pay the FDIC assessments on all deposit amounts in noninterest-bearing transaction accounts calculated in accordance with paragraph (c) of this section.

* * * * *

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. E8–26569 Filed 11–4–08; 4:15 pm]

BILLING CODE 6714–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. CE285, Special Conditions No. 23–225A–SC]

Final Special Conditions: AmSafe Aviation; Inflatable Restraints Installation; Approved Model List of Normal and Utility Category Airplanes, and Agricultural Airplanes Certificated in the Normal/Utility/Restricted Category

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for AmSafe Aviation to amend the list of approved models. These airplanes, as modified by AmSafe Aviation, will have novel and unusual design features associated with the lap belt or shoulder harness portion of the safety belt, which contains an integrated airbag device. The applicable airworthiness regulations do not contain adequate and appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the airworthiness standards.

DATES: The effective date of these amended special conditions is October 31, 2008. Comments must be received on or before December 8, 2008.

ADDRESSES: Mail two copies of your comments on these amended special conditions to: Federal Aviation Administration (FAA), Regional Counsel, ACE–7, Attention: Rules Docket, Docket No. CE285, 901 Locust, Room 506, Kansas City, Missouri 64106, or you may deliver two copies to the Regional Counsel at the above address. Mark your comments: Docket No. CE285. You may inspect comments in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Mr. Bob Stegeman, Federal Aviation Administration, Small Airplane Directorate, Aircraft Certification Service, ACE–111, 901 Locust, Kansas City, Missouri, 816–329–4140, fax 816–329–4090, e-mail *Robert.Stegeman@faa.gov.*

SUPPLEMENTARY INFORMATION: The FAA has determined that notice and opportunity for prior public comment hereon are impracticable because these procedures would significantly delay issuance of the approval design and thus delivery of the affected aircraft. In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA, therefore, finds that good cause exists for making these amended special conditions effective upon issuance.

Comments Invited

We invite interested persons to participate in the making of these special conditions by submitting such written data, views, or arguments as they may desire. Identify the regulatory docket or notice number and submit the comments in duplicate to the address specified above. All comments received on or before the closing date for comments will be considered by the Administrator. The special conditions may be changed in light of the comments received. All comments received will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include a self-addressed, stamped postcard on which the following statement is made: ''Comments to CE285.'' The postcard will be date stamped and returned to the commenter.

Background

On June 18, 2008, AmSafe Aviation, 1043 North 47th Avenue, Phoenix, AZ 85043, applied to add several more models to an existing supplemental type certificate. The AML STC allows for the installation of inflatable restraints in airplane models included herein that were certificated prior to the dynamic seat rule specified in 14 CFR part 23, § 23.562.

AmSafe Aviation has previously applied for and obtained an Approved Model List (AML) Supplemental Type Certificate (STC) for the installation of Inflatable Two-, Three-, Four- or Five-Point Restraint Safety Belts with an Integrated Airbag Device in airplanes certificated in the Part 23 Normal/Utility and Restricted-Agricultural categories.

This special condition includes additional normal and utility category aircraft.

The inflatable restraint system is either a two-, three-, four-, or five-point safety belt restraint system consisting of a shoulder harness and a lap belt with an inflatable airbag attached to either the lap belt or the shoulder harness. The inflatable portion of the restraint system will rely on sensors to electronically activate the inflator for deployment. The inflatable restraint system will be made available on the pilot, co-pilot, and passenger seats of these airplanes.

If an emergency landing occurs, the airbag will inflate and provide a protective cushion between the occupant's head and structure within the airplane. This will reduce the potential for head and torso injury. The inflatable restraint behaves in a manner that is similar to an automotive airbag. However, in this case, the airbag is integrated into the lap or shoulder belt. While airbags and inflatable restraints are standard in the automotive industry, the use of an inflatable restraint system is novel for aircraft operations.

The FAA has determined that this project will be accomplished on the basis of not lowering the current level of safety of the airplanes' original certification basis. The FAA has two primary safety concerns with the installation of airbags or inflatable restraints:

- That they perform properly under foreseeable operating conditions; and
- That they do not perform in a manner or at such times as to impede the pilot's ability to maintain control of the airplane or constitute a hazard to the airplane or occupants.

The latter point has the potential to be the more rigorous of the requirements. An unexpected deployment while conducting the takeoff or landing phases of flight may result in an unsafe condition. The unexpected deployment may either startle the pilot, or it may generate a force sufficient to cause a sudden movement of the control yoke. Either action could result in a loss of control of the airplane, the consequences of which are magnified due to the low operating altitudes during these phases of flight. This consideration is of special concern for aircraft designated for agricultural use because these aircraft spend a majority of their flight time at low altitudes. The FAA has considered this when establishing these amended special conditions.

The inflatable restraint system relies on sensors to electronically activate the inflator for deployment. These sensors could be susceptible to inadvertent activation, causing deployment in a potentially unsafe manner. The consequences of an inadvertent deployment must be considered in establishing the reliability of the system. AmSafe Aviation must show that the effects of an inadvertent deployment in flight are not a hazard to the airplane or that an inadvertent deployment is extremely improbable.

In addition, general aviation and agricultural aircraft are susceptible to a large amount of cumulative wear and tear on a restraint system. It is likely that the potential for inadvertent deployment increases as a result of this cumulative damage. Therefore, the impact of wear and tear on inadvertent deployment must be considered. Due to the effects of this cumulative damage, a life limit must be established for the appropriate system components in the restraint system design.

There are additional factors to be considered to minimize the chances of inadvertent deployment. General aviation airplanes are exposed to a unique operating environment, since the same airplane may be used by both experienced and student pilots. The effect of this environment on inadvertent deployment must be understood. Therefore, qualification testing of the firing hardware/software must consider the following:

- The airplane vibration levels appropriate for general aviation and agricultural airplanes; and
- The inertial loads that result from typical flight/ground maneuvers, gusts, hard landings and flight maneuvering unique to both general aviation and agricultural aircraft operations.

Any tendency for the firing mechanism to activate as a result of these loads or acceleration levels is unacceptable.

Other influences on inadvertent deployment include high intensity electromagnetic fields (HIRF) and lightning. Since the sensors that trigger deployment are electronic, they must be protected from the effects of these threats. To comply with HIRF and lightning requirements, the AmSafe Aviation inflatable restraint system is considered a critical system, since its inadvertent deployment could have a hazardous effect on the airplane.

Given the level of safety of the retrofitted airplane occupant restraints,

the inflatable restraint system must show that it will offer an equivalent level of protection in the event of an emergency landing. If a deployment occurs, the restraint must still be at least as strong as a Technical Standard Order approved belt and shoulder harnesses. There is no requirement for the inflatable portion of the restraint to offer protection during multiple impacts.

The inflatable restraint system must deploy and provide protection for each occupant during crash conditions as specified in the original certification basis. Therefore, the test emergency landing loads identified in the original certification basis of the airplane must be used to satisfy this requirement. It must be shown that the inflatable restraint will deploy and provide protection under crash conditions as specified in the original certification basis. Compliance will be demonstrated using the test condition specified in the original certification basis. It must be shown that the crash sensor will trigger when exposed to a rapidly applied deceleration, like an actual crash event. Therefore, the test crash pulses identified in § 23.562 must be used to satisfy this requirement, although the peak ''G'' may be reduced to a level meeting the original certification requirements of the aircraft. Testing to these pulses will demonstrate that the crash sensor will trigger when exposed to a rapidly applied deceleration, like an actual crash event.

It is possible a wide range of occupants will use the inflatable restraint. Thus, the protection offered by this restraint should be effective for occupants that range from the fifth percentile female to the ninety-fifth percentile male.

In support of this operational capability, there must be a means to verify the integrity of this system before each flight. As an option, AmSafe Aviation can establish inspection intervals where they have demonstrated the system to be reliable between these intervals.

An inflatable restraint may be ''armed'' even though no occupant is using the seat. While there will be means to verify the integrity of the system before flight, it is also prudent to require that unoccupied seats with active restraints not constitute a hazard to any occupant. This will protect any individual performing maintenance inside the cockpit while the aircraft is on the ground. The restraint must also provide suitable visual warnings that would alert rescue personnel to the presence of an inflatable restraint system.

In addition, the design must prevent the inflatable seatbelt from being incorrectly buckled and/or installed such that the airbag would not properly deploy. As an alternative, AmSafe Aviation may show that such deployment is not hazardous to the occupant and will still provide the required protection.

The cabins of the various model airplanes identified in these special conditions are confined areas, and the FAA is concerned that noxious gases may accumulate if an airbag deploys. When deployment does occur, either by design or inadvertently, there must not be a release of hazardous quantities of gas or particulate matter into the cockpit.

An inflatable restraint should not increase the risk already associated with fire. Therefore, the inflatable restraint should be protected from the effects of fire, so that an additional hazard is not created by, for example, a rupture of the inflator.

Finally, the airbag is likely to have a large volume displacement, and it may impede the egress of an occupant. Since the bag deflates to absorb energy, it is likely that the inflatable restraint would be deflated at the time an occupant would attempt egress. However, it is appropriate to specify a time interval after which the inflatable restraint may not impede rapid egress. Ten seconds has been chosen as reasonable time. This time limit will offer a level of protection throughout the impact event.

Special conditions for the installation of AAIR systems on other certificated airplanes have been issued and no substantive public comments were received. Since the same special conditions were issued multiple times for different model airplanes with no substantive public comments, the FAA began issuing direct final special conditions with an invitation for public comment. This was done to eliminate the waiting period for public comments and to allow AmSafe Aviation to proceed with the project.

These previous special conditions were typically issued for a single model airplane or for variants of a model from a single airplane manufacturer, and required dynamic testing of each AAIR system installation for showing compliance. Since AmSafe Aviation has previously demonstrated by dynamic testing, and has the supporting data, that the Electronics Module Assembly (EMA) and inflator assembly will function as intended in a simulated dynamic emergency landing, it is not necessary to repeat the test for each airplane model shown in these amended special conditions.

Type Certification Basis

Under the provisions of 14 CFR part 21, § 21.101, AmSafe Aviation must show that affected airplane models, as changed, continue to meet the applicable provisions of the regulations incorporated by reference in the Type Certificate Numbers listed below or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate data sheet are commonly referred to as the original ''type certification basis'' and can be found in the Type Certificate Data Sheets for the numbers listed below. The following models are covered by this amended special condition:

LIST OF ALL AIRPLANE MODELS AND APPLICABLE TCDS

Make	Model	TC holder	TCDS	Certification basis
1 Aerostar	PA–60–600 (Aerostar 600) PA–60–601 (Aerostar 601) PA–60–601P (Aerostar 601P) PA–60–602P (Aerostar 602P) PA–60–700P (Aerostar 700P)	Aerostar Aircraft Corporation.	A17WE, Revision 22	14 CFR PART 23.
1 All American	10A	All American Aircraft, Inc	A–792	CAR 3.
1 American Champion (Champion).	402	American Champion Aircraft Corp.	A3CE, Revision 5	CAR 3.

LIST OF ALL AIRPLANE MODELS AND APPLICABLE TCDS—Continued

Make	Model	TC holder	TCDS	Certification basis
1 American Champion (Bellanca) (Champion) (Aeronca).	7AC, 7ACA, 7EC, 7GCB, S7AC, S7EC, 7GCBA (L–16A), 7BCM, 7ECA, 7GCBC (L–16B), 7CCM, 7FC, 7HC, S7CCM, 7GC, 7JC, 7DC, 7GCA, 7KC, S7DC, 7GCAA, 7KCAB.	American Champion Aircraft Corp.	A–759, Revision 67	CAR 4a.
1 American Champion (Bellanca) (Trytek) (Aeronca).	11AC, S11AC, 11BC, S11BC	American Champion Aircraft Corp.	A–761, Revision 17	CAR 4a.
1 American Champion (Bellanca) (Trytek) (Aeronca).	11CC, S11CC	American Champion Aircraft Corporation.	A–796, Revision 14	CAR 3.
1 VARGA (Morrisey)	2150, 2150A, 2180	Augustair, Inc.	4A19, Revision 9	CAR 3.
1 Bellanca	14–13, 14–13–2, 14–13–3, 14–13–3W	Bellanca Aircraft Corporation.	A–773, Revision 10	CAR 4a.
1 Bellanca	14–9, 14–9L	Bellanca Aircraft Corporation.	TC716	CAR 4a.
1 Cessna	120, 140	Cessna Aircraft Company.	A–768, Revision 34	CAR 4a.
1 Cessna	140A	Cessna Aircraft Company.	5A2, Revision 21	CAR 3.
1 Cessna	150, 150J, 150A, 150K, 150B, A150K, 150C, 150L, 150D, A150L, 150E, 150M, 150F, A150M, 150G, 152, 150H, A152.	Cessna Aircraft Company.	3A19, Revision 44	CAR 3.
1 Cessna	170, 170A, 170B	Cessna Aircraft Company.	A–799, Revision 54	CAR 3.
1 Cessna	172, 172I, 172A, 172K, 172B, 172L, 172C, 172M, 172D, 172N, 172E, 172P, 172F (USAF T–41A), 172Q, 172G, 172H, (USAF T–41A).	Cessna Aircraft Company.	3A12, Revision 73	CAR 3.
1 Cessna	175, 175A, 175B, 175C, P172D, R172E (USAF T–41B) (USAF T–41C and D), R172F (USAF T–41D), R172G (USAF T–41C or D), R172H (USAF T–41D), R172J, R172K, 172RG.	Cessna Aircraft Company.	3A17, Revision 45	CAR 3.
1 Cessna	177, 177A, 177B	Cessna Aircraft Company.	A13CE, Revision 24	14 CFR PART 23.
Cessna	177RG	Cessna Aircraft Company.	A20CE, Revision 21	14 CFR PART 23.
Cessna	180, 180E, 180A, 180F, 180B, 180G, 180C, 180H, 180D, 180J, 180E, 180K.	Cessna Aircraft Company.	5A6, Revision 66	CAR 3.
1 Cessna	182, 182K, 182A, 182L, 182B, 182M, 182C, 182N, 182D, 182P, 182E, 182Q, 182F, 182R, 182G, R182, 182H, T182, 182J, TR182.	Cessna Aircraft Company.	3A13, Revision 64	CAR 3.
1 Cessna	185, A185E, 185A, A185F, 185B, 185C, 185D, 185E.	Cessna Aircraft Company.	3A24, Revision 37	CAR 3.
Cessna AgWagon	188, 188A, 188B, A188, A188A, A188B, T188C.	Cessna Aircraft Company.	A9CE, Revision 27	14 CFR PART 23.
1 Cessna	190 (LC–126A,B,C), 195, 195A, 195B	Cessna Aircraft Company.	A–790, Revision 36	CAR 3.
1 Cessna	206, U206B, TP206D, P206, U206C, TP206E, P206A, U206D, TU206A, P206B, U206E, TU206B, P206C, U206F, TU206C, P206D, U206G, TU206D, P206E, TP206A, TU206E, U206, TP206B, TU206F, U206A, TP206C, TU206G.	Cessna Aircraft Company.	A4CE, Revision 43	CAR 3.
1 Cessna	208, 208A, 208B	Cessna Aircraft Company.	A37CE, Revision 12	14 CFR PART 23.
1 Cessna	210, 210K, 210A, T210K, 210B, 210L, 210C, T210L, 210D, 210M, 210E, T210M, 210F, 210N, T210F, P210N, 210G, T210N, T210G, 210R, 210H, P210R, T210H, T210R, 210J, 210–5 (205), T210J, 210–5A (205A).	Cessna Aircraft Company.	3A21, Revision 46	CAR 3.
1 Cessna	310, 310J, 310A(USAF U–3A),310J–1, 310B, E310J, 310C, 310K, 310D, 310L, 310E(USAF U–3B), 310N, 310F, 310P, 310G, T310P, 310H, 310Q, E310H, T310Q, 310I, 310R, T310R.	Cessna Aircraft Company.	3A10, Revision 62	CAR 3.

LIST OF ALL AIRPLANE MODELS AND APPLICABLE TCDS—Continued

Make	Model	TC holder	TCDS	Certification basis
1 Cessna	320, 320F, 320–1, 335, 320A, 340, 320B, 340A, 320C, 320D, 320E.	Cessna Aircraft Company.	3A25, Revision 25	CAR 3.
1 Cessna	321 (Navy OE–2)	Cessna Aircraft Company.	3A11, Revision 6	CAR 3.
1 Cessna	336	Cessna Aircraft Company.	A2CE, Revision 7	CAR 3.
1 Cessna	337A (USAF 02B), T337E, 337B, 337F, M337B (USAF 02A), T337F, T337B, 337G, 337C, T337G, T337C, 337H, 337D, P337H, T337D, T337H, T337H–SP.	Cessna Aircraft Company.	A6CE, Revision 40	CAR 3/14 CFR PART 23.
1 Cessna	401, 401A, 401B, 402, 402A, 402B, 402C, 411, 411A, 414, 414A, 421, 421A, 421B, 421C, 425.	Cessna Aircraft Company.	A7CE, Revision 46	CAR 3.
1 Cessna	404, 406	Cessna Aircraft Company.	A25CE, Revision 11	14 CFR PART 23.
1 Cessna	441	Cessna Aircraft Company.	A28CE, Revision 12	14 CFR PART 23.
1 Commander Aircraft	Model 112, Model 114, Model 112TC, Model 112B, Model 112TCA, Model 114A, Model 114B, Model 114TC.	Commander Aircraft Company.	A12SO, Revision 21	14 CFR PART 23.
Diamond	DA20–A1, DA20–C1	Diamond Aircraft Industries, Inc..	TA4CH, Revision 14	14 CFR PART 23.
1 Great Lakes	2T–1A, 2T–1A–1, 2T–1A–2	Great Lakes Aircraft Company, LLC.	A18EA, Revision 10	Aeronautical Bulletin No. 7–A.
1 Helio (Taylorcraft)	15A, 20	Helio Aircraft Corporation.	3A3, Revision 7	CAR 4a.
1 Learjet	23	Learjet Inc	A5CE, Revision 10	CAR 3.
1 Lockheed	402–2	Lockheed Aircraft International.	2A11, Revision 4	CAR 3.
1 Land-Air (TEMCO) (Luscombe).	11A, 11E	Luscombe Aircraft Corporation.	A–804, Revision 14	CAR 3.
1 Maule	Bee Dee M–4, M–5–180C, MXT–7–160, M–4–180V, M–4 M–5–200, MX–7–180A, M–4C, M–5–210C, MXT–7–180A, M–4S, M–5–210TC, MX–7–180B, M–4T, M–5–220C, M–7–235B, M–4–180C, M–5–235C, M–7–235A, M–4–180S, M–6–180, M–7–235C, M–4–180T, M–6–235, MX–7–180C, M–4–210, M–7–235, M–7–260, M–4–210C, MX–7–235, MT–7–260, M–4–210S, MX–7–180, M–7–260C, M–4–210T, MX–7–420, M–7–420AC, M–4–220, MXT–7–180, MX–7–160C, M–4–220C, MT–7–235, MX–7–180AC, M–4–220S, M–8–235, M–7–420A, M–4–220T, MX–7–160, MT–7–420.	Maule Aerospace Technology, Inc.	3A23, Revision 30	CAR 3.
1 Mooney	M20, M20A, M20B, M20C, M20D, M20E, M20F, M20G, M20J, M20K (Up to S/N 25–2000), M20L.	Mooney Airplane Company, Inc.	2A3, Revision 47	CAR 3.
1 Interceptor (Aero Commander) (Meyers).	200, 200A, 200B, 200C, 200D, 400	Prop-Jets, Inc	3A18, Revision 16	CAR 3.
1 Beech	35–33, J35, 35–A33, K35, 35–B33, M35, 35–C33, N35, 35–C33A, P35, E33, S35, E33A, V35, E33C, V35A, F33, V35B, F33A, 36, F33C, A36, G33, A36TC, H35, B36TC, G36.	Raytheon Aircraft Company.	3A15, Revision 90	CAR 3.
1 Beech	45 (YT–34), A45 (T–34A, B–45), D45 (T–34B).	Raytheon Aircraft Company.	5A3, Revision 25	CAR 03.
1 Beech	19A, B23, B19, C23, M19A, A24, 23, A24R, A23, B24R, A23A, C24R, A23–19, A23–24.	Raytheon Aircraft Company.	A1CE, Revision 34	CAR 3.
1 Beech	3N, 3NM, 3TM, JRB–6, D18C, D18S, E18S, E18S–9700, G18S, H18, C–45G, TC–45G, C–45H, TC–45H, TC–45J or UC–45J (SNB–5), RC–45J (SNB–5P).	Raytheon Aircraft Company.	A–765	Revision 74 CAR 03.
1 Beech	35, A35, E35, B35, F35, C35, G35, D35, 35R.	Raytheon Aircraft Company.	A–777, Revision 57	CAR 03.

LIST OF ALL AIRPLANE MODELS AND APPLICABLE TCDS—Continued

Make	Model	TC holder	TCDS	Certification basis
1 Raytheon	200, A100–1 (U–21J), 200C, A200 (C–12A), 200CT, A200 (C–12C), 200T, A200C (UC–12B), B200, A200CT (C–12D), B200C, A200CT (FWC–12D), B200CT, A200CT (C–12F), B200T, A200CT (RC–12D), 300, A200CT (RC–12G), 300LW, A200CT (RC–12H), B300, A200CT (RC–12K), B300C, A200CT (RC–12P), 1900, A200CT (RC–12Q), 1900C, B200C (C–12F), 1900D, B200C (UC–12M), B200C (C–12R), B200C (UC–12F), 1900C (C–12J).	Raytheon Aircraft Company.	A24CE, Revision 91	14 CFR PART 23.
1 Beech	B95A, D55, D95A, D55A, E95, E55, 95–55, E55A, 95–A55, 56TC, 95–B55, A56TC, 95–B55A, 58, 95–B55B (T–42A), 58A, 95–C55, 95, 95–C55A, B95, G58.	Raytheon Aircraft Company.	3A16, Revision 81	CAR 3.
1 Beech	60, A60, B60	Raytheon Aircraft Company.	A12CE, Revision 23	14 CFR PART 23.
1 Beech	58P, 58PA, 58TC, 58TCA	Raytheon Aircraft Company.	A23CE, Revision 14	14 CFR PART 23.
1 Cessna	CESSNA F172D CESSNA F172E CESSNA F172F CESSNA F172G CESSNA F172H CESSNA F172K CESSNA F172L CESSNA F172M CESSNA F172N CESSNA F172P	Reims Aviation S.A	A4EU, Revision 11	CAR 10/CAR 3.
1 Socata	TB 9, TB 10, TB 20, TB 21, TB 200	SOCATA-GROUPE AEROSPATIALE.	A51EU, Revision 14	14 CFR PART 23.
1 Pitts	S–1S, S–1T, S–2, S–2A, S–2S, S–2B, S–2C.	Sky International Inc. (Aviat Aircraft, Inc.).	A8SO, Revision 21	14 CFR PART 23.
1 Taylorcraft	19, F19, F21, F21A, F21B, F22, F22A, F22B, F22C.	Taylorcraft Aviation, LLC	1A9, Revision 19	CAR 3.
1 Taylorcraft	BC, BCS12–D, BCS, BC12–D1, BC–65, BCS12-D1, BCS–65, BC12D–85, BC12–65 (Army L–2H), BCS12D–85, BCS12–65, BC12D–4–85, BC12-D, BCS12D–4–85.	Taylorcraft Aviation, LLC	A–696, Revision 22	CAR 04.
1 Taylorcraft	(Army L–2G) BF, BFS, BF–60,BFS–60, BF–65, BFS–65,(Army L–2K) BF 12–65, BFS–65.	Taylorcraft, Inc	A–699, Revision 5	CAR 4a.
1 Luscombe	8, 8D, 8A, 8E, 8B, 8F, 8C, T–8F	The Don Luscombe Aviation History Foundation, Inc.	A–694, Revision 23	CAR 4a.
Sierra Hotel Aero, Inc. (Navion).	Navion (L–17A), Navion A (L–17B) (L–17C),Navion B, Navion D, Navion E, Navion F, Navion G, Navion H.	Sierra Hotel Aero, Inc	A–782, Revision 51	CAR 3.
Piper	J–3	Piper Aircraft Inc	ATC 660, Revision 0	Not listed.
Piper	J3C–40, J3C–50, J3C–50S, J3C–65, J3C–65S, PA–11, PA–11S.	Piper Aircraft Inc	A–691, Revision 33	CAR 4a.
FS 2003 Corporation (Piper).	PA–12, PA–12S	FS 2003 Corporation	A–780, Revision 13	CAR 3.
FS 2002 Corporation (Piper).	PA–14	FS 2002 Corporation	A–797, Revision 11	CAR 3.
Piper	PA–15	Piper Aircraft Inc	A–800, Revision 11	CAR 3.
Piper	PA–16, PA–16S	Piper Aircraft Inc	1A1, Revision 13	CAR 3.
Piper	PA–17	Piper Aircraft Inc	A–805, Revision 12	CAR 3.
2 Piper	PA–18, PA–18S, PA–18A, PA–18S "125", PA–18AS "125", PA–18A "135", PA–18S "135", PA–18AS "135", PA–18 "150", PA–18A "150", PA–18S "150", PA–18AS "150", PA–19S.	The New Piper Aircraft, Inc.	1A2, Revision 37	CAR 3.
Piper	PA–20, PA–20–115, PA–20–135, PA–20S, PA–20S–115, PA–20S–135.	Piper Aircraft Inc	1A4, Revision 24	CAR 3.

LIST OF ALL AIRPLANE MODELS AND APPLICABLE TCDS—Continued

Make	Model	TC holder	TCDS	Certification basis
Piper	PA–22, PA–22–108, PA–22–135, PA–22–150, PA–22–160, PA–22S–135, PA–22S–150, PA–22S–160.	Piper Aircraft Inc	1A6, Revision 34	CAR 3.
Piper	PA–23, PA–23–160, PA–23–235, PA–23–250.	Piper Aircraft Inc	1A10, Revision 51	CAR 3.
Piper	PA–24, PA–24–250,PA–24–260, PA–24–400.	Piper Aircraft Inc	1A15, Revision 34	CAR 3.
1 Piper	PA–28–140, PA–28–151, PA–28–150, PA–28–161, PA–28–160, PA–28–181, PA–28–180, PA–28R–201, PA–28–235, PA–28R–201T, PA–28S–160, PA–28–236, PA–28S–180, PA–28RT–201, PA–28R–180, PA–28RT–201T, PA–28R–200, PA–28–201T.	The New Piper Aircraft, Inc.	2A13, Revision 47	CAR 3.
1 Piper	PA–30, PA–39, PA–40	The New Piper Aircraft, Inc.	A1EA, Revision 16	CAR 3.
1 Piper	PA–32–260, PA–32R–301 (SP), PA–32–300, PA–32R–301 (HP),PA–32S–300, PA–32R–301T, PA–32R–300, PA–32–301, PA–32RT–300, PA–32–301T, PA–32RT–300T, PA–32–301FT, PA–32–301XTC.	The New Piper Aircraft, Inc.	A3SO, Revision 29	CAR 3.
1 Piper	PA–34–200, PA–34–200T, PA–34–220T	The New Piper Aircraft, Inc.	A7SO, Revision 16	14 CFR PART 23.
1 Piper	PA–31P, PA–31T, PA–31T1, PA–31T2, PA–31T3, PA–31P–350.	The New Piper Aircraft, Inc.	A8EA, Revision 22	CAR 3.
1 Piper	PA–36–285, PA–36–300, PA–36–375	The New Piper Aircraft, Inc.	A9SO, Revision 9	14 CFR PART 23.
1 Piper	PA–36–285, PA–36–300, PA–36–375	The New Piper Aircraft, Inc.	A10SO, Revision 12	14 CFR PART 21/14 CFR PART 23.
Piper	PA–38–112	The New Piper Aircraft, Inc.	A18SO, Revision 4	14 CFR PART 23.
1 Piper	PA–44–180, PA–44–180T	The New Piper Aircraft, Inc.	A19SO, Revision 9	14 CFR PART 23.
1 Piper	PA–31, PA–31–300, PA–31–325, PA–31–350.	The New Piper Aircraft, Inc.	A20SO, Revision 10	CAR 3.
1 Piper	PA–42, PA–42–720, PA–42–1000	The New Piper Aircraft, Inc.	A23SO, Revision 17	14 CFR PART 23.
1 Piper	PA–46–310P, PA–46–350P, PA–46–500TP.	The New Piper Aircraft, Inc.	A25SO, Revision 14	14 CFR PART 23.
Piper	PA–46R–350T	Piper Aircraft, Inc	A25SO, Revision 16	14 CFR PART 23.
1 Tiger Aircraft LLC (American General).	AA–1, AA–1A, AA–1B, AA–1C	Tiger Aircraft LLC	A11EA, Revision 10	14 CFR PART 23.
1 Tiger Aircraft	AA–5, AA–5A, AA–5B, AG–5B	Tiger Aircraft LLC	A16EA, Revision 13	14 CFR PART 23.
1 Twin Commander	500, 500–A, 500–B, 500–U, 520, 560, 560–A, 560–E, 500–S.	Twin Commander Aircraft Corporation.	6A1, Revision 45	CAR 3.
1 Twin Commander	560–F, 681, 680, 690, 680E, 685, 680F, 690A, 720, 690B, 680FL, 690C, 680FL(P), 690D, 680T, 695, 680V, 695A, 680W, 695B.	Twin Commander Aircraft Corporation.	2A4, Revision 46	CAR 3.
1 Univair (Stinson)	108, 108–1, 108–2, 108–3, 108–5	Univair Aircraft Corporation.	A–767, Revision 27	CAR 3.
1 Univair	(ERCO) 415–D (ERCO) E (ERCO) G (Forney) F–1 (Forney) F–1A (Alon) A–2 (Alon) A2–A (Mooney) M10	Univair Aircraft Corporation.	A–787, Revision 33	CAR 3.
1 Univair (Mooney)	(ERCO) 415–C, (ERCO) 415–CD	Univair Aircraft Corporation.	A–718, Revision 29	CAR 4a.

The following aircraft are certified in the restricted category:

LIST OF ALL AIRPLANE MODELS AND APPLICABLE TCDS

Make	Model	TC holder	TCDS	Certification basis
Air Tractor	AT–250, AT–300, AT–301, AT–302, AT–400, AT–400A.	Air Tractor, Inc	A9SW, Revision 12	14 CFR PART 23.
Air Tractor	AT–401, AT–401A, AT–401B, AT–402, AT–402A, AT–402B, AT–501, AT–502, AT–502A, AT–502B, AT–503, AT–503A.	Air Tractor, Inc	A17SW, Revision 10	14 CFR PART 23.
Air Tractor	AT–802A, AT–802, AT–602	Air Tractor, Inc	A19SW, Revision 4	14 CFR PART 23.
Allied Ag Cat	G–164, G–164A, G–164B, G–164B with 73″, G–164B–15T, G–164B–34T, G–164B–20T, G–164C, G–164D, G–164D with 73″ wing gap.	Allied Ag Cat Productions, Inc.	1A16, Revision 24	CAR 8.
Gippsland Aeronautics	GA200	Gippsland Aeronautics Pty. Ltd..	A00001LA, Revision 1	14 CFR PART 23.
2 Piper	PA–18A, PA–18A "135", PA–18A "150"	The New Piper Aircraft, Inc.	AR–7, Revision 11	CAR 8.
LAVIA S.A. (Piper)	PA–25, PA–25–235, PA–25–260	Latino Americana De Aviación (LAVIA) S.A.	2A10, Revision 24	CAR 8.
Thrush Aircraft, Inc. (Snow, Rockwell, Ayres).	S–2B, S–2C, 600–S2C	Thrush Aircraft, Inc	2A7, Revision 16	CAR 8.
Thrush Aircraft, Inc. (Snow, Rockwell, Ayres).	600 S–2D, S–2R, S2R–T34, S2R–T15, S2R–T11, S2R–R3S, S2R–R1340.	Thrush Aircraft, Inc	A3SW, Revision 18	CAR 3.
Thrush Aircraft, Inc. (Snow, Rockwell, Ayres).	600 S2D, S2R–R1340, S2R–G10, S–2R, S2R–R1820, S2R–G5, S2R–T34, S2R–T65, S2R–G1, S2R–T15, S2RHG–T65, S2RHG–T34, S2R–R3S, S2R–T45, S2R–T660, S2R–T11, S2R–G6.	Thrush Aircraft, Inc	A4SW, Revision 28	CAR 8.
Weatherly	620, 620TP, 620A, 620B, 620B–TG	Weatherly Aircraft Company.	A26WE, Revision 7	14 CFR PART 23.
3 Ximango	AMT–100, AMT–200, AMT–300, AMT–200S.	Aeromot-Industria Mecanico Metalugica Ltd.	TG00004AT, Revision 4	14 CFR PART 23.

Aircraft identified with a 1 have special conditions for AmSafe Aviation Inflatable Restraints published under Special Conditions 23–182–SC.

Piper PA–18A, PA–18A "135" and PA–18A "150" (identified with a 2) are type certificated in Normal/Utility Category on TCDS 1A2 and in Restricted Category on TCDS AR–7. The same aircraft may be operated under either TCDS in accordance with the restrictions listed on TCDS AR–7.

Ximango (identified with a 3) is certificated in the Utility Category.

For all the models listed above, the certification basis also includes all exemptions, if any; equivalent level of safety findings, if any; and the other special conditions.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, part 23 as amended) do not contain adequate or appropriate safety standards for the AmSafe Aviation, inflatable restraint as installed on these models because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions, as appropriate, as defined in § 11.19, are issued in accordance with § 11.38, and become part of the type certification basis in accordance with § 21.101.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, the special conditions would also apply to that model under the provisions of § 21.101.

Novel or Unusual Design Features

The various airplane models will incorporate the following novel or unusual design feature:

The AmSafe Aviation Inflatable Two-, Three-, Four-, or Five-Point Restraint Safety Belt with an Integrated Airbag Device.

The purpose of the airbag is to reduce the potential for injury in the event of an accident. In a severe impact, an airbag will deploy from the restraint, in a manner similar to an automotive airbag. The airbag will deploy between the head of the occupant and airplane interior structure. This will, therefore, provide some protection to the head of the occupant. The restraint will rely on sensors to electronically activate the inflator for deployment.

The Code of Federal Regulations state performance criteria for seats and restraints in an objective manner. However, none of these criteria are adequate to address the specific issues raised concerning inflatable restraints. Therefore, the FAA has determined that, in addition to the requirements of part 21 and part 23, special conditions are needed to address the installation of this inflatable restraint.

Accordingly, these amended special conditions are adopted for the various airplane models equipped with the AmSafe Aviation, two-, three-, four, or five-point inflatable restraint. Other conditions may be developed, as needed, based on further FAA review and discussions with the manufacturer and civil aviation authorities.

Applicability

As discussed above, these amended special conditions are applicable to the Approved Model List (AML) above. Should AmSafe Aviation apply at a later date for a supplemental type certificate to modify any other model included on the type certificates listed above to incorporate the same novel or unusual

design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on the previously identified airplane models. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

Under standard practice, the effective date of final special conditions would be 30 days after the date of publication in the **Federal Register**; however, as the certification date for these airplane models, as modified by AmSafe Aviation, is imminent, the FAA finds that good cause exists to make these amended special conditions effective upon issuance.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

Citation

■ The authority citation for these amended special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113 and 44701; 14 CFR 21.16 and 21.101; and 14 CFR 11.38 and 11.19.

The Amended Special Conditions

The FAA has determined that this project will be accomplished on the basis of not lowering the current level of safety of the occupant restraint system for the airplane models listed in these special conditions. Accordingly, the FAA is issuing the following amended special conditions as part of the type certification basis for these models, as modified by AmSafe, Aviation.

Inflatable Two-, Three-, Four-, or Five-Point Restraint Safety Belt with an Integrated Airbag Device Installed in an Airplane Model.

1a. It must be shown that the inflatable restraint will provide restraint protection under the emergency landing conditions specified in the original certification basis of the airplane. Compliance will be demonstrated using the static test conditions specified in the original certification basis for each airplane.

1b. It must be shown that the crash sensor will trigger when exposed to a rapidly applied deceleration, like an actual emergency landing event. Therefore, compliance may be demonstrated using the deceleration pulse specified in § 23.562, which may be modified as follows:

I. The peak longitudinal deceleration may be reduced; however, the onset rate of the deceleration must be equal to or greater than the emergency landing pulse identified in § 23.562.

II. The peak longitudinal deceleration must be above the deployment threshold of the sensor, and equal or greater than the forward static design longitudinal load factor required by the original certification basis of the airplane.

2. The inflatable restraint must provide adequate protection for each occupant. In addition, unoccupied seats that have an active restraint must not constitute a hazard to any occupant.

3. The design must prevent the inflatable restraint from being incorrectly buckled and/or incorrectly installed such that the airbag would not properly deploy. Alternatively, it must be shown that such deployment is not hazardous to the occupant and will provide the required protection.

4. It must be shown that the inflatable restraint system is not susceptible to inadvertent deployment as a result of wear and tear or the inertial loads resulting from in-flight or ground maneuvers (including gusts and hard landings) that are likely to be experienced in service.

5. It must be extremely improbable for an inadvertent deployment of the restraint system to occur, or an inadvertent deployment must not impede the pilot's ability to maintain control of the airplane or cause an unsafe condition (or hazard to the airplane). In addition, a deployed inflatable restraint must be at least as strong as a Technical Standard Order (C22g or C114) restraint.

6. It must be shown that deployment of the inflatable restraint system is not hazardous to the occupant or will not result in injuries that could impede rapid egress. This assessment should include occupants whose restraints are loosely fastened.

7. It must be shown that an inadvertent deployment that could cause injury to a sitting person is improbable. In addition, the restraint must also provide suitable visual warnings that would alert rescue personnel to the presence of an inflatable restraint system.

8. It must be shown that the inflatable restraint will not impede rapid egress of the occupants 10 seconds after its deployment.

9. For the purposes of complying with HIRF and lightning requirements, the inflatable restraint system is considered a critical system since its deployment could have a hazardous effect on the airplane.

10. It must be shown that the inflatable restraints will not release hazardous quantities of gas or particulate matter into the cabin.

11. The inflatable restraint system installation must be protected from the effects of fire such that no hazard to occupants will result.

12. There must be a means to verify the integrity of the inflatable restraint activation system before each flight or it must be demonstrated to reliably operate between inspection intervals.

13. A life limit must be established for appropriate system components.

14. Qualification testing of the internal firing mechanism must be performed at vibration levels appropriate for a general aviation airplane.

Issued in Kansas City, Missouri on October 31, 2008.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–26663 Filed 11–6–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR Part 102

[CBP Dec. 08–42]

Technical Corrections Relating to the Rules of Origin for Goods Imported Under the NAFTA and for Textile and Apparel Products

Correction

In rule document E8–25734 beginning on page 64518 in the issue of Thursday, October 30, 2008, make the following correction:

§102.21 [Corrected]

On page 64539, in §102.21, in the table, in the first column, in the firstentry, ''6209.20.1000....''should read ''6209.20.1000–''.

[FR Doc. Z8–25734 Filed 11–6–08; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56, 57, and 71

RIN 1219–AB24

Asbestos Exposure Limit

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Final rule, technical amendment.

SUMMARY: The Mine Safety and Health Administration (MSHA) is amending and clarifying its existing health standards for asbestos exposure. The amendments make no substantive change to the existing standards, MSHA's enforcement of the standards, or the protection afforded miners under the standards.

DATES: This technical amendment is effective November 7, 2008.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey at *silvey.patricia@dol.gov* (e-mail), 202–693–9440 (Voice), or 202–693–9441 (Fax).

SUPPLEMENTARY INFORMATION: MSHA published a final rule amending its health standards for asbestos exposure at metal and nonmetal mines, surface coal mines, and surface areas of underground coal mines on February 29, 2008 (73 FR 11284). The rule became effective on April 29, 2008. To assure that the mining community fully understands MSHA's intent with respect to certain provisions of the existing standards, the Agency is issuing this technical amendment. This technical amendment clarifies MSHA's definition of asbestos and analytical methods the Agency uses to enforce the existing asbestos exposure limit. As stated above, these clarifications do not change any substantive requirements and reflect MSHA's intent as explained in the preamble to the final rule issued on February 29, 2008.

List of Subjects

30 CFR Parts 56 and 57

Air quality, Asbestos, Chemicals, Hazardous substances, Metals, Mine safety and health.

30 CFR Part 71

Air quality, Asbestos, Chemicals, Coal mining, Hazardous substances, Mine safety and health.

Richard E. Stickler,

Acting Assistant Secretary for Mine Safety and Health.

■ For the reasons set out in the preamble, MSHA is amending title 30 of the Code of Federal Regulations as follows.

PART 56—SAFETY AND HEALTH STANDARDS—SURFACE METAL AND NONMETAL MINES

■ 1. The authority citation for part 56 continues to read as follows:

Authority: 30 U.S.C. 811.

■ 2. Amend § 56.5001 by revising the introductory text of paragraph (b)(1), adding a definition for asbestos fiber, and revising paragraph (b)(3) to read as follows:

§ 56.5001 Exposure limits for airborne contaminants.

* * * * *

(b) *Asbestos standard*—(1) *Definitions.* Asbestos is a generic term for a number of asbestiform hydrated silicates that, when crushed or processed, separate into flexible fibers made up of fibrils.

* * * * *

Asbestos fiber means a fiber of asbestos that meets the criteria of a fiber.

* * * * *

(3) *Measurement of airborne asbestos fiber concentration.* Potential asbestos fiber concentration shall be determined by phase contrast microscopy (PCM) using the OSHA Reference Method in OSHA's asbestos standard found in 29 CFR 1910.1001, Appendix A, or a method at least equivalent to that method in identifying a potential asbestos exposure exceeding the 0.1 f/cc full-shift limit or the 1 f/cc excursion limit. When PCM results indicate a potential exposure exceeding the 0.1 f/cc full-shift limit or the 1 f/cc excursion limit, samples shall be further analyzed using transmission electron microscopy according to NIOSH Method 7402 or a method at least equivalent to that method.

* * * * *

PART 57—SAFETY AND HEALTH STANDARDS—UNDERGROUND METAL AND NONMETAL MINES

■ 3. The authority citation for part 57 continues to read as follows:

Authority: 30 U.S.C. 811.

■ 4. Amend § 57.5001 by revising the introductory text of paragraph (b)(1), adding a definition for asbestos fiber, and revising paragraph (b)(3) to read as follows:

§ 57.5001 Exposure limits for airborne contaminants.

* * * * *

(b) *Asbestos standard*—(1) *Definitions.* Asbestos is a generic term for a number of asbestiform hydrated silicates that, when crushed or processed, separate into flexible fibers made up of fibrils.

* * * * *

Asbestos fiber means a fiber of asbestos that meets the criteria of a fiber.

* * * * *

(3) *Measurement of airborne asbestos fiber concentration.* Potential asbestos fiber concentration shall be determined by phase contrast microscopy (PCM) using the OSHA Reference Method in OSHA's asbestos standard found in 29 CFR 1910.1001, Appendix A, or a method at least equivalent to that method in identifying a potential asbestos exposure exceeding the 0.1 f/cc full-shift limit or the 1 f/cc excursion limit. When PCM results indicate a potential exposure exceeding the 0.1 f/cc full-shift limit or the 1 f/cc excursion limit, samples shall be further analyzed using transmission electron microscopy according to NIOSH Method 7402 or a method at least equivalent to that method.

* * * * *

PART 71—MANDATORY HEALTH STANDARDS—SURFACE COAL MINES AND SURFACE WORK AREAS OF UNDERGROUND COAL MINES

■ 5. The authority citation for part 71 continues to read as follows:

Authority: 30 U.S.C. 811, 951, 957.

■ 6. Amend § 71.702 by revising the introductory text of paragraph (a), adding a definition for asbestos fiber, and revising paragraph (c) to read as follows:

§ 71.702 Asbestos standard.

(a) *Definitions.* Asbestos is a generic term for a number of asbestiform hydrated silicates that, when crushed or processed, separate into flexible fibers made up of fibrils.

* * * * *

Asbestos fiber means a fiber of asbestos that meets the criteria of a fiber.

* * * * *

(c) *Measurement of airborne asbestos fiber concentration.* Potential asbestos fiber concentration shall be determined by phase contrast microscopy (PCM) using the OSHA Reference Method in OSHA's asbestos standard found in 29 CFR 1910.1001, Appendix A, or a method at least equivalent to that method in identifying a potential asbestos exposure exceeding the 0.1 f/cc full-shift limit or the 1 f/cc excursion limit. When PCM results indicate a potential exposure exceeding the 0.1 f/cc full-shift limit or the 1 f/cc excursion limit, samples shall be further analyzed using transmission electron microscopy according to NIOSH Method 7402 or a method at least equivalent to that method.

[FR Doc. E8–26440 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–43–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201 and 255

[Docket No. RM 2000–7]

Compulsory License for Making and Distributing Phonorecords, Including Digital Phonorecord Deliveries

AGENCY: Copyright Office, Library of Congress.

ACTION: Interim rule and request for comments.

SUMMARY: The Copyright Office is announcing an interim regulation to clarify the scope and application of the Section 115 compulsory license to make and distribute phonorecords of a musical work by means of digital phonorecord deliveries. The Office seeks comments on the interim regulation.

EFFECTIVE DATE: December 8, 2008. Comments must be received in the Office of the General Counsel of the Copyright Office no later than January 6, 2009.

ADDRESSES: If hand delivered by a private party, an original and five copies of a comment or reply comment should be brought to the Library of Congress, U.S. Copyright Office, Room 401, 101 Independence Avenue, SE., Washington, DC 20559, between 8:30 a.m. and 5 p.m. The envelope should be addressed as follows: Office of the General Counsel, U.S. Copyright Office. If delivered by a commercial courier, an original and five copies of a comment or reply comment must be delivered to the Congressional Courier Acceptance Site (''CCAS'') located at 2nd and D Streets, NE., Washington, DC between 8:30 a.m. and 4 p.m. The envelope should be addressed as follows: Office of the General Counsel, U.S. Copyright Office, LM 403, James Madison Building, 101 Independence Avenue, SE., Washington, DC 20559. Please note that CCAS will not accept delivery by means of overnight delivery services such as Federal Express, United Parcel Service or DHL. If sent by mail (including overnight delivery using U.S. Postal Service Express Mail), an original and five copies of a comment or reply comment should be addressed to U.S. Copyright Office, Copyright GC/I&R, P.O. Box 70400, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Tanya M. Sandros, General Counsel, or Stephen Ruwe, Attorney Advisor, Copyright GC/I&R, P.O. Box 70400, Washington, DC 20024. Telephone: (202) 707–8380. Telefax: (202) 707–8366.

SUPPLEMENTARY INFORMATION:

Background

On July 16, the Copyright Office published a notice of proposed rulemaking (the ''NPRM'') to amend its regulations to clarify the scope and application of the Section 115 compulsory license to make and distribute phonorecords of a musical work by means of digital phonorecord deliveries (''DPDs''). 73 FR 40802. Specifically, the notice proposed to amend the definition of ''digital phonorecord delivery'' to clarify that a digital phonorecord delivery under the compulsory license provided under 17 U.S.C. 115 includes the following: permanent digital downloads of phonorecords; limited downloads, which use technology that causes the downloaded file to be available for listening only either during a limited time (*e.g.*, a time certain or a time tied to ongoing subscription payments) or for a limited number of performances; and all buffer copies delivered to a transmission recipient. The NPRM also put forward that the Section 115 license included coverage for all reproductions made to facilitate the making and distributing of DPDs.

In the course of its analysis, the Office categorized a number of different types of reproductions that can be made for the purpose of making DPDs: Server–end Complete Copies, Recipient–end Complete Copies, Server–end Buffer Copies, and Recipient–end Buffer Copies.[1] As described in the NPRM, a Server–end Complete Copy is a copy of a sound recording of an entire musical work which resides on the server of a digital music service and serves as the source of the transmission that results in a DPD. A Recipient–end Complete Copy is a copy of a sound recording of an entire musical work which is made on the recipient's computer or device during the course of the transmission. A Server–end Buffer Copy is a copy of a portion of a sound recording of a musical work (which, along with a number of other buffer copies, typically will cumulatively constitute a recording of the entire musical work) that is made on the transmitting entity's server and typically exists for a short period of time, sometimes a few seconds or less. A Recipient–end Buffer Copy is a copy of a portion of a sound recording of a musical work (which, along with a number of other buffer copies, typically will cumulatively constitute a recording of the entire musical work) that is made on the recipient's computer or device and typically exists for a short period of time, sometimes a few seconds or less.

In the NPRM, the Office proposed that a DPD would exist whenever a transmission includes any of the following: a Recipient–end Complete Copy and/or a Recipient–end Buffer Copy. The Office tentatively proposed that both of these kinds of copies satisfied the statutory requirements of being ''phonorecords'' that are ''specifically identifiable.'' The Office indicated that Server–end Copies did not satisfy the requirements for a DPD because they are not ''delivered.''

The Office proposed to interpret the compulsory license as including a license to make Server–end copies as well as all other intermediate copies used to facilitate a digital transmission that results in the making and distribution of a DPD, even though those copies may not themselves constitute DPDs. Thus, a Server–end copy that is the source of a transmission that results in a DPD, such as a download, will be included within the scope of the compulsory license, although it is not itself a DPD for which payment would be required. On the other hand, a Server–end copy that is the source of a transmission of a performance that does not result in the making and distribution of a DPD would not fall within the scope of the compulsory license.

With respect to limited downloads, the Office proposed the following conclusion: ''While policy reasons might exist for distinguishing such a limited download from a permanent reproduction, we can find no basis in the statute for considering a limited download to be something other than a phonorecord. Moreover, the fact that a limited download is a phonorecord does not in any way prevent the Copyright Royalty Judges from valuing it differently and setting a lower rate.'' 73 FR at 40808. Accordingly, the Office tentatively concluded that limited downloads, like other Recipient–end Complete Copies, satisfy the requirements for DPDs.

In response to requests by some interested parties and in light of the intervening decision of the United States Court of Appeals for the Second Circuit in *The Cartoon Network LP v.*

[1] We call these reproductions ''copies'' not in the technical sense as defined in 17 U.S.C. 101, but in the more general dictionary sense in which the term ''copies'' is understood. We recognize that these reproductions are of sounds other than those accompanying a motion picture or other audio visual work, which when fixed in material objects from which sounds may be perceived would properly be categorized as ''phonorecords.'' Additionally, we acknowledge that parties disagree on the copyright implications of the reproductions, an analysis of which is contained herein.

CSC Holdings, Inc., 536 F.3d 121 (2d Cir. Aug. 4, 2008), the Office extended the comment period and, on September 19, 2008, conducted a hearing. Having considered the comments and the testimony at the hearing, the Register of Copyrights now issues this interim regulation and requests comments.

Summary of Interim Regulation

In the NPRM, the Office proposed to define a ''digital phonorecord delivery'' as including all buffer copies made in the course of streaming, which would have meant that all music streaming activity would be included within the scope of the compulsory license.[2] However, in light of the recent comments and testimony, and the uncertainty created by the Second Circuit's Cartoon Network opinion concerning the fixation of buffer copies, the interim regulation announced today is more modest in scope than the proposed regulation. The Office is not currently prepared to issue a regulation that definitively addresses whether such copies are within the scope of the compulsory license, except to the extent the transmission also results in the making of copies which more certainly qualify as DPDs. As such, the interim regulation takes no position on whether or when a buffer copy independently qualifies as a DPD, or whether and when it is necessary to obtain a license to cover the reproduction or distribution of a musical work in order to engage in activities such as streaming.

The interim regulation clarifies that (1) whenever there is a transmission that results in a DPD, all reproductions made for the purpose of making the DPD are also included as part of the DPD, and (2) limited downloads qualify as DPDs. The interim regulation does not attempt to define the threshold at which a DPD occurs. That remains contested, as discussed below.

Authority To Issue Regulations

The Office requested comments on whether the issues raised in the NPRM could be addressed in an administrative rulemaking. In response, the Digital Media Association (''DiMA'') as well as the Business Music Industry; Verizon Communications; CTIA—The Wireless Association (''CTIA''); the National Association of Broadcasters (''NAB''); Google/YouTube; and Electronic Frontier Foundation, Public Knowledge, Center for Democracy and Technology, Consumers Union, Consumer Federation of America, U.S. PIRG, and the Computer & Communications Industry Association (collectively referred to as ''Public Interest Commenters'') raised questions and concerns regarding the Office's authority to issue a rule that would have a wide–reaching impact on activities outside the scope of Section 115.

For example, Verizon, CTIA, and NAB argued that the proposed rule is a substantive rule of copyright law and therefore is not a matter relating to administration of the functions and duties of the Copyright Office. They asserted that the proposed rule would both reinterpret substantive principles of copyright law and fundamentally reset the balance between copyright owners and users. They maintained that the proposed rule is distinguishable from any judicially approved exercise of Office rulemaking authority under Sections 701 or 702. Further, they noted that authority under Sections 701 and 702 is distinguishable from the authority granted to the Register to make determinations on ''material questions of substantive law'' under Chapter 8, which is accompanied by specific procedural limitations that indisputably are not present in association with the proposed rule. In addition, DiMA asserted that the Office's authority to issue a rule at this time, in the midst of the Copyright Royalty Board (the ''CRB'') ratemaking proceeding, is foreclosed and that to do so would impermissively interject the Office into the CRB proceeding. DiMA maintains that this result would contravene specific provisions of the Copyright Act that narrowly circumscribe the Office's authority to be involved in a CRB rate–setting proceeding.

On the other hand, SESAC noted the Office's specific and limited scope of authority under Section 115, and asserted that the Office should not go beyond its statutory authority and opine on the relative values of separate and independent rights implicated in a given transmission. Similarly, the American Society of Composers, Authors and Publishers and Broadcast Music, Inc. (''ASCAP/BMI'') acknowledged the Office's statutory mandate to address administration of the Section 115 license. However, they specifically noted that any statements by the Office affecting the definition or applicability of the performance right are beyond the limited authority granted to the Office to administer Section 115. Other comments, such as the one filed by the Recording Industry Association of America (''RIAA''), and a joint filing by National Music Publishers Association, including its wholly owned licensing subsidiary, The Harry Fox Agency, Inc.; the Songwriters' Guild of America; the Nashville Songwriters Association International; and the Association of Independent Music Publishers, (Collectively ''Copyright Owners'') expressed the view that the Register does possess the authority to issue such rules.[3]

Section 702 authorizes the Register of Copyrights ''to establish regulations not inconsistent with law for the administration of the functions and duties made the responsibility of the Register under this title.'' Among the functions and duties of the Register is the responsibility to issue regulations prescribing how a licensee shall file a notice of intention to use the statutory license, 17 U.S.C. 115(b)(1), and regulations governing the submission of monthly and annual statements of account. 17 U.S.C. 115(c)(4). Pursuant to this authority, the Register has issued regulations that, *inter alia*, govern the content of the notice and the statements of account associated with the use of the Section 115 license. *See* 37 CFR 201.18 and 201.19. These regulations include definitions of statutory terms, which clarify the application of the terms in the context of the statutory license thus enabling a licensee to understand how to accurately report the making and distribution of a phonorecord under Section 115.

Courts have recognized the Register's authority to promulgate regulations interpreting the statute under the authority granted in Section 702 and specific provisions in the law, such as the statutory licenses. In *Cablevision Systems Development Co. v. Motion Picture Association of America, Inc. (''Cablevision'')* the court acknowledged Section 702 as the source of general authority for the Office to conduct rulemaking proceedings to carry out specific responsibilities. Cablevision 836 F.2d 599 (D.C. Cir. 1988), *cert. denied*, 487 U.S. 1235 (1988). In Cablevision, the Register issued

[2] The Office noted that the fact that the compulsory license is available for such activity should not be construed as meaning that a license is necessary for all such activity. Rather, the license would simply be available for online music services who do not wish to expose themselves to potential liability in cases where a musical copyright owner asserts that the making of, *e.g.*, buffer copies constitutes an infringement of the reproduction right.

[3] Most of the commenters who objected to the Register's authority appear to have done so out of fear that the Register would address issues such as whether buffer copies constitute phonorecords—issues which, as set forth below, the Register has declined to resolve in this proceeding. Many of those commenters expressed concern that in order to address those issues, the rulemaking would have consequences for activities that have no relationship to the section 115 compulsory license. However, the more modest regulation announced today is more narrowly focused and would appear to have little if any applicability outside the scope of the compulsory license.

regulations under Section 111(d)(1) that directed cable systems to deposit royalty fees with the Copyright Office. Those regulations included an interpretation of the statutory term, ''gross receipts,'' which was central to the calculation of royalty fees for the public performance of secondary transmissions of broadcast signals under the statutory license. Opponents of the regulation argued that the authority of the Register was limited to the ''ministerial task of designing forms.'' The court, however, rejected this narrow approach, noting that authority to design forms has a substantial policy component and that the Copyright Office ''certainly has greater expertise in such matters than the federal courts.'' Thus, under the court's reasoning, the issuance of a rule interpreting a statutory term for the purpose of administering the license was not a violation of the rulemaking authority granted to the Register, provided that the interpretation was reasonable.

Other circuits have reached the same conclusion. In *Satellite Broadcasting and Communications Association of America v. Oman (''SBCA'')*, the court found that ''the Copyright Office is a federal agency with authority to promulgate rules concerning the meaning and application of § 111.'' SBCA 17 F.3d 344, 347 (11th Cir. 1994). In reconsidering its earlier determination that a satellite carrier could be considered a cable system making it eligible to utilize the Section 111 statutory license, the court revised its determination in light of a final rule issued by the Copyright Office which concluded that a satellite carrier was not a cable system under Section 111. The court acknowledged that the interpretation of the agency was due deference unless arbitrary, capricious, or manifestly contrary to the provisions of the Copyright Act. *Id.*

The current rulemaking is consistent with the Office's practice of promulgating regulations to construe statutory terms that are critical to the administration of a statutory license administered by the Office. The Office is relying on both its general rulemaking authority under Section 702 and the specific grant of authority found in Section 115(b)(1) and (c)(4) to issue rules governing notices of intention and statements of account, in a manner parallel to what happened when it adopted a definition of ''gross receipts'' and construed the term ''cable system,'' with the only difference being that the Office considered these terms under its power to promulgate rules under a different statutory license. *See* 17 U.S.C 115(b)(1); (c)(4) and § 111.

Opponents of the proposed regulation argue that notwithstanding these earlier cases, the authority of the Register to issue the proposed rule is foreclosed under *Gonzales v. Oregon*, 546 U.S. 243 (2006). They maintain that Title 17 provides the Register no general rulemaking authority, and consequently, the Office cannot issue the proposed rule. The parties, however, focus only on Section 702 and fail to recognize the express authority provided to the Register in Section 115. Moreover, Gonzales does not undermine the earlier rulings in *Cablevision or SBCA. Gonzales* recognizes, as do *Cablevision and SBCA*, that an agency's interpretation of a statute is due deference when the statute is ambiguous and when Congress has delegated the authority to the agency to promulgate rules carrying the force of law. Gonzales, 564 U.S. at 255 (citing *Chevron U.S.S., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984) and *United States v. Mead Corp.*, 533 U.S. 218, 226–227 (2001)). The facts in *Gonzales*, however, led to a finding that the Attorney General lacked the authority to issue a regulation about the scope of ''legitimate medical purpose'' under his authority to adopt rules governing the registration of physicians. Specifically, the court found that the Attorney General had no authority to issue a rule that extended beyond registration practices to ''an interpretation of the substantive federal law requirements (under 21 CAR § 1306.04 (2005)) for a valid prescription.'' *Id.* at 261. The court also rejected the position of the Attorney General that his authority to deregister physicians provided the necessary authority for the rule. The court rejected that approach because it would vest power in the Attorney General to criminalize actions of registered physicians–an activity not contemplated by the statute. *Id.* at 261, 262. Similarly, the court found that the regulatory authority claimed by the Attorney General was ''inconsistent with the design of the statute'' because the statute does not delegate rulemaking authority solely to the Attorney General. In some instances, he must share that authority with or defer to the Secretary of Health and Human Services. *Id.* at 265.

Unlike the disputed rule in Gonzales, the interim rule which is the subject of today's notice has meaning only for the Section 115 license. The interim rule is a clarification of the statutory definition of a DPD to incorporate the Office's determination that the Section 115 license covers server copies and intermediate copies made to facilitate the making and distribution of a DPD and that a limited download is a DPD. The rule extends the traditional understanding of the scope of the Section 115 license, that phonorecords made for the purpose of making additional reproductions of the sound recording and the musical works embodied therein are covered under the license, to the digital realm. As the court in Cablevision noted, and as discussed previously, the authority to issue regulations for the filing of statements of account includes a ''substantial policy component.'' Thus, the Office issues this rule under its authority to interpret statutory terms that are central to its role in promulgating regulations to account for the royalties owed for the making and distribution of phonorecords under the statutory license. Without this clarification, no guidance would exist regarding whether liability attached to these reproductions relative to the statutory license. In addition, the rule makes clear that DPDs includes digital phonorecords that may be limited either by time or number of uses, an issue that was raised in the original petition for a rulemaking but a conclusion that does not now appear to be in dispute.

The Office also finds no basis for DiMA's assertion that the Office is foreclosed from issuing a rule at this time, in the midst of the CRB ratemaking proceeding. The statute does not constrain the Office from issuing regulations for the purpose of administering a statutory license when the Copyright Royalty Judges are also conducting a concurrent rate setting proceeding for the same statutory license. Nor is there any reason for the Office to delay the issuance of its interim rule when, as here, the interim rule amends Copyright Office regulations to incorporate concepts that seemingly are not in dispute by the parties participating in this rulemaking proceeding. Moreover, to the extent that the interim rule adds clarity to an issue upon which the Register is competent to rule and may offer guidance to the Copyright Royalty Judges, there is nothing improper about the exercise of the Register's authority at this time. In any event, parties have an opportunity to comment specifically on the interim rule within the comment period, since this is an interim rule.

In its NPRM, the Office proposed a much broader regulation. Consequently, the Office discusses herein the original proposal and the reasons for adopting a more limited regulation.

Discussion

A. Digital Phonorecord Deliveries in General

As the Office stated in its NPRM, in considering whether the reproductions made by a transmission service are digital phonorecord deliveries and fit within the scope of the Section 115 license, the starting point is the statutory definition of a DPD. 17 U.S.C. 115(d). It defines a DPD, in relevant part, as:

> each individual delivery of a phonorecord by digital transmission of a sound recording which results in a specifically identifiable reproduction by or for any transmission recipient of a phonorecord of that sound recording, regardless of whether the digital transmission is also a public performance of the sound recording or any nondramatic musical work embodied therein. A digital phonorecord delivery does not result from a real–time, non–interactive subscription transmission of a sound recording where no reproduction of the sound recording or the musical work embodied therein is made from the inception of the transmission through to its receipt by the transmission recipient in order to make the sound recording audible.

17 U.S.C. 115(d). In order for a reproduction of a sound recording to qualify as a DPD under the statutory criteria, the reproduction must meet all the criteria specified in the definition: (1) it must be delivered, (2) it must be a phonorecord, and (3) it must be specifically identifiable.

(1) *Delivery*. While several parties disputed the second and third criteria specified in the definition of a DPD, no parties put forward arguments against the proposed finding that reproductions identified in the NPRM as Recipient–end copies are ''delivered'' and therefore satisfy the first requirement for being a DPD.[4]

(2) *Phonorecord (Fixation)*. In considering whether the reproductions made by a transmission service are phonorecords, the Office's NPRM turned to the definition found in 17 U.S.C. 101. The statute defines phonorecords as:

> material objects in which sounds, other than those accompanying a motion picture or other audiovisual work, are fixed by any method now known or later developed, and from which the sounds can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device. The term ''phonorecords'' includes the material object in which the sounds are first fixed.

17 U.S.C. 101. The question is whether each reproduction made during the course of a digital transmission meets this definition and thus satisfies the second prong of the statutory definition for a DPD. The Office proposed that a buffer copy made in the course of a service's transmission on either the Server–end or the Recipient–end is sufficiently fixed to meet the definition of a phonorecord. This proposal was strongly opposed by parties representing users of the works.

Parties such as DiMA, Verizon, CTIA, NAB, Google/YouTube, Public Interest Commenters, New Media Rights, and Cablevision disputed the Office's conclusion that all buffer copies qualified as ''fixed'' phonorecords or copies. They uniformly cited to the Second Circuit's decision in *Cartoon Network*, which reversed *Twentieth Century Fox Film Corp. v. Cablevision Sys. Corp.*, 478 F. Supp. 2d 607 (S.D.N.Y. 2007), a decision cited in the NPRM. 73 FR at 40809. They argued that the *Cartoon Network* decision undermines the legal analysis contained in the NPRM.

On the other hand, RIAA disagreed with the *Cartoon Network* decision, but found it unnecessary to debate the fixation issue. It argued that some copies created by transmission services are persistent enough that they would meet any definition of the term ''fixed,'' and services that wish to obtain a Section 115 license as a ''safe harbor'' should have that option. Copyright Owners also argued that the *Cartoon Network* decision is inapplicable to the transmission services in question because the buffer copies made by streaming music services are distinguishable from the ones considered in the *Cartoon Network* case. Under the view of the Copyright Owners, buffer copies made by streaming music services are more analogous to the RAM copies considered in cases cited in the Copyright Office's *DMCA Section 104 Report.*

The Copyright Owners also concluded that the *Cartoon Network* decision's analysis of the ''duration'' requirement is unsupported by the Copyright Act or prior judicial interpretation. They argued that the *Cartoon Network* court took a ''stopwatch'' approach by measuring the duration of the subject buffer copies and then opined that they did not last for a sufficient number of seconds. In response, the Copyright Owners asserted that Section 101 does not require that a copy last for any specified period of time. 17 U.S.C. 101. They argued that the *Cartoon Network* approach suffers from a lack of standards–statutory or otherwise–to guide this judge–made ''duration'' requirement. The Copyright Owners instead endorsed the approach proposed in the NPRM, which examines whether the copies in question exist for a sufficient period of time to be capable of being ''perceived, reproduced or otherwise communicated.'' 73 FR at 40808. They stated that such an approach does not depend upon an arbitrary assessment. Moreover, it adheres to the overarching consensus of other courts that have considered this issue.

In the NPRM, the Office's tentative conclusions relating to the status of buffer copies as phonorecords relied in part on the District Court's decision in *Twentieth Century Fox*, which had concluded that buffer copies made in a somewhat different context than the streaming of music were infringing ''copies'' under the copyright law. 478 F. Supp. 2d at 621–22. The court rejected arguments by the defendant that the buffer copies did not qualify as ''copies'' because they were ''not fixed'' and were ''otherwise de minimis.'' *Id.* at 621. In finding the buffer copies were ''fixed'' the court reasoned,

> The Copyright Act, however, provides that a work is ''fixed'' if it ''is sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated for a period of more than transitory duration.'' Here, as discussed, the portions of programming residing in buffer memory are used to make permanent copies of entire programs on the Arroyo servers. Clearly, the buffer copies are capable of being reproduced. Furthermore, the buffer copies, in the aggregate, comprise the whole of plaintiffs' programming.

Id. (citations omitted) (quoting 17 U.S.C. 101). The court relied in part on the Copyright Office's *DMCA Section 104 Report*, noting,

> Indeed, the United States Copyright Office, in its August 2001 report on the Digital Millennium Copyright Act (''*DMCA Report*''), has indicated that buffer copies are ''copies'' within the meaning of the Copyright Act. Specifically, the Copyright Office concluded that temporary copies of a work in RAM are generally ''fixed'' and thus constitute ''copies'' within the scope of the copyright owner's right of reproduction, so long as they exist for a sufficient amount of time to be capable of being copied, perceived or communicated. (*DMCA Report* at xxii, 110–11).

Id. at 621–22.

The issue addressed in *Twentieth Century Fox* and in the *DMCA Section 104 Report* was whether temporary buffer copies meet the ''fixation'' requirement of the copyright law.

[4] Several parties disputed the proposed finding that every ''delivery'' constitutes a ''distribution'' These arguments are addressed in a later section regarding the threshold requirements for use of the Section 115 license.

Phonorecords (a necessary element of a DPD; *see* 17 U.S.C. 115(d)) are defined as ''material objects in which sounds, other than those accompanying a motion picture or other audiovisual work, are fixed by any method now known or later developed, and from which the sounds can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device.'' 17 U.S.C. 101 (emphasis added). The statute defines ''fixed'' as follows:

> A work is 'fixed' in a tangible medium of expression when its embodiment in a copy or phonorecord, by or under the authority of the author, is sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated for a period of more than transitory duration. A work consisting of sounds, images, or both, that are being transmitted, is 'fixed' for purposes of this title if a fixation of the work is being made simultaneously with its transmission.

17 U.S.C. 101.

In the *DMCA Section 104 Report*, the Office interpreted the ''more than a transitory duration'' element of fixation as follows: ''The dividing line, then, can be drawn between reproductions that exist for a sufficient period of time to be capable of being 'perceived, reproduced, or otherwise communicated' and those that do not.'' *DMCA Section 104 Report* at 111. As noted above, the Southern District of New York had agreed with this analysis in *Twentieth Century Fox*. 478 F. Supp. 2d at 621–22.

In the NPRM, the Office reviewed that analysis and observed, ''The Office has no reason to believe that developments in either technology or the law require us to revisit the above–stated conclusions. As such, Server–end Buffer Copies and Recipient–end Buffer Copies appear to be phonorecords and therefore satisfy the second requirement for being a DPD.'' 73 FR at 40809. Nineteen days later, the United States Court of Appeals for the Second Circuit reversed the district court's *Twentieth Century Fox* decision. *Cartoon Network*, 536 F.3d at 130. Among other things, the court took issue with the *DMCA Section 104 Report's* analysis of buffer copies and fixation, stating, ''[a]ccording to the Copyright Office, if the work is capable of being copied from that medium for any amount of time, the answer to both questions is 'yes.' The problem with this interpretation is that it reads the 'transitory duration' language out of the statute.'' *Id.* at 129. The court concluded that the buffer copies made by a cable television service in the course of creating server copies ''are not 'embodied' in the buffers for a period of more than transitory duration, and are therefore not 'fixed' in the buffers.'' *Id.* at 130.

The Office does not consider the Second Circuit's opinion to be definitive on the issue involved in this rulemaking. The court's reasoning leaves at least something to be desired and offers no guidance as to when a copy might be considered to be ''embodied'' for ''a period of more than transitory duration.'' Based on the *Cartoon Network* opinion, it appears that the duration requirement necessitates an embodiment for more than 1.2 seconds (the duration of the buffer copies at issue in that case) but does not require a duration of more than ''several minutes.'' *Id.* at 128, 131 (discussing *MAI Sys. Corp. v. Peak Computer Inc.*, 991 F.2d 511 (9th Cir. 1993)). Indeed, it leaves open the possibility that a buffer copy that exists for several seconds might have sufficient duration to satisfy the fixation requirement. We can glean no principle from the Second Circuit's opinion which offers any guidance as to where the line is to be drawn.[5]

While the Second Circuit's opinion criticizes the analysis in the Office's *DMCA Section 104 Report*, the latter did attempt to provide a guiding principle for determining when the duration requirement has been met:

> In establishing the dividing line between those reproductions that are subject to the reproduction right and those that are not, we believe that Congress intended the copyright owner's exclusive right to extend to all reproductions from which economic value can be derived. The economic value derived from a reproduction lies in the ability to copy, perceive or communicate it. Unless a reproduction manifests itself so fleetingly that it cannot be copied, perceived or communicated, the making of that copy should fall within the scope of the copyright owner's exclusive rights. The dividing line, then, can be drawn between reproductions that exist for a sufficient period of time to be capable of being 'perceived, reproduced, or otherwise communicated'' and those that do not.

DMCA Section 104 Report at 111.

For present purposes, we need not resolve whether the Second Circuit's critique of the Office's analysis is compelling. It is sufficient to note that the record in this rulemaking and the *Cartoon Network* opinion create sufficient uncertainty to make it inadvisable to engage in rulemaking activity based on the Office's analysis in the *DMCA Section 104 Report*. Consequently, the interim rule does not address whether streaming of music that involves the making of buffer copies, but which makes no further copies, falls within the Section 115 compulsory license, or whether such buffer copies qualify as DPDs. It seems likely that in at least some, and perhaps many cases, buffer copies may constitute DPDs, but we do not reach any broad conclusions on that point in light of the current state of the law and the factual record before us.

As a practical matter, the marketplace may decide that issue. Most licenses that purport to be made pursuant to Section 115 are not, in fact, compulsory licenses. They are voluntary licenses between music publishers and licensees who agree to payment of the royalties at the rates that have been established for the actual compulsory license. To the extent that music publishers and licensees are willing to use the Section 115 model to license reproductions, including buffer copies, that are made in the course of streaming, then as a practical matter the marketplace may decide to treat buffer copies as DPDs, although not necessarily as DPDs entitled to the same royalty as more permanent copies.

While we leave open the question whether buffer copies may be DPDs that fall within the Section 115 compulsory license, we note that certain streaming services involve the making of cache copies. To the extent that cache copies are placed on the recipient's hard drive and may exist for some indefinite period of time beyond the entire performance of the phonorecord, the Office understands that such copies would appear to satisfy the fixation/reproduction requirement.

(3) Specifically identifiable. Section 115 defines ''digital phonorecord delivery,'' in relevant part, as ''each individual delivery of a phonorecord by digital transmission of a sound recording which results in a specifically identifiable reproduction by or for any transmission recipient of a phonorecord of that sound recording.'' 17 U.S.C. 115(d). With regard to interpretation of the phrase ''specifically identifiable reproduction by or for any transmission recipient of a phonorecord of that sound recording,'' the Copyright Owners concurred with the tentative proposal in the Copyright Office's NPRM, which offered that the plain meaning of the statute indicates that a reproduction may be either ''specifically identifiable'' by any transmission recipient or

[5] Although the factual record in this proceeding is insufficient, it is quite possible that the buffer copies typically made in streaming exist for a longer period of time—and perhaps a considerably longer period of time—than the 1.2–second buffer copies at issue in *Cartoon Network*. If so, that case might be distinguishable on its facts.

''specifically identifiable'' for any transmission recipient. In endorsing the view in the NPRM's tentative proposal, they noted that contrary to arguments based upon a comment appearing in legislative history, Congress could easily have included a requirement that the reproduction be specifically identifiable to the transmitting service, but it did not.

However, several parties including, RIAA, Verizon, CTIA, and NAB raised questions regarding the Office's proposed interpretation of the phrase. These parties agreed with the Office's observation that the phrase ''specifically identifiable'' is ''unique in copyright law,'' but they went on to cast doubt on the grammatical construction used by the Office in arriving upon the tentatively proposed plain meaning. Verizon and NAB maintained that the phrasing could not mean that the phonorecord was ''specifically identifiable'' by the recipient, offering phrases with analogous grammatical structure to illustrate their point. For example, they pointed out that the phrase ''an instantly recognizable painting by Picasso'' does not indicate that the painting is ''instantly recognizable'' by Picasso. Similarly, they noted that in the statutory phrase ''specifically identifiable reproduction by or for any transmission recipient,'' the adjectival clause ''specifically identifiable'' is not linked to the transmission recipient. They therefore asserted that it is equally plausible to construe the ''specifically identifiable'' phrase as referring to the transmitting service.

RIAA also argued that the proposed interpretation is contrary to the statute's legislative history. Verizon, CTIA, and NAB took a similar position arguing that the tentatively proposed rule would be inconsistent with the overall statute and that the phrase is ambiguous. They pointed to *Muniz v. Hofman*, 422 U.S. 454, 468 (1975) and *Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 642 (1990) for the principle that where statutory language is susceptible to multiple constructions, it should be construed by reference to the legislative intent and the overall structure of the statutory provision. They went on to urge that the Office should follow its own previous reasoning that, where two interpretations of statutory language are both plausible: ''Turning to the legislative history is appropriate where, as here, the precise meaning is not apparent and a clear understanding of what Congress meant is crucial to an accurate determination of how Congress intended the digital performance right and the statutory scheme to operate.'' *Final Rule, Public Performance of Sound Recordings: Definition of a Service*, 65 FR 77292, 77296.

Commenters' attempts to indicate that there is ambiguity in the statute cited to the Senate and House Committee Reports on the Digital Performance Right in Sound Recordings Act (the ''1995 House and Senate Reports'') as evidence of the proposed ambiguity. Reliance on such evidence is misplaced. As the Supreme Court has directed, extraneous material such as legislative history ''are only admissible to solve doubt and not to create it.'' *Railroad Com. of Wisconsin v. Chicago, B. & Q. R. Co.*, 257 U.S. 563, 589 (1922). As Verizon and NAB's comments reveal, the phrase has precisely the same generally applicable meaning as the phrase ''instantly recognizable'' as used in the phrase ''an instantly recognizable painting by Picasso.''

Furthermore, even assuming we were persuaded by the arguments that the phrase ''specifically identifiable'' is ambiguous and should be read with reference to the legislative history, as is urged by Verizon, CTIA and NAB, the legislative history does not serve to clarify any supposed ambiguity in the meaning of the words ''specifically identifiable'' but rather suggests a limit on whom the adjectival clause ''specifically identifiable'' is to be applied. Construing the phrase in the manner suggested would require the insertion of additional language indicating that the adjectival clause ''specifically identifiable'' may only be applied ''to the transmission service.'' The Office declines commenters' invitation to make such an insertion. Instead, the Office's interim rule follows the principle of statutory construction that one ''should not read words into a statute that are not there.'' *U.S. v. Watkins*, 278 F.3d 961, 965 (9th Cir. 2002).

After considering the arguments raised by the parties, the Copyright Office accepts the structure of the phrase ''specifically identifiable reproduction by or for any transmission recipient of a phonorecord of that sound recording'' as it is explained and advanced by Verizon, CTIA, and NAB. Throughout the course of this proceeding leading up to the Office's tentatively proposed rule, the parties and the Office focused on two competing, yet flawed, interpretations. Under the previously proposed interpretations, a reproduction could be on the one hand ''specifically identifiable'' to the transmission service or on the other hand ''specifically identifiable'' by any transmission recipient or ''specifically identifiable'' for any transmission recipient. However, in light of the comments submitted by Verizon, CTIA, and NAB, the Office agrees that the sentence does not link the adjectival clause ''specifically identifiable'' to the transmission recipient. It also recognizes that nothing in the sentence links the adjectival clause ''specifically identifiable'' to the transmission service. In keeping with the insightful examples of similarly constructed language provided by Verizon, CTIA, and NAB, the Office concludes that ''specifically identifiable'' plainly, unambiguously and without limitations means ''specifically identifiable'' to anyone or anything, including the transmission service, the transmission service's computer, the transmission recipient, or the transmission recipient's computer.

While the Office takes no position as to whether each individual delivery of a phonorecord by digital transmission results in a specifically identifiable reproduction, there can be little question that certain streaming services involve the making of legally recognizable copies. To the extent that such copies may be identifiable by any person or computer, including any identification as an essential step in actually making the phonorecord perceptible to the recipient, the Office understands that such copies would satisfy the requirement of being ''specifically identifiable.''

B. Incidental DPDs

The Office recognizes the parties' views that certain reproductions created by transmission services may be categorized as so–called incidental DPDs. Section 115 requires that rates and terms shall distinguish between general DPDs and incidental DPDs. However, the statute does not offer a definition of incidental DPDs. Indeed, the statute does not specifically refer to incidental DPDs; it simply directs the Copyright Royalty Judges to set rates that ''distinguish between (i) digital phonorecord deliveries where the reproduction or distribution of a phonorecord is incidental to the transmission which constitutes the digital phonorecord delivery, and (ii) digital phonorecord deliveries in general.'' The lack of a specific definition of incidental DPDs has created a great deal of confusion among those parties with an interest in the Section 115 license. The Office notes that the parties have seemed less interested in defining what constitutes an incidental DPD and more concerned about receiving clarification as to whether specific types of digital

transmissions services fall within the scope of the statutory license.

The parties urging the Office to interpret the meaning of incidental DPD have not offered specific suggestions as to how the Office should define the term. Rather they offered conclusions as to which specific types of digital transmission services should be deemed to create reproductions that fall inside or outside the definition of incidental DPD. Support for these conclusions was made largely on policy or economic grounds.

As indicated previously, the Office understands that an incidental DPD is nothing more than a subset of DPDs. However, we can find little reason to delineate the contours of that subset. Whether a DPD is ''incidental'' or ''general,'' it is included under the Section 115 license. The Office questions whether the concept of incidental DPDs as set forth in the statute lends itself to further clarification in a regulation of general application. The Office observes that the legislative history of the Digital Performance in Sound Recordings Act of 1995 indicates that Congress recognized the likelihood of several different types of digital transmission systems. The Office also recognizes Congress' indication that certain DPDs may be incidental to the purpose of the transmission. S. Rep. No. 104–128 at 39.[6] However, the Office notes that, except for one discrete example of a type of service that would result in an incidental DPD, neither the statute nor the legislative history attempts to offer criteria for determining the purpose of a transmission.

The Office understands that neither the statute, the legislative history, nor the proposals submitted by commenters clearly propose any conclusive methods or criteria for determining the purpose of a transmission. Moreover, the only consequence of a determination that a digital phonorecord delivery is ''incidental'' is that a separate rate must be set for an incidental phonorecord delivery (although, in any event, it is inherent in the ratemaking provisions of Section 115 that several different rates may be set for various kinds of digital phonorecord deliveries). In setting rates for the activities specified in Section 115, the Copyright Royalty Judges are to distinguish between general and incidental DPDs, and they have the authority to set different rates for different types of DPDs, depending on their analysis of the economics of the service and the other circumstances set forth in section 801(b)(1). The Office therefore proposes that any determination regarding the purpose of a transmission, upon which the determination of when a DPD is an incidental DPD appears to turn, should be made in the context of a factual inquiry before the CRJs, if such a determination proves to be relevant.[7]

C. Limited Downloads

In the petition for a rulemaking that initiated this proceeding, RIAA characterized a limited download as an ''on–demand transmission of a time–limited or other use–limited (i.e. non–permanent) download to a local storage device (*e.g.* the hard drive of the user's computer), using technology that causes the downloaded file to be available for listening only either during a limited time (*e.g.* a time certain or a time tied to ongoing subscription payments) or for a limited number of times'' and asked the office to determine whether and to what extent limited downloads come within the scope of the Section 115 license. R*IAA Petition* at 1. As the Office has previously indicated, and explains again in this Notice below, whether a service is interactive or non–interactive does not appear to be relevant in the context of the Section 115 license. Therefore, the Office's regulatory text adopts a slightly altered characterization of limited downloads, as a subset of DPDs that ''may be made available to the transmission recipient for a limited period of time or for a specified number of performances.'' Applying the above–stated understandings regarding DPDs in general, the Office concludes that limited downloads fall within the definition for DPDs in that they are delivered; they satisfy the requirements for being a phonorecord; and they are specifically identifiable.[8] This conclusion regarding limited downloads is reflected in the interim rule.

D. Threshold Requirements for Use of the Section 115 License

Several parties expressed concern with the NPRM's proposed interpretation of 17 U.S.C. 115(a)(l), which states that ''A person may obtain a compulsory license only if his or her primary purpose in making phonorecords is to distribute them to the public for private use, including by means of a digital phonorecord delivery.'' Public Interest Commenters questioned the Office's proposed understanding that DPDs are, by the fact of their having been delivered, distributed within the meaning of the copyright law. They urged the Office to avoid preempting any judicial resolution regarding whether Internet transmissions may result in distribution of ''material objects.'' Google/YouTube asserted that the Office's proposal overlooks a legal distinction between copying that facilitates the delivery or ''distribution'' of a reproduction of a sound recording, on the one hand, and copying that merely enables the public performance of a sound recording, on the other. It also maintained that a ''performance'' to consumers, with or without the benefit of an intervening distribution entity, does not constitute the ''distribution'' of a copy of the content at issue. DiMA also argued that various types of streaming, other than interactive streaming, may or may not make reproductions at the recipient end of a transmission, and such reproductions may not always be for the ''primary purpose'' of making phonorecords.

Verizon, CTIA, and NAB claimed that the NPRM contained a near tautology when it asserted that by virtue of having been delivered, phonorecords are distributed within the meaning of copyright law. They also argued that the approach advanced by the Office all but reads the ''primary purpose'' requirement out of Section 115. They acknowledged that a primary purpose in making the DPD may be to distribute it. But they argued that the NPRM ignores the fact that, even if a buffer copy is a DPD, the primary purpose of making such a DPD is not to ''distribute'' anything. It is rather an essential step in

[6] ''For example, if a transmission system was designed to allow transmission recipients to hear sound recordings substantially at the time of transmission, but the sound recording was transmitted in a highspeed burst of data and stored in a computer memory for prompt playback (such storage being technically the making of a phonorecord), and the transmission recipient could not retain the phonorecord for playback on subsequent occasions (or for any other purpose), delivering the phonorecord to the transmission recipient would be incidental to the transmission.'' S. Rep. No. 104–128 at 39.

[7] The Office observes that nothing in the law prevents the CRJs from setting different rates for various kinds of incidental DPDs.

[8] The Office understands that there may be many types of limited downloads made available to transmission recipients for varying periods of time or number of performances. Nothing in the law prevents the CRJs from setting different rates for various kinds of limited downloads. The Office observes that the agreement submitted to the CRJs on September 22, 2008 assigns rates for specific types of limited downloads. *See* Mechanical and Digital Phonorecord Delivery Rate Determination Proceeding, 73 FR 57033, 57034 (Oct. 1, 2008)(proposed 37 CFR § 385.11 (definition of ''Limited download'')). The Office notes that to the extent DPDs fall within the characterization of limited downloads as set forth in the Office's interim rule (which is broader than the category identified in the submitted agreement) they are licensable under Section 115 regardless of the rates assigned to them, or indeed regardless of whether any rate has been assigned to them.

the effectuation of a performance. They then cited to statements made by the Register that a ''stream'' does not constitute a distribution and that buffer and other intermediate copies are for all practical purposes useless. Finally, they offered the argument that characterizing all buffers as distributed would undermine many established principles, provisions and practices of copyright law including fair use, the concept of publication, and registration practices.

As indicated above, the Office's interim rule, unlike the NPRM, takes no position as to whether a buffer copy constitutes a phonorecord. However, it is apparent that when a transmission to an individual consumer does result in a DPD, the phonorecord is made for the purpose of allowing the recipient to make a private use of that phonorecord, even if that use is simply to hear the performance of the phonorecord contemporaneously with the transmission. Similarly, it appears that enabling a recipient to make such a private use is a service's primary purpose in making phonorecords on a recipient's device. The Office notes that Congress intended the Section 115 license to cover DPDs ''regardless of whether the digital transmission is also a public performance of the sound recording or any nondramatic musical work embodied therein.'' 17 U.S.C. 115(d).

The Office's interim rule also does not determine whether all phonorecords which satisfy the previously addressed requirements for being DPDs are necessarily ''distributed.'' This position is consistent with the Office's prior legal conclusions as well as the Register's statements and policy arguments to Congress that a stream in and of itself does not constitute a distribution. However, under the Office's above–stated analysis, there is no dispute that limited download services as well as certain streaming services involve the making of legally recognizable copies that fit within the definition of a DPD. To the extent that such phonorecords exist on the recipient's computer for some period of time beyond their performance, it is reasonable to consider the phonorecord as having been ''distributed.'' At the very least, where services involve the making of DPDs that exist on the recipient's computer for some period of time beyond their performance and which can be used to replay the phonorecord, it would appear that such phonorecords have been ''distributed.''[9] Whether the delivery of a phonorecord that lasts no longer than the streamed performance constitutes a distribution is an issue that need not be resolved for purposes of this rulemaking.

E. Non–DPD Copies Under the Section 115 License

Among the commenters, Verizon, CTIA, and NAB were alone in disputing the tentative proposal in the NPRM stating that server copies, and all other intermediate copies, used to make DPDs under the Section 115 license fall within the scope of the license. They argued that the primary purpose in making server ''phonorecords'' is not ''to distribute them to the public for private use'' and that therefore they are not eligible for the 115 license. However, this argument misunderstands the Office's interpretation in the NPRM of the coverage provided by the Section 115 license.

The Office understands that the Section 115 license has traditionally provided coverage beyond those phonorecords made and distributed to the public for private use, so long as such phonorecords were used to achieve the primary purpose of making and distributing phonorecords under the Section 115 license. Indeed, when it enacted Section 115 in 1976, Congress stated that it intended the license to cover ''every possible manufacturing or other process capable of reproducing a sound recording in phonorecords.''[10] As stated in the NPRM, the right to make master recordings, which are used to make the phonorecords that are actually distributed has long been understood to be included in the Section 115 license. Similarly, server copies, as well as all other intermediate copies used to make and distribute DPDs under the Section 115 license, perform a function in the world of DPDs that is parallel to master recordings and manufacturing equipment in the physical world. Consequently, the interim rule confirms that server copies and intermediate reproductions may come within the scope of the license. The Office notes that a person seeking to operate under the Section 115 license must still satisfy the threshold requirements of the license. But, having done so, that licensee's coverage may extend to phonorecords other than those that are actually distributed provided that they are made for the purpose of making and distributing a DPD. On the other hand, server and intermediate copies that are the source of a transmission that does not result in the making and distribution of a DPD would not fall within the scope of the compulsory license. Finally, the Office notes that server and intermediate copies covered under the Section 115 license that are not distributed do not entitle the owner to separate royalty payments. 17 U.S.C. 115(c)(1).

F. Issues Outside the Scope of This Proceeding

1. Interactive vs. Non–interactive

The Office recognizes that nearly all of the commenters have expressed some preference to distinguish between phonorecords that are, or may be, made by Interactive Streaming Services versus those made by Non–interactive Streaming Services. As the Office stated in its NPRM, distinctions relating to interactivity are appropriate in the context of the Section 114 license, which is available only for nonintereactive transmissions, and such distinctions may be appropriate to raise as a matter of economic value or policy before the CRJs–for example, in setting rates–or Congress. However, whether a service is interactive or non–interactive does not appear to be relevant in determining whether particular reproductions of phonorecords may be covered under the current Section 115 license, except perhaps under the last sentence of Section 115(d), which does address the potential for non–interactivity to be relevant. However, this sentence must be read in its entirety, which provides:

> A digital phonorecord delivery does not result from a real–time, non–interactive subscription transmission of a sound recording where no reproduction of the sound recording or the musical work embodied therein is made from the inception of the transmission through to its receipt by the transmission recipient in order to make the sound recording audible.

15 U.S.C. 115(d) (emphasis added).

The Office acknowledges that it may be more common for interactive streams to result in DPDs and that it may be relatively uncommon for non–interactive streams to do so. However, if phonorecords are delivered by a transmission service, then under the last sentence of 115(d) it is irrelevant whether the transmission that created the phonorecords is interactive or non–interactive. To the extent that each stream creates a DPD, it appears that the only proffered justification for

[9] NMPA referred the Office to evidence indicating that three leading streaming music services create such copies. See Statement of Jacqueline Charlesworth *http://www.copyright.gov/docs/section115/2008/rm__2000–7__NMPA__hearing__statement.pdf.*

[10] H. Rep. No. 94–1476, at 110. *See also*, The Copyright Act of 1976, Transitional and Supplementary Provisions, Sec. 106 (''...parts of instruments serving to reproduce phonorecords mechanically ... such parts made on or after January 1, 1978, constitute phonorecords.''

distinguishing between the interactive and non–interactive transmissions is the business justification that interactive DPDs have a greater economic impact. The Office would not dispute a finding that non–interactive and interactive streams have different economic value, or even that a rate of zero might be appropriate for DPDs made in the course of non–interactive streams. Nor does it question the motivation for the industry's adoption of an agreement that distinguishes between the two. However, the Office maintains that any such distinctions can and should be addressed by different rates rather than being based on an unfounded assertion that non–interactive streaming cannot involve the making and distribution of phonorecords which are licensable under Section 115.

2. Policy Arguments

As has happened throughout this proceeding, a number of commenters proposed revisions that they would like Congress to adopt, including provisions that would expressly exempt transient copies made during the course of an authorized digital performance of a sound recording and declare that server copies made to facilitate an authorized public performance have no independent economic value. The Office notes, as it did in the NPRM, that such matters are beyond the scope of the current proceeding, not to mention the Office's regulatory power. Commenters also asserted that the proposed rule would have created problems regarding commenters' current understanding of other sections of the Copyright Act, such as the Section 114 and 112 licenses and Chapter 10's treatment of audio home recording. The interim rule, however, is limited to clarifying that reproductions created in the process of making a DPD are covered under the license and to acknowledge that a DPD may be limited either by time or to a specific number of plays. Consequently, there is no need to address the concerns raised by the parties about the effect of the proposed rule on other provisions in the copyright law.

G. Regulatory Text

The text of the interim regulation adopted today is based upon the text proposed in the NPRM, but with some fairly significant modifications. The text defines a digital phonorecord delivery as follows:

''digital phonorecord delivery'' is each individual delivery of a phonorecord by digital transmission of a sound recording which results in a specifically identifiable reproduction by or for any transmission recipient of a phonorecord of that sound recording, regardless of whether the digital transmission is also a public performance of the sound recording or any nondramatic musical work embodied therein. The reproduction of the phonorecord must be sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated for a period of more than transitory duration. Such a phonorecord may be permanent or it may be made available to the transmission recipient for a limited period of time or for a specified number of performances. A digital phonorecord delivery includes all phonorecords that are made for the purpose of making the digital phonorecord delivery.

The second sentence of the definition did not appear in the original proposed regulatory text. It is included in the interim regulation to clarify that any DPD requires that the phonorecord that is delivered must meet the requirements of fixation, including the durational requirement. However, the regulatory text takes no position on the threshold for satisfying that durational requirement, and therefore is not inconsistent with the approach taken in either the *DMCA Section 104 Report* or the *Cartoon Network* case.

The definition also makes clear that a DPD may be made available on a limited basis and that DPDs include any phonorecords made for the purpose of making the DPD. Thus, phonorecords such as server copies that are not sufficient to constitute a DPD (because they are not ''delivered'') but are nevertheless made for the purpose of delivering a DPD (such as a full or limited download or a cache copy at the end of the stream if that copy meets the fixation requirement) are nevertheless part of the DPD if a phonorecord is in fact delivered. And buffer copies, if they meet the fixation requirement, may also be DPDs or be included *as parts of* DPDs. If a buffer copy does not meet the fixation requirement, it is irrelevant whether it is *part of a* DPD because it cannot be an infringing ''copy.''

List of Subjects

37 CFR Part 201

Copyright, General provisions.

37 CFR Part 255

Compulsory license fees, Phonorecords.

Proposed Regulations

■ In consideration of the foregoing, the Copyright Office proposes to amend parts 201 and 255 of 37 CFR, as follows:

PART 201—GENERAL PROVISIONS

■ 1. The authority citation for part 201 continues to read as follows:

Authority: 17 U.S.C. 702.

■ 2. Amend § 201.18 as follows:

■ a. By redesignating paragraphs (a)(2) through (a)(6) as (a)(4) through (a)(8); and

■ b. By adding new paragraphs (a)(2) and (a)(3).

The revisions and additions to § 201.18 read as follows:

201.18 Notice of intention to obtain a compulsory license for making and distributing phonorecords of nondramatic musical works.

(a) * * *

(2) A person is entitled to serve or file a Notice of Intention and thereby obtain a compulsory license pursuant to 17 U.S.C. 115 only if his primary purpose in making phonorecords is to distribute them to the public for private use, including by means of a digital phonorecord delivery.

(3) For the purposes of this section, a ''digital phonorecord delivery'' is each individual delivery of a phonorecord by digital transmission of a sound recording which results in a specifically identifiable reproduction by or for any transmission recipient of a phonorecord of that sound recording, regardless of whether the digital transmission is also a public performance of the sound recording or any nondramatic musical work embodied therein. The reproduction of the phonorecord must be sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated for a period of more than transitory duration. Such a phonorecord may be permanent or it may be made available to the transmission recipient for a limited period of time or for a specified number of performances. A digital phonorecord delivery includes all phonorecords that are made for the purpose of making the digital phonorecord delivery.

* * * * *

■ 3. Amend § 201.19 as follows:

■ a. By amending paragraph (a)(1) to add '', including by means of a digital phonorecord delivery.'' after ''of nondramatic musical works''.

■ b. By redesignating paragraphs (a)(3) through (a)(12) as paragraphs (a)(4) through (a)(13); and

■ c. By adding a new paragraph (a)(3).

The revisions to § 201.19 read as follows:

201.19 Royalties and statements of account under compulsory license for making and distributing phonorecords of nondramatic works.

(a) * * *

(3) For the purposes of this section, a ''digital phonorecord delivery'' is each individual delivery of a phonorecord by

digital transmission of a sound recording which results in a specifically identifiable reproduction by or for any transmission recipient of a phonorecord of that sound recording, regardless of whether the digital transmission is also a public performance of the sound recording or any nondramatic musical work embodied therein. The reproduction of the phonorecord must be sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated for a period of more than transitory duration. Such a phonorecord may be permanent or it may be made available to the transmission recipient for a limited period of time or for a specified number of performances. A digital phonorecord delivery includes all phonorecords that are made for the purpose of making the digital phonorecord delivery.

* * * * *

PART 255—ADJUSTMENT OF ROYALTY PAYMENTS UNDER COMPULSORY LICENSE FOR MAKING AND DISTRIBUTING PHONORECORDS

■ 4. The authority citation for part 255 continues to read as follows:

Authority: 17 U.S.C. 702.

■ 5. Section 255.4 is revised to read as follows:

§ 255.4 Definition of digital phonorecord delivery.

A ''*digital phonorecord delivery*'' is each individual delivery of a phonorecord by digital transmission of a sound recording which results in a specifically identifiable reproduction by or for any transmission recipient of a phonorecord of that sound recording, regardless of whether the digital transmission is also a public performance of the sound recording or any nondramatic musical work embodied therein. The reproduction of the phonorecord must be sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated for a period of more than transitory duration. Such a phonorecord may be permanent or it may be made available to the transmission recipient for a limited period of time or for a specified number of performances. A digital phonorecord delivery includes all phonorecords that are made for the purpose of making the digital phonorecord delivery.

Dated: October 22, 2008.

Marybeth Peters,

Register of Copyrights.

Approved by:

James H. Billington,

The Librarian of Congress.

[FR Doc. E8–26666 Filed 11–6–08; 8:45 am]

BILLING CODE 1410–30–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2008–0728; FRL–8729–1]

Approval and Promulgation of Implementation Plans; Revisions to the Nevada State Implementation Plan; Clark County

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: Under the Clean Air Act, EPA is taking direct final action to approve a revision to the Clark County portion of the Nevada State Implementation Plan (SIP). This revision consists of transportation conformity criteria and procedures related to interagency consultation and enforceability of certain transportation-related control measures and mitigation measures. The intended effect is to include the transportation conformity criteria and procedures in the applicable SIP.

DATES: This rule is effective on January 6, 2009, without further notice, unless EPA receives adverse comments by December 8, 2008. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2008–0728, by one of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions.
2. *E-mail: vagenas.ginger@epa.gov.*
3. *Mail or deliver:* Ginger Vagenas (AIR–2), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* portal is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: The index to the docket for this action is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Ginger Vagenas, EPA Region IX, (415) 972–3964, *vagenas.ginger@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

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I. Transportation Conformity

Transportation conformity is required under section 176(c) of the Clean Air Act (CAA or Act) to ensure that federally supported highway, transit projects, and other activities are consistent with (''conform to'') the purpose of the SIP. Conformity applies to areas that are currently designated nonattainment, and to areas that have been redesignated to attainment after 1990 (maintenance areas) with plans developed under section 175A of the Act, for the following transportation related criteria pollutants: Ozone, particulate matter ($PM_{2.5}$ and PM_{10}), carbon monoxide (CO), and nitrogen dioxide (NO_2).

Conformity to the purpose of the SIP means that transportation activities will not cause new air quality violations, worsen existing violations, or delay timely attainment of the relevant national ambient air quality standards

(NAAQS). The transportation conformity regulation is found in 40 CFR part 93 and provisions related to conformity SIPs are found in 40 CFR 51.390.

II. Background for This Action

EPA promulgated the Federal transportation conformity criteria and procedures (the conformity rule) on November 24, 1993. See 58 FR 62188. Among other things, the rule required states to address all provisions of the conformity rule in their SIPs (''conformity SIPs''). Under 40 CFR 51.390, most sections of the conformity rule were required to be copied verbatim. States were also required to tailor all or portions of the following three sections of the conformity rule to meet their state's individual circumstances: 40 CFR 93.105, which addresses consultation procedures; 40 CFR 93.122(a)(4)(ii), which addresses written commitments to control measures that are not included in a metropolitan planning organization's (MPO's) transportation plan and transportation improvement program that must be obtained prior to a conformity determination, and the requirement that such commitments, when they exist, must be fulfilled; and 40 CFR 93.125(c), which addresses written commitments to mitigation measures that must be obtained prior to a project-level conformity determination, and the requirement that project sponsors must comply with such commitments, when they exist.

On August 10, 2005, the ''Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users'' (SAFETEA–LU) was signed into law. SAFETEA–LU revised section 176(c) of the Clean Air Act's transportation conformity provisions. One of the changes streamlines the requirements for conformity SIPs. Under SAFETEA–LU, states are required to address and tailor only three sections of the conformity rule in their conformity SIPs: 40 CFR 93.105, 40 CFR 93.122(a)(4)(ii), and, 40 CFR 93.125(c), described above. In general, states are no longer required to submit conformity SIP revisions that address the other sections of the conformity rule. These changes took effect on August 10, 2005, when SAFETEA–LU was signed into law.

III. State Submittal and EPA Evaluation

EPA has designated portions of Clark County, Nevada, as nonattainment for the carbon monoxide, 8-hour ozone, and respirable particulate matter (PM_{10}) national ambient air quality standards (NAAQS). See 40 CFR 81.329. Thus, a ''conformity SIP'' for the portions of Clark County so designated must be prepared, adopted, and submitted to EPA to comply with the CAA, as amended by SAFETEA–LU.

In response to these requirements, on April 1, 2008, the Nevada Division of Environmental Protection (NDEP) submitted the Clark County Transportation Conformity Plan (TCP) to EPA for approval as a revision to the Clark County portion of the Nevada SIP. The Clark County Board of County Commissioners adopted the Clark County TCP on January 15, 2008. Appendix A of the Clark County TCP documents public notice and hearing for this SIP revision in compliance with CAA section 110(l) and 40 CFR 51.102. On July 3, 2008, this submittal was found to meet the completeness criteria in 40 CFR Part 51 Appendix V, which must be met before formal EPA review. There is no previous version of the Clark County TCP in the SIP.

Upon EPA approval, the Federal transportation conformity regulations will apply, except for those sections addressed by the current submittal, i.e., the requirements under 40 CFR 93.122(a)(4)(ii) and 93.125(c) for enforceability of control measures and mitigation measures, and under 40 CFR 93.105 for interagency consultation.

We have reviewed the Clark County TCP to assure consistency with the Clean Air Act as amended by SAFETEA–LU and EPA regulations (40 CFR part 93 and 40 CFR 51.390) governing state procedures for transportation conformity and interagency consultation and have concluded that the plan is approvable. Details of our review are set forth in a technical support document (TSD), which has been included in the docket for this action. Specifically, in our TSD, we identify how the submitted procedures satisfy our requirements under 40 CFR 93.105 for interagency consultation with respect to the development of transportation plans and programs, SIPs, and conformity determinations, the resolution of conflicts, and the provision of adequate public consultation, and our requirements under 40 CFR 93.122(a)(4)(ii) and 93.125(c) for enforceability of control measures and mitigation measures. EPA approval of this SIP revision is consistent with Federal law and regulations, and will obviate the need for SIP revisions that would have otherwise been triggered by changes to the underlying Federal regulations.

IV. Public Comment and Final Action

As authorized in section 110(k)(3) of the Act, and for the reasons set forth above, EPA is fully approving the Clark County Transportation Conformity Plan, submitted on April 1, 2008, as a revision to the Clark County portion of the Nevada SIP. We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted plan. If we receive adverse comments by December 8, 2008, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on January 6, 2009. This will incorporate the Clark County TCP into the federally enforceable SIP.

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 6, 2009. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 24, 2008.

Wayne Nastri,

Regional Administrator, Region IX.

■ Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart DD—Nevada

■ 2. Section 52.1470 is amended by adding paragraph (c)(72) to read as follows:

§ 52.1470 Identification of plan.

* * * * *

(c) * * *

(72) The following plan revision was submitted on April 1, 2008, by the Governor's designee.

(i) Incorporation by reference.

(A) Clark County Department of Air Quality and Environmental Management.

(*1*) Clark County Transportation Conformity Plan (January 2008), adopted by the Clark County Board of County Commissioners on January 15, 2008.

[FR Doc. E8–26513 Filed 11–6–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 59

[EPA–HQ–OAR–2006–0971; FRL–8738–7]

RIN 2060–AP33

National Volatile Organic Compound Emission Standards for Aerosol Coatings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on the National Volatile Organic Compound Emission Standards for Aerosol Coatings, which establishes national reactivity-based emission standards for the aerosol coatings category (aerosol spray paints) under the Clean Air Act (CAA). In this direct final action, EPA is moving the applicability and compliance dates for aerosol coatings from January 1, 2009, to July 1, 2009. EPA is also making initial notifications required due on the compliance date, as opposed to 90 days in advance of the compliance date.

DATES: This rule is effective on December 29, 2008 without further notice, unless EPA receives adverse comment by December 8, 2008, or December 22, 2008 if a hearing is requested. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified under Docket ID No. EPA–HQ–OAR–2006–0971 by one of the following methods:

• *www.regulations.gov.* Follow the online instructions for submitting comments.

• *E-mail: a-and-r-docket@epa.gov.*

• *Fax:* (202) 566–9744.

• *Mail:* National Volatile Organic Compound Emission Standards for Aerosol Coatings, Environmental Protection Agency, Mail Code: 2822T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include two copies.

• *Hand Delivery:* EPA Docket Center, 1301 Constitution Avenue, NW., EPA Headquarters Library, Room 3334, EPA West Building, Washington, DC 20460. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2006–0971. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov*, your e-

mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the National Volatile Organic Compound Emission Standards for Aerosol Coatings, EPA/DC, EPA West Building, EPA Headquarters Library, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For further information, contact Ms. J. Kaye Whitfield, U.S. EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Natural Resources and Commerce Group (E143–03), Research Triangle Park, NC 27711; telephone number (919) 541–2509; facsimile number (919) 541–3470; e-mail address: *whitfield.kaye@epa.gov*. For information concerning the CAA Section 183(e) consumer and commercial products program, contact Mr. Bruce Moore, U.S. EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Natural Resources and Commerce Group (E143–03), Research Triangle Park, North Carolina 27711, telephone number: (919) 541–5460, facsimile number (919) 541–3470, e-mail address: *moore.bruce@epa.gov*.

SUPPLEMENTARY INFORMATION:

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K. Congressional Review Act

I. Why is EPA using a direct final rule?

EPA is publishing this rule without a prior proposed rule because we view this as a non-controversial action and anticipate no adverse comment. The final rule has a provision that allows regulated entities to petition EPA to add compounds to Tables 2A, 2B, and 2C—Reactivity Factors of subpart E, 40 CFR part 59. It is necessary to move the compliance date to allow time to add compounds that are currently used in aerosol coatings, but were not included on the list of reactivity factors in Table 2 of the final rule. Removing the requirement for a 90 day advance submittal of initial notifications will make the aerosol coatings rule consistent with the requirements of other part 59 rules, increasing consistency and clarity for the regulated entities.

Although we do not anticipate adverse comments on this action, in the ''Proposed Rules'' section of today's **Federal Register**, we are publishing a separate document that will serve as the proposed rule to the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59) if adverse comments are received on this direct final rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information about commenting on this rule, see the **ADDRESSES** section of this document. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect. We would address all public comments in any subsequent final rule based on the proposed rule.

II. Does this action apply to me?

The entities potentially affected by this direct final rule are the same entities that are subject to the Aerosol Coatings final rule. The entities affected by the Aerosol Coatings final rule include: Manufacturers, processors, distributors, importers of aerosol coatings for sale or distribution in the United States, and manufacturers, processors, distributors, or importers who supply the entities listed above with aerosol coatings for sale or distribution in interstate commerce in the United States.

III. What should I consider as I prepare my comments for EPA?

A. *Submitting CBI.* Do not submit this information to EPA through *www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

B. Tips for Preparing Your Comments. When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.

- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

IV. What are the amendments made by this direct final rule?

In this direct final action, EPA is moving the applicability and compliance dates for aerosol coatings, as specified in sections 59.501(c) and 59.502(a), from January 1, 2009, to July 1, 2009. Also, EPA is making initial notifications required in sections 59.501(f)(3)(i), 59.511(b) and 59.511(e) due on the compliance date, as opposed to 90 days in advance of the compliance date. These two actions are necessary to allow EPA time to add compounds and applicable reactivity factors that are currently used in aerosol coatings but were not included on the list in Table 2 of the final rule; allow regulated entities sufficient time to develop initial notification reports based on revised tables; and, in the case of making initial notifications due on the compliance date, make the aerosol coatings rule consistent with the requirements of other part 59 rules, increasing consistency and clarity for the regulated entities.

Section 59.511(j) anticipated that there may be some compounds that aerosol coating manufacturers are currently using, or intend to use, that were not included in Table 2 of the final rule. Section 59.511(j) allowed for regulated entities to petition EPA to add such compounds to the list. EPA received such petitions, but has not been able to finalize the additions to the list with sufficient time to allow manufacturers to certify compliance based on the deadlines in the final rule. Delaying the compliance date and the date when initial notifications are due will allow EPA time to finalize the additions to the list through appropriate public notice and comment procedures, and allow regulated entities sufficient time to prepare initial notification reports, and review and certify their compliance with the limits based on the revised tables.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This action is not a ''significant regulatory action'' under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO.

B. Paperwork Reduction Act

This action does not impose any new information collection burden because it does not add any new information collection requirements; it only moves dates by which regulated entities are required to submit information and otherwise comply with the rule. No additional information collection is necessary for this action. However, OMB has previously approved the information collection requirements contained in the existing regulations 40 CFR part 59 under the provisions of the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2266.01. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's final rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's regulations at 13 CFR 121.201; (2) a governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. We have determined that small businesses will not incur any adverse impacts because this action does not create any new requirements or burdens; it only moves the dates by which persons are required to submit information and otherwise comply with the rule. No costs are associated with these amendments.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. The action imposes no enforceable duty on any State, local or tribal governments or the private sector. Therefore, this action is not subject to the requirements of sections 202 or 205 of UMRA.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. As noted above, this rule does not create any new requirements or burdens; it extends the date by which regulated entities must be in compliance.

E. Executive Order 13132: Federalism

EO 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the EO to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in EO 13132. The CAA establishes the relationship between the Federal Government and the States, and this action does not impact that relationship. The final rule requirements will not supersede State regulations that are more stringent. Thus, EO 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in EO 13175 (65 FR 67249, November 9, 2000). The final regulatory action does not have a substantial direct effect on one or more Indian tribes, in that this action imposes no regulatory burdens on tribes. Thus, EO 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets EO 13045 (62 FR 19885, April 23, 1997) as applying to those regulatory actions that concern

health or safety risks, such that the analysis required under section 5–501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because it is based solely on technology performance.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (Pub. L. 104–113, Section 12(d), 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities, unless to do so would be inconsistent with applicable law or otherwise impractical. The VCS are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the EPA does not use available and applicable VCS.

This final rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This action extends the compliance date of the rule from January 1, 2009, to July 1, 2009, and does not relax the control measures on sources regulated by the rule.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing the final rule amendment and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule amendment in the **Federal Register**. The final rule amendment is not a ''major rule'' as defined by 5 U.S.C. 804(2). This final rule is effective on December 29, 2008.

List of Subjects in 40 CFR Part 59

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: October 30, 2008.

Stephen L. Johnson,

Administrator.

■ For the reasons set out in the preamble, title 40, Chapter I of the Code of Federal Regulations is amended as follows:

PART 59—[AMENDED]

■ 1. The authority citation for part 59 continues to read as follows:

Authority: 42 U.S.C. 7414 and 7511b(e).

Subpart E—[Amended]

■ 2. Section 59.501 is amended by revising the first sentence of paragraph (c) and the first sentence of paragraph (f)(3)(i) to read as follows:

§ 59.501 Am I subject to this subpart?

* * * * *

(c) Except as provided in paragraph (e) of this section, the provisions of this subpart apply to aerosol coatings manufactured on or after July 1, 2009, for sale or distribution in the United States. * * *

* * * * *

(f) * * *

(3) * * *

(i) You must submit an initial notification no later than the compliance date stated in § 59.502(a), or on or before the date that you start manufacturing aerosol coating products that are sold in the United States, whichever is later.

* * * * *

■ 3. Section 59.502 is amended by revising paragraph (a) to read as follows:

§ 59.502 When do I have to comply with this subpart?

(a) Except as provided in § 59.509 and paragraphs (b) and (c) of this section, you must be in compliance with all provisions of this subpart by July 1, 2009.

* * * * *

■ 4. Section 59.511 is amended by revising the first sentence of paragraph (b) introductory text and the first sentence of paragraph (e) introductory text to read as follows:

§ 59.511 What notification and reports must I submit?

* * * * *

(b) You must submit an initial notification no later than the compliance date stated in § 59.502(a), or on or before the date that you first manufacture, distribute, or import aerosol coatings, whichever is later. * * *

* * * * *

(e) If you claim the exemption under § 59.501(e), you must submit an initial notification no later than the compliance date stated in § 59.502(a), or on or before the date that you first manufacture aerosol coatings, whichever is later. * * *

* * * * *

[FR Doc. E8–26614 Filed 11–6–08; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 440

[CMS–2213–F]

RIN 0938–AO17

Medicaid Program; Clarification of Outpatient Hospital Facility (Including Outpatient Hospital Clinic) Services Definition

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: Outpatient hospital services are a mandatory part of the standard Medicaid benefit package. This final rule aligns the Medicaid definition of outpatient hospital services more

closely to the Medicare definition in order to: Improve the functionality of the applicable upper payment limits (which are based on a comparison to Medicare payments for the same services), provide more transparency in determining available hospital coverage in any State, and generally clarify the scope of services for which Federal financial participation (FFP) is available under the outpatient hospital services benefit category.

DATES: *Effective Date:* These regulations are effective December 8, 2008.

FOR FURTHER INFORMATION CONTACT: Jeremy Silanskis, (410) 786–1592.

SUPPLEMENTARY INFORMATION:

I. Background

A. Definition of Outpatient Hospital Services

Section 1905(a)(2)(A) of the Social Security Act (the Act) lists outpatient hospital services as a benefit that can be covered under a State Medicaid program, and it is a mandatory benefit for most eligible Medicaid populations under sections 1902(a)(10)(A) and 1902(a)(10)(C)(iv) of the Act. Though the statute does not provide a definition for these services, federal regulations at 42 CFR 440.20 were established to define: An outpatient hospital service, the circumstances under which outpatient services are delivered, and qualifications for Medicaid outpatient hospital service providers.

As discussed in the proposed rule, the proposed changes would address ambiguity in the definition of outpatient hospital services which allowed for a high possibility of overlap between outpatient hospital facility services and other covered Medicaid benefits. CMS viewed the overlap in service definitions as problematic for several reasons. The broad definition of outpatient hospital services did not clearly limit the scope of the outpatient hospital service benefit to those services over which the outpatient hospital has oversight and control. The overlap could result in payment at the high levels customary for outpatient hospital facility services instead of at the lower levels associated with the other covered benefits. Also, the definition's ambiguity potentially allowed States to include services paid for under other Medicaid benefit categories in the State plan in the calculation for Medicaid and uncompensated care cost supplemental payments for outpatient hospital services. In addition, the definition was inconsistent with the applicable upper payment limit (UPL), which is based on the premise of some level of comparability between the Medicare and Medicaid definitions of outpatient hospital and clinic services.

B. Calculation of Outpatient Hospital and Clinic Upper Payment Limits

Regulations at 42 CFR 447.321 define the UPLs for Medicaid outpatient hospital and clinic services. The UPLs for outpatient hospital and clinic facilities are based on the amount that would be paid under Medicare payment principles. We proposed to clarify this standard by incorporating into the regulatory text guidance concerning the methods for demonstrating compliance with the UPLs.

In consideration of the Congressional moratorium on the proposed rule on Cost Limits for Governmentally-Operated Providers (the ''Government Provider Payment Rule''), published on January 18, 2007 (72 FR 2236), we are reserving action on the proposed provisions at § 447.321. We may consider publication of the UPL guidance at a future date. If the UPL guidance is published in the future, we will respond to the public comments concerning those regulatory clarifications at that time. Since this final rule only concerns changes to the outpatient hospital service definition, we have modified the title of the final regulation to read: Clarification of Outpatient Hospital Facility Services Definition.

C. Proposed Regulation

CMS published a proposed rule in the **Federal Register** on September 28, 2007 (72 FR 55158), entitled ''Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit.'' We provided for a 30 day public comment period and received a total of 333 timely comments from States, local government, providers, and health care associations. Brief summaries for each proposed provision, a summary of the public comments we received, and our responses to comments, are set forth below.

II. Provisions of the Proposed Rule and Response to Comments

General Comments

Comment: A substantial number of commenters urged CMS to withdraw the proposed rule. They stated the regulatory changes are in violation with the Congressional Moratorium passed as part of the Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007. Nearly all of the comments concerning a violation of the moratorium focused on: The exclusion of graduate medical education costs and payment in the outpatient upper payment limit calculation, and the inclusion of certain terminology and citations in the proposed rule that were a part of the proposed rule on Cost Limits for Governmentally-Operated Providers (the ''Government Provider Payment Rule''), published on January 18, 2007 (72 FR 2236) and the proposed rule for Medicaid Graduate Medical Education (the ''GME Rule'') published on May 23, 2007 (72 FR 28930).

Response: The proposed rule addressed completely different policy concerns from those published in the proposed Government Provider Payments Rule and the GME Rule. Those rules concern the amount of the permissible payment for government providers or for institutions offering graduate medical education, rather than the scope of the outpatient hospital benefit.

In our proposed rule, we integrated the proposed provisions in with the provisions of the Government Provider Payment Rule because that rule had been published in final form. Integrating this proposed rule with the provisions of the Government Provider Payment Rule misstated the existing regulatory framework. We regret any concern this may have caused.

Therefore, we are reserving action on the proposed clarifications to the outpatient hospital and clinic upper payment limits at 42 CFR 447.321. We may address these provisions at a future date, at which time we will respond to the public comments we received concerning the payment limit clarifications.

Comment: A number of commenters asserted that the rule did more than clarify ambiguous regulatory language and formalize existing CMS policy. Many commenters stated that the proposed regulation was unwarranted and poor public policy. One commenter opined that ''CMS has (not) adequately demonstrated the need for the proposed changes to the regulations regarding the definition of outpatient hospital services.'' Another commenter stated: ''The proposed regulatory changes seem arbitrary, not developed with care and not fulfilling CMS's own purposes.'' Still, an additional commenter stated that the rule ''is neither transparent nor clarifying.'' Many commenters stated that the rule was not a minor clarification of CMS policy.

Response: As discussed in the proposed rule, the purpose of the regulation is to establish consistency between the definition of Medicaid outpatient hospital services and the applicable upper payment limit for

those services, to provide more transparency in determining available hospital coverage in any State, and to generally clarify the scope of services for which Federal financial participation (FFP) is available under the outpatient hospital services benefit category.

For example, in our review of State plan amendments, we found that one State was including numerous services defined under other Medicaid benefit categories and non-Medicaid covered services within the Medicaid outpatient hospital benefit category. Some or all of these services were provided in settings that did not involve the high overhead costs of a hospital facility. The State's apparent purpose in defining the services as part of the outpatient hospital services benefit was to include the services in the calculation of the outpatient hospital upper payment limit, in order to justify targeted supplemental payments to hospitals that would otherwise violate applicable upper payment limits.

We are concerned that such arrangements increase the outpatient hospital upper payment limit without any justification based on any increased cost or service levels, and thus is not consistent with efficient and effective management of a Medicaid program.

This regulation will clarify that such arrangements, in which higher payments are not justified by increased costs or service levels, are not permitted. Therefore, we respectfully disagree that the regulation does not provide additional clarification or that the proposed changes are arbitrary.

Comment: One commenter requested that CMS ''clarify what UPL, if any, applies to each service that is provided in hospital outpatient facilities, but which would not be within the scope of the definition of outpatient hospital services under 42 CFR 440.20.''

Response: The regulations at 42 CFR recognize facility services provided to outpatients in outpatient hospital and clinic setting. As of the publication of this final regulation, there are no upper payment limits for non-institutional practitioner services defined in regulation. As with any rate methodology, payments for other non-institutional services must comply with section 1902(a)(30)(A) of the Act, which requires that State plans have methods and procedures to assure that payments are consistent with economy, efficiency and quality of care. To establish such compliance, CMS may ask a State to explain a reasonable basis for its rates. Within the scope of 1902(a)(30)(A), CMS allows States to determine payment rate methodologies for non-institutional practitioner services consistent with regulations at 42 CFR 430.10 and 447.204.

Comment: One commenter requested that CMS clarify how a State should account in its UPL calculation for mandatory outpatient hospital services that are not covered by Medicare as outpatient hospital services, or are specified in Medicaid regulations as a separate State Plan category of service. The commenter was under the impression that such services could be required outpatient hospital services pursuant to current 42 CFR 440.20(a)(4) (which would be moved to 42 CFR 440.20(a)(5) under this rule).

Response: The provisions at 42 CFR 440.20(a)(5) are generally intended to provide States with the discretion to limit the outpatient hospital service definition to exclude services that are not typically provided in hospitals within the State. We do not interpret this section of the regulation to expand the available scope of services beyond those recognized under the Medicare outpatient prospective payment system or paid by Medicare as an outpatient hospital services under an alternative payment methodology. Instead, the provision allows States to define the benefit category to exclude services that are not typically provided in hospitals within the State.

Comment: One comment supported implementing the proposal into a final regulation and offered that ''using consistent definitions across these programs helps to simplify a very complex array of regulations and pricing policies.''

Response: We thank the commenter for supporting the provisions of the proposed regulation.

Outpatient Hospital Service Definition

We proposed to define Medicaid outpatient hospital services at 42 CFR 440.20 to include those services recognized under the Medicare outpatient prospective payment system (defined under 42 CFR 419.2(b)) and those services paid by Medicare as an outpatient hospital service under an alternate payment methodology. Further, we have proposed to limit the definition to exclude services that are covered and reimbursed under the scope of another Medicaid service category under the Medicaid State plan and required that services be furnished by an outpatient hospital facility or a department of an outpatient hospital as described at 42 CFR 413.65.

Comment: Several commenters stated that the proposed rule eliminates hospital overhead from many hospital and ambulatory services. Further, a number of commenters noted that the rule discourages safety net providers from providing community-based primary and preventive ambulatory care services that improve community health and reduce future health care costs.

Response: This rule would not have such effects. There is nothing in this rule that precludes States from paying for community-based primary and preventive ambulatory care services at rates that fully account for costs to provide such services. This rule would, however, provide for greater transparency in paying for such costs because the payments would be made directly on a fee-for-service basis rather than indirectly through complex facility or supplemental payment programs. As a result, it will be easier to compare the cost-effectiveness of different providers.

In other words, while this regulation would require that States distinctly reimburse hospitals for the facility expenses and separately reimburse for the practitioners who provide the Medicaid services within the facility, it would not eliminate any Medicaid benefit category, place reimbursement restrictions on those categories, or alter the qualifications that must be met to provide a Medicaid covered service. Any non-institutional Medicaid service covered under a State's plan may continue to be provided in a safety-net hospital, a clinic, or other non-institutional setting by a service practitioner who meets the provider qualifications for the service set forth in the State plan.

Further, under section 1902(a)(32) of the Act, the hospital may collect payment on behalf of the practitioner if the practitioner is required to turn over the Medicaid fee on condition of employment or a contractual arrangement.

Comment: Many commenters questioned whether the Medicare definition included in the proposed regulation considers the role of the Medicaid program in providing services to other populations. Commenters noted that the Medicare and Medicaid programs are different in both scope and the populations that they serve. In addition, the commenters pointed out that Medicare is a Federal program with national standards, whereas Medicaid is a State/Federal partnership with programmatic variations among the States. One commenter cited examples of services provided to children that are not covered under the Medicare programs, such as: Dental and vision services, annual check-ups, and immunizations. By restricting the scope of Medicaid services to those covered under Medicare, the commenter stated

that CMS would be lowering the reimbursement for these important services that hospitals provide to children insured by Medicaid, which fall below the cost of care. The commenter suggested that CMS delay implementation of the regulation and review the potential impact of the regulation on Medicaid eligible children and the providers that serve them.

Response: We believe that the difference in populations served by Medicare and Medicaid has no impact on the nature and scope of outpatient hospital facility services recognized by Medicare under OPPS or an alternate fee schedule. We note that Medicare covers individuals under the age of 65 with disabilities and that the Medicare program recognizes procedures for a wide array of services that are not unique to individuals over age 65. We have examined the Medicare payment systems and are unable to identify hospital facility costs that are not recognized by the Medicare program that would be unique to children or other populations that are not covered under the Medicare program.

To the extent that there are such services, however, we interpret the phrase ''would be included'' at 42 CFR 440.20(a)(4) of this rule to include services that are not actually paid by Medicare under OPPS or an alternate payment methodology, but that would be paid under those methodologies if furnished to a Medicare beneficiary.

This is consistent with the goal of this regulation, which is to limit the scope of Medicaid State plan outpatient facility services to the type and scope of services that are generally recognized as actual hospital services. We believe that the outpatient services described in the proposed regulation represent the full and appropriate scope of services provided in outpatient hospital settings. The services mentioned in the comments are covered under other, distinct Medicaid service definitions. These services may continue to be provided and reimbursed by Medicaid within hospital settings under the coverage policies and reimbursement methodologies defined by States specific to those services.

Comment: Several of the commenters stated that under the Medicare program, physical therapy is recognized as a separate benefit and the service providers are qualified to provide services without physician supervision. Under the Medicaid program, these commenters urged, many States exclusively offer physical therapy services within outpatient hospitals under the outpatient hospital benefit category.

Response: The proposed regulation allows for services that are not covered under another Medical Assistance benefit category under the State plan to be included as part of the outpatient hospital facility benefit if the services are recognized under the Medicare OPPS or paid as outpatient hospital services under an alternate fee schedule. Therefore, if a State chooses to only cover and pay for these services as part of the outpatient hospital benefit and the services are recognized under the Medicare OPPS or paid as outpatient hospital services under an alternate fee schedule, the services may be part of the outpatient hospital Medicaid definition. However, if the services are covered as a non-institutional practitioner service under a separate benefit category, the State must pay for those services under the reimbursement methodology specific to that benefit category and may not define the services in the State plan as outpatient hospital facility services. Regardless, physical therapy services may continue to be paid under the Medicaid program in outpatient hospital settings.

Comment: One commenter stated that free-standing outpatient rehabilitation facilities should be treated as outpatient hospitals and not be recognized as clinics. This commenter explained that, regardless of the setting, outpatient services should be paid the same reimbursement rate.

Response: This regulation does not alter the requirements for participation in the Medicaid program as an outpatient hospital facility. For purposes of the Medicaid program, the regulation continues to require that a facility be licensed or formally approved as a hospital by an officially designated authority for State standard-setting and meet the requirements for participation in Medicare as a hospital. Moreover, this regulation does not preclude a State from establishing identical payment rates for outpatient rehabilitation services whether furnished in an outpatient hospital setting or in a non-hospital clinic setting. Indeed, this regulation would encourage this practice because rehabilitation services that are covered under a non-hospital benefit category would be considered to be in that benefit category rather than an outpatient hospital service.

Comment: One commenter stated that 8000 or more students will be negatively impacted by the proposed rule changes. The commenter suggested that the reimbursement dollars for outpatient hospital services should be used to fund services in schools.

Response: We respectfully disagree. Under Title XIX of the Social Security Act, specific services are listed as coverable under the Medicaid program. The outpatient hospital benefit category recognizes the unique nature of services furnished by an outpatient hospital facility. Services furnished in schools or other non-hospital settings, or by non-hospital practitioners, can still be covered under other benefit categories.

Therefore, this regulation does not prohibit States from covering services provided in schools under Medicaid benefit categories. Rather, the regulation would define services that may be covered under the outpatient hospital services benefit under a Medicaid State plan to focus on those services unique to an outpatient hospital.

Further, federal Medicaid funds are not specifically allocated to outpatient hospital services, and thus a shift in coverage from one benefit category to another would not necessarily affect available funding for any particular service. In other words, this rule would not divert federal funding from schools. Federal funding is available to match State or local non-federal expenditures for covered Medicaid services in accordance with a State's federal medical assistance percentage and the reimbursement methodology described in the State's approved Medicaid plan.

Comment: A commenter requested clarification of the impact on the provision of rehabilitation services in outpatient settings. The commenter noted that this impact could affect services in State psychiatric hospitals for patients over 64 and undermine progress on the President's New Freedom Initiative.

Response: The regulation clarifies the scope of outpatient hospital facility services that are eligible for federal financial participation. To the extent that rehabilitative services are recognized under the Medicare outpatient prospective payment system or an alternate fee schedule for outpatient hospital services and are not defined in a State's Medicaid plan under another Medicaid benefit, the services may remain under the outpatient hospital benefit category. We note that the psychiatric hospitals in question are typically inpatient facilities, usually with little or no outpatient volume. These institutions provide care to Medicaid inpatients under a separate Medicaid benefit category for inpatient hospital services that would not be affected by this rule.

Comment: One commenter suggested that the regulation could result in non-coverage of certain pathology services. This commenter recommended that a special provision be included in the regulation to allow pathology services

provided by outpatient hospitals to be reimbursed under the outpatient hospital benefit category using the appropriate State plan fee schedule.

Response: The intention of the regulation is to appropriately recognize the unique nature of outpatient hospital services. Pathology services are typically delivered by physicians and in some instances are an integral part of a hospital service. To the extent that the pathology services in question are recognized under the Medicare outpatient prospective payment system or an alternate Medicare fee schedule for outpatient hospital services and are not defined in a State's Medicaid plan under another Medicaid benefit, the services may be included by the State under the outpatient hospital benefit category. To the extent that the services would be covered by the State plan under the physician services benefit, they should not be included in the Medicaid outpatient hospital services benefit.

Comment: A commenter requested that CMS include a provision in the final rule that would allow reimbursement of clinical diagnostic lab services as an outpatient hospital services as long as there is not duplicative payment for the services. The commenter noted that CMS should make clear that outpatient hospitals and free-standing clinics may continue to receive payment for these services.

Response: We did not accept this comment because we believe it is more consistent with statutory requirements for clinical diagnostic laboratory services to be claimed under the Medicaid benefit category for laboratory services. Laboratory services are a mandatory benefit category, and thus the services would remain covered even though not included as outpatient hospital services. Only when reported separately can CMS and States ensure consistency with the unique requirements applicable to laboratory services. Laboratories are subject to a different regulatory review than outpatient hospitals, under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100–578, implemented in part by regulations at 42 CFR part 493. Moreover, section 1903(i) of the Act limits Medicaid reimbursement for clinical diagnostic laboratory services to the amount of the Medicare fee schedule for the services on a per test basis. Implementation of these provisions will be improved by ensuring that laboratory services are claimed under the benefit category specifically for such services.

Comment: One commenter stated that excluding rehabilitative, school-based and practitioner services from the definition of outpatient hospital services cuts funding and the availability of services.

Response: As previously explained, federal Medicaid funds are not specifically allocated to outpatient hospital services. The Centers for Medicare and Medicaid Services matches expenditures for covered Medicaid services in accordance with a State's federal medical assistance percentage and the reimbursement methodology described in the State's Medicaid plan. The purpose of the regulation is to define the scope of outpatient hospital services unique to the outpatient hospital setting and for which a hospital may receive a facility payment, and not to limit the availability of services under other benefit categories. The above services are provided by Medicaid qualified professionals and are reimbursed on a fee-for-service basis regardless of the setting in which the services are performed.

Comment: One commenter stated that CMS's decision to eliminate reimbursement for Medicaid services covered in the State Plan is not consistent with the Medicaid statute.

Response: The regulation does not eliminate any Medicaid benefit category recognized under the Social Security Act or the settings in which those services may be rendered. By clarifying the scope of outpatient hospital facility services available for Federal financial participation, CMS intends to recognize the nature of services that are uniquely furnished by outpatient hospitals, including the high overhead facility costs associated with such services. At the same time, we do not believe it is effective and efficient to include other services that do not have those unique characteristics in the outpatient hospital services benefit category. These other services are more appropriately included in other benefit categories, and paid at rates warranted by the nature of the service regardless of the setting. Thus, we believe that this rule is consistent with the Medicaid statute and CMS's charge to preserve the fiscal integrity of the program.

Comment: One commenter stated that the definition of Medicare criteria for ''provider-based status'' is a complicated standard. The commenter suggested that some hospitals that have the authority to claim a facility fee under the preceding Medicaid rules would only receive payments for professional services under the proposed rule.

Response: The intention of the regulation is to recognize the high facility overhead expenses that are associated with the delivery of services unique to an outpatient hospital or a department of an outpatient hospital that, according to 42 CFR 413.65, ''is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider.'' The commenter is correct in that only a provider-based entity that is providing outpatient hospital services as defined under the regulation may receive Medicaid payment under the outpatient hospital benefit category.

This final regulation would not permit Medicaid payment under the outpatient hospital service benefit for services furnished in settings that are not within the scope of the certified hospital, even if the setting is owned by the hospital and provider-based. In other words, the services must be furnished by the main hospital or the department of the hospital (a provider-based entity furnishing the same type of care as the hospital). However, States may cover and pay for such a service under other appropriate State plan benefit categories.

Comment: One commenter stated that excluding physician, physical, occupational and speech therapy, clinical diagnostic laboratory services, ambulance services, durable medical equipment and outpatient audiology services from the definition of outpatient hospital services does not represent the reality of the scope of care provided in hospital settings. The commenter notes that CMS did not demonstrate that access to these services is available in the community and outside of a hospital outpatient department.

Response: We are not discouraging hospitals from providing primary and preventive care services in hospital settings. The proposed rule makes a distinction between outpatient services that are billed by a recognized hospital facility in which services are furnished and those billed by physicians and other professionals. Under Medicaid, States generally pay a fee schedule rate for physician and other professional services and a separate rate to hospitals providing outpatient services. Physicians and other professionals cited in the example, who provide services in a hospital facility, will be reimbursed at the professional rate.

Comment: One commenter noted that overlap in Medicaid service categories is a long-standing Medicaid policy and cited a CMS response to comments on

a nurse-midwife regulation: ''While we view each category of service as separate and distinct, the categories are not mutually exclusive. Some services * * * can be classified in more than one category. It is also possible that a service provided may meet the requirements under one category and not another even though, as a general rule, the service could be classified under either category. The specific circumstances under which a service is provided and how the provider bills for the service determines how the service is categorized and which regulatory requirements apply.''

Response: Through this regulation, we are seeking to clearly distinguish between services unique to an outpatient hospital facility and services of practitioners to permit targeting of coverage and payment. The regulation would assist in avoiding duplicative or excessive payments that could result from the overlap of the outpatient hospital service definition and a professional service definition.

Comment: A commenter stated that by ''limiting the locations where services may be provided and requiring separation of professional and other charges, the proposed regulation will result in the reduction of the quality of care provided to consumers,'' particularly any aspects of care for behavioral health clients who require services in settings outside the walls of the clinic and require professional and non-professional efforts which address aspects of behavioral health problems that are not directly treatment of the client. Further, the commenter noted that providing the services outside of the clinic historically allowed for a high quality of care.

Response: As previously stated, the intention of the regulation is not to limit or prescribe the location where a Medicaid service may be rendered. Any qualified Medicaid provider may render a Medicaid covered service in a non-institutional setting, including a hospital. The regulation does not impact the definition of a clinic service (42 CFR 440.90). A behavioral health client who is Medicaid eligible may receive a service, from a qualified Medicaid provider, defined under the State plan within a clinic or in the community. We do not understand the comment that professional and non-professional efforts may be required to provide Medicaid services to an individual because only a Medicaid qualified provider may render and receive payment for a non-institutional professional service.

Comment: A commenter noted that the proposed rule change does not define the terms ''traditional,'' ''non-traditional,'' ''facility services,'' or ''non-facility services.''

Response: In issuing this regulation, we have looked to the plain language of the statutory Medicaid benefit categories to distinguish between services uniquely furnished by an outpatient hospital facility and those furnished by individual practitioners or other providers. We note that both outpatient hospitals and clinics are eligible for facility payments, but they are included in the statute as separate benefit categories. When we used the terms ''traditional'' and ''non-traditional'' in the preamble, we meant to distinguish between those services generally recognized as outpatient hospital services.

As discussed in the proposed rule, we did not consider services to be appropriately included in the outpatient hospital services category solely for purposes of including those services in the outpatient hospital upper payment limit.

Comment: One commenter referenced CMS's comments in the 1983 revised definition of outpatient hospital services ''States would still be required to cover the other mandatory services (such as physician services) and some optional services when they are provided in the outpatient hospital setting * * *'' The commenter argued that CMS is not concerned with an overlap in service definitions. Instead, the commenter contended, CMS's concern is with reimbursing hospitals higher rates for Medicaid services, such as physician services. The commenter maintained that the regulation represents new policy and not a simple clarification of the outpatient hospital service definition.

Further, the commenter stated that CMS's contention that the overlap in service definitions may not have been the intent of the Congress and that the Medicaid statute was enacted over forty years ago, yet CMS never took issue with varied payment rates in service setting or required consistent service definitions between Medicare and Medicaid.

Response: As previously discussed we are not restricting the settings in which Medicaid covered services may be provided to covered individuals by qualified Medicaid providers. The purpose of the regulation is to define the scope of outpatient hospital services unique to the outpatient hospital setting and for which a hospital may receive a facility payment, and not to limit the availability of outpatient services under other benefit categories. The rule does not prohibit the provision of any covered Medicaid physician service in an outpatient setting.

The commenter is correct that CMS has not previously restricted State flexibility to include services under the outpatient hospital benefit, even when the sole purpose was to affect the outpatient hospital upper payment limit. This rule represents a new initiative to preserve the fiscal integrity of the Medicaid program.

We do not intend through this regulation to deny coverage of any Medicaid covered service to an individual eligible for Medicaid or deny payment to a qualified Medicaid provider. The provisions of this regulation help to ensure that coverage and payment under State plans will be consistent with economy, efficiency and quality of care.

Comment: A commenter cited services that are excluded from Medicare coverage that may be covered by a state under its Medicaid program: Dental services, vision care, foot care and immunizations. The commenter noted that these services are not paid by Medicare under the Outpatient Prospective Payment System (OPPS) or under an alternative payment methodology, and therefore would have to be excluded from hospital outpatient services for Medicaid purposes.

Response: As previously discussed, the services included in the comment are covered under a distinct Medicaid benefit category and would have specific provider qualifications, coverage provisions and payment policies. The services may continue to be provided to a Medicaid beneficiary in any non-institutional setting, including outpatient hospitals, by a qualified Medicaid provider. In addition, CMS allows States discretion in setting payment rates that meet the requirements of section 1902(a)(30)(A) of the Act and regulations at 42 CFR 430.10 and 447.204.

Comment: One commenter stated that Medicare does not recognize dental services under OPPS or an alternative payment methodology, whereas the service is a covered benefit under the Medicaid program. To be consistent with the Medicare program, the commenter suggested that CMS remove the statement that outpatient hospital services may be furnished ''by or under the direction of a dentist'' from the regulatory language.

Response: Medicare does recognize a number of dental procedures provided in hospital settings. In addition, the regulation does not prohibit the provision of a covered Medicaid dental procedure in an outpatient hospital. However, the regulation will require

that the payments for dental services be reimbursed under the Medicaid dental benefit category, which is distinct from the outpatient hospital benefit category. Again, States have discretion in setting payment rates for dental services within the authority of section 1902(a)(30)(A) of the Act and regulations at 42 CFR 430.10 and 447.204.

Comment: A commenter explained that the regulation may be at odds with State flexibility in establishing payment methodologies and rates, noting that one of CMS' rationales is to prevent States from paying higher rates in hospitals for the same services paid at lesser rates in other facilities. The commenter noted that CMS did not provide a basis that the services provided in the hospital setting are the same as services provided in other settings or a basis for paying the same amount regardless of the setting. The commenter stated that it is appropriate to pay hospitals higher amounts for services provided in hospital settings because of the higher costs associated with the hospital. Further, the commenter suggested that CMS is attempting to re-define the coverage rules for outpatient hospital services in order to place limitations on the payment for those services.

Response: We distinguish in this regulation between coverage of services that are uniquely furnished by an outpatient hospital and coverage of services furnished by practitioners or other providers. We do not understand the comment that services rendered by professionals, or qualified Medicaid practitioners, would be different in outpatient hospital settings than those provided by the same professional in a private practice or other community setting. But, if so, a State has flexibility to vary the payment rate for practitioner or other provider services furnished in an outpatient hospital setting.

As previously discussed, one impetus for this regulation was that the ambiguous coverage definition in the Medicaid regulations for outpatient hospital services allowed States to artificially increase the outpatient hospital upper payment limit and direct supplemental payments to a select group of hospitals. Therefore, to prevent this artificial inflation of the upper payment limit we must clarify the covered facility services that may be defined as part of the outpatient hospital benefit category and, thus, may be included in the applicable UPL calculation.

Comment: Several commenters noted that some hospitals treat the hospital facility payment as an all-inclusive rate and pay physicians furnishing services to hospital outpatients. These commenters stated that the Medicare program recognizes this unique reimbursement methodology and waives requirements under OPPS for certain facilities.

Response: We considered whether it would be warranted to permit an exception for those facilities with a waiver of Medicare OPPS requirements. Since the purpose of this regulation is to align the definition of Medicaid outpatient hospital facility services with Medicare's definition, we interpret the phrases ''would be included, in the setting delivered'' and ''paid by Medicare as an outpatient hospital services under an alternate payment methodology'' at 42 CFR 440.20(a)(4) of this rule to recognize those hospitals that receive the exception to the OPPS requirements under the Medicaid definition. Therefore, States may define the outpatient benefit to include an exception for these hospitals, limited to the all-inclusive services that are recognized by Medicare. However, the State must furnish to CMS documentation that a hospital provider has received the Medicare exception and include a reasonable estimate of Medicare payment for the providers in the upper payment limit demonstration by using alternate data sources recognized by Medicare specifically for those providers.

Comment: Several commenters were concerned that moving reimbursable services out of outpatient hospital settings would reduce access to services. One commenter noted that Medicaid practitioner fees are inadequate and do not promote access of primary care outside of hospital-based physician practices. The commenter noted that most primary care physician practices within her state have converted to provider-based entities in order to receive higher payment rates.

Response: States have considerable flexibility under federal law to establish payment rates for Medicaid services that are sufficient to ensure access to services while meeting the requirements of section 1902(a)(30)(A) of the Act and regulations at 42 CFR 430.10 and 447.204. CMS does not have the authority to require States to increase payment rates for Medicaid services. The outpatient hospital benefit provides for coverage of those services unique to outpatient hospitals and payments can take into account the overhead costs in hospital settings. To the extent that providers are ''converting'' to provider-based entities with the sole intention of receiving increased reimbursement, we do not view this as an appropriate means of receiving higher reimbursement under the Medicaid program.

Comment: Several commenters stated that CMS' concerns with duplicative payments were baseless because State claims processing systems screen for duplicative payments.

Response: The potential for duplicative payments is merely one reason for implementing this regulation. In addition, we are attempting to align the Medicaid definition of outpatient hospital services with the applicable UPL, provide transparency to the services covered under the benefit, and clarify the appropriate services under the benefit that may be claimed for federal financial participation.

Comment: One commenter stated that CMS did not present an adequate justification for the regulation and that State Plan Amendment reviews allow CMS to address the requirements authorized under the proposed rule.

Response: As discussed in the proposed regulation, the ambiguous definition of outpatient hospital services does not clearly prevent including in the benefit non-hospital facility services that would not be included in the benefit under the Medicare program. Therefore, we disagree that the provisions of the regulation may be carried out through State plan review.

Comment: One commenter stated that the intent of the Congress was to separate the Medicaid and Medicare program and not ''equate'' Medicaid services to Medicare.

Response: One purpose of this amendment is to align the Medicaid definition more closely to the Medicare definition in order to improve the functionality of the applicable upper payment limits under 42 CFR 447.321 (which are based on a comparison to Medicare payments for the same services), provide more transparency in determining available coverage in any State, and generally clarify the scope of services. While we understand the difference between the populations served under the Medicare and Medicaid programs, we believe that the services recognized under the Medicare OPPS and the alternate fee schedules for outpatient hospital services encompass outpatient hospital facility services that are typically provided to the general public.

Comment: Several commenters stated that the regulation is inconsistent and confusing because allowable services under the Medicaid State plan overlap with some of the services paid for under the Medicare OPPS. For instance, one commenter noted that OPPS pays for prosthetic devices, prosthetics, supplies, and orthotic devices, durable medical

equipment, and clinical diagnostic laboratory services and prosthetic devices and durable medical equipment are ''separate'' Medicaid State plan service categories.

In addition, the commenter remarked that OPPS coverage definition for prosthetics and DME are more restrictive than what is allowable under the Medicaid State plan. Several commenters requested that CMS specify whether as service covered under the Medicaid regulations as a separate State plan category of services is considered an outpatient hospital service when furnished in an outpatient hospital facility and included in OPPS. One commenter requested that CMS justify treating a service recognized under Medicare as a hospital service differently under the Medicaid program.

Response: As we indicated in the proposed rule, services provided under a distinct Medicaid benefit category will operate under the coverage and reimbursement provisions for those services under the Medicaid State plan. If a service is described under a separate benefit category in the State plan that service may still be provided in an outpatient hospital setting. Coverage and payment for that service will be governed by the relevant provisions in the State plan for the service, and any applicable federal restrictions. For example, clinical diagnostic laboratory services are subject to a statutory limit regardless of setting, described at section 1903(i) of the Act, up to the amount that Medicare pays on a per test basis. Further, outpatient DME under Medicaid is paid under the home health benefit, as medical equipment. There is a separate benefit category that includes prosthetic devices.

Comment: One commenter stated that 42 CFR 419.2(b) does not contain an all-inclusive list of costs allowable within OPPS.

Response: In this rule, we allow coverage of all of the outpatient hospital services recognized under the Medicare OPPS or an alternate fee schedule paid for outpatient services provided in hospitals that are not included in another benefit category under the State plan. The referenced regulations are the authority under the Medicare program for OPPS and the alternate fee schedule for outpatient services. Services or costs that are allowable under that authority, whether specifically listed or not, would be allowable if not otherwise covered.

Comment: One commenter questioned the impact of the regulation on EPSDT services or services that are difficult for Medicaid recipients to access (such as dental services). Specifically, the commenter requested that CMS clarify if any upper payment limits apply to these services and suggested that the payment rates in hospitals should not be limited to community rates because the community rates do not recognize outpatient overhead expenses. The commenter explained that limiting the outpatient hospital scope of services ''to reduce payments to hospitals'' undermines the Congressional intent and creates access issues.

Response: CMS is not discouraging hospitals from providing certain services in the hospital setting; this regulation addresses only the benefit category under which such services should be claimed. EPSDT and dental services are distinct Medicaid benefit categories and the coverage and payment provisions for those services are described separately from outpatient hospital services in the Medicaid State plan.

As previously discussed, States have discretion in defining the payment methodology for non-institutional services within the authority of section 1902(a)(30)(A) of the Act and regulations at 42 CFR 430.10 and 447.204. As of the publication of this regulation, there are no upper payment limits for services provided to Medicaid outpatients other than in clinics and outpatient hospital settings. Again, the purpose of the regulation is not to reduce payments, but to clarify those services that are uniquely provided in outpatient hospital settings.

Comment: A commenter requested that CMS explain the rationale behind eliminating a State's ability to pay hospitals' bundled rates. The commenter argued that since OPPS is a bundled methodology designed to promote efficiency and discourage over-utilization, States should have the ability to continue to bundle hospital services in an effort to promote efficiencies beyond those provided for under OPPS.

Response: The regulation does not define how States may structure base Medicaid payments for outpatient hospital services, but removes from that bundle services that are not unique to the outpatient hospital. States continue to have the ability to ''bundle'' all covered outpatient hospital services and make payments within the applicable upper payment limit for those services. To the extent that the commenter is referring to ''bundling'' facility and professional services, we do not view such bundles as efficient or economical and note that the majority of private payers make distinct payments for facility and professional costs.

Comment: One commenter requested clarification as to the impact on clinic services based on the inclusion of clinics under title of the proposed regulation.

Response: In response to this comment, we determined that it was confusing to add the word ''clinic'' without the entire phrase ''outpatient hospital clinic.'' The intent was to clarify that outpatient hospital services include outpatient services provided either in a hospital facility itself or in a clinic that meets the standards for provider-based status as a department of the hospital. We have thus revised the title of the final regulation to clarify that the service clarifications in the final rule apply only to outpatient hospital services.

Comment: One commenter noted that the proposed definition of outpatient hospital services will remove services from State DSH calculations and further cut hospital Medicaid reimbursement.

Response: One of the purposes of the regulation is to clarify the services that are available for federal financial participation under the outpatient hospital benefit category. We believe the services included in the proposed rule described those services that are unique to outpatient hospital settings. To the extent that States are currently defining additional services as outpatient hospital services in order to include their costs in calculating the hospital-specific limit under the disproportionate share hospital (DSH) program, those services would no longer be allowable in the DSH calculation under the final rule. On the other hand, payment for those services would not be subject to outpatient hospital upper payment limits.

Comment: One commenter urged CMS to specify that outpatient hospital services must be provided in provider-based settings.

Response: As § 440.20(4)(ii) explains, outpatient hospital clinic and hospital facility services ''are furnished by an outpatient hospital facility, including an entity that meets the standards for provider-based status as a department of an outpatient hospital as set forth in § 413.65 of this chapter.'' As mentioned previously, the outpatient hospital services benefit includes only services of hospitals and departments of hospitals, not services provided in other settings, even if hospital-owned and provider-based. All other Medicaid covered services provided in a hospital-owned setting must be covered and paid for under a distinct Medicaid State plan benefit category and reimbursement methodology.

Comment: One commenter requested additional clarification on the scope of services paid under alternate Medicare

payment methodologies as outpatient hospital services that would be included under this proposed definition.

Response: The final rule allows for coverage of any service that may be claimed as an outpatient hospital institutional service under the Medicare program with the exception of those services that are covered under another Medicaid benefit category in the State plan. Please refer to Medicare rules and guidance for further information on the scope of the Medicare outpatient hospital benefit.

Comment: One commenter requested that CMS ''confirm that costs for services not explicitly excluded from the OPPS are therefore includable (assuming that these services meet the other proposed criteria).''

Response: Only those services that are included in OPPS or an alternate Medicare fee schedule may be included as part of the Medicaid outpatient hospital benefit category.

Comment: One commenter stated that Title 42, § 410.20(b) of the CFR also excludes certain categories of hospitals from the Medicare OPPS. The commenter requested that CMS clarify that services included under this provision may be defined as Medicaid outpatient hospital services.

Response: The commenter was apparently referring to 42 CFR 419.20, since 42 CFR 410.20 refers to coverage of physician services. This rule does not require that States apply the OPPS payment system, but only that the definition of outpatient hospital services be consistent with the scope of services included under OPPS. In other words, whether a hospital is excluded from OPPS or not, the scope of outpatient hospital services would be uniform for both Medicare and Medicaid.

Comment: Many commenters stated that the rule would eliminate rural health clinics (RHCs) as eligible providers for DSH payments, even though their RHCs are largely an extension of a hospital, wherein the hospital: ''employs the RHC's personnel, pays its bills, performs quality assurance, credentials the physicians and physician assistants employed by the RHC, and provides medical supplies to the RHC.'' These commenters stated that eliminating RHCs from State DSH calculations would ''impede care'' in rural areas and create ''financial incentives to use scarce and expensive emergency department services'' rather than less costly RHC facilities. Many of these commenters referred to a Fifth Circuit Court of Appeals decision which allowed for the inclusion of services rendered in RHCs to be part of the outpatient hospital DSH calculation. Several commenters opined that CMS does not have the authority to overturn the decision.

Response: The Fifth Circuit Court of Appeals decision was based in large part on an interpretation that, under then-current regulations, services rendered in hospital-based RHCs meet the definition of outpatient hospital services (and may be included in a hospital's DSH calculation even though paid as RHC services). The decision relied on the ambiguity in those regulations permitting an overlap between services that meet the definition of outpatient hospital services and also meet the definition of a service under another benefit category. Under this final rule, there would be no such overlap, and the services at issue in the Fifth Circuit case would have to be treated consistently for all purposes. This means: that unless the services provided in the RHCs meet the new definition of Medicaid outpatient hospital services, because the RHCs are provider-based outpatient departments of a hospital in accordance with 42 CFR 413.65, and the Medicaid agency recognizes the RHCs consistently as Medicaid outpatient hospital service providers, the services provided in rural health clinics could no longer be recognized as outpatient hospital services.

This makes sense because the payment systems for hospitals and for RHCs are completely different. Hospital payments are not required to reflect actual costs, but must include an adjustment to take into account the situation of hospitals that serve a disproportionate share of low income patients. In contrast, RHCs are paid through a prospective payment system based on actual costs that should reflect essentially the full cost of Medicaid services. There is no need for adjustments to reflect higher costs for RHCs, because the payment level is on a full cost basis.

Comment: Many commenters opposed the proposed rule because the upper payment limit references to the Medicare cost report (CMS 2552) do not recognize graduate medical education (GME) costs. Several of these commenters remarked that restricting GME payments violates the 1-year congressional moratorium, passed as part of the U.S. Troop Readiness, Veterans Care, Katrina Recovery, and Iraq Appropriations Act of 2007, stating that the regulation presents ''restrictions on Medicaid graduate medical education (GME) payments.'' One commenter noted that GME costs ''are included on hospital cost reports and Medicare pays them,'' while another commenter stated that GME costs are located on the Medicare cost report at Worksheet B, Part 1, Column 25. Several commenters stated that the exclusion of GME from the cost report references used to calculate outpatient upper payment limits will have a tremendous financial impact on teaching hospitals.

Response: This regulation does not prohibit States from covering or paying for GME and thus does not address the issues set forth in the proposed rule that was subject to a congressional moratorium. In addition, the provisions of the proposed regulation at 42 CFR 447.321(b)(1)(i)(B) have not been included in this final regulation.

However, regardless of whether a Medicaid program determines to make a GME payments or adjustments for outpatient hospital services, the Medicare program does not make GME payments for outpatient hospital services. As we explained in the proposed rule, the aggregate UPL based on Medicare is reasonable only when there is a consistent definition of outpatient hospital services between Medicare and Medicaid.

Comment: One commenter requested additional information regarding the overlap between the proposed changes to 42 CFR 440.20(d) and diagnostic services under the proposed rehabilitative services regulation under 42 CFR 440.130(d) particularly, how States should reconcile the provisions.

Response: We have reviewed the changes proposed to 42 CFR 440.130(d) and do not see a conflict with the regulatory changes implemented in this final regulation. Rehabilitative services fall under a distinct Medicaid benefit category and are defined and paid under the Medicaid State plan provisions for rehabilitative services.

III. Provisions of the Final Regulations

As a result of our review of the comments we received during the public comment period, we are making revisions to the proposed regulation published on September 28, 2007. The title of the proposed regulation is revised to make it clear that the definition of outpatient hospital services also applies to services provided in outpatient hospital clinics. The title will now read: ''Outpatient hospital facility (including outpatient hospital clinic) services.'' In addition, we have modified the phrase ''a department of an outpatient hospital'' at § 440.20(a)(4)(ii) to read ''a department of a provider'' as this exact terminology is used in the referenced Medicaid provider-based definition at 42 CFR 413.65. We are also reserving action on the proposed changes to 42 CFR 447.321, the

outpatient hospital and clinic upper payment limits. We may address these provisions at a future date. All other provisions are adopted as proposed.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended, the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–04), and Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year). This is not a significant or economically significant rule because the size of the anticipated reduction in Federal financial participation is not estimated to have an economically significant effect of more than $100 million in each of the Federal fiscal years 2008 through 2012.

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that small entities include small businesses, non-profit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by being non-profit organizations or by meeting the SBA definition of a small business of having revenues of less than $7.0 million to $34.5 million in any 1 year. The Secretary has determined that this final rule would not have a direct impact on providers of outpatient hospital services that furnish services pursuant to section 1905(a)(2)(A) of the Act. This rule will directly affect States and we do not know nor can we predict the manner in which States will adjust or respond to the provisions of this rule.

CMS is unable to determine the percentage of providers of outpatient hospital services that are considered small businesses according to the Small Business Administration's size standards with total revenues of $7.0 million to $34.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we defined a small rural hospital as a hospital that is located outside of a Core Based Statistical Area for Medicaid payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined and the Secretary has determined that this final rule will not have a direct significant economic impact on small rural hospitals. The rule would directly affect States and we do not know nor can we predict the manner in which States would adjust or respond to the provisions of this rule.

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2008, that threshold level is approximately $130 million. Since this rule will not mandate spending in any 1 year of $130 million or more, the requirements of the UMRA are not applicable.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs of State and local governments, preempts State law, or otherwise has Federalism implications. Since this rule would not impose any costs on State or local governments, preempt State law, or otherwise have Federalism implications, the requirements of E.O. 13132 are not applicable.

B. Anticipated Effects

On March 3, 2008, the Committee on Oversight and Government Reform published a report titled: ''The Administration's Medicaid Regulations: Summaries of State Responses.[1]'' The report provided a state-by-state analysis of the anticipated monetary effects of several proposed Medicaid regulations, including CMS 2213–P. In addition, the report quoted specific concerns from Medicaid Directors in relation to the proposed rules.

Of the States that participated in the analysis, twenty-two reported no potential loss in FFP, four reported a specific monetary loss, and eighteen reported there may be a potential loss of FFP but were unable to estimate a monetary amount as a result of CMS 2213–P. One year after implementation of CMS 2213–P, California estimated a potential $266 million loss; while Illinois projected a loss of $700 million after one year. In addition, Missouri estimated losses of approximately $6 million and Louisiana calculated a $3 million impact after one year.

Based upon our review of the Medicaid Directors' concerns and the public comments received in response to the proposed rule, we believe that the potential for monetary loss is overstated in the analysis due to misunderstandings of the goal and scope of the proposed rule. Though many of these misunderstandings are clarified in our responses to the public's comments, we will attempt to address the primary concerns detailed in the Committee's report.

The purpose of this final regulation is to improve the functionality of the applicable upper payment limits under 42 CFR 447.321 (which are based on a comparison to Medicare payments for the same services), provide more transparency in determining available hospital coverage in any State, and generally clarify the scope of services for which Federal financial participation (FFP) is available under the outpatient hospital services benefit category.

As discussed in detail in the response to public comment, the rule will not eliminate any covered Medicaid services under Title XIX, restrict the provision of a Medicaid service by a qualified Medicaid provider to a Medicaid outpatient, or dictate the methodologies through which States may reimburse providers for services in accordance with applicable federal statute and regulations. In our review of State plan amendments for outpatient hospital services, CMS noted only one State that would be in violation of the

proposed rule at the time of publication. Since the publication of the proposed rule, the State has taken measures to remove from the State plan those services that would no longer be covered as part of the outpatient hospital benefit.

In response to this concern, we emphasize that States continue to have the authority to pay for any Medicaid service that is rendered in a non-institutional setting by a qualified Medicaid provider and establish economic and efficient payment rates for those services that attract sufficient willing and qualified providers. Removing these services from the outpatient hospital benefit category does not equate to non-coverage or non-payment of the services in outpatient hospitals or other non-institutional settings. Therefore, we do not believe there will be a monetary impact as States will continue to have the ability to receive Federal matching funds for covered Medicaid services paid under the appropriate benefit category. However, to the extent a State would not choose to adjust payment methods appropriately, there could be a financial impact on the State. But, this is at the discretion of the State and CMS can not quantify this possibility.

Instead, the regulation calls for States to define Medicaid services under the appropriate coverage and payment provisions of the State plan. Currently, services provided in non-institutional settings, with the exception of outpatient hospitals and clinics, do not have specific upper payment limits defined in regulation. States are free to set economic and efficient State plan payment rates in consideration of the Medicaid costs of providing services within the various settings where outpatients receive care. In some instances, this could result in increased Medicaid payments for some of these services. Therefore, we do not anticipate that the regulation defining what is covered as an outpatient hospital facility service will result in significant reductions in FFP for Medicaid service providers or place significant administrative burdens upon States.

We specifically requested comments on the regulatory impact analysis and the comments and responses are summarized below. Several providers and States noted a loss of specified or unspecified dollar amounts that would result from the change in the coverage definition. However, the public comments did not provide for any concrete evidence that would support such a significant reduction in FFP. Therefore, we are unable to determine if those reported monetary losses are based upon misunderstandings of the regulation's scope and intent or whether States' action in response to the regulation, within allowable Medicaid authority, will offset the potential losses.

The second major concern voiced through the public's comments and the Committee's report addressed the potential FFP and administrative impact of the upper payment limit requirements. Particularly, the Illinois Medicaid Director responded to the Committee's report by stating that CMS 2213–P ''will constrain the ability of states like Illinois to use the room in the UPL to supplement their relatively low federal DSH allotments.'' Several public commenters and Medicaid Directors also indicated that the UPL requirements would place new administrative burdens upon State Medicaid agencies. We are puzzled by the comments because the proposed rule did not deviate from the current regulatory definition of the Medicaid outpatient hospital upper payment limit, a reasonable estimate of Medicare payment for equivalent services, or CMS's historic expectations of a reasonable upper payment limit for the services. However, these types of concerns should be alleviated because the clarifying provisions to the UPL regulation have been removed from this final rule.

Finally, based on the public comments, many felt that we failed to fully discuss the potential impact of the regulation on State disproportionate share hospital calculations for outpatient hospital services. We believe that Louisiana's Medicaid Director raised this issue in the Committee report by stating: ''Implementation of the proposed rule may cause a loss of essential medical services in underserved rural areas.'' As noted in the response to public comments, a rural health clinic or other Medicaid provider that does not meet the definition of a department of a hospital or outpatient hospital and/or is paid under a State plan reimbursement methodology other than that defined for outpatient hospital services may not be considered in a State's Medicaid DSH calculation for outpatient hospital services.

Louisiana is currently including rural health clinics in the Medicaid DSH calculation. Because the scope of services provided within these clinics and what, if any, relationship exists between the clinics and a main hospital provider are not transparent in the State plan, CMS is unable to determine if the clinics are departments of an outpatient hospital and could continue to be included in the State's DSH calculation. Therefore, we do not dispute the amount reported to the Committee by Louisiana. Likewise, for any other State that is including the uncompensated costs of services that would no longer be considered outpatient hospital services there would be a potential reduction in uncompensated costs that could be recognized through Medicaid DSH payments. However, we believe that most States could find other allowable uncompensated inpatient and outpatient hospital costs that could be recognized for Medicaid DSH purposes and that, at least in part, offset potential losses that result from this regulation.

Public Comments

Within the proposed regulation's regulatory impact analysis, we noted that data was unavailable to calculate the exact impact of the regulation because of the lack of transparency with State outpatient hospital coverage provisions and the resulting payments for services. However, we stated that we did not believe that the regulation would have a significant impact because we believed that a majority of States were in compliance with the provisions of the proposed rule. We specifically requested public comments concerning the regulatory impact analysis and have revised the analysis as part of this final rule.

Comment: Several commenters opposed the rule because of CMS's inability to conduct a regulatory impact analysis. One commenter argued that ''before a regulation of this magnitude is implemented, the impact should be specified and addressed.'' Some commenters also stated that, absent an impact analysis, the rule was bad public policy and should be withdrawn. Several commenters argued that the impact analysis was in violation of Executive Order 12886 and the Congressional Review Act.

Response: CMS specifically requested that the public provide comments on the regulatory impact analysis and data to help develop the analysis. We have revised the statement accordingly.

Comment: A number of commenters stated that since CMS has identified only one State that would violate the proposed rule, the administrative burden and restrictions in defining the Medicaid outpatient hospital benefit placed upon States is unjustified.

Response: We believe that the vast majority of States are in compliance with the regulation. Therefore, we do not agree that the regulation would cause a significant administrative burden. As detailed in the proposed regulation, we are implementing the

regulation to ensure consistency between the Medicaid outpatient hospital service definition and the applicable UPL requirements, provide more transparency in determining available hospital coverage in any State, and generally clarify the scope of services for which Federal financial participation (FFP) is available under the outpatient hospital services benefit category. As stated previously, we are not including any changes to the UPL provisions in this final rule, which should alleviate concern over administrative burden at this time. If we address these provisions in the future, we will respond to comments on the associated administrative burden at that time.

Comment: One commenter noted that the RIA should include the potential impact on units of government and disproportionate share hospital payments.

Response: Again, we believe that the majority of States are in compliance with the clarification of the definition of Medicaid outpatient hospital services. The revised RIA includes a discussion of DSH payments.

List of Subjects in 42 CFR Part 440

Grant programs—health, Medicaid.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 440—SERVICES GENERAL PROVISIONS

■ 1. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 2. Section 440.20 is amended by revising the section heading and paragraph (a) to read as follows:

§ 440.20 Outpatient hospital facility (including outpatient hospital clinic) services and rural health clinic services.

(a) Outpatient hospital services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that—

(1) Are furnished to outpatients;

(2) Are furnished by or under the direction of a physician or dentist;

(3) Are furnished in a facility that—

(i) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting; and

(ii) Meets the requirements for participation in Medicare as a hospital;

(4) Are limited to the scope of facility services that—

(i) Would be included, in the setting delivered, in the Medicare outpatient prospective payment system (OPPS) as defined under § 419.2(b) of this chapter or are paid by Medicare as an outpatient hospital service under an alternate payment methodology;

(ii) Are furnished by an outpatient hospital facility, including an entity that meets the standards for provider-based status as a department of a provider set forth in § 413.65 of this chapter;

(iii) Are not covered under the scope of another Medical Assistance service category under the State Plan; and

(5) May be limited by a Medicaid agency in the following manner: A Medicaid agency may exclude from the definition of ''outpatient hospital services'' those types of items and services that are not generally furnished by most hospitals in the State.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: July 18, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: August 20, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8–26554 Filed 11–6–08; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 08–2330; MB Docket No. 08–98; RM–11435]

Television Broadcasting Services; Honolulu and Waimanalo, Hawaii

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission grants a petition for rulemaking filed by Pacifica Broadcasting Company, permittee of KALO–DT, and Oceania Christian Church, permittee of KUPU–DT, to substitute DTV channel *38 for post-transition DTV channel *10 at Honolulu, Hawaii and DTV channel 15 for post-transition DTV channel 38 at Waimanalo, Hawaii.

DATES: This rule is effective December 8, 2008.

FOR FURTHER INFORMATION CONTACT: Shaun A. Maher, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MB Docket No. 08–98, adopted October 21, 2008, and released October 22, 2008. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street, SW., Washington, DC 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–478–3160 or via e-mail *http://www.BCPIWEB.com*. To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

The Commission will send a copy of this Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television, Television broadcasting.

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.622 [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Hawaii, is amended by adding DTV channel *38 and removing DTV channel *10 at Honolulu and by adding DTV channel 15 and removing DTV channel 38 at Waimanalo.

Federal Communications Commission.

Clay C. Pendarvis,

Associate Chief, Video Division, Media Bureau.

[FR Doc. E8–26508 Filed 11–6–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 08–2329; MB Docket No. 08–121; RM–11449]

Television Broadcasting Services; La Grande, OR

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission grants a petition for rulemaking filed by Fisher Radio Regional Group, Inc., permittee of station KUNP–DT, to substitute DTV channel 16 for post-transition DTV channel 29 at La Grande, Oregon.

DATES: This rule is effective December 8, 2008.

FOR FURTHER INFORMATION CONTACT: Shaun A. Maher, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 08–121, adopted October 21, 2008, and released October 22, 2008. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street, SW., Washington, DC, 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/).* (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–478–3160 or via e-mail *http://www.BCPIWEB.com.* To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television, Television broadcasting.

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.622 [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Oregon, is amended by adding DTV channel 16 and removing DTV channel 29 at La Grande.

Federal Communications Commission.

Clay C. Pendarvis,

Associate Chief, Video Division, Media Bureau.

[FR Doc. E8–26510 Filed 11–6–08; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 73, No. 217
Friday, November 7, 2008

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 305 and 319

[Docket No. APHIS–2007–0161]

RIN 0579–AC89

Importation of Longan From Taiwan

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to allow the importation of commercial shipments of fresh longan with stems from Taiwan into the United States. As a condition of entry, the longan would be subject to cold treatment and special port-of-arrival inspection procedures for certain quarantine pests. In addition, the fruit would have to be accompanied by a phytosanitary certificate stating that the fruit was inspected and found to be free of certain pests, and the individual cartons or boxes in which the longan are shipped would have to be stamped or printed with a statement prohibiting their importation into or distribution in the State of Florida. This action would allow for the importation of commercial shipments of fresh longan with stems from Taiwan into the United States while continuing to provide protection against the introduction of quarantine pests into the United States.

DATES: We will consider all comments that we receive on or before January 6, 2009.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0161* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2007–0161, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2007–0161.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. Alex Belano, Assistant Branch Chief, Commodity Import Analysis and Operations, PPQ, APHIS, 4700 River Road, Unit 140, Riverdale, MD 20737–1231; (301) 734–8758.

SUPPLEMENTARY INFORMATION:

Background

The regulations in ''Subpart—Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–47, referred to below as the regulations) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests that are new to or not widely distributed within the United States.

The Animal and Plant Health Inspection Service (APHIS) has received a request from the Government of Taiwan to allow the importation of fresh longan, *Dimocarpus longan*, with stems from Taiwan into the United States. As part of our evaluation of Taiwan's request, we prepared a pest risk assessment (PRA) and a risk management document (RMD). Copies of the PRA and the RMD may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT** and may be viewed on the Internet on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for a link to Regulations.gov and information on the location and hours of the reading room).

The PRA, titled ''Evidence-Based, Pathway-Initiated Risk Assessment of the Importation of Fresh Longan, *Dimocarpus longan* Lour., from Taiwan into the United States'' (November 2007), evaluates the risks associated with the importation of longan from Taiwan. As noted in that document, we identified 26 pests of quarantine significance present in Taiwan that could be introduced into the United States via longan. Of these 26 pests, the PRA identified 5 as having high unmitigated pest risk potential: The melon fruit fly (*Bactrocera cucurbitae*), the oriental fruit fly (*B. dorsalis*), the yellow peach moth (*Conogethes punctiferalis*), the macadamia nut borer (*Cryptophlebia ombrodelta*), and the cashew leaf thrips (*Rhipiphorothrips cruentatus*). The remaining 21 pests, which were identified as having medium unmitigated pest risk potential, were the litchi rust mite (*Aceria litchii*), the summer fruit tortrix moth (Adoxophyes orana), the litchi fruit borer (*Conopomorpha sinensis*), larvae of the dull cornelian butterfly (*Deudorix epijarbas*), 4 mealybugs (*Maconellicoccus hirsutus, Nipaecoccus viridis, Planococcus lilacinus,* and *P. minor*), and 13 scale insects (*Aulacaspis tubercularis, Ceroplastes rubens, Coccus discrepans, C. formicarii, C. viridis, Drepanococcus chiton, Fiorinia pinicola, Icerya seychellarum, Kerria lacca, K. greeni, Pseudaonidia trilobitiformis, Pulvinaria taiwana,* and *Thysanofiorinia nephelii*).

The risk management document considered the protections that would be afforded by compliance with the regulations, determined that they were appropriate to address the risks presented by some of the pests of concern, and suggested some additional mitigations to address the remaining identified risks. Based on those suggestions in the risk management document, we propose the following measures be applied to longan imported from Taiwan into the United States.

Commercial Consignments

Only commercial consignments of longan would be allowed to be imported from Taiwan. This condition would reduce the likelihood that longan will introduce injurious plant pests into the continental United States. Produce grown commercially is less likely to be infested with plant pests than noncommercial consignments. Noncommercial consignments are more prone to infestations because the

commodity is often ripe to overripe, could be of a variety with unknown susceptibility to pests, and is often grown with little or no pest control. Commercial consignments, as defined in § 319.56–2, are consignments that an inspector identifies as having been imported for sale and distribution. Such identification is based on a variety of indicators, including, but not limited to: Quantity of produce, type of packaging, identification of grower or packinghouse on the packaging, and documents consigning the fruits or vegetables to a wholesaler or retailer.

Phytosanitary Certificate With Additional Declaration

Consignments of longan from Taiwan would also be required to be accompanied by a phytosanitary certificate of inspection and pest freedom issued by the national plant protection organization (NPPO) of Taiwan, with an additional declaration stating that the longan in the shipment had been inspected and found free of the yellow peach moth, macadamia nut borer, and cashew leaf thrips. This condition would require the NPPO of Taiwan to conduct phytosanitary inspections for all quarantine-significant pests.

Cold Treatment

We would require that the longan be subjected to cold treatment for melon fruit fly, oriental fruit fly, and litchi fruit borer using proposed APHIS treatment schedule T107–h, which would provide two options for conducting the cold treatment: An option in which the fruit is held at 33.8 °F or below for 17 days, and an option in which the fruit is held at 34.5 °F or below for 20 days.

This condition, in conjunction with other safeguards that would be required for longan from Taiwan, would reduce the likelihood that longan would introduce injurious plant pests into the continental United States. The proposed cold treatment schedule, conducted in accordance with § 305.15, has been determined to be an effective quarantine treatment for melon fruit fly, oriental fruit fly, and litchi fruit borer in longan.

The schedule listed for cold treatment T107–h in § 305.16 currently provides three options for conducting the cold treatment: An option in which the fruit is held at 33.4 °F or below for 13 days, an option in which the fruit is held at 33.8 °F or below for 15 days, and an option in which the fruit is held at 34.5 °F or below for 18 days. However, a review [1] by APHIS has determined that there is not adequate scientific justification to conclude that the pests for which T107–h is an approved treatment will be neutralized if the option of holding the fruit at 33.4 °F or below for 13 days is used. Accordingly, we are proposing to remove this option from the cold treatment schedule in T107–h. Additionally, based on the recommendations in the review, we would extend by 2 days the treatment times required in the other options available for this cold treatment. Thus, the longan would have to be treated at 33.8 °F for 17 days or 34.5 °F for 20 days. For the same reasons, we are also proposing to revise the schedule listed for cold treatment T107–j in § 305.16 to replace the 13-day treatment option with a 15-day treatment option. However, we are not revising the 18-day treatment option for this schedule because T107–j is approved only for oriental fruit fly and the 18-day treatment option has been shown to be effective at neutralizing that pest.

Special Inspection Procedures

Longan imported into the United States from Taiwan under this rule would be subject to special inspection procedures at the port of arrival for the quarantine pests yellow peach moth, macadamia nut borer, and cashew leaf thrips.

Specifically, a random sample of fruit from each consignment would be inspected to detect any pest infestation. The sampling would be conducted at a higher rate than normal to help ensure detection of the high-risk pests. The relatively large size of the yellow peach moth and the macadamia nut borer would allow for detection of these pests on commodities. Fruit damage caused by the cashew leaf thrips would also be visible during inspection. Port-of-arrival inspection in accordance with the special inspection procedures is also the approved mitigation for the medium-risk pests identified in the PRA other than the litchi rust mite.

Limited Distribution

Fresh longan from Taiwan would be prohibited from entering Florida. All individual cartons or boxes in which the longan were shipped must be stamped or marked with the following statement: ''Not for importation into or distribution within FL.''

Longan shipments into the State of Florida would be prohibited due to the risk of introducing the litchi rust mite. This is consistent with other import programs in which shipments of litchis and longan are prohibited into Florida for the same pest. This condition would limit the risk of exotic pest establishment in areas of the United States where longan are grown.

To reflect our proposed addition of fresh longan with stems from Taiwan to the list of fruits and vegetables whose importation into the United States is authorized, we would add an entry for longan from Taiwan to the table of commodities enterable from foreign localities in § 305.2(h)(2)(i) of the phytosanitary treatments regulations, and we would designate proposed cold treatment schedule T107–h as an approved treatment for melon fruit fly, oriental fruit fly, and litchi fruit borer in longan from Taiwan. In addition, we would amend the table in § 319.56–13(a) of the regulations to add an entry for longan under Taiwan, indicating in that entry that the longan would be prohibited from entering Florida, could be imported in commercial shipments only, and would have to be treated with an approved treatment listed in 7 CFR part 305. Finally, we would add a new paragraph to § 319.56–13(b) to reflect the proposed requirement that each shipment of longan be accompanied by a phytosanitary certificate issued by the NPPO of Taiwan with an additional declaration stating that the longan are free of yellow peach moth, macadamia nut borer, and cashew leaf thrips.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

For this proposed rule, we have prepared an economic analysis. The analysis, which is set out below, provides a cost-benefit analysis, as required by Executive Order 12866, as well as an initial regulatory flexibility analysis that considers the potential economic effects of this proposed rule on small entities, as required by the Regulatory Flexibility Act. Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects. In particular, we are

[1] A copy of the treatment evaluation document may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT** and may be viewed on the Internet on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for a link to Regulations.gov and information on the location and hours of the reading room).

interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

Reason for the Action

APHIS is responding to a request from the Government of Taiwan to amend the fruits and vegetables regulations to allow the commercial importation of longan with stems from Taiwan into the United States. Longan with stems would be imported under certain conditions that would address risks associated with several pests, including fruit flies. Phytosanitary risks would be mitigated using a systems approach. Import requirements would include requirements for cold treatment, limited distribution with box markings (to address the risk posed by the litchi rust mite), phytosanitary certification of inspection and pest freedom by the national plant protection organization of Taiwan, and special procedures for port-of-arrival inspection. As a signatory to the International Plant Protection Convention, the United States has agreed not to prescribe or adopt any phytosanitary measure concerning the importation of plants, plant products, and other regulated articles unless such measures are made necessary by phytosanitary considerations and are technically justified.

Objectives and Legal Basis for the Proposed Rule

The objective of the proposed rule is to allow the importation of fresh longan with stems from Taiwan. Importation would be allowed on the condition that the fruit is subject to certain import conditions including prohibited distribution into Florida.

Section 319.56 of Title 7, Chapter III of the Code of Federal Regulations sets phytosanitary requirements for the importation of fruits and vegetables into the United States. Section 305.2 of Title 7, Chapter III requires approved phytosanitary treatments. The Plant Protection Act (7 U.S.C. 7701 *et seq.*) is the statutory basis for parts 305 and 319. It authorizes the Secretary of Agriculture to implement programs and policies designed to prevent the introduction and spread of plant pests and diseases.

Description and Estimate of Small Entities Affected by the Proposed Rule

As background to the discussion of possible effects for small entities, we first consider U.S. and world longan production and current imports by the United States. Production of longan in the United States has trended upward over the past few years. However, U.S. commercial production of longan is limited to Florida and Hawaii. As a rare fruit, longan accounts for a small percentage of the total value of tropical specialty fruit sales. Producers and importers that may be affected by this proposed rule are likely to be small, based on Small Business Administration (SBA) size standards as related to the North American Industry Classification System (NAICS). Further, longan from Taiwan would not be allowed into Florida, and therefore would not directly compete with U.S. producers for sales in that State.

Florida

In 1996, 91 percent of Florida's longan production was located in Miami-Dade County, and the remaining acreage was located in neighboring counties.[2] There are between 20 and 40 different longan cultivars world-wide, but 99 percent of the Floridian acreage is planted with the ''Kohala'' cultivar.[3] The harvest season can last from July to September, but mainly occurs in August.

In 2002, the Florida Agricultural Market Research Center, in combination with the University of Florida Institute of Food and Agricultural Sciences (IFAS), published an agricultural land study. This report states that, in 2001, crop acreage for longan in Miami-Dade County totaled 495 acres, including non-bearing acreage.[4] Latest estimates are around 850 acres, including acreage that has been planted in Palm Beach County and Lee County.[5] Revenue reports from 1998 show that 275 acres of the longan fruit crop sold at freight-on-board prices of $3.60 per pound yielding a total value of $8.9 million.[6] Ninety-five percent of the longan crop was sold outside Miami-Dade County. While the IFAS research does not report the destination of longan leaving the county, demand for the longan as a minor tropical fruit is rather small and geographically limited, with most of the crop sold on the local fresh market.[7] We are unaware of large-scale commercial shipments of longan by Florida producers. Additionally, we note that the proposed rule would not allow the importation or distribution of commercial shipments of longan with stems from Taiwan into Florida.

Hawaii

In 2006, the U.S. Department of Agriculture's National Agricultural Statistics Service (NASS), in cooperation with the Hawaiian Department of Agriculture, reported that there were 65 farms in Hawaii that grew longan. It is possible that these farms grew more than one type of fruit. These Hawaiian farms had a total of 155 acres of longan, 75 of which were harvested. There is no commercial production for canned, dried, or processed longan, as 99 percent of the fruit is sold fresh. Utilized production totaled 190,000 pounds, which was valued at $657,000. Utilized production reported by NASS may be understated by as much as one-fourth because some growers did not participate in the NASS surveys.[8] A 2007 report shows that the value of sales for longan produced in Hawaii has steadily increased from $147,000 in 2002 to $657,000 in 2006. Longan is now the second most important tropical specialty fruit after mango.[9] The total value of sales of tropical specialty fruits in Hawaii equaled $2.6 million in 2006.

With regard to the distribution of Hawaiian longan, it is estimated that about 40 percent is irradiated and moved to the mainland for sale in metropolitan areas such as Chicago, IL, and San Francisco, CA. The remaining longan is sold within the State at resort hotels, at farmers' markets, or in Honolulu's Chinatown.[10] Hawaii's production and sales are a small but

[2] University of Florida, IFAS Extension, ''Florida Crop/Pest Management Profile: Lychee and Longan.'' Mark Mossler and O. Norman Nesheim. March 2002. *http://edis.ifas.ufl.edu/pdffiles/PI/PI05000.pdf.*

[3] University of Florida, IFAS Extension. ''Longan Growing in the Florida Home Landscape.'' Jonathan Crane, Carlos Balerdi, Steven Sargent, Ian Maguire. pg. 1. Revised Sept. 2005. *http://edis.ifas.ufl.edu/pdffiles/MG/MG04900.pdf.*

[4] Florida Agricultural Market Research Center, IFAS. Miami-Dade Agricultural Land Retention Study. Summary and Recommendations Vol. 1 Table 13 ''Summary of Miami-Dade Tropical Fruit Acreage, 1990–2001.'' p. 40. April 2002. *http://www.agmarketing.ifas.ufl.edu/dlfiles/Summary.pdf.*

[5] Crane, Jonathan. Tropical Fruit Specialist at the University of Florida IFAS, personal communication, February 29, 2008.

[6] Florida Agricultural Market Research Center, IFAS. Miami-Dade Agricultural Land Retention Study. Economic Issues Vol 3. p. 4. April 2002. *http://www.agmarketing.ifas.ufl.edu/dlfiles/DadeAgLandRetentionAppendixVolumeB.pdf.*

[7] Florida Department of Agriculture and Consumer Services. Charles H. Bronson. Florida Agriculture Statistical Directory. pg. 31. April 1, 2007. *http://www.florida-agriculture.com/pubs/pubform/pdf/Florida_Agricultural_Statistical_Directory.pdf.*

[8] Love, Ken. West Hawaii Director for the Hawaii Tropical Growers Association, personal communication, April 15, 2008.

[9] National Agricultural Statistics Service, Department of Agriculture State of Hawaii. ''Hawaii Tropical Specialty Fruits.'' Sept. 4, 2007. *http://www.nass.usda.gov/hi/fruit/tropfrt.pdf.* Includes atemoya, breadfruit, caimito, canistel, cherimoya, durian, jaboticaba, jackfruit, langsat, longan, loquat, litchi, mango, mangosteen, persimmon, poha, rambutan, rollina, sapodilla, soursop, starfruit, and white sapote.

[10] Love, Ken. West Hawaii Director for the Hawaii Tropical Growers Association, personal communication, April 15, 2008.

growing part of the fresh longan industry in the United States.

Taiwan and Other Foreign Production and Exports

Taiwan is a major producer of longan.[11] In 2002, Taiwan produced over 242 million pounds of longan, on over 29,000 acres.[12] Most of the fresh longan is domestically consumed. A small amount of longan is exported to other countries, including the United States, as dried, preserved, canned, or fresh. The main cultivar in Taiwan is the ''Fengko.''

Thailand and China are the frontrunners in longan production and trade. In 2003, Thailand produced around 875 million pounds of longan on over 1.9 million acres.[13] Of Thailand's total longan exports, about 70 percent is shipped fresh to Hong Kong, Singapore, Malaysia, and China.[14] China has an even larger longan industry. In 2000, China produced 1.3 million pounds on 1.1 million acres.[15] APHIS regulations allow both Thailand and China to export fresh longan fruit with stems into the United States, excluding Florida, under certain conditions.

Taiwan may be currently exporting prepared or preserved longan to the United States, but available statistics combine data for litchi and longan; disaggregation of the data is not possible. Foreign Agricultural Service data, for example, show that in 2007, U.S. imports of prepared or preserved litchi/longan from Taiwan totaled 19,600 pounds and were valued at $45,000 (Harmonized Schedule code 2008993500). Thailand and China export much larger volumes of prepared or preserved litchi/longan to the United States: 7.4 million pounds and 2.4 million pounds, respectively, in 2007, with a combined value of $5.1 million (equaling 97 percent of U.S. litchi/longan imports). The percentage share of these litchi/longan imports that were only longan is unknown. Furthermore, quantities of fresh longan with stems imported from China and Thailand are also not known.

The Taiwanese Government estimates that fresh longan exports to the United States would total around 397,000 pounds.[16] Because of data aggregation, we are unable to more fully assess the relative size of projected fresh longan imports from Taiwan, or compare them to the quantities of fresh longan either imported from Thailand and China or produced domestically. We welcome information that would allow us to better understand the U.S. fresh longan market.

Impact on Small Entities

Entities affected by this proposed rule are likely to be small, based on SBA size standards as related to NAICS. Businesses most likely to be affected by this rule would be longan producers, for which the SBA small-entity standard is annual sales of not more than $750,000. Production of longan is classified under NAICS code 111339 (Other Non-Citrus Fruit Farming). In 2006, NASS reported that there were 65 farms in Hawaii that grew longan, and this number has not changed since 2003.[17] The Tropical Fruit Growers of South Florida lists 25 members that sell longan from their farms.[18] A University of Florida publication from 2004 also lists four nurseries selling longan plants.[19] The 2002 Census of Agriculture shows that approximately 95 percent of fruit and nut tree farmers (NAICS 1113) in the United States had sales that year of under $500,000. It is reasonable to assume that most, if not all, longan producers in the United States are small entities.

Some importers of longan could be affected by the proposed rule as well. These industries and their small-entity size standards are: Fresh fruit and vegetable wholesalers (NAICS 424480, not more than 100 employees), wholesalers and other grocery stores (NAICS 445110, not more than $23 million in annual receipts), warehouse clubs and superstores (NAICS 452910, not more than $23 million in annual receipts) and fruit and vegetable markets (NAICS 445230, not more than $6 million in annual receipts). As with producers, it is likely that affected longan importers would be predominantly small entities.

Fresh longan fruit with stems is currently admissible from other countries besides China and Thailand, including the Bahamas, Bermuda, Dominican Republic, Haiti, and Jamaica. Allowing Taiwan to export fresh longan with stems to the United States is not expected to have any significant effect on APHIS program operations, since longan is currently imported from these various other regions subject to similar conditions.

In sum, the quantity of fresh longan with stems projected to be exported from Taiwan to the United States is probably small compared to current import levels from other countries. However, because trade data for prepared or preserved fruit combine longan with litchi, actual prepared or preserved longan quantities imported by the United States are not known. Moreover, the market for fresh longan is distinct from the market for prepared or preserved longan, and trade data on fresh longan imports are not available. It is likely that imports from Taiwan would at least partially substitute for imports from countries such as China and Thailand. Longan from Taiwan would not be allowed into Florida, and therefore would not directly compete with U.S. producers for sales in that State.

U.S. producers of longan are predominantly small entities and operate primarily in Hawaii and southern Florida; there are relatively few producers, and the number of harvested acres is relatively small. Some domestic import firms may benefit from any additional trade that results from the proposed rule. We welcome information that would enable us to better understand potential effects of this proposed rule on U.S. small entities.

Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

The proposed rule would not result in U.S. entities being subject to reporting, recordkeeping, or other compliance requirements other than, for importers, the records normally required of brokerage firms and other import businesses. Phytosanitary certification and fulfillment of related import conditions would be the responsibility of the exporting party and are discussed below under the heading ''Paperwork Reduction Act.''

[11] All Asian production and export numbers are converted from hectares and metric tons. 1 MT = 2,204.64 lbs; 1 ha = 2.471 acres.

[12] Yen, C.R. ''Longan Production in Taiwan.'' ACTA Agriculture Vol. Jan. 2005, No. 665, p. 61–66.

[13] Office of Agricultural Economics. Agricultural Statistics of Thailand 2003. Fruit Trees, Table 72: Longan. *http://www.oae.go.th/statistic/yearbook/2003/indexe.html.*

[14] Anupunt, P. *Lychee and Longan Production in Thailand.* Acta Horticulture Vol. Jan. 2005. p. 52–59.

[15] Huang, H.B and X. Huang. *Lychee and Longan Production in China.* Acta Horticulture Vol. Jan. 2005. p. 27–36.

[16] Estimates from Taiwan is 180 MT equivalent to 1 MT = 2,204.64 lbs.

[17] National Agricultural Statistics Service, Department of Agriculture State of Hawaii. ''Hawaii Tropical Specialty Fruits.'' Sept 4, 2007. *http://www.nass.usda.gov/hi/fruit/tropfrt.pdf.*

[18] Tropical Fruit Growers of South Florida. Buy Fruit and Trees—TFGSF Directory of Members. 2007. *http://www.tropicalfruitgrowers.com/buy.htm#longan.*

[19] University of Florida. IFAS Extension. ''Nursery List for Tropical Fruit Trees.'' Andrew Rose and Jeanne Ethridge. pg. 21, Table 44. Revised Oct. 2004. *http://edis.ifas.ufl.edu/pdffiles/CN/CN00800.pdf.*

Alternatives

APHIS does not expect the proposed rule to result in significant economic impacts for small entities, and therefore has not set forth alternatives that would aim at minimizing any such impacts.

Executive Order 12988

This proposed rule would allow commercial shipments of fresh longan with stems from Taiwan into the United States. If this proposed rule is adopted, State and local laws and regulations regarding longan imported under this rule would be preempted while the fruit is in foreign commerce. Fresh fruits are generally imported for immediate distribution and sale to the consuming public and would remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. If this proposed rule is adopted, no retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2007–0161. Please send a copy of your comments to: (1) Docket No. APHIS–2007–0161, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

The United States Department of Agriculture is responsible for preventing plant pests and noxious weeds from entering the United States, preventing the spread of plant disease not widely distributed in the United States, and eradicating imported pest and noxious weeds when eradication is feasible.

Under the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the Secretary of Agriculture is authorized to carry out operations or measures to detect, eradicate, suppress, control, prevent, or retard the spread of plant pests new to the United States or not known to be widely distributed throughout the United States.

The regulations in ''Subpart—Fruits and Vegetables'' prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests that are new to or not widely distributed within the United States.

APHIS is proposing to allow the importation of commercial shipments of fresh longan with stems from Taiwan into the United States. As a condition of entry, the longan would be subject to cold treatment and special port-of-arrival inspection procedures for certain quarantined pests. In addition, the fruit would have to be accompanied by a phytosanitary certificate stating that the fruit was inspected and found to be free of certain pests, and the individual cartons or boxes in which the longan are shipped would have to be stamped or printed with a statement prohibiting their importation into or distribution in the State of Florida.

Implementing this proposed rule will require respondents to complete documents such as a phytosanitary certificate, recordkeeping, inspection, and the stamping of boxes.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.0018 hours per response.

Respondents: NPPOs, importers of longan.

Estimated annual number of respondents: 12,004.

Estimated annual number of responses per respondent: 1.0012.

Estimated annual number of responses: 12,018.

Estimated total annual burden on respondents: 22 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

List of Subjects

7 CFR Part 305

Irradiation, Phytosanitary treatment, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements.

7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we propose to amend 7 CFR parts 305 and 319 as follows:

PART 305—PHYTOSANITARY TREATMENTS

1. The authority citation for part 305 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

2. In § 305.2, the table in paragraph (h)(2)(i) is amended by adding, in alphabetical order, under Taiwan, a new entry for longan to read as follows:

§ 305.2 Approved treatments.

* * * * *

(h) * * *

(2) * * *

(i) * * *

Location	Commodity	Pest	Treatment schedule
*	*	*	*
Taiwan			
*	*	*	*
	Longan	*Bactrocera dorsalis, B. cucurbitae, Conopomorpha sinensis.*	CT T107–h.
*	*	*	*

* * * * *

3. In § 305.16, the table is amended by revising the entries for treatment schedules T107–h and T107–j to read as follows:

§ 305.16 Cold treatment schedules.

Treatment schedule	Temperature (°F)	Exposure period
*	*	*
T107–h	33.8 or below	17 days.
	34.5 or below	20 days.
T107–j	33.8 or below	15 days.
	34.5 or below	18 days.
*	*	*

* * * * *

PART 319—FOREIGN QUARANTINE NOTICES

4. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

5. Section 319.56–13 is amended as follows:

a. In paragraph (a), the table is amended by adding, in alphabetical order, under Taiwan, a new entry for longan to read as set forth below.

b. By adding a new paragraph (b)(5)(xvii) to read as set forth below.

§ 319.56–13 Fruits and vegetables allowed importation subject to specified conditions.

(a) * * *

Country/locality of origin	Common name	Botanical name	Plant part(s)	Additional requirements
*	*	*	*	*
Taiwan				
*	*	*	*	*
	Longan	*Dimocarpus longan*	Fruit and stems	(b)(2)(v), (b)(3), (b)(5)(xv), (b)(5)(xvii).
*	*	*	*	*

* * * * *

(b) * * *

(5) * * *

(xvii) Must be accompanied by a phytosanitary certificate issued by the national plant protection organization of the exporting country of origin with an additional declaration stating that the fruit is free of *Conogethes punctiferalis, Cryptophlebia ombrodelta,* and *Rhipiphorothrips cruentatus.*

* * * * *

Done in Washington, DC, this 3rd day of November 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–26612 Filed 11–6–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 25, 121, and 129

[Docket No. FAA–2006–24281]

Aviation Rulemaking Advisory Committee Meeting on Transport Airplane and Engine Issues—Aging Aircraft Program: Widespread Fatigue Damage

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting, reopening of comment period.

SUMMARY: This notice announces a public meeting of the FAA's Aviation Rulemaking Advisory Committee (ARAC) to discuss transport airplane and engine (TAE) issues. The purpose of the meeting is to solicit comments and information on a technical document related to a notice of proposed rulemaking that the FAA published on April 18, 2006, on Widespread Fatigue Damage, and its accompanying initial regulatory evaluation. This notice also announces the opening of a period of public comment on that technical document, which has been posted in docket FAA–2006–24281. Commenters may post their comments in the docket.

DATES: The meeting is scheduled for Thursday, December 11, 2008, starting at 9 a.m. Pacific Standard Time. Persons unable to attend the meeting are invited to provide written comments to the Federal Docket Management System, on or before December 22, 2008. Persons planning to make oral presentations at the meeting must request arrangements for that with the FAA by December 1, 2008 by contacting the appropriate person under the **FOR FURTHER INFORMATION CONTACT** section. We also ask those who are not planning to make a presentation but are planning to attend the meeting to inform us as well.

ADDRESSES: The meeting will be held at the Best Western Hotel, 15901 West Valley Hwy., Tukwila, WA 98188. Attendance is open to the public, but will be limited to space available. Persons unable to attend the meeting may send comments identified by Docket Number FAA–2006–24281 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Bring comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the electronic form of all comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://DocketsInfo.dot.gov.*

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time and follow the online instructions for accessing the docket. Or, go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Requests to present a statement at the meeting or questions regarding the logistics of the meeting, as well as responses from persons planning to attend the meeting, should be directed to Annette Kovite, Federal Aviation Administration, Transport Airplane Directorate, Aircraft Certification Service, Standardization Branch, ANM–113, 1601 Lind Avenue, SW., Renton, WA 98057–3356; telephone (425) 227–1262; fax (425) 227–1320; e-mail: *Annette.Kovite@faa.gov.* Please provide us with the following information: Full legal name, country of citizenship, and name of your industry association or applicable affiliation. If you are attending as a private citizen, please indicate that.

Questions concerning this proposed rule should be directed to Walter Sippel, FAA, Transport Airplane Directorate, Aircraft Certification Service, Transport Airplane Airframe/Cabin Safety Branch, ANM–115, 1601 Lind Avenue, SW., Renton, WA 98057–3356; telephone (425) 227–2774, fax (425) 227–1232, e-mail: *walter.sippel@faa.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. app. III), notice is given of an ARAC meeting to be held at the Best Western Hotel in Tukwila, WA on December 11, 2008. This ad hoc meeting is being held to review and receive public comments on changes made to the notice of proposed rulemaking and initial regulatory evaluation on Widespread Fatigue Damage published on April 18, 2006 (74 FR 19928).

The agenda for the meeting is as follows:

- Opening remarks.
- Presentation and explanation of technical document related to notice of proposed rulemaking No. 06–04, Aging Aircraft Program: Widespread Fatigue Damage, published on April 18, 2006 (71 FR 19928), and its accompanying initial regulatory evaluation, which may be found in Docket FAA–2006–24281.
- Oral presentation of public comments.

Background

The FAA received extensive comments on the Widespread Fatigue Damage (WFD) notice of proposed rulemaking (74 FR19928) and on the estimated costs and benefits of that proposed rule specified in its accompanying regulatory evaluation, which may be found in the docket. Based on those comments, and on our analysis of those comments, we have developed a technical document that suggests changes to both the proposed rule and to the assumptions made in our initial regulatory evaluation. Those changes could decrease the estimated cost of the proposed rule from $360 million to $4 million in present value.

Comment Period

To allow the public to comment on the technical document we are reopening the comment period. We have posted it in the docket for the Widespread Fatigue Damage rulemaking (FAA–2006–24281) with the title ''Technical Document—Aging Aircraft Program: Widespread Fatigue Damage.'' A period of public comment on that document begins with publication of this notice in the **Federal Register** and ends on December 22, 2008. Public comments may be posted to the docket at any time during the comment period by following any of the means of posting comments listed in the **ADDRESSES** section of this document. In addition, as discussed below, we invite attendance at the public meeting of ARAC on Transport Airplane and Engine Issues on December 11, 2008, where people may make comments in person. If you are posting comments to the docket and would like us to address them at the meeting, it would help us if you would post those comments by December 1. All comments posted to the docket will be considered, but we may not be able to address late-posted comments at the meeting.

Participation at the Meeting

The purpose of the meeting of the Transport Airplane and Engine Issues Group on December 11, 2008, is to discuss the technical document and the effect our analysis could have on the proposed rule and initial regulatory evaluation for Widespread Fatigue Damage. The public is invited to make oral presentations and comments on the

technical document at this meeting. To assist us in planning for this meeting, please notify us by December 1, 2008 if you are planning to attend. Persons who wish to present oral statements at the meeting should arrange with the FAA in advance for time to do this at the meeting. We should receive requests from persons who wish to present oral statements at the meeting no later than December 1, 2008. Requests to speak should include a written summary of oral remarks to be presented and an estimate of time needed for the presentation. An agenda of speakers will be available at the meeting. The names of those individuals who make their request to present oral statements after the date specified above may not appear on the written agenda. To accommodate as many speakers as possible, the amount of time allocated to each speaker may be less than the amount of time requested. Persons requiring audiovisual equipment should notify the FAA when requesting to be placed on the agenda.

Public Meeting Procedures

The FAA will use the following procedures to facilitate the meeting:

(1) There will be no admission fee or other charge to attend or to participate in the meeting. The meeting will be open to all persons who are scheduled to attend or present statements or who register between 8 a.m. and 9 a.m. on the day of the meeting. While the FAA will make every effort to accommodate all persons wishing to participate, admission will be subject to availability of space in the meeting room. Advising us in advance if you're planning to attend the meeting will help us plan for adequate room to accommodate those who wish to attend. The meeting may adjourn early if scheduled speakers complete their statements in less time than is scheduled for the meeting.

(2) An individual presenting oral remarks, whether speaking in a personal capacity or as a representative of an organization, may be limited to a 10-minute statement. If possible, we will notify the speaker if additional time is available.

(3) We will try to accommodate all speakers. If the available time does not permit this, speakers generally will be scheduled on a first-come-first-served basis. However, the FAA reserves the right to exclude some speakers if necessary to present a balance of viewpoints and issues.

(4) If you need assistance or require a reasonable accommodation for the meeting or meeting documents, please contact Annette Kovite, listed in the **FOR FURTHER INFORMATION CONTACT** section. Sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested by December 1, 2008.

(5) The committee's Assistant Chair for Transport Airplane and Engine Issues will preside over the meeting. The Designated Federal Official and a panel of FAA personnel involved in this rulemaking will be present to address the technical document and questions and comments presented.

(6) The meeting will be recorded by a court reporter. A transcript of the meeting and any material accepted by the FAA representatives during the meeting will be included in the public docket. Any person who is interested in purchasing a copy of the transcript should contact the court reporter directly. Additional transcript purchase information will be available at the meeting.

(7) The FAA will review and consider all material presented by participants at the meeting. Position papers or material presenting views or arguments related to the rulemaking may be accepted at the discretion of the presiding officer and subsequently placed in the public docket. We request that persons participating in the meeting provide enough copies of all materials for distribution to the committee and FAA representatives; other copies may be provided to the audience at the discretion of the participant.

(8) Statements made by FAA representatives are intended to facilitate discussion of the issues or to clarify issues. Any statement made during the meeting by an FAA representative is not intended to be, and should not be construed as, a position of the FAA.

(9) The meeting is designed to solicit public views and gather additional information on the rulemaking. Therefore, the meeting will be conducted in an informal and non-adversarial manner. No individual will be subject to cross-examination by any other participant; however, FAA representatives may ask questions to clarify a statement and to ensure a complete and accurate record.

Issued in Washington, DC, on November 3, 2008.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

[FR Doc. E8–26566 Filed 11–6–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2008–0957; Airspace Docket No. 08–AAL–27]

Proposed Revision of Class E Airspace; Galena, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to revise Class E airspace at Galena, AK. Two Standard Instrument Approach Procedures (SIAPs) are being amended for the Edward G. Pitka Airport at Galena, AK. Adoption of this proposal would result in revising Class E airspace upward from 700 feet (ft.) and 1,200 ft. above the surface at the Edward G. Pitka Airport, Galena, AK.

DATES: Comments must be received on or before December 22, 2008.

ADDRESSES: Send comments on the proposal to the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001. You must identify the docket number FAA–2008–0957/ Airspace Docket No. 08–AAL–27, at the beginning of your comments. You may also submit comments on the Internet at *http://www.regulations.gov*. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

An informal docket may also be examined during normal business hours at the office of the Manager, Safety, Alaska Flight Service Operations, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587.

FOR FURTHER INFORMATION CONTACT: Gary Rolf, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number (907) 271–5898; fax: (907) 271–2850; e-mail: *gary.ctr.rolf@faa.gov*. Internet address: *http://www.alaska.faa.gov/at*.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking

by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2008–0957/Airspace Docket No. 08–AAL–27.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of Notice of Proposed Rulemakings (NPRMs)

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov* or the Superintendent of Document's Web page at *http://www.access.gpo.gov/nara/index.html*.

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, ATA–400, 800 Independence Avenue, SW., Washington, DC 20591 or by calling (202) 267–8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71, which would revise Class E airspace at the Edward G. Pitka Airport, in Galena, AK. The intended effect of this proposal is to revise existing Class E airspace upward from 700 ft. and 1,200 ft. above the surface to contain Instrument Flight Rules (IFR) operations at the Edward G. Pitka Airport, Galena, AK.

The FAA Instrument Flight Procedures Production and Maintenance Branch has amended two SIAPs for the Edward G. Pitka Airport. The amended SIAPs are (1) the Area Navigation (RNAV) Global Positioning System (GPS) Runway (RWY) 7, Original, and (2) the RNAV (GPS) RWY 25, Original. Class E controlled airspace extending upward from 700 ft. and 1,200 ft. above the surface in the Edward G. Pitka Airport area would be revised by this action. The proposed airspace is sufficient in size to contain aircraft executing the instrument procedures at the Edward G. Pitka Airport, Galena, AK.

The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 in FAA Order 7400.9R, *Airspace Designations and Reporting Points*, signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle 1, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart 1, Section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it proposes to create Class E airspace sufficient in size to contain aircraft executing instrument procedures at the Edward G. Pitka Airport, AK, and represents the FAA's continuing effort to safely and efficiently use the navigable airspace.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9R, *Airspace Designations and Reporting Points*, signed August 15, 2007, and effective September 15, 2007, is to be amended as follows:

* * * * *

Paragraph 6005 Class E Airspace Extending Upward from 700 Feet or More Above the Surface of the Earth.

* * * * *

AAL AK E5 Galena, AK [Revised]

Galena, Edward G. Pitka Airport, AK
(Lat. 60°44′10″ N., long. 156°56′14″ W)
Galena VORTAC
(Lat. 60°44′17″ N., long. 156°46′38″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of the Edward G. Pitka Airport, AK, and within 14 miles of the Galena VORTAC, AK, extending clockwise from the 088°(T)/111°(M) radial to the 163°(T)/186°(M) radial

of the Galena VORTAC, AK, and within 22 miles of the Galena VORTAC, AK, extending from the 268° radial to the 315° radial of the Galena VORTAC, AK, and within 4 miles north of the 088° radial of the Galena VORTAC, AK, extending from the 6.7-mile radius of the Edward G. Pitka Airport to 14 miles east of the Galena VORTAC, AK, and within 4 miles south of the 268° radial of the Galena VORTAC, AK, extending from the 6.7-mile radius to 22 miles west of the Galena VORTAC, AK; and that airspace extending upward from 1,200 feet above the surface within a 73-mile radius of the Edward G. Pitka Airport, AK.

* * * * *

Issued in Anchorage, AK, on October 27, 2008.

Anthony M. Wylie,

Manager, Alaska Flight Services Information Area Group.

[FR Doc. E8–26656 Filed 11–6–08; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2008–0728; FRL–8729–2]

Approval and Promulgation of Implementation Plans; Revisions to the Nevada State Implementation Plan; Clark County

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under the Clean Air Act, EPA is proposing to approve a revision to the Clark County portion of the Nevada State Implementation Plan (SIP). This revision consists of transportation conformity criteria and procedures related to interagency consultation and enforceability of certain transportation-related control measures and mitigation measures. We are proposing to approve a local plan to include the transportation conformity criteria and procedures in the applicable SIP.

DATES: Any comments on this proposal must arrive by *December 8, 2008.*

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2008–0728, by one of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions.
2. *E-mail: vagenas.ginger@epa.gov.*
3. *Mail or deliver:* Ginger Vagenas (AIR–2), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* portal is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: The index to the docket for this action is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Ginger Vagenas, EPA Region IX, (415) 972–3964, *vagenas.ginger@epa.gov.*

SUPPLEMENTARY INFORMATION: This proposal addresses the Clark County Transportation Conformity Plan, submitted on April 1, 2008 by the Nevada Division of Environmental Protection (NDEP) to comply with certain requirements that apply to the nonattainment portions of Clark County. In the Rules and Regulations section of this **Federal Register**, we are approving this local plan in a direct final action without prior proposal because we believe this SIP revision is not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: September 24, 2008.

Wayne Nastri,

Regional Administrator, Region IX.

[FR Doc. E8–26515 Filed 11–6–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 59

[EPA–HQ–OAR–2006–0971; FRL–8738–8]

RIN 2060–AP33

National Volatile Organic Compound Emission Standards for Aerosol Coatings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the National Volatile Organic Compound Emission Standards for Aerosol Coatings, which establishes national reactivity-based emission standards for the aerosol coatings category (aerosol spray paints) under the Clean Air Act (CAA). In this ''Rules and Regulations'' section of this **Federal Register**, we are making these same amendments as a direct final rule, without a prior proposed rule. If we receive no adverse comment, we will not take further action on this proposed rule.

DATES: Comments must be received by December 8, 2008, or December 22, 2008 if a hearing is requested.

Public Hearing: If anyone contacts EPA requesting to speak at a public hearing concerning the proposed regulation by November 17, 2008, we will hold a public hearing on November 24, 2008.

ADDRESSES: Comments. Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2006–0971 by mail to National Volatile Organic Compound Emission Standards for Aerosol Coatings, Environmental Protection Agency, Mail Code: 2822T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of two copies. Comments may also be submitted electronically or through

hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the Direct Final Rule located in the ''Rules'' section of this **Federal Register**.

Public Hearing: If you are interested in attending the public hearing, contact Ms. Joan Rogers at (919) 541–4487 to verify that a hearing will be held. If a public hearing is held, it will be held at 10 a.m. at EPA's Campus located at 109 T.W. Alexander Drive in Research Triangle Park, NC, or an alternate site nearby. If no one contacts EPA requesting to speak at a public hearing concerning this rule by November 17, 2008, this meeting will be cancelled without further notice.

FOR FURTHER INFORMATION CONTACT: For further information, contact Ms. J. Kaye Whitfield, U.S. EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Natural Resources and Commerce Group (E143–03), Research Triangle Park, NC 27711; telephone number (919) 541–2509; facsimile number (919) 541–3470; e-mail address: *whitfield.kaye@epa.gov*. For information concerning the Clean Air Act (CAA) Section 183(e) consumer and commercial products program, contact Mr. Bruce Moore, U.S. EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Natural Resources and Commerce Group (E143–03), Research Triangle Park, North Carolina 27711, telephone number: (919) 541–5460, facsimile number (919) 541–3470, e-mail address: *moore.bruce@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Why Is EPA Issuing This Proposed Rule?

This document proposes to take action on the National Volatile Organic Compound Emission Standards for Aerosol Coatings to move the applicability and compliance dates for aerosol coatings from January 1, 2009 to July 1, 2009. Also, EPA is making initial notifications required due on the compliance date, as opposed to 90 days in advance of the compliance date. We have published a direct final rule to make these same amendments in the ''Rules and Regulations'' section of this **Federal Register** because we view this as a non-controversial action and anticipate no adverse comment. We have explained our reasons for this action in the preamble to the direct final rule.

If we receive no adverse comment, we will not take further action on this proposed rule. If we receive adverse comment, we will withdraw the direct final rule, and it will not take effect. We would address all public comments in any subsequent final rule based on this proposed rule.

We do not intend to institute a second comment period on the action. Any parties interested in commenting must do so at this time.

The regulatory text for the proposal is identical to that for the direct final rule and published in the ''Rules and Regulations'' section of this **Federal Register**.

II. Does This Action Apply to Me?

The entities potentially affected by this proposed rule are the same entities that are subject to the Aerosol Coatings final rule. The entities affected by the Aerosol Coatings final rule include: Manufacturers, processors, distributors, importers of aerosol coatings for sale or distribution in the United States, and manufacturers, processors, distributors, or importers who supply the entities listed above with aerosol coatings for sale or distribution in interstate commerce in the United States.

III. Statutory and Executive Order Reviews

For a complete discussion of all the administrative requirements applicable to this action, see the Direct Final Rule in the ''Rules and Regulations'' section of this **Federal Register**.

List of Subjects in 40 CFR Part 59

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: October 30, 2008.

Stephen L. Johnson,

Administrator.

[FR Doc. E8–26613 Filed 11–6–08; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 08–2334; MB Docket No. 08–197; RM–11491]

Radio Broadcasting Services; Silverpeak, NV

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document sets forth a proposal to amend the FM Table of Allotments, Section 73.202(b) of the Commission's rules, 47 CFR 73.202(b). The Commission requests comment on a petition filed by Shamrock Communications, Inc. Petitioner proposes the allotment of FM Channel 291C at Silverpeak, Nevada, as that community's first local service. Channel 291C can be allotted in accordance with the Commission's minimum distance separation requirements with a site restriction of 42.0 km (26.1 miles) east of Silverpeak. The proposed coordinates for Channel 291C at Silverpeak are 47–49–22 North Latitude and 117–09–53 West Longitude. *See* **SUPPLEMENTARY INFORMATION** *infra*.

DATES: Comments must be filed on or before December 15, 2008, and reply comments on or before December 30, 2008.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve petitioner's counsel as follows: Kenneth E. Satton, Esq., Patricia M. Chuh, Esq., Wilkinson Barker Knauer, LLP, 2300 N Street, NW., Suite 700, Washington, DC 20037.

FOR FURTHER INFORMATION CONTACT: Deborah A. Dupont, Media Bureau, (202) 418–7072.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rulemaking*, MB Docket No. 08–197, adopted October 22, 2008, and released October 24, 2008. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington DC 20554, (800) 378–3160, or via the company's Web site, *http://www.bcpiweb.com*. This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

The Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rulemaking is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings,

such as this one, which involve channel allotments. *See* 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, *see* 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Nevada, is amended by adding Silverpeak, Channel 291C.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. E8–26511 Filed 11–6–08; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 73, No. 217

Friday, November 7, 2008

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Notice of Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Office of the Secretary, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended), this notice announces the White House Liaison's intention to request approval from the Office of Management and Budget for an extension and revision of a currently approved information collection for Advisory Committee and Research and Promotion Board Membership Background Information (AD–755).

DATES: Comments on this notice must be received by January 6, 2009 to be assured of consideration.

Additional Information or Comments: Address all comments concerning this notice to the Office of the White House Liaison, U.S. Department of Agriculture, 1400 Independence Ave., SW., Whitten Building, Room 219–A, Washington, DC 20250.

SUPPLEMENTARY INFORMATION:

Title: Advisory Committee and Research and Promotion Board Membership Background Information.

OMB Number: 0505–0001.

Expiration Date of Approval: March 30, 2009.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: The primary objective for the use of the AD–755 form is to determine the qualification, suitability and availability of a candidate to serve on advisory committees and/or research and promotion boards. The information will be used to both conduct background clearances and to compile annual reports on advisory committees.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 30 minutes per response.

Respondents: Individuals or households.

Estimated Number of Respondents: 1684.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 842.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to the Office of the White House Liaison, U.S. Department of Agriculture, 1400 Independence Ave., SW., Whitten Building, Room 219–A, Washington, DC 20250. All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Edward T. Schafer,

Secretary of Agriculture.

[FR Doc. E8–26600 Filed 11–6–08; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 4, 2008.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Agricultural Marketing Service

Title: Regulations Governing the Inspection and Grading of Manufactured or Processed Dairy Products—Recordkeeping.

OMB Control Number: 0581–0110.

Summary of Collection: The Agricultural Marketing Act of 1946 directs the Department to develop programs that will provide and enable the marketing of agricultural products. One of these programs is the USDA voluntary inspection and grading program for dairy products where these dairy products are graded according to U.S. grade standards by an USDA grader. The dairy products so graded

may be identified with the USDA grade mark. Dairy processors, buyers, retailers, institutional users, and consumers have requested that such a program be developed to assure the uniform quality of dairy products purchased. In order for any service program to perform satisfactorily, there must be written guides and rules, which in this case are regulations for the provider and user.

Need and Use of the Information: The Agricultural Marketing Service will collect information to ensure that the dairy inspection program products are produced under sanitary conditions and buyers are purchasing a quality product. The information collected through recordkeeping are routinely reviewed and evaluated during the inspection of the dairy plant facilities for USDA approval. Without laboratory testing results required by recordkeeping, the inspectors would not be able to evaluate the quality of dairy products.

Description of Respondents: Business or other for-profit.

Number of Respondents: 487.

Frequency of Responses: Recordkeeping.

Total Burden Hours: 1,388.

Agricultural Marketing Service

Title: Regulations for Inspection of Eggs.

OMB Control Number: 0581–0113.

Summary of Collection: Congress enacted the Egg Products Inspection Act (21 U.S.C. 1031–1056) (EPIA) to provide a mandatory inspection program to assure egg products are processed under sanitary conditions, are wholesome, unadulterated, and properly labeled; to control the disposition of dirty and checked shell eggs; to control unwholesome, adulterated, and inedible egg products and shell eggs that are unfit for human consumption; and to control the movement and disposition of imported shell eggs and egg products that are unwholesome and inedible. Regulations developed under 7 CFR part 57 provide the requirements and guidelines for the Department and industry needed to obtain compliance. The Agricultural Marketing Service (AMS) will collect information using several forms. Forms used to collect information provide method for measuring workload, record of compliance and non compliance and a basis to monitor the utilization of funds.

Need and Use of the Information: AMS will used the information to assure compliance with the Act and regulations, to take administrative and regulatory action and to develop and revise cooperative agreements with the States, which conduct surveillance inspections of shell egg handlers and processors. If the information is not collected, AMS would not be able to control the processing, movement, and disposition of restricted shell eggs and egg products and take regulatory action in case of noncompliance.

Description of Respondents: Business or other for-profit; Federal Government; State, Local or Tribal Government.

Number of Respondents: 864.

Frequency of Responses: Recordkeeping; Reporting: On occasion; Quarterly.

Total Burden Hours: 1,530.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. E8–26611 Filed 11–6–08; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Availability of Final Environmental Impact Statement and Record of Decision for the Southern Rockies Lynx Amendment

AGENCY: Forest Service, USDA.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act (NEPA) and the National Forest Management Act, (NFMA), the USDA Forest Service announces the availability of the Final Environmental Impact Statement (FEIS) and Record of Decision (ROD) for the Southern Rockies Lynx Amendment and the opening of the administrative appeal period.

DATES: The management direction will become effective 7 days after the date of publication of the legal notice published in the Denver Post, the newspaper of record. Administrative appeals must be postmarked or received within 45 days of the date the legal notice is published in the Denver Post.

ADDRESSES: Copies of the FEIS and ROD are available upon request from the Rocky Mountain Regional Office, 740 Simms St., Golden, Colorado 80401 or via the internet on the following Web site *http://www.fs.fed.us/r2/lynx/index.html*.

This decision is subject to review through the administrative appeals process pursuant to 36 CFR 217.3. Any appeals must be postmarked or received by the Appeal Reviewing Officer within 45 days of the date the legal notices are published in the Denver Post, the newspaper of record. Any notice of appeal must be fully consistent with 36 CFR 217.9. Addresses for submitting appeals can be founding the Record of Decision.

FOR FURTHER INFORMATION CONTACT: Martha Delporte, Regional Planner, *mdelporte@fs.fed.us*, telephone 303–275–5381; or Nancy Warren, Regional Threatened, Endangered and Sensitive Species Program leader, *nwarren@fs.fed.us*, telephone 303–275–5064.

SUPPLEMENTARY INFORMATION: The purpose of this project is to amend eight Land and Resource Management Plans (''Plans'') to incorporate management direction that will conserve and promote the recovery of the Canada lynx on National Forest System lands, while preserving the overall multiple-use direction in existing Plans. The Plans to be amended are: Arapaho-Roosevelt National Forests 1997 Revised Plan (Colorado); Grand Mesa, Uncompahgre and Gunnison National Forests 1983 Plan (Colorado); Pike-San Isabel National Forests 1984 Plan (Colorado); Rio Grande National Forest 1996 Revised Plan (Colorado); San Juan National Forest 1983 Plan (Colorado); White River National Forest 2002 Revised Plan (Colorado); Routt National Forest 1997 Revised Plan (Colorado); and Medicine Bow National Forests 2003 Revised Plan (Wyoming).

The State of Colorado's Department of Natural Resources is a cooperating agency on this project because of their special expertise on the status of lynx and the Colorado lynx reintroduction project.

The DEIS (Notice of Availability published Jan. 30, 2004) and Supplemental DEIS (Notice of Availability published Nov. 24, 2006) presented analysis of four alternatives. Five alternatives were analyzed in the FEIS. The responsible official determined that Alternative F-modified best meets the purpose and need, responds to primary issues and public comments, and meets the agency's responsibilities.

Under § 219.14(b) of Title 36, Code of Federal Regulations, Part 219—Planning, Subpart A—National Forest System Land Management Planning (36 CFR part 219, subpart A) otherwise known as the 2008 planning rule, this amendment has been approved using the provisions of the 1982 planning rule (See 36 CFR parts 200 to 299, Revised as of July 1, 2000). This plan amendment is appropriate, using the 1982 rule provisions, as allowed by 2008 rule, at 219.14 (b)(3), which says that during the transition, ''plan amendments may continue using the provisions of the planning regulation in

effect before November 9, 2000'' and further says that if the provisions of the 1982 rule are used, the responsible official may ''elect to use the administrative appeal and review procedures'' at 36 CFR part 217 (See 36 CFR 219.14(b)(3)(iii)). The applicable appeal regulation states that ''[I]mplementation of any decision subject to appeal pursuant to this part shall not occur for 7 calendar days following publication of the legal notice of the decision as required in this part.'' (36 CFR 217.10(a)). Therefore, the approved Southern Rockies Lynx Amendment is effective 7 calendar days following publication of the legal notice of this decision in the Newspaper of Record, the Denver Post.

Antoine L. Dixon,

Deputy Regional Forester, Resources.

[FR Doc. E8–26309 Filed 11–6–08; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

White River National Forest; Colorado; Wild and Scenic Rivers Suitability Study

ACTION: Notice of intent to prepare an environmental impact statement.

AGENCY: U.S. Forest Service, USDA.

SUMMARY: The Forest Service is conducting a Wild and Scenic Rivers suitability study on four eligible river segments described in the WRNF Land and Resource Management Plan 2002 Revision. These segments are Colorado River Segments 1 and 2 and Deep Creek Segments 1 and 2. The results of the suitability study will be analyzed and incorporated into the Bureau of Land Management, Glenwood Springs and Kremmling Field Offices Environmental Impact Statement for their Resource Management Plan Revisions that is already underway. Separate Records of Decision will be issued for the Forest Service as well as the Bureau of Land Management.

DATES: Comments and resource information should be submitted to the Forest Service by December 2, 2008. Public open house meetings will be held in Glenwood Springs, Colorado, on November 20, 2008, and in Eagle, Colorado, on November 24, 2008. The meetings will be held from 4:30 p.m. to 6:30 p.m. The draft environmental impact statement is expected in September 2009.

ADDRESSES: Written comments may be submitted by any of the following methods:

- Fax: (970) 468–7735
- E-mail: *wrnf_scoping_comments@fs.fed.us*
- Hard copy: Peech Keller, NEPA Coordinator, White River National Forest, P.O. Box 620, Silverthorne, CO 80498.

FOR FURTHER INFORMATION CONTACT: Peech Keller, 970–262–3495.

SUPPLEMENTARY INFORMATION: The Forest Service is conducting a Wild and Scenic Rivers suitability study on four eligible river segments described in the White River National Forest Land and Resource Management Plan 2002 Revision. These segments are Colorado River Segments 1 and 2 and Deep Creek Segments 1 and 2. The suitability analysis will follow the guidance in FSH 1909.12 (Land Management Handbook), Chapter 80 (Wild and Scenic River Evaluation), and guidance from the Interagency Wild and Scenic Rivers Coordinating Council. The results of the suitability study will be analyzed and incorporated into the Bureau of Land Management, Glenwood Springs and Kremmling Field Offices Resource Management Plan Revisions and associated Environmental Impact Statement that is already underway. The final environmental impact statement is expected in July 2010. The anlaysis will tier from the White River National Forest Land and Resource Management Plan 2002 EIS and incorporate the White River National Forest Land and Resource Management Plan. Separate Records of Decision will be issued from the Forest Service as well as the Bureau of Land Management.

Purpose and Need for Action

To meet the requirements of the Section 5(d)(1) of the Wild and Scenic Rivers Act of 1968 (16 U.S.C. 1271–1287; Pub. L. 90–542, 82 Stat. 906, as amended), which directs federal agencies to consider potential Wild and Scenic Rivers in their land and water planning process, the White River National Forest completed the eligibility phase of the Wild and Scenic Rivers study for four segments of the Colorado River (Glenwood Canyon) and Deep Creek during its 2002 Land and Resource Management Plan Revision. The Forest Service is now preparing a wild and scenic river study report to determine the suitability of these segments for possible inclusion in the National Wild and Scenic Rivers System. Section 5(d)(1) of the Wild and Scenic Rivers Act allows for the study of new potential wild and scenic rivers not designated under Section 3(a) or designated for study under Section 5(a) of the Act. Section 5(d)(1) states, ''In all planning for the use and development of water and related land resources, consideration shall be given by all Federal agencies involved to potential national, wild, scenic, and recreational river areas.''

Proposed Action

The Forest Service will conduct a suitability analysis on four eligible river segments described in the White River National Forest Land and Resource Management Plan 2002 Revision to determine which, if any, of the segments are suitable for inclusion in the National Wild and Scenic Rivers System. These segments are Colorado River Segments 1 and 2 and Deep Creek Segments 1 and 2. The eligibility phase of the analysis was completed for Deep Creek in a joint Forest Service and BLM study completed in 1995. The eligibility phase of the analysis was completed for the Colorado River segments in the Land and Resource Management Plan 2002 Revision.

The suitability analysis will follow the guidance in FSH 1909.12 (Land Management Handbook), Chapter 80 (Wild and Scenic River Evaluation), and guidance from the Interagency Wild and Scenic Rivers Coordinating Council.

Possible Alternatives

The Forest Service will analyze a reasonable range of alternatives. The Forest Service will take into consideration all issues raised during public scoping. As directed by FSH 1909.12, Chapter 80, the Forest Service will, at a minimum, analyze the following alternatives:

1. No action (continuation of current management);
2. National designation of all eligible segments of the river;
3. Protection of eligible segments by means other than national designation; and
4. Designation of some eligible segments.

Lead and Cooperating Agencies

The lead agency for this effort is the Bureau of Land Management, Glenwood Springs Field Office and Kremmling Field Office. The USDA Forest Service, White River National Forest is a cooperating agency.

Responsible Official

The Responsible Official for the Forest Service decision is Rick Cables, Rocky Mountain Regional Forester; 740 Simms St., Golden, CO 80401.

Nature of Decision To Be Made

The Forest Service will determine which, if any, of the four eligible segments studied for suitability are suitable for inclusion in the National Wild and Scenic Rivers System. If none of the segments are found suitable, they will be dropped from further consideration and managed according to the objectives and specific management prescriptions outlined in the White River National Forest Land and Resource Management Plan 2002 Revision. If a segment is found suitable, it will receive interim protection as described in the Wild and Scenic Rivers Act until Congressional action is taken regarding the segments' designation.

Scoping Process

Public open house meetings will be held in Glenwood Springs, Colorado, on November 20, 2008, and in Eagle, Colorado, on November 24, 2008. The meetings will be held from 4:30 p.m. to 6:30 p.m. The Forest Service will announce the public scoping meetings via local news media, mailings, and the Forest Service Web site (*http://www.fs.fed.us/r2/whiteriver/*). Comments concerning the scope of the analysis should be received by December 2, 2008.

Comments Requested

Comments and resource information should be submitted to the Forest Service within 30 days of this notice in the **Federal Register**. Comments of particular interest will provide information related to the factors described in FSH 1909.12 (Land Management Planning Handbook), Chapter 80 (Wild and Scenic River Evaluation), Section 82.41 (Basis for Suitability). They are as follows:

1. Characteristics that do or do not make the area a worthy addition to the National System. These characteristics are described in the act (paras. 2 through 7) and may include additional suitability factors in paragraphs 8 through 13.

2. The current status of land ownership and use in the area.

3. The reasonably foreseeable potential uses of the land and water that would be enhanced, foreclosed, or curtailed if the area were included in the National System.

4. The federal agency that will administer the area should it be added to the National System.

5. The extent to which the agency proposes that administration of the river, including the costs thereof, be shared by state and local agencies.

6. The estimated cost to the United States of acquiring necessary lands and interests in land and of administering the area should it be added to the National System.

7. A determination of the degree to which the state or its political subdivisions might participate in the preservation and administration of the river should it be proposed for inclusion in the National System.

The following additional suitability factors may also be considered:

8. An evaluation of the adequacy of local zoning and other land use controls in protecting the river's outstandingly remarkable values by preventing incompatible development.

9. The state/local government's ability to manage and protect the outstandingly remarkable values on nonfederal lands. This factor requires an evaluation of the river protection mechanisms available through the authority of state and local governments. Such mechanisms may include, for example, statewide programs related to population growth management, vegetation management, water quantity or quality, or protection of river-related values such as open space and historic areas.

10. Support or opposition to designation. Assessment of this factor will define the political context. The interest in designation or nondesignation by federal agencies; state, local and tribal governments; national and local publics; and the state's Congressional delegation should be considered.

11. The consistency of designation with other agency plans, programs, or policies and in meeting regional objectives. Designation may help or impede the goals of Tribal governments, or other federal, state or local agencies. For example, designation of a river may contribute to state or regional protection objectives for fish and wildlife resources. Similarly, adding a river that includes a limited recreation activity or setting to the National System may help meet statewide recreation goals. Designation might, however, limit irrigation and/or flood control measures in a manner inconsistent with regional socioeconomic goals.

12. The contribution to river system or basin integrity. This factor reflects the benefits of a ''systems'' approach, for example, expanding the designated portion of a river in the National System or developing a legislative proposal for an entire river system (headwaters to mouth) or watershed. Numerous benefits may result from managing an entire river or watershed, including the ability to design a holistic protection strategy in partnership with other agencies and the public.

13. The potential for water resources development. The intent of the act is to preserve selected rivers from the harmful effects of water resources projects. Designation will limit development of water resources projects as diverse as irrigation and flood control measures, hydropower facilities, dredging, diversion, and channelization.

Early Notice of Importance of Public Participation in Subsequent Environmental Review: A draft environmental impact statement will be prepared for comment. The comment period on the draft environmental impact statement will be 90 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 90 days comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the

National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Comments received, including the names and addresses of those who comment, will be considered part of the public record on this proposal and will be available for public inspection.

Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21.

Dated: October 31, 2008.

Mary G. Morgan,

Acting Forest Supervisor, White River National Forest.

[FR Doc. E8–26610 Filed 11–6–08; 8:45 am]

BILLING CODE 3410–11–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* December 8, 2008.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia, 22202–3259.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION:

Additions

On 09/05/08 and 08/29/08, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (73 FR 51787 and 73 FR 50931, respectively) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the services and impact of the additions on the current or most recent contractors, the Committee has determined that the services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. The action will result in authorizing small entities to furnish the services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following services are added to the Procurement List:

Services

Service Type/Location: Base Supply Center, NAS Patuxent River, Patuxent River, MD.

NPA: Industries for the Blind, Inc., West Allis, WI.

Contracting Activity: DEPT OF THE NAVY, FISC NORFOLK.

Service Type/Location: Custodial and Landscaping, FBI Building, Houston, Texas, 1 Justice Park, Houston, TX.

NPA: On Our Own Services, Inc., Houston, TX.

Contracting Activity: General Services Administration, Public Buildings Service, Acquisition, Ft. Worth, TX.

Barry S. Lineback,

Acting Director, Program Operations.

[FR Doc. E8–26596 Filed 11–6–08; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to the Procurement List.

SUMMARY: The Committee is proposing to add to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must be Received on or Before: December 7, 2008.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice for each service will be required to procure the services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Services

Service Type/Location: Custodial Grounds Maintenance, Multiple Locations Parcel #13, St John, VI.

Service Type/Location: Grounds Maintenance, Multiple Locations St Thomas, 6310 Est Nazaareth, Red Hook, Whintberg #3 Great Northside Qtr., St Thomas, VI.

NPA: The Corporate Source, Inc., New York, NY.

Contracting Activity: NATIONAL PARK SERVICE, SOUTHEAST REGION.

Service Type/Location: Laundry Service, Fort Indiantown Gap, USPFO of PA, Annville, PA.

NPA: Opportunity Center, Incorporated, Wilmington, DE.

Contracting Activity: DEPT OF THE ARMY, XRAW7NX USPFO ACTIVITY PA ARNG.

Service Type/Location:

Reception Service Support, Fort Sill, Post Wide, Fort Sill, OK.

Reception Service Support, Fort Lewis, Post Wide, Fort Lewis, WA.

Reception Service Support, Fort Hood, Post Wide, Fort Hood, TX.

Reception Service Support, Fort Bliss, Post Wide, Fort Bliss, TX.

Reception Service Support, Fort Campbell, Post Wide, Fort Campbell, KY.

Reception Service Support, Employment Source Program Office, 600 Ames Street, Fayetteville, NC.

Reception Service Support, Fort Bragg, Post Wide, Fort Bragg, NC.

NPA: Employment Source, Inc., Fayetteville, NC.

Contracting Activity: DEPT OF THE ARMY, XR W6BB FT BRAGG.

Barry S. Lineback,

Acting Director, Program Operations.

[FR Doc. E8–26597 Filed 11–6–08; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Proposed Information Collection; Comment Request; Application for Investment Assistance

AGENCY: Economic Development Administration.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before January 6, 2009.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov.*)

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Maureen Klovers, Program Analyst, (p) 202–482–2785, (f) 202–482–2838, *mklovers@eda.doc.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Economic Development Administration's (EDA) mission is to lead the federal economic development agenda by promoting innovation and competitiveness, and preparing American regions for growth and success in the worldwide economy. This information collection is necessary to determine the applicant's eligibility for investment assistance under EDA's authorizing statute, the Public Works and Economic Development Act of 1965, as amended (42 U.S.C. 3121 *et seq.*), and regulations (13 CFR Chapter III). The information collection also determines the quality of the proposed scope of work to address the pressing economic distress of the region in which the proposed project will be located, the merits of the activities for which the investment assistance is requested, and the ability of the eligible applicant to carry out the proposed activities successfully.

Form ED–900 is used to collect the necessary information. This form was approved for use by the Office of Management and Budget (OMB) on February 15, 2008, and was made available for use by the public on October 1, 2008. It replaced EDA's previous suite of application materials: (i) The *Pre-Application for Investment Assistance* (Form ED–900P), (ii) the *Application for Investment Assistance* (Form ED–900A), and (iii) all program-specific components required to complete the ED–900A. EDA continues to require additional government-wide federal grant assistance forms from the Standard Form 424 family and certain Department of Commerce forms as part of the application package.

EDA believes the new ED–900 has significantly reduced the paperwork burden on applicants and government personnel. The introduction of this form is expected to reduce applicant burden from a combined 46 hours to complete the aforementioned documents to 22 hours for the Form ED–900. In addition, because Form ED–900 consolidated all EDA requirements into a single application, it facilitates electronic application submission through *http://www.grants.gov.*

II. Method of Collection

EDA will accept hardcopy submissions or electronic submissions through *http://www.grants.gov.*

III. Data

OMB Control Number: 0610–0094.

Form Number(s): ED–900.

Type of Review: Regular submission.

Affected Public: Individuals or households; business or other for-profit organizations; not-for-profit institutions; State, local, or tribal governments; Economic Development District Organizations.

Estimated Number of Respondents: 875.

Estimated Time per Response: 22 hours.

Estimated Total Annual Burden Hours: 18,953.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 3, 2008.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E8–26557 Filed 11–6–08; 8:45 am]

BILLING CODE 3510–34–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials Technical Advisory Committee; Notice of Partially Closed Meeting; Date Correction

The Materials Technical Advisory Committee will meet on November 20, 2008, 10 a.m., Herbert C. Hoover Building, Room 3884, 14th Street between Constitution & Pennsylvania

Avenues, NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials and related technology.

Agenda

Open Session

1. Opening Remarks and Introduction.
2. Update on recent proposed License Exception Intra-Company Transfer rule published October 3, 2008 and October 27, 2008, public meetings.
3. Report on Inaugural ETRAC (Emerging Technology and Research Advisory Committee).
4. Recap of Update 2008 and reminder of Mandatory use of SNAP–R for license submittal.
5. Report of Composite Working group and ECCN review subgroup.
6. Public comments from teleconference and physical attendees.
7. Election of new MTAC Chairman and any other business.

Closed Session

8. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 section 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yspringer@bis.doc.gov* no later than November 13, 2008.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the materials should be forwarded prior to the meeting to Ms. Springer via e-mail.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on July 17, 2008, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended, that the portion of the meeting dealing with matters the premature disclosure of which would likely frustrate the implementation of a proposed agency action as described in 5 U.S.C. 552b(c)(9)(B) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 section 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482–2813.

Dated: November 3, 2008.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. E8–26622 Filed 11–6–08; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

(A–489–807)

Certain Steel Concrete Reinforcing Bars From Turkey; Notice of Extension of Time Limits for Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: November 7, 2008.

FOR FURTHER INFORMATION CONTACT: Elizabeth Eastwood, AD/CVD Operations, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–3874.

SUPPLEMENTARY INFORMATION:

Background

On June 4, 2008, the Department of Commerce (the Department) published a notice of initiation of administrative review of the antidumping duty order on certain steel concrete reinforcing bars (rebar) from Turkey. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part*, 73 FR 31813 (June 4, 2008). The period of review is April 1, 2007, through March 31, 2008, and the preliminary results are currently due no later than December 31, 2008. The review covers seven producers/exporters of the subject merchandise to the United States.

Extension of Time Limit for Preliminary Results

Pursuant to section 751(a)(3)(A) of Tariff Act of 1930, as amended (the Act), the Department shall make a preliminary determination in an administrative review of an antidumping order within 245 days after the last day of the anniversary month of the date of publication of the order. Section 751(a)(3)(A) of the Act further provides, however, that the Department may extend the 245-day period to 365 days if it determines it is not practicable to complete the review within the foregoing time period. We determine that it is not practicable to complete this administrative review within the time limits mandated by section 751(a)(3)(A) of the Act. Although the Department has received the initial questionnaire responses from most of the respondents, upon review of the questionnaire responses, the Department believes it needs to issue supplemental questionnaires to clarify responses on the record. Preparing these supplemental questionnaires and analyzing the respondents' responses requires additional time. Therefore, we have fully extended the deadline for completing the preliminary results until April 30, 2009. The deadline for the final results of the review continues to be 120 days after the publication of the preliminary results.

This extension notice is published in accordance with sections 751(a)(3)(A) and 777(i) of the Act.

Dated: November 3, 2008.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E8–26624 Filed 11–6–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–807]

Certain Steel Concrete Reinforcing Bars From Turkey; Final Results of Antidumping Duty Administrative Review and Determination To Revoke in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On May 5, 2008, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on certain steel concrete reinforcing bars (rebar) from Turkey. This review covers four producers/exporters of the subject merchandise to the United States. The period of review (POR) is April 1, 2006, through March 31, 2007.

Based on our analysis of the comments received and on our verification findings, we have made certain changes in the margin calculations. Therefore, the final results differ from the preliminary results. The final weighted-average dumping margins for the reviewed firms are listed below in the section entitled ''Final Results of Review.''

Finally, we have determined to revoke the antidumping duty order with

respect to Turkish rebar produced and exported by Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S. (Habas).

DATES: *Effective Date:* November 7, 2008.

FOR FURTHER INFORMATION CONTACT: Elizabeth Eastwood, AD/CVD Operations, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC, 20230; telephone (202) 482–3874.

SUPPLEMENTARY INFORMATION:

Background

The administrative review covers the following four producers/exporters: Ekinciler Demir ve Celik Sanayi A.S./ Ekinciler Dis Ticaret A.S. (Ekinciler); Habas; Izmir Demir Celik Sanayi A.S. (IDC); and Nursan Celik Sanayi ve Haddecilik, A.S./Nursan Dis Ticaret A.S (Nursan).

On May 5, 2008, the Department published in the **Federal Register** the preliminary results of the 2006–2007 administrative review of the antidumping duty order on rebar from Turkey. *See Certain Steel Concrete Reinforcing Bars from Turkey; Preliminary Results of Antidumping Duty Administrative Review and Notice of Intent to Revoke in Part,* 73 FR 24535 (May 5, 2008) (*Preliminary Results*). Also in May 2008, the Department verified the sales responses of Ekinciler and Habas.

We invited parties to comment on our preliminary results. In July 2008, we received case and rebuttal briefs from the domestic industry, Ekinciler, and Habas. The Department convened a hearing in this review on August 26, 2008.

The Department has conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The product covered by this order is all stock deformed steel concrete reinforcing bars sold in straight lengths and coils. This includes all hot-rolled deformed rebar rolled from billet steel, rail steel, axle steel, or low-alloy steel. It excludes (i) plain round rebar, (ii) rebar that a processor has further worked or fabricated, and (iii) all coated rebar. Deformed rebar is currently classifiable under subheadings 7213.10.000 and 7214.20.000 of the *Harmonized Tariff Schedule of the United States* (HTSUS). The HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of this order is dispositive.

Period of Review

The POR is April 1, 2006, through March 31, 2007.

Determination To Revoke Order, in Part

The Department may revoke, in whole or in part, an antidumping duty order upon completion of a review under section 751 of the Act. While Congress has not specified the procedures that the Department must follow in revoking an order, the Department has developed a procedure for revocation that is described in 19 CFR 351.222. This regulation requires, *inter alia,* that a company requesting revocation must submit the following: (1) A certification that the company has sold the subject merchandise at not less than normal value (NV) in the current review period and that the company will not sell subject merchandise at less than NV in the future; (2) a certification that the company sold commercial quantities of the subject merchandise to the United States in each of the three years forming the basis of the request; and (3) an agreement to immediate reinstatement of the order if the Department concludes that the company, subsequent to the revocation, sold subject merchandise at less than NV. *See* 19 CFR 351.222(e)(1). Upon receipt of such a request, the Department will consider: (1) Whether the company in question has sold subject merchandise at not less than NV for a period of at least three consecutive years; (2) whether the company has agreed in writing to its immediate reinstatement in the order, as long as any exporter or producer is subject to the order, if the Department concludes that the company, subsequent to the revocation, sold the subject merchandise at less than NV; and (3) whether the continued application of the antidumping duty order is otherwise necessary to offset dumping. *See* 19 CFR 351.222(b)(2)(i).

On April 27 and 30, 2007, respectively, Ekinciler and Habas requested revocation of the antidumping duty order with respect to their sales of subject merchandise, pursuant to 19 CFR 351.222(b). These requests were accompanied by certifications that: (1) Ekinciler and Habas sold the subject merchandise at not less than NV during the current POR and will not sell the merchandise at less than NV in the future; and (2) they sold subject merchandise to the United States in commercial quantities for a period of at least three consecutive years. Ekinciler and Habas also agreed to immediate reinstatement of the antidumping duty order, as long as any exporter or producer is subject to the order, if the Department concludes that, subsequent to the revocation, they sold the subject merchandise at less than NV. Our analysis of each company's revocation request is presented below.

1. Ekinciler

Regarding Ekinciler, we do not find that its request for revocation meets all of the criteria under 19 CFR 351.222(b). Specifically, we find that Ekinciler has sold rebar at less than NV in the two previous administrative reviews in which it was involved (*i.e.*, its dumping margins were above *de minimis*). *See Certain Steel Concrete Reinforcing Bars From Turkey; Final Results of Antidumping Duty Administrative Review and New Shipper Review and Determination to Revoke in Part,* 72 FR 62630 (Nov. 6, 2007) (*2005–2006 Final Results*) and *Certain Steel Concrete Reinforcing Bars From Turkey; Final Results and Rescission of Antidumping Duty Administrative Review in Part,* 71 FR 65082 (Nov. 7, 2006) (*2004–2005 Final Results*), unchanged in *Notice of Amended Final Results and Rescission of Antidumping Duty Administrative Review in Part: Certain Steel Concrete Reinforcing Bars From Turkey,* 71 FR 75711 (Dec. 18, 2006) (*2004–2005 Amended Final Results*).

Ekinciler contends that it is entitled to revocation in this segment of the proceeding, based on its claim that it anticipates that it will receive a zero or *de minimis* margin for the prior reviews, following completion of the court's review of Ekinciler's appeal of the final results. However, it is not the Department's policy to take pending court appeals into account when determining whether revocation of the merchandise produced and exported by a particular company from an existing antidumping duty order is warranted. *See, e.g., Certain Fresh Cut Flowers From Colombia; Final Results of Antidumping Duty Administrative Review, and Notice of Revocation (in Part),* 59 FR 15159, 15166 (Mar. 31, 1994); *Color Television Receivers from the Republic of Korea; Final Results of Antidumping Duty Administrative Reviews,* 61 FR 4408, 4414 (Feb. 6, 1996). While we acknowledge that the Department's determinations in the two prior segments of this proceeding are currently in litigation, there is no final and conclusive judgment from any court supporting Ekinciler's arguments. In fact, the Court of International Trade (CIT) affirmed the Department's analysis in the 2004–2005 review which resulted in a dumping margin above *de minimis*

for Ekinciler. *See Ekinciler Demir* v. *United States,* 32 Slip Op. 2008–34 (CIT, March 20, 2008) (currently on appeal). The CIT's decision in that case supports our conclusion that Ekinciler continued to dump subject merchandise during the last three years, and Ekinciler has provided no information on the record to undermine that conclusion. Therefore, we determine that Ekinciler does not qualify for revocation of the order on rebar pursuant to 19 CFR 351.222(b)(2), and that the order with respect to merchandise produced and exported by Ekinciler should not be revoked.

2. Habas

We have determined that the request from Habas meets all of the criteria under 19 CFR 351.222. With regard to the criteria of subsection 19 CFR 351.222(b)(2), our final margin calculations show that Habas sold rebar at not less than NV during the current review period. In addition, Habas sold rebar at not less than NV in the two previous administrative reviews in which it was involved (*i.e.*, its dumping margins were zero or *de minimis*). *See 2005–2006 Final Results,* and *2004–2005 Final Results,* unchanged in *2004–2005 Amended Final Results.*

Based on our examination of the sales data submitted by Habas, we determine that it sold the subject merchandise in the United States in commercial quantities in each of the consecutive years cited by it to support its request for revocation. *See* the April 29, 2008, Memorandum to the File from Irina Itkin entitled, ''Analysis of Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S.'s Commercial Quantities for Request for Revocation.'' Thus, we find that Habas had zero or *de minimis* dumping margins for its last three administrative reviews and sold subject merchandise in commercial quantities in each of these years. Also, we find that application of the antidumping duty order to Habas is no longer warranted for the following reasons: (1) Habas had zero or *de minimis* margins for a period of at least three consecutive years; (2) Habas has agreed to immediate reinstatement of the order if the Department finds that it has resumed making sales at less than NV; and (3) the continued application of the order is not otherwise necessary to offset dumping. Therefore, we find that Habas qualifies for revocation of the antidumping duty order on rebar under 19 CFR 351.222(b)(2). Accordingly, we are revoking the order with respect to subject merchandise produced and exported by Habas. For further discussion, see the Issues and Decision Memorandum (the Decision Memo) at Comment 1.

Effective Date of Revocation

The revocation of Habas applies to all entries of subject merchandise that are produced and exported by Habas, and are entered, or withdrawn from warehouse, for consumption on or after April 1, 2007. The Department will order the suspension of liquidation ended for all such entries and will instruct U.S. Customer and Border Protection (CBP) to release any cash deposits or bonds. The Department will further instruct CBP to refund with interest any cash deposits on entries made on or after April 1, 2007.

Cost of Production

As discussed in the *Preliminary Results,* we conducted an investigation to determine whether Ekinciler and Habas made home market sales of the foreign like product during the POR at prices below their costs of production (COP) within the meaning of section 773(b)(1) of the Act. We performed the cost test for these final results following the same methodology as in the *Preliminary Results,* except as discussed in the Decision Memo. We found 20 percent or more of each respondent's sales of a given product during the reporting period were at prices less than the weighted average COP for this period. Thus, we determined that these below-cost sales were made in ''substantial quantities'' within an extended period of time and at prices which did not permit the recovery of all costs within a reasonable period of time in the normal course of trade. *See* sections 773(b)(2)(B)–(D) of the Act.

Therefore, for purposes of these final results, we found that Ekinciler and Habas made below-cost sales not in the ordinary course of trade. Consequently, we disregarded these sales for each respondent and used the remaining sales as the basis for determining NV pursuant to section 773(b)(1) of the Act.

Analysis of Comments Received

The issues raised in the case briefs by parties to this administrative review, and to which we have responded, are listed in the Appendix to this notice and addressed in the Decision Memo, which is adopted by this notice. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum, which is on file in the Central Records Unit, room 1117, of the main Department building.

In addition, a complete version of the Decision Memo can be accessed directly on the Web at *http://ia.ita.doc.gov/frn/*. The paper copy and electronic version of the Decision Memo are identical in content.

Changes Since the Preliminary Results

Based on our analysis findings at verification, we have made certain changes in the margin calculations. Specifically, we based our margin calculations for both respondents on sales databases submitted at our request after verification, and we revised the 2005/2006 depreciation expense calculation for Ekinciler related to certain capitalized assets. These changes are discussed in detail in the relevant sections of the Decision Memo.

Final Results of Review

We determine that the following weighted-average margin percentages exist for the period April 1, 2006, through March 31, 2007:

Manufacturer/Producer/Exporter	Margin percentage
Ekinciler Demir ve Celik Sanayi A.S./Ekinciler Dis Ticaret A.S	2.75
Habas Sinai ve Tibbi Gazlar Istithsal Endustrisi A.S	0.00

Review-Specific Average Rate Applicable to the Following Companies:

Manufacturer/Producer/Exporter	Margin percentage
Izmir Demir Celik Sanayi A.S ...	2.75
Nursan Celik Sanayi ve Haddecilik, A.S./Nursan Dis Ticaret A.S	2.75

Assessment

The Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries. Pursuant to 19 CFR 351.212(b)(1), for all sales made by Ekinciler, because we have the reported entered value of the U.S. sales, we have calculated importer-specific assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of those sales.

For the companies which were not selected for individual review, we have calculated an assessment rate based on the weighted average of the cash deposit rates calculated for the companies selected for individual review excluding any which are *de minimis* or determined entirely on AFA.

Pursuant to 19 CFR 351.106(c)(2), we will instruct CBP to liquidate without regard to antidumping duties any entries for which the assessment rate is *de minimis* (*i.e.*, less than 0.50 percent). The Department intends to issue

assessment instructions to CBP 15 days after the date of publication of these final results of review.

Because we have revoked the order with respect to subject merchandise produced and exported by Habas, we will instruct CBP to terminate the suspension of liquidation for exports of such merchandise entered, or withdrawn from warehouse, for consumption on or after April 1, 2007, and to refund all cash deposits collected.

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003). This clarification will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know their merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

Cash Deposit Requirements

Further, the following deposit requirements will be effective for all shipments of rebar from Turkey (except shipments from Habas, as noted above) entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rates for the reviewed companies will be the rates shown above, except if the rate is less than 0.50 percent, *de minimis* within the meaning of 19 CFR 351.106(c)(1), the cash deposit will be zero; (2) for previously investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, or the less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 16.06 percent, the all-others rate established in the LTFV investigation. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility, under 19 CFR 351.402(f)(2), to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing these results of review in accordance with sections 751(a)(1), 751(d) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: November 3, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

Appendix—Issues in Decision Memorandum

Company-Specific Issues

1. Unreported Home Market Sales for Habas.
2. Cost Calculation Period for Ekinciler.
3. Depreciation Expenses for Ekinciler.

[FR Doc. E8–26623 Filed 11–6–08; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–863]

Sixth Administrative Review of Honey From the People's Republic of China: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''Department'') is conducting an administrative review of the antidumping duty order on honey from the People's Republic of China (''PRC''), covering the period of review (''POR'') of December 1, 2006, through November 30, 2007. As discussed below, we preliminarily determine that certain respondents in this review made sales in the United States at prices below normal value (''NV''). If these preliminary results are adopted in our final results of review, we will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on entries of subject merchandise during the POR for which importer-specific assessment rates are above *de minimis*.

DATES: *Effective Date:* November 7, 2008.

FOR FURTHER INFORMATION CONTACT: Paul Walker, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–0413.

SUPPLEMENTARY INFORMATION:

Background

On November 30, 2006, we received requests from both Petitioners [1] and certain PRC companies to conduct administrative reviews for a total of 32 companies.[2] On January 28, 2008, the Department initiated an administrative review of these 32 producers/exporters of subject merchandise from the PRC. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 73 FR 4829 (January 28, 2008) (''Initiation'').

[1] The petitioners are the members of the American Honey Producers Association and the Sioux Honey Association (hereinafter referred to as ''Petitioners'').

[2] Alfred L. Wolff (Beijing) Co., Ltd., Anhui Honghui Foodstuff (Group) Co., Ltd., Anhui Native Produce Imp & Exp Corp. (''Anhui Native''), Cheng Du Wai Yuan Bee Products Co., Ltd. (''Cheng Du Wai''), Chengdu Stone Dynasty Art Stone, Dongtai Peak Honey Industry Co., Ltd. (''Dongtai Peak''), Eurasia Bee's Products Co., Ltd., Golden Tadco Int'l., Hangzhou Golden Harvest Health Industry Co., Ltd., Hanseatische Nahrungsmittel Fabrik R Import-Export GMBH, Haoliluck Co., Ltd., Hubei Yusun Co., Ltd., Inner Mongolia Altin Bee-Keeping, Inner Mongolia Youth Trade Development Co., Ltd. (''IMY''), Jiangsu Kanghong Natural Healthfoods Co., Ltd., Jiangsu Light Industry Products Imp & Exp (Group) Corp., Mgl Yung Sheng Honey Co., Ltd. (also DBA Fresh Honey Co., Ltd.), Nefelon Limited Company, OEI International Inc., Qingdao Aolan Trade Co., Ltd., QHD Sanhai Honey Co., Ltd., Qinhuangdao Municipal Dafeng Industrial Co., Ltd., Shanghai Bloom International Trading Co., Ltd., Shanghai Foreign Trade Co., Ltd., Shanghai Hui Ai Mal Tose Co., Ltd., Shanghai Taiside Trading Co., Ltd., Sichuan-Dujiangyan Dubao Bee Industrial Co., Ltd., Tianjin Eulia Honey Co., Ltd., Wuhan Bee Healthy Co., Ltd., Wuhan Shino-Food Trade Co., Ltd., Wuhu Qinshi Tangye Co., Ltd. (''Tangye'') and Xinjiang Jinhui Food Co., Ltd.

Respondent Selection

On April 2, 2008, in accordance with section 777A(c)(2) of the Tariff Act of 1930, as amended (''Act''), the Department selected Cheng Du Wai and Anhui Native as mandatory respondents in this review, since they were the two largest exporters by volume during the POR, based on CBP data of U.S. imports under Harmonized Tariff Schedule of the United States (''HTSUS'') subheadings 0409.00.00, 1702.90.90 and 2106.90.99. *See* Memorandum to James Doyle, Director, Office 9, from Toni Dach, International Trade Analyst, Office 9, ''Antidumping Administrative Review of Honey from the People's Republic of China: Respondent Selection Memorandum,'' dated April 2, 2008. On April 11, 2008, the Department issued antidumping duty questionnaires to Cheng Du Wai and Anhui Native, and provided a courtesy copy of the questionnaire to Dongtai Peak.

On May 5, 2008, the Department issued a second questionnaire to Cheng Du Wai because it did not respond to the Department's initial antidumping duty questionnaire. Cheng Du Wai did not respond to the second questionnaire.

Between April 30, 2008, and May 16, 2008, Dongtai Peak submitted voluntary responses to the Department's questionnaire. Between May 9, 2008 and October 4, 2008, Anhui Native responded to the Department's questionnaire and subsequent supplemental questionnaires. On May 28, 2008, the Department placed on the record a ''no shipments'' letter from Tangye.

Because Cheng Du Wai did not respond to the Department's initial or second questionnaire, on June 10, 2008, the Department selected IMY, the third largest exporter, according to CBP data, as an additional mandatory respondent. See Memorandum to James Doyle, Director, Office 9, from Paul Walker, Senior Case Analyst, Office 9, ''Honey from the People's Republic of China: Selection of Additional Mandatory Respondent,'' dated June 10, 2008. Additionally, on June 10, 2008, the Department sent IMY an initial antidumping duty questionnaire. On July 3, 2008, the Department issued a second questionnaire to IMY because it did not respond to the Department's initial antidumping duty questionnaire. IMY did not respond to the second questionnaire.

Separate Rates

On April 23, 2008, the Department sent separate rate applications and separate rate certifications to the 29 companies (including IMY) which did not receive an antidumping duty questionnaire.[3] No company submitted a separate rate application or certification. On May 15, 2008, the Department issued a second separate rate application and certification to the 29 companies that did not respond to the Department's initial separate rate application and certification. No company responded to this second opportunity to submit a separate rate application or certification.

Rescission of Reviews

On June 10, 2008, Petitioners withdrew their request for review for 21 companies. On June 25, 2008, in accordance with section 351.213(d)(1) of the Department's regulations, we rescinded the administrative review with respect to these 21 companies. *See Sixth Administrative Review of Honey From the People's Republic of China: Notice of Partial Rescission of Antidumping Duty Administrative Review,* 73 FR 36040 (June 25, 2008). Therefore, this review covers 11 producers/exporters[4] of the subject merchandise and the PRC-wide entity.

Surrogate Country and Surrogate Values

On June 7, 2007, the Department sent interested parties a letter requesting comments on the surrogate country and information pertaining to valuing factors of production (''FOPs''). On October 16, 2008, Petitioners submitted surrogate value comments from various Indian sources. No other interested party submitted comments on the surrogate country and information pertaining to valuing FOPs.

Case Schedule

On August 11, 2008, in accordance with section 751(a)(3)(A) of the Act, we extended the time period for issuing the preliminary results by 75 days, until November 15, 2008.[5] *See Sixth Administrative Review of Honey from the People's Republic of China: Extension of Time Limit for the Preliminary Results,* 73 FR 46588 (August 11, 2008). On October 10, 2008, the Department informed interested parties that it intends to issue the preliminary results of the instant review no later than October 31, 2008.

Partial Recission of Review

Dongtai Peak

As discussed in the **SUPPLEMENTARY INFORMATION** section above, between April 30, 2008, and May 16, 2008, Dongtai Peak submitted voluntary responses to the Department's antidumping duty questionnaire. In Dongtai Peak's questionnaire responses, Dongtai Peak requested that the Department calculate an individual weighted-average dumping margin for Dongtai Peak as a voluntary respondent, pursuant to section 782(a) of the Act, arguing that the Department has the resources and time to review Dongtai Peak as a voluntary respondent due to Cheng Du Wai's lack of participation in this proceeding.

For these preliminary results, the Department has rescinded the review with respect to Dongtai Peak. While Dongtai Peak is correct that the Department can choose to review a voluntary respondent, 19 CFR 351.213(d)(3) provides that the Department may rescind an administrative review, ''with respect to a particular exporter or producer, if the Secretary concludes that, during the period covered by the review, there were no entries, exports, or sales of the subject merchandise, as the case may be.'' We examined CBP entry data for Dongtai Peak, and Dongtai Peak's voluntary submissions, and are satisfied that the record indicates that there were no U.S. entries of subject merchandise from Dongtai Peak during the POR. Accordingly, following the Department's practice, we are preliminarily rescinding this review with respect to Dongtai Peak. *See, e.g., Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Notice of Preliminary Results and Partial Rescission of the Third Antidumping Duty Administrative Review,* 72 FR 53527, 53530 (September 19, 2007), unchanged in *Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review and Partial*

[3] We note that the Department's initial antidumping duty questionnaire contained a request for separate rate information. Thus, because Anhui Native, Cheng Du Wai and Dongtai Peak had already received the Department's initial antidumping duty questionnaire, we did not send these companies a separate rate application and separate rate certification. Moreover, because IMY had not yet been selected as a mandatory respondent as of April 23, 2008, it received a separate rate application and certification.

[4] Alfred L. Wolff (Beijing) Co., Ltd., Anhui Native, Cheng Du Wai, Dongtai Peak, Haoliluck Co., Ltd., Hubei Yusun Co., Ltd., IMY, Mgl. Yung Sheng Honey Co., Ltd. (also DBA Fresh Honey Co., Ltd.), Nefelon Limited Company, Qinhuangdao Municipal Dafeng Industrial Co., Ltd. and Tangye. Of these 11 producer/exporters, Anhui Native, Cheng Du Wai and IMY were selected as mandatory respondents, as discussed above.

[5] We note that because November 15, 2008, falls on a weekend, the actual date is the first business day following the weekend, November 17, 2008.

Rescission, 73 FR 15479, 15480 (March 24, 2008) (collectively, ''*Fish Fillets*'').

Tangye

In addition, for these preliminary results, the Department has rescinded the review with respect to Tangye. As discussed in the **SUPPLEMENTARY INFORMATION** section above, on May 28, 2008, the Department placed on the record a no shipments letter from Tangye. We examined CBP entry data for Tangye and are satisfied that the record indicates that there were no U.S. entries of subject merchandise from Tangye during the POR. Accordingly, following the Department's practice, we are preliminarily rescinding this review with respect to Tangye. *See, e.g., Fish Fillets.*

Scope of the Order

The products covered by this order are natural honey, artificial honey containing more than 50 percent natural honey by weight, preparations of natural honey containing more than 50 percent natural honey by weight and flavored honey. The subject merchandise includes all grades and colors of honey whether in liquid, creamed, comb, cut comb, or chunk form, and whether packaged for retail or in bulk form.

The merchandise subject to this order is currently classifiable under subheadings 0409.00.00, 1702.90.90 and 2106.90.99 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the Department's written description of the merchandise under order is dispositive.

Facts Available

Section 776(a)(2) of the Act, provides that, if an interested party: (A) Withholds information that has been requested by the Department; (B) fails to provide such information in a timely manner or in the form or manner requested subject to sections 782(c)(1) and (e) of the Act; (C) significantly impedes a proceeding under the antidumping statute; or (D) provides such information but the information cannot be verified, the Department shall, subject to subsection 782(d) of the Act, use facts otherwise available in reaching the applicable determination.

Section 782(c)(1) of the Act provides that if an interested party ''promptly after receiving a request from {the Department} for information, notifies {the Department} that such party is unable to submit the information requested in the requested form and manner, together with a full explanation and suggested alternative forms in which such party is able to submit the information,'' the Department may modify the requirements to avoid imposing an unreasonable burden on that party.

Section 782(d) of the Act provides that, if the Department determines that a response to a request for information does not comply with the request, the Department will inform the person submitting the response of the nature of the deficiency and shall, to the extent practicable, provide that person the opportunity to remedy or explain the deficiency. If that person submits further information that continues to be unsatisfactory, or this information is not submitted within the applicable time limits, the Department may, subject to section 782(e) of the Act, disregard all or part of the original and subsequent responses, as appropriate.

Section 782(e) of the Act states that the Department shall not decline to consider information deemed ''deficient'' under section 782(d) if: (1) The information is submitted by the established deadline; (2) the information can be verified; (3) the information is not so incomplete that it cannot serve as a reliable basis for reaching the applicable determination; (4) the interested party has demonstrated that it acted to the best of its ability in providing the information and meeting the requirements established by the Department; and (5) the information can be used without undue difficulties.

Furthermore, section 776(b) of the Act states that if the Department ''finds that an interested party has failed to cooperate by not acting to the best of its ability to comply with a request for information from the administering authority or the Commission, the administering authority or the Commission * * *, in reaching the applicable determination under this title, may use an inference that is adverse to the interests of that party in selecting from among the facts otherwise available.'' *See also* Statement of Administrative Action accompanying the Uruguay Round Agreements Act, H.R. Rep. No. 103–316 at 870 (1994). Adverse inferences are appropriate ''to ensure that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully.'' *Id.* An adverse inference may include reliance on information derived from the petition, the final determination in the investigation, any previous review, or any other information placed on the record. *See* section 776(b) of the Act.

Anhui Native

In its questionnaire responses, Anhui Native stated that it incurred Customs duties and antidumping duties. It is the Department's practice to exclude antidumping duties from the margin calculation. *See, e.g., Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results and Partial Rescission of New Shipper Reviews,* 73 FR 36840 (June 30, 2008). Thus, Anhui Native should have only reported non-antidumping Customs duties in its section C database. However, a careful review of the CBP form 7501s submitted by Anhui Native shows that Anhui Native reported the antidumping duty in its section C database.

For these preliminary results, in accordance with section 776(a)(2)(B) of the Act and 782(c)(1) of the Act, we have determined that the use of neutral facts available is appropriate for Anhui Native's Customs duties. As neutral facts available, we are applying the average of Anhui Native's reported Customs duties, as found in its CBP form 7501s, and applying this average to the applicable deduction from Anhui Native's reported U.S. price. However, the Department intends to provide Anhui Native an opportunity to submit the correct data after the preliminary results, in accordance with section 782(d) of the Act. In addition, because Anhui Native's Customs duties and U.S. price are proprietary, see the Anhui Native Analysis Memo for further details. *See* Memorandum to the File, through Scot Fullerton, Program Manager, Office 9, from Paul Walker, Senior Analyst, Office 9, ''Administrative Review of Honey from the People's Republic of China: Company Analysis Memorandum for Anhui Native Produce Import & Export Corp.,'' dated concurrently with this notice (''Anhui Native Analysis Memo'').

Cheng Du Wai and IMY

As discussed in the ''Supplementary Information'' section above, Cheng Du Wai and IMY did not respond to the initial antidumping duty questionnaires issued by the Department on April 11, 2008, and June 10, 2008, respectively. Additionally, the Department issued letters to Cheng Du Wai and IMY on May 5, 2008, and July 3, 2008, respectively, and confirmed delivery for both letters. In both letters, the Department noted that responses to its questionnaires were past due and requested that each company notify the Department as to whether it intended to participate further in this administrative review. Cheng Du Wai and IMY did not respond to either of these letters. Therefore, the Department finds that Cheng Du Wai and IMY did not cooperate to the best of their abilities, and their non-responsiveness

necessitates the use of facts available, pursuant to sections 776(a)(2)(A), (B) and (C) of the Act.

Based upon Cheng Du Wai's and IMY's failure to submit responses to the Department's questionnaires and follow-up letters, the Department finds that Cheng Du Wai and IMY withheld requested information, failed to provide the information in a timely manner and in the form requested, and significantly impeded this proceeding, pursuant to sections 776(a)(2)(A), (B) and (C) of the Act. Further, because Cheng Du Wai and IMY failed to demonstrate that they qualify for separate rate status, we consider both entities part of the PRC-wide entity. Thus, we find that the PRC-wide entity, including Cheng Du Wai and IMY, withheld requested information, failed to provide information in a timely manner and in the form requested, and significantly impeded this proceeding. Therefore, the Department must rely on the facts otherwise available in order to determine a margin for the PRC-wide entity, pursuant to section 776(a)(2)(A), (B) and (C) of the Act. *See Non-Malleable Cast Iron Pipe Fittings from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 71 FR 69546 (December 1, 2006) and accompanying Issues and Decision Memorandum at Comment 1.

PRC-Wide Entity

Because Cheng Du Wai and IMY, which are part of the PRC-wide entity, failed to cooperate to the best of their ability in providing the requested information, as discussed above, we find it appropriate, in accordance with sections 776(a)(2)(A), (B) and (C), as well as section 776(b), of the Act, to assign total adverse facts available (''AFA'') to the PRC-wide entity. *See Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Preliminary Results of the First Administrative Review and New Shipper Review,* 72 FR 10689, 10692 (March 9, 2007) (decision to apply total AFA to the NME-wide entity unchanged in *Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results of the First Antidumping Duty Administrative Review and First New Shipper Review,* 72 FR 52052 (September 12, 2007)). By doing so, we ensure that the companies that are part of the PRC-wide entity will not obtain a more favorable result by failing to cooperate than had they cooperated fully in this review.

As discussed above, section 776(b) of the Act authorizes the Department to use, as AFA, information derived from the petition, the final determination in the less-than-fair-value (''LTFV'') investigation, any previous administrative review, or any other information placed on the record. In selecting an AFA rate, the Department's practice has been to assign non-cooperative respondents the highest margin determined for any party in the LTFV investigation or in any administrative review. *See Certain Steel Nails from the People's Republic of China: Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances,* 73 FR 33977 (June 16, 2008). As AFA, we are assigning the PRC-wide entity, which includes Cheng Du Wai and IMY, the highest rate from any segment of this proceeding, which in this case is $2.65 per kilogram, as established in this administrative review. See Anhui Native Analysis Memo. Corroboration of this rate is not required because this rate is based on, and calculated from, information submitted by Anhui Native in the course of this administrative review, *i.e.*, it is not secondary information. *See* 19 CFR 351.308(c) and (d) and section 776(c) of the Act.

NME Country Status

In every case conducted by the Department involving the PRC, the PRC has been treated as an NME country. In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. *See Brake Rotors From the People's Republic of China: Final Results and Partial Rescission of the 2004/2005 Administrative Review and Notice of Rescission of 2004/2005 New Shipper Review,* 71 FR 66304 (November 14, 2006). None of the parties to this proceeding has contested such treatment. Accordingly, we calculated NV in accordance with section 773(c) of the Act, which applies to NME countries.

Separate Rate Determination

A designation as an NME remains in effect until it is revoked by the Department. *See* section 771(18)(C) of the Act. Accordingly, there is a rebuttable presumption that all companies within the PRC are subject to government control and, thus, should be assessed a single antidumping duty rate. *See Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products From the People's Republic of China,* 71 FR 53079 (September 8, 2006); *Final Determination of Sales at Less Than Fair Value and Final Partial Affirmative Determination of Critical Circumstances: Diamond Sawblades and Parts Thereof from the People's Republic of China,* 71 FR 29303 (May 22, 2006).

It is the Department's standard policy to assign all exporters of the merchandise subject to review in NME countries a single rate unless an exporter can affirmatively demonstrate an absence of government control, both in law (*de jure*) and in fact (*de facto*), with respect to exports. To establish whether a company is sufficiently independent to be entitled to a separate, company-specific rate, the Department analyzes each exporting entity in an NME country under the test established in *Notice of Final Determination of Sales at Less than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588 (May 6, 1991) (''*Sparklers*''), as amplified by *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585 (May 2, 1994) (''*Silicon Carbide*'').

Absence of *De Jure* Control

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) any other formal measures by the government decentralizing control of companies. *See Sparklers,* 56 FR at 20589.

Throughout the course of this administrative review, only Anhui Native has placed sufficient evidence on the record that demonstrate an absence of *de jure* control. *See* Anhui Native's submission of May 9, 2008 at 2–8 and Exhibit 2; *see also* Anhui Native's submission of July 3, 2008 at 2–7 and Exhibit 2. Additionally, Anhui Native has placed on the record a number of documents to demonstrate an absence of *de jure* control including the ''Foreign Trade Law of the People's Republic of China'' and the ''Company Law of the People's Republic of China.'' The Department has analyzed such PRC laws and has found that they establish an absence of *de jure* control. *See Preliminary Results of New Shipper Review: Certain Preserved Mushrooms From the People's Republic of China,* 66 FR 30695, 30696 (June 7, 2001). We have no information in this proceeding that would cause us to reconsider this determination. Thus, we find that the evidence on the record supports a

preliminary finding of an absence of *de jure* government control based on: (1) An absence of restrictive stipulations associated with the exporter's business license; (2) the legal authority on the record decentralizing control over the respondent, as demonstrated by the PRC laws placed on the record of this review; and (3) other formal measures by the government decentralizing control of companies.

Absence of *De Facto* Control

As stated in previous cases, there is some evidence that certain enactments of the PRC central government have not been implemented uniformly among different sectors and/or jurisdictions in the PRC. *See Notice of Final Determination of Sales at Less Than Fair Value: Certain Preserved Mushrooms from the People's Republic of China,* 63 FR 72255 (December 31, 1998). Therefore, the Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of government control which would preclude the Department from assigning separate rates. The Department typically considers four factors in evaluating whether each respondent is subject to *de facto* government control of its export functions: (1) Whether the exporter sets its own export prices independent of the government and without the approval of a government authority; (2) whether the respondent has the authority to negotiate and sign contracts, and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of its management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses. *See Silicon Carbide,* 59 FR at 22587; *Sparklers,* 56 FR at 20589.

The Department conducted a separate rates analysis for Anhui Native, which has asserted the following: (1) There is no government participation in setting export prices; (2) sales managers and authorized employees have the authority to create binding sales contracts; (3) it does not have to notify any government authorities of management selections; (4) there are no restrictions on the use of export revenue; and (5) it is responsible for financing its own losses. The questionnaire responses of Anhui Native do not suggest that pricing is coordinated among exporters. During our analysis of the information on the record, we found no information indicating the existence of government control of export activities. *See* Anhui Native's submission of May 9, 2008, at 2–8, and Exhibit 2; *see also* Anhui Native's submission of July 3, 2008, at 2–7 and Exhibit 2. Consequently, we preliminarily determine that Anhui Native has met the criteria for the application of a separate rate.

As discussed above, the Department initiated this administrative review with respect to 32 companies, and thereafter rescinded the review on 21 of those 32 companies. In addition, we are preliminarily rescinding the review with respect to Dongtai Peak and Tangye due to the lack of shipments during the POR. Thus, in addition to Anhui Native, Cheng Du Wai and IMY, six additional companies remain subject to this review. The remaining six companies [6] (collectively referred to as ''the six companies'') were twice issued separate rate applications and certifications to which they did not respond.

Because these six companies did not provide separate rate information, the Department finds that they are not entitled to a separate rate. Therefore, these six companies will be considered part of the PRC-wide entity, subject to the PRC-wide rate.

Surrogate Country

When the Department investigates imports from an NME country, section 773(c)(1) of the Act directs it to base NV, in most circumstances, on the NME producer's FOPs, valued in a surrogate market economy country or countries considered to be appropriate by the Department. In accordance with section 773(c)(4) of the Act, in valuing the FOPs, the Department shall utilize, to the extent possible, the prices or costs of FOPs in one or more market economy countries that are at a level of economic development comparable to that of the NME country and significant producers of comparable merchandise. The sources of the surrogate factor values are discussed under the ''Normal Value'' section below and in the Memorandum to the File through James Doyle, Director, Office 9, through Scot Fullerton, Program Manager, Office 9, from Paul Walker, Senior Case Analyst, Office 9, ''Sixth Administrative Review of Honey from the People's Republic of China: Surrogate Factor Valuations for the Preliminary Results,'' dated concurrently with this notice (''Surrogate Values Memo'').

As discussed in the ''NME Country Status'' section, the Department considers the PRC to be an NME country. The Department determined that India, Indonesia, the Philippines, Colombia and Thailand are countries comparable to the PRC in terms of economic development. See Memorandum from Ron Lorentzen, Director, Office of Policy, to Scot Fullerton, Office 9, Import Administration, ''Antidumping Administrative Review of Honey from the People's Republic of China: Request for a List of Surrogate Countries,'' dated (March 25, 2008). Moreover, it is the Department's practice to select an appropriate surrogate country based on the availability and reliability of data from these countries. *See Department Policy Bulletin No. 04.1: Non-Market Economy Surrogate Country Selection Process,* dated March 1, 2004. The Department finds India to be a reliable source for surrogate values because India is at a comparable level of economic development pursuant to 773(c)(4) of the Act, is a significant producer of comparable merchandise, and has publicly available and reliable data. Furthermore, the Department notes that India has been the primary surrogate country in past segments, and the only surrogate value data submitted on the record are from Indian sources. Given the above facts, the Department has selected India as the primary surrogate country for this review.

U.S. Price

In accordance with section 772(a) of the Act, we calculated the export price [7] (''EP'') for sales to the United States for Anhui Native. We calculated EP based on the price to unaffiliated purchasers in the United States. In accordance with section 772(c) of the Act, as appropriate, we deducted from the starting price to unaffiliated purchasers foreign inland freight, foreign brokerage and handling, customs duties, domestic brokerage and handling and other movement expenses incurred. For the services provided by an NME vendor or paid for using an NME currency we based the deduction of these movement charges on surrogate values. *See* Surrogate Values Memo for details regarding the surrogate values for movement expenses. For expenses provided by a market economy vendor and paid in U.S. dollars, so we used the actual cost per kilogram of the freight. *See* Anhui Native Analysis Memo.

[6] Alfred L. Wolff (Beijing) Co., Ltd., Haoliluck Co., Ltd., Hubei Yusun Co., Ltd., Mgl. Yung Sheng Honey Co., Ltd. (also DBA Fresh Honey Co., Ltd.), Nefelon Limited Company and Qinhuangdao Municipal Dafeng Industrial Co., Ltd.

[7] Though Anhui Native's Section C database lists each of its sales as constructed export price, we note that the first U.S. customer is unaffiliated with Anhui Native.

Normal Value

Methodology

Section 773(c)(1) of the Act provides that the Department shall determine the NV using an FOP methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act. The Department bases NV on the FOP because the presence of government controls on various aspects of NMEs renders price comparisons and the calculation of production costs invalid under the Department's normal methodologies.

Factor Valuations

In accordance with section 773(c) of the Act, we calculated NV based on FOP data reported by Anhui Native for the POR. To calculate NV, we multiplied the reported per-unit factor-consumption rates by publicly available surrogate values (except as discussed below).

In selecting the surrogate values, we considered the quality, specificity, and contemporaneity of the data. As appropriate, we adjusted input prices by including freight costs to make them delivered prices. In accordance with *Sigma,* we added to each Indian import surrogate value, a surrogate freight cost calculated from the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory, where appropriate. *See Sigma Corp.* v. *United States,* 117 F. 3d 1401, 1407–1408 (Fed. Cir. 1997) (''*Sigma*'').

For these preliminary results, in accordance with the Department's practice, we used data from the *Indian Import Statistics* in order to calculate surrogate values for most of Anhui Native's material inputs. In selecting the best available information for valuing FOPs in accordance with section 773(c)(1) of the Act, the Department's practice is to select, to the extent practicable, surrogate values which are non-export average values, most contemporaneous with the POR, product-specific, and tax-exclusive. *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value, Negative Preliminary Determination of Critical Circumstances and Postponement of Final Determination: Certain Frozen and Canned Warmwater Shrimp From the Socialist Republic of Vietnam,* 69 FR 42672, 42682 (July 16, 2004), unchanged in *Final Determination of Sales at Less Than Fair Value: Certain Frozen and Canned Warmwater Shrimp From the Socialist Republic of Vietnam,* 69 FR 71005 (December 8, 2004). The record shows that the Indian import statistics represent import data that are contemporaneous with the POR, product-specific, and tax-exclusive. Where we could not obtain publicly available information contemporaneous to the POR with which to value FOPs, we adjusted the surrogate values, where appropriate, using the Indian Wholesale Price Index (''WPI'') as published in *OECD Stat* by the Organization for Economic Development and Cooperation.

To value unfiltered/unprocessed honey (''raw honey''), the Department used the raw honey price [8] published by the Regional Centre for Development Cooperation (''RCDC'') for these preliminary results. The Department finds that the RCDC raw honey price is reliable, as the organization collects its own raw and processed honey price information directly from various Indian honey markets. The RCDC is a non-governmental organization, which works to strengthen the community-based management of natural resources in Orissa and surrounding states, and maintains updated market prices of various non-timber forest products for various major markets in India. However, because the raw honey price data published by RCDC are dated after the POR, we deflated the price to be contemporaneous with the POR using WPI.

We valued electricity using price data for small, medium, and large industries, as published by the Central Electricity Authority of the Government of India in its publication titled *Electricity Tariff & Duty and Average Rates of Electricity Supply in India,* dated July 2006. These electricity rates represent actual country-wide, publicly-available information on tax-exclusive electricity rates charged to industries in India. Since the rates are dated before the POR, we inflated the values to be contemporaneous with the POR using WPI. *See* Surrogate Values Memo.

Consistent with 19 CFR 351.408(c)(3), we valued direct, indirect, and packing labor, using the most recently calculated regression-based wage rate, which relies on 2005 data. This wage rate can currently be found on the Department's Web site on Import Administration's home page, Import Library, Expected Wages of Selected NME Countries, revised in May 2008, *ia.ita.doc.gov/wages/05wages/05wages-051608.html.* The source of these wage-rate data on the Import Administration's web site is the Yearbook of Labour Statistics 2002, ILO (Geneva: 2002), Chapter 5B: Wages in Manufacturing. Because this regression-based wage rate does not separate the labor rates into different skill levels or types of labor, we have applied the same wage rate to all skill levels and types of labor reported by Anhui Native.

To value water, the Department used data from the Maharashtra Industrial Development Corporation (*http://www.midindia.orgwww.midcindia.org*) since they include a wide range of industrial water tariffs. This source provides 386 industrial water rates within the Maharashtra province from June 2003: 193 of the water rates were for the ''inside industrial areas'' usage category and 193 of the water rates were for the ''outside industrial areas'' usage category. Because the value was not contemporaneous with the POR, we adjusted the rate for inflation.

We valued truck freight expenses using a per-unit average rate calculated from data on the following Web site: *http://www.infobanc.com/logistics/logtruck.htm.* The logistics section of this website contains inland freight truck rates between many large Indian cities. Since this value is dated after the POR, we deflated the values to be contemporaneous with the POR using WPI. *See* Surrogate Values Memo.

We valued brokerage and handling using a simple average of the brokerage and handling costs that were reported in public submissions that were filed in three antidumping duty cases. *See* Surrogate Values Memo. Specifically, we averaged the public brokerage and handling expenses reported by (a) Agro Dutch Industries Ltd. in the antidumping duty administrative review of certain preserved mushrooms from India, (b) Kejirwal Paper Ltd. in the LTFV investigation of certain lined paper products from India, and (c) Essar Steel in the antidumping duty administrative review of hot-rolled carbon steel flat products from India. *See Certain Preserved Mushrooms From India: Final Results of Antidumping Duty Administrative Review,* 71 FR 10646 (March 2, 2006); *Notice of Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Affirmative Preliminary Determination of Critical Circumstances in Part: Certain Lined Paper Products From India,* 71 FR 19706 (April 17, 2006) (unchanged in *Notice of Final Determination of Sales at Less Than Fair Value, and Negative Determination of Critical Circumstances: Certain Lined Paper Products from India,* 71 FR 45012 (August 8, 2006)), and *Certain Hot-*

[8] The honey price published by RCDC can be found at *http://www.banajata.org/m/a1.htm.*

Rolled Carbon Steel Flat Products From India: Preliminary Results of Antidumping Duty Administrative Review, 71 FR 2018, 2021 (January 12, 2006) (unchanged in *Certain Hot-Rolled Carbon Steel Flat Products From India: Final Results of Antidumping Administrative Review,* 71 FR 40694 (July 18, 2006)). The Department derived the average per-unit amount from each source and adjusted each average rate for inflation. Finally, the Department averaged the average per-unit amounts to derive an overall average rate for the POR.[9]

To value factory overhead, sales, general and administrative expenses, and profit; we relied upon publicly available information in the 2006–2007 annual report of Mahabaleshwar Honey Production Cooperative Society Ltd., an Indian producer of subject merchandise. *See* Surrogate Values Memo.

We made currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Preliminary Results of the Review

The Department has determined that the following preliminary dumping margins exist for the period December 1, 2006 through November 30, 2007:

HONEY FROM THE PRC

Manufacturer/exporter	Margin (per kilogram)
Anhui Native	$2.65
PRC-wide Entity [10]	$2.65

The Department will disclose calculations performed for these preliminary results to the parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

In accordance with 19 CFR 351.301(c)(3)(ii), for the final results of this administrative review, interested parties may submit publicly available information to value FOPs within 20 days after the date of publication of these preliminary results. Interested parties must provide the Department with supporting documentation for the publicly available information to value each FOP. Additionally, in accordance with 19 CFR 351.301(c)(1), for the final results of this administrative review, interested parties may submit factual information to rebut, clarify, or correct factual information submitted by an interested party less than ten days before, on, or after, the applicable deadline for submission of such factual information. However, the Department notes that 19 CFR 351.301(c)(1) permits new information only insofar as it rebuts, clarifies, or corrects information recently placed on the record. The Department generally cannot accept the submission of additional, previously absent-from-the-record alternative surrogate value information pursuant to 19 CFR 351.301(c)(1). *See Glycine from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part,* 72 FR 58809 (October 17, 2007) and accompanying Issues and Decision Memorandum at Comment 2.

Interested parties may submit case briefs and/or written comments no later than 30 days after the date of publication of these preliminary results of review. *See* 19 CFR 351.309(c)(ii). Rebuttal briefs and rebuttals to written comments, limited to issues raised in such briefs or comments, may be filed no later than 37 days after the date of publication of these preliminary results of review. *See* 19 CFR 351.309(d). The Department urges interested parties to provide an executive summary of each argument contained within the case briefs and rebuttal briefs.

Any interested party may request a hearing within 30 days of publication of these preliminary results. *See* 19 CFR 351.310(c). Requests should contain the following information: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs. If we receive a request for a hearing, we plan to hold the hearing seven days after the deadline for submission of the rebuttal briefs at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

The Department will issue the final results of this administrative review, which will include the results of its analysis of issues raised in any such comments, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Consistent with the *Fifth AR Final Results,* we will direct CBP to assess importer-specific assessment rates based on the resulting per-unit (*i.e.*, per kilogram) amount on each entry of the subject merchandise during the POR. *See Honey from the People's Republic of China: Final Results and Rescission, In Part, of Aligned Antidumping Duty Administrative Review and New Shipper Review,* 73 FR 42321 (July 21, 2008) ("*Fifth AR Final Results*"). The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. If these preliminary results are adopted in our final results of review, the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries. For assessment purposes, we calculated importer-specific assessment rates for honey from the PRC. Specifically, we divided the total duties for each importer by the total quantity of subject merchandise sold to that importer during the POR to calculate a per-unit assessment amount. We will direct CBP to assess importer-specific assessment rates based on the resulting per-unit (*i.e.*, per kilogram) amount on each entry of the subject merchandise during the POR if any importer-specific assessment rate calculated in the final results of this review is above *de minimis*.

For Dongtai Peak and Tangye, companies for which this review is preliminarily rescinded, antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(2).

Cash Deposit Requirements

The following cash-deposit requirements will be effective upon publication of these final results for shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of these final results, as provided by section 751(a)(2)(C) of the Act: (1) For subject merchandise exported by Anhui Native the cash deposit rate will be $2.65 per kilogram; (2) for all other PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, and thus, are a part of the PRC-wide entity, the cash-deposit rate will be the PRC-wide rate of $2.65 per-kilogram; and (3) for all non-PRC exporters of subject merchandise, the cash-deposit rate will be the rate applicable to the PRC supplier of that exporter. These deposit requirements shall remain in effect until further notice.

[9] These data have been placed on the record of this case and can be found in attachments to the Factors Memo.

[10] The PRC-wide entity includes Alfred L. Wolff (Beijing) Co., Ltd., Cheng Du Wai, Haoliluck Co., Ltd., Hubei Yusun Co., Ltd., IMY, Mgl. Yung Sheng Honey Co., Ltd. (also DBA Fresh Honey Co., Ltd.), Nefelon Limited Company and Qinhuangdao Municipal Dafeng Industrial Co., Ltd.

Notification of Interested Parties

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review, and this notice are in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: October 31, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E8–26616 Filed 11–6–08; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN: 0648–XL63

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting of the North Pacific Fishery Management Council Outreach Group.

SUMMARY: The North Pacific Fishery Management Council's Outreach group will meet in Anchorage at the North Pacific Research Board office.

DATES: The meeting will be held on Monday, November 24, 2008, from 10 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at the North Pacific Research Board, 1007 West 3rd Avenue, Suite 100, Anchorage, AK 99501.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Nicole Kimball, North Pacific Fishery Management Council; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The Council Outreach Workgroup is meeting to conduct initial planning to develop recommendations to the Council to improve its outreach and communication with Alaska Natives and communities.

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen, (907) 271–2809, at least 5 working days prior to the meeting date.

Dated: November 4, 2008.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E8–26576 Filed 11–6–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF DEFENSE

Department of the Air Force

Intent To Grant an Exclusive Patent License

SUMMARY: Pursuant to the provisions of Part 404 of Title 37, Code of Federal Regulations, the Department of the Air Force announces its intention to grant First Technology Safety Systems, Inc., a business entity of Michigan, having a place of business at 47460 Galleon Drive, Plymouth, Michigan 48170, an exclusive license in any right, title and interest the Air Force has in: U.S. Patent No. 7,204,165 issued April 17, 2007, entitled ''Anthropomorphic Manikin Head Skull Cap Load Measurement Device'' by John A. Plaga *et al.*, as well as other related know-how.

FOR FURTHER INFORMATION CONTACT: A license for this patent and related know-how will be granted unless a written objection is filed within fifteen (15) days from the date of publication of this Notice. For further information, please contact Christopher J. Menke, Attorney, Air Force Materiel Command Law Office, AFMCLO/JAZ, Building 11, Suite D18, 2240 B Street, Wright-Patterson AFB OH 45433–7109. Telephone: (937) 904–5031; Facsimile (937) 255–3733.

Bao-Anh Trinh,

Air Force Federal Register Liaison Officer.

[FR Doc. E8–26650 Filed 11–6–08; 8:45 am]

BILLING CODE 5001–05–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Partially Closed Meeting of the U.S. Naval Academy Board of Visitors

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The U.S. Naval Academy Board of Visitors will meet to make such inquiry, as the Board shall deem necessary into the state of morale and discipline, the curriculum, instruction, physical equipment, fiscal affairs, and academic methods of the Naval Academy. The meeting will include discussions of personnel issues at the Naval Academy, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. The executive session of this meeting will be closed to the public.

DATES: The open session of the meeting will be held on Monday, December 15, 2008, from 8 a.m. to 11 a.m. The closed Executive Session will be held from 11 a.m. to 12 p.m.

ADDRESSES: The meeting will be held in Bo Coppedge Room, Alumni Hall, U.S. Naval Academy, Annapolis, MD.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander David S. Forman, USN, Executive Secretary to the Board of Visitors, Office of the Superintendent, U.S. Naval Academy, Annapolis, MD 21402–5000, telephone: 410–293–1503.

SUPPLEMENTARY INFORMATION: This notice of meeting is provided pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. App.). The executive session of the meeting will consist of discussions of personnel issues at the Naval Academy and internal Board of Visitors matters. The proposed closed session from 11 a.m. to 12 p.m. will include a discussion of new and pending administrative/minor disciplinary infractions and nonjudicial punishments involving the Midshipmen attending the Naval Academy to include but not limited to individual honor/conduct violations within the Brigade. Discussion of such information cannot be adequately segregated from other topics, which precludes opening the

executive session of this meeting to the public.

Accordingly, the Secretary of the Navy has determined in writing that the meeting shall be partially closed to the public because it will be concerned with matters listed in section 552b(c)(5), (6), and (7) of title 5, United States Code.

Dated: November 3, 2008.

T.M. Cruz,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8–26647 Filed 11–6–08; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Performance Review Board Membership

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to 5 U.S.C. 4314(c)(4), the Department of the Navy (DON) announces the appointment of members to the DON's numerous Senior Executive Service (SES) Sub Pay Pools (SPPs)/Performance Review Boards (PRBs). The purpose of the SPP/PRBs is to provide fair and impartial review of the annual SES performance appraisal prepared by the senior executive's immediate and second level supervisor; to make recommendations to appointing officials regarding acceptance or modification of the performance rating; and to make recommendations for performance bonuses and basic pay increases. Composition of the specific SPP/PRBs will be determined on an ad hoc basis from among individuals listed below:

ADAMS, P.C. MS.
ALLARD, T. DR.
ARCHITZEL, D. RADM
ARNY, L.W. MR.
BALDERSON, D. MS.
BALDERSON, W.M. MR.
BARBER, A.H. MR.
BARNUM, H.C. MR.
BAUMAN, D.M. MR.
BELAND, R.W. DR.
BETRO, T.A. MR.
BILLINGSLEA, M. MR.
BLAIR, A.K. MS.
BLINCOE, R.J. MR.
BOURBEAU, S.J. MS.
BOZIN, S.D. RADM
BRANCH, E.B. MR.
BRAY, W.P. MR.
BRENNAN, A.M. MS.
BROOK, D. DR.
BROTHERTON, A.E. MS.
BROWN, M. RDML
BROWN, W.A. RDML
CALI, R.T. MR.
CAREY, R.J. MR.
CARLIN, R.T. DR.
CARR, N. RDML
CASTELLAW, J. LTGEN
COHN, H.A. MR.
COLEMAN, R. LTGEN
COOK, C.E. MR.
COOLEY, K. MR.
COX, A.D. MR.
CREEDON, C. MR.
CWALINA, B.B. MR.
DAVENPORT, D. RADM
DAVIS, A.R. MS.
DAVIS, L.C. DR.
DEBBINK, D. VADM
DECKER, J. MS.
DECKER, M.H. MR.
DEITCHMAN, M. MR.
DELIGNE, W.J. MR.
DEUTSCH, K. RADM
DILLON, B. MR.
DRISKO, M. MS.
DUNAWAY, D. RDML
DUNN, S.C. MR.
EASTBURG, S. RDML
ECCLES, T. RDML
EHRLER, S.M. MR.
ELLIS, W.G. MR.
ENEWOLD, G. RADM
ESSIG, P. CAPT
ETTER, D.M., THE HONORABLE
EVANS, G.L. MS.
EVANS, I.E. MS.
EVANS, J.J. MR.
EXLEY, R.L. MR.
FERGUSON, J.F. MR.
FERGUSON, M. VADM
FERKO, J.G. MR.
FISCHER, J.W. DR.
FITZGERALD, M. VADM
FLYNN, T.V. RDML
FRANKFURT, T. MR.
FRANTZ, G.T. MR.
FRICK, M.S. RDML
GAHAGAN, D. CAPT
GALGANO, M. MR.
GALLOWAY, J. MR.
GAVIN, V.S. MR.
GIBBS, R. MR.
GLAS, R. MR.
GODDARD, C.H. RDML
GONZALEZ, A.H. MR.
GOODHART, J.C. MR.
GORDON, F.E. DR.
GRIFFES, M.D. MR.
GRIFFIN, R. MR.
GUARD, H. MR.
HAMILTON, C. RADM
HANEY, C. RADM
HANNAH, B.W. DR.
HARNED, N. MS.
HARRELL, M. MS.
HARVEY, J.C. VADM
HAYNES, R.S. MR.
HEELY, T. RADM
HERR, F. DR.
HILARIDES, W.H. RDML
HOGUE, R.D. MR.
HONECKER, M.W. MR.
HOWARD, J.S. MR.
ISELIN, S. MR.
JAGGARD, M.F. MR.
JAMES, J.H. MR.
JIMENEZ, F., THE HONORABLE
JOHNSON, J.L. MR.
JOHNSON, S. RADM
JONES, W. DR.
JUNKER, B.R. DR.
KARLE, I. DR.
KASKIN, J.D. MR.
KAY, W. MS.
KEEN, S.L. MS.
KEENEY, C. MS.
KLEINTOP, M.U. MS.
KRAMLICH, R.S. LTGEN
KRASIK, S.A. MS.
KRUM, R.A. MR.
KUNESH, N.J. MR.
LAKE, R. BGEN
LANDAU, S.P. MR.
LAUX, T.E. MR.
LAWRENCE, J.P. DR.
LEACH, R.A. MR.
LEDVINA, T.N. MR.
LEFEBVRE, P. MR.
LEGGIERI, S.R. MS.
LEIKACH, K. MR.
LOFTUS, J.V. MS.
LONG, L. MS.
LUCCHINO, C. MS.
LUNDBERG, D.A. MR.
LUNNEY, J.E. MR.
LUTTERLOH, S. MR.
MAGLICH, M.F. MR.
MAGNUS, R. LTGEN
MAGUIRE, M.M. MS.
MARSHALL, J.B. MR.
MASCIARELLI, J.R. MR.
MCCARTHY, E. MS.
MCCARTHY, J. MR.
MCCORMACK, JR., D.F. MR.
MCCOY, K.M. RDML
MCCURDY, J. MR.
MCGRATH, M.F. MR.
MCLAUGHLIN, P.M. MR.
MCMAHON, M. RDML
MCNAIR, J.W. MR.
MEADOWS, L.J. MS.
MEEKS JR., A.W. DR.
MENG, J.C. DR.
MILLER, C.A. MR.
MITCHELL, S. MR.
MOLZAHN, W.R. MR.
MONTGOMERY, J.A. DR.
MURRAY, S. MS.
MUTH, C.C. MS.
NAVAS JR., W.A., THE HONORABLE
NYALKO, L.J. MS.
O'NEIL, S.M. MR.
PAOLETTI, C. MR.
PENN, B.J., THE HONORABLE
PERSONS, B.J. MR.
PIC, J.E. MR.
PIVIROTTO, R.R. MR.
PLUNKETT, B.J. MR.
RAPS, S.P. MS.

REEVES, C.R. MR.
REIST, J. BGEN
ROBERTS, T. MS.
RODRIGUEZ, RDML
ROLLOW, T.A. MR.
ROSENTHAL, R.J. MR.
RYZEWIC, W.H. MR.
SANDEL, E.A. MS.
SANDERS, D.K. MR.
SCHAEFER, J.C. MR.
SCHREGARDUS, D.R. MR.
SCHUETTE, L. DR.
SEE, V. RDML
SHANNON, W. RDML
SHARP, B.A. MR.
SHEPHARD, M.R. MS.
SIEL JR., C.R. MR.
SKINNER, W. RDML
SMERCHANSKY, J.H. MR.
SMITH, R.F. MR.
SMITH, R.M. MR.
SOLHAN, G.W. MR.
SOMOROFF, A.R. DR.
SORENSON, D. CAPT
SPANN, L.H. MR.
STACKLEY, S. MR.
STEFFEE, D.P. MR.
STEWART, P. CAPT
STILLER, A.F. MS.
SUMMERALL, W. MR.
TAMBURRINO, P.M. MR.
TESCH, T.G. MR.
THACKRAH, J. MR.
THOMSEN, J.E.
TIMME, W.G. RDML
TOWNSEND, D.K. MS.
WALLS, V.J. MR.
WARD, J.D. MR.
WEDDEL, D.W. MR.
WEYMAN, A.S. MR.
WHITTEMORE, A. MS.
WHITTMANN, J. MR.
WIERINGA, J.A. RDML
WOOD, B.H. MR.

FOR FURTHER INFORMATION CONTACT: Ms. LaToya Bedgood, Office of Civilian Human Resources, telephone: 202–685–6659.

Dated: November 3, 2008.

T.M. Cruz,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8–26649 Filed 11–6–08; 8:45 am]

BILLING CODE 3810–FF–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Sunshine Act Notice; Correction

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Notice of public meeting; correction.

SUMMARY: The Defense Nuclear Facilities Safety Board published a document in the **Federal Register** of November 5, 2008, concerning notice of a public hearing and meeting on the Department of Energy's (DOE) and National Nuclear Security Administration's incorporation of safety into the design and construction of new DOE defense nuclear facilities and into major modification of existing facilities. The document contained one incorrect date.

FOR FURTHER INFORMATION CONTACT: Brian Grosner, General Manager, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue, NW., Suite 700, Washington, DC 20004–2901, (800) 788–4016. This is a toll-free number.

Correction

In the **Federal Register** of November 5, 2008, in FR Doc. E8–26512, on page 65838, in the third column, lines 23 and 24, correct the date ''March 27, 2007'' to read: ''March 22, 2007.''

Dated: November 5, 2008.

A.J. Eggenberger,

Chairman.

[FR Doc. E8–26696 Filed 11–5–08; 4:15 pm]

BILLING CODE 3670–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before December 8, 2008.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, Washington, DC 20503. Commenters are encouraged to submit responses electronically by e-mail to *oira_submission@omb.eop.gov* or via fax to (202) 395–6974. Commenters should include the following subject line in their response ''Comment: [insert OMB number], [insert abbreviated collection name, e.g., ''Upward Bound Evaluation]''. Persons submitting comments electronically should not submit paper copies.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: November 3, 2008.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Federal Student Aid

Type of Review: Revision.

Title: Federal Family Education Loan (FFEL) Program, Federal Perkins Loan (Perkins Loan) Program, William D. Ford Federal Direct Loan (Direct Loan) Program, and Teacher Education Assistance for College and Higher Education (TEACH) Grant Program Discharge Application: Total and Permanent Disability.

Frequency: On Occasion.

Affected Public: Individuals or household (primary).

Reporting and Recordkeeping Hour Burden:

Responses: 30,000.

Burden Hours: 15,000.

Abstract: The Discharge Application: Total and Permanent Disability serves as the means by which an individual who is totally and permanently disabled (in accordance with the U.S. Department of Education's regulations) applies for a discharge of his or her student loans made under the FFEL, Perkins Loan, or Direct Loan program loans, or TEACH Grant service obligation. The currently approved TPD Discharge Application is amended to (1) incorporate changes to the terms and conditions of total and permanent disability discharges that were made by final regulations

published November 1, 2007 (72 FR 61960), and (2) add provisions for the discharge of a TEACH Grant recipient's service obligation based on a total and permanent disability, in accordance with the final regulations for the TEACH Grant Program that were published on June 23, 2008.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 3687. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E8–26547 Filed 11–6–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 6, 2009.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, Washington, DC 20503. Commenters are encouraged to submit responses electronically by e-mail to *oira_submission@omb.eop.gov* or via fax to (202) 395–6974. Commenters should include the following subject line in their response ''Comment: [insert OMB number], [insert abbreviated collection name, e.g., ''Upward Bound Evaluation'']. Persons submitting comments electronically should not submit paper copies.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes the notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: November 3, 2008.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Elementary and Secondary Education

Type of Review: Extension.

Title: Rural Education Achievement Program.

Frequency: Annually.

Affected Public: State, Local, or Tribal Gov't, SEAs or LEAs (primary).

Reporting and Recordkeeping Hour Burden:

Responses: 5,052.

Burden Hours: 4,830.

Abstract: This data collection is pursuant to the Secretary's authority under Part B of Title VI of the Elementary and Secondary Education Act (ESEA), to award funds under two grant programs designed to address the unique needs of rural school districts—the Small, Rural School Achievement Program (ESEA Section 6212) and the Rural and Low-Income School Program (ESEA Section 6221). Under the Small, Rural School Achievement Program, the Secretary awards grants directly to eligible local educational agencies (LEAs) on a formula basis. Under the Rural and Low-income School Program, eligible school districts are sub-recipients of funds the Department awards to SEAs on a formula basis. For both grant programs, the Department awards funds based a determination of the eligibility of individual school districts and calculating formula allocations each eligible district should receive.

The Department has devised a two-tier strategy to accomplish the funding process for the REAP program: (1) The Department collects from SEAs the information the Department needs to make eligibility and funds allocation determinations, and (2) LEAs submit applications for grant funding.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 3904. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E8–26548 Filed 11–6–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management, invites

comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 6, 2009.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: November 4, 2008.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Postsecondary Education

Type of Review: Revision.

Title: Child Care Access Means Parents in School (CCAMPIS) Program Annual Performance Report Form.

Frequency: Annually.

Affected Public: Not-for-profit institutions.

Reporting and Recordkeeping Hour Burden:

Responses: 175.

Burden Hours: 1,050.

Abstract: CCAMPIS Program grantees must submit the report annually. The report provides the Department of Education with information needed to evaluate a grantee's performance and compliance with program requirements in accordance with the program authorizing statute. The data collected is also aggregated to provide national information on project participants and program outcomes.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 3902. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E8–26617 Filed 11–6–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

October 6, 2008.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP96–272–082.

Applicants: Northern Natural Gas Company.

Descriptions: Northern Natural Gas Co submits 11 Revised Sheet 66B.01, et. al. to FERC Gas Tariff, Fifth Revised Volume 1, to be effective 10/4/08.

Filed Date: 10/03/2008.

Accession Number: 20081003–0306.

Comment Date: 5 p.m. Eastern Time on Wednesday, October 15, 2008.

Docket Numbers: RP02–361–073. CP07–51–001.

Applicants: Gulfstream Natural Gas System, L.L.C.

Descriptions: Gulfstream Natural Gas System submits Original Sheet No. 8.02 to FERC Gas Tariff, Original Volume 1, to be effective 9/1/08.

Filed Date: 10/01/2008.

Accession Number: 20081003–0304.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 14, 2008.

Docket Numbers: RP04–274–000. RP00–157–015.

Applicants: Kern River Gas Transmission Company. Kern River Gas Transmission Company.

Descriptions: Kern River Gas Transmission Co submits an Offer of Settlement and Stipulation and revised tariff sheets proposed to be effective on 10/1/08.

Filed Date: 09/30/2008.

Accession Number: 20081002–0037.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 14, 2008.

Docket Numbers: RP09–7–001.

Applicants: Texas Gas Transmission, LLC.

Descriptions: Texas Gas Transmission, LLC submits Sub Second Revised Sheet No. 2120, to Third Revised Volume No. 1, to be effective 11/1/08.

Filed Date: 10/02/2008.

Accession Number: 20081003–0301.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 14, 2008.

Docket Numbers: CP07–207–003.

Applicants: Colorado Interstate Gas Company.

Descriptions: Colorado Interstate Gas Company submits its implementation and compliance filing for High Plans Project.

Filed Date: 10/01/2008.

Accession Number: 20081003–0211.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 14, 2008.

Docket Numbers: CP09–1–000.

Applicants: Collbran Valley Gas Gathering, LLC.

Descriptions: Collbran Valley Gas Gathering, LLC submits it abbreviated application for limited jurisdiction certificate and requests for waivers of regulatory requirements.

Filed Date: October 1, 2008.

Accession Number: 20081001–4000.

Comment Date: 5 p.m. Eastern Time on Tuesday, October 14, 2008.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously

intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E8–26574 Filed 11–6–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

November 3, 2008.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP88–67–084.
Applicants: Texas Eastern Transmission LP.
Description: Texas Eastern Transmission, LP submits Twenty-Eighth Revised Sheet No. 25 *et al.* to FERC Gas Tariff, Seventh Revised Volume No. 1 *et al.*, to be effective 12/1/08.
Filed Date: 10/30/2008.
Accession Number: 20081031–0180.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP97–81–050.
Applicants: Kinder Morgan Interstate Gas Transmission LLC.
Description: Kinder Morgan Interstate Gas Transmission LLC submits First Revised Sheet 8 to FERC Gas Tariff, Fourth Revised Volume 1–A, to be effective 11/1/08.
Filed Date: 10/30/2008.
Accession Number: 20081031–0179.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP99–176–171.
Applicants: Natural Gas Pipeline Company of America.
Description: Natural Gas Pipeline Company of America LLC submits two amendments to an existing negotiated rate transportation rate schedule FTS agreement between Natural and Tenaska Marketing Ventures to be effective 11/1/08.
Filed Date: 10/30/2008.
Accession Number: 20081031–0153.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP99–176–172.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: Natural Gas Pipeline Company of America LLC submits First Revised Sheet 33D *et al.* to FERC Gas Tariff Seventh Revised Volume 1, to be effective 12/1/08.
Filed Date: 10/30/2008.
Accession Number: 20081031–0156.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP99–176–173.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: Natural Gas Pipeline Company of America LLC submits original sheet 33L.02 to FERC gas tariff seventh revised volume 1, to be effective 12/1/08.
Filed Date: 10/30/2008.
Accession Number: 20081031–0155.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP99–176–174.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: Natural Gas Pipeline Company of America LLC submits Original Sheet 33L.01 to FERC Gas Tariff, Seventh Revised Volume 1, to be effective 12/1/08.
Filed Date: 10/30/2008.
Accession Number: 20081031–0154.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP06–595–011.
Applicants: Discovery Gas Transmission LLC.
Description: Discovery Gas Transmission LLC submits Eleventh Revised Sheet 22 *et al.* to FERC Gas Tariff, Original Volume 1, to be effective 11/1/08.
Filed Date: 10/30/2008.
Accession Number: 20081031–0152.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP09–36–000.
Applicants: Williston Basin Interstate Pipeline Co.
Description: Williston Basin Interstate Pipeline Co submits Ninth Revised Sheet No. 32 *et. al.* to FERC Gas Tariff, Second Revised Volume 1, to be effective 12/1/08.
Filed Date: 10/29/2008.
Accession Number: 20081030–0081.
Comment Date: 5 p.m. Eastern Time on Monday, November 10, 2008.

Docket Numbers: RP09–37–000.
Applicants: Transcontinental Gas Pipe Line Corp.
Description: Transcontinental Gas Pipe Line Corp submits Fifth Revised Sheet No. 166 *et al* to FERC Gas Tariff, Third Revised Volume No. 1 *et al*, to be effective 11/28/08.
Filed Date: 10/29/2008.
Accession Number: 20081031–0176.
Comment Date: 5 p.m. Eastern Time on Monday, November 10, 2008.

Docket Numbers: RP09–38–000.
Applicants: Sabine Pipe Line LLC.
Description: Sabine Pipe Line LLC submits Second Revised Sheet 317 *et al.* to FERC Gas Tariff, Original Volume No. 1, to be effective 11/30/08.
Filed Date: 10/30/2008.
Accession Number: 20081031–0178.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP09–39–000.
Applicants: Kinder Morgan Interstate Gas Transmission LLC.
Description: Kinder Morgan Interstate Gas Transmission LLC submits First Revised Sheet 8 to FERC Gas Tariff, Fourth Revised Volume 1–A, to be effective 11/1/08.
Filed Date: 10/30/2008.
Accession Number: 20081031–0179.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211

and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E8–26575 Filed 11–6–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

November 4, 2008.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP00–157–021.
Applicants: Kern River Gas Transmission Company.
Description: Kern River Gas Transmission Company submits a refund report detailing refunds paid on October 1, 2008, and October 3, 2008, pursuant to the Settlement filed September 30, 2008, in accordance with 18 CFR 154.501(e).
Filed Date: 10/31/2008.
Accession Number: 20081031–5153.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP03–36–037.
Applicants: Dauphin Island Gathering Partners.
Description: Dauphin Island Gathering Partners submits Thirty-First Revised Sheet 10 *et al.* to FERC Gas Tariff, Fifth Revised Volume 1, to be effective 11/1/08.
Filed Date: 10/31/2008.
Accession Number: 20081103–0154.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP08–350–001.
Applicants: Southern Star Central Gas Pipeline, Inc.
Description: Southern Star Central Gas Pipeline, Inc. submits Substitute Sixth Revised Sheet 10 *et al.* to FERC Gas Tariff, Original Volume 1 and 2, to be effective 11/1/08.
Filed Date: 10/31/2008.
Accession Number: 20081103–0155.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP08–523–002.
Applicants: Southeast Supply Header, LLC.
Description: Southeast Supply Header, LLC submits Original Sheet 332A to FERC Gas Tariff, Original Volume 1, to be effective 10/1/08.
Filed Date: 10/31/2008.
Accession Number: 20081104–0029.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP09–16–001.
Applicants: Cimarron River Pipeline, LLC.
Description: Cimarron River Pipeline, LLC submits First Revised Sheet 20 to FERC Gas Tariff, Original Volume 1, to be effective 11/1/08.
Filed Date: 10/31/2008.
Accession Number: 20081103–0156.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP96–200–199.
Applicants: CenterPoint Energy Gas Transmission Company.
Description: Center Point Energy Gas Transmission Company submits a negotiated rate agreement between CEGT and Lacede Energy Resources, Inc.
Filed Date: 10/31/2008.
Accession Number: 20081103–0149.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP96–200–200.
Applicants: CenterPoint Energy Gas Transmission Company.
Description: CenterPoint Energy Gas Transmission Company submits two amended agreements with Chesapeake Energy Marketing, Inc.
Filed Date: 10/31/2008.
Accession Number: 20081104–0028.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP96–272–084.
Applicants: Northern Natural Gas Company.
Description: Northern Natural Gas Company submits 53rd Revised Sheet 66A *et al.* to FERC Gas Tariff, Fifth Revised Volume 1, effective 11/1/08.
Filed Date: 10/31/2008.
Accession Number: 20081103–0150.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP98–18–037.
Applicants: Iroquois Gas Transmission System, L.P.
Description: Iroquois Gas Transmission System, LP submits First Revised Sheet 6M to FERC Gas Tariff, First Revised Volume 1, to be effective 11/1/08.
Filed Date: 10/31/2008.
Accession Number: 20081103–0151.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP99–480–023.
Applicants: Texas Eastern Transmission LP.
Description: Texas Eastern Transmission, LP submits Sub Original Sheet 120 to FERC Gas Tariff, Seventh Revised Volume 1, to be effective 11/1/08.
Filed Date: 10/31/2008.
Accession Number: 20081103–0152.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP99–518–108.
Applicants: Gas Transmission Northwest Corporation.
Description: Gas Transmission Northwest Corporation submits Forty-Fifth Revised Sheet 15 *et al.* to FERC

Gas Tariff, Third Revised Volume 1–A, to be effective 11/1/08.

Filed Date: 10/31/2008.

Accession Number: 20081103–0153.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP09–40–000.

Applicants: CenterPoint Energy Gas Transmission Company.

Description: CenterPoint Energy Gas Transmission Company submits Second Revised Sheet 264A *et al.* to FERC Gas Tariff, Sixth Revised Volume 1, to be effective 12/1/08.

Filed Date: 10/31/2008.

Accession Number: 20081103–0157.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP09–41–000.

Applicants: Dominion Cove Point LNG, LP.

Description: Dominion Cove Point LNG, LP submits Eleventh Revised Sheet 10 *et al.* to FERC Gas Tariff Original Volume 1.

Filed Date: 10/31/2008.

Accession Number: 20081103–0144.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP09–42–000.

Applicants: Hardy Storage Company, LLC.

Description: Hardy Storage Company submits First Revised Sheet 13 to FERC Gas Tariff Original Volume 1.

Filed Date: 10/31/2008.

Accession Number: 20081103–0143.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP09–43–000.

Applicants: Guardian Pipeline, L.L.C.

Description: Guardian Pipeline, LLC submits Sixth Revised Sheet 100 *et al.* to FERC Gas Tariff Original Volume 1.

Filed Date: 10/31/2008.

Accession Number: 20081103–0142.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP09–44–000.

Applicants: National Fuel Gas Supply Corporation.

Description: National Fuel Gas Supply Corporation submits 121st Revised Sheet 9 to FERC Gas Tariff Fourth Revised Volume 1.

Filed Date: 10/31/2008.

Accession Number: 20081103–0145.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP09–45–000.

Applicants: Trunkline Gas Company, LLC.

Description: Trunkline Gas Company, LLC submits Annual Interruptible Storage Revenue Credit Surcharge Adjustment re FERC Gas Tariff, Third Revised Volume 1.

Filed Date: 10/31/2008.

Accession Number: 20081103–0146.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP09–46–000.

Applicants: Southern LNG Inc.

Description: Southern LNG Inc. submits Twenty-Second Revised Sheet 5 to FERC Gas Tariff Original Volume 1.

Filed Date: 10/31/2008.

Accession Number: 20081103–0147.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP09–47–000.

Applicants: Wyoming Interstate Company, Ltd.

Description: Wyoming Interstate Company, Ltd submits Twenty-Third Revised Sheet 4C *et al.* to FERC Gas Tariff Second Revised Volume 2.

Filed Date: 10/31/2008.

Accession Number: 20081103–0148.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: RP09–48–000.

Applicants: Algonquin Gas Transmission Company.

Description: Algonquin Gas Transmission, LLC submits Third Revised Sheet 40 to its FERC Gas Tariff, Fifth Revised Volume 1, to be effective 12/1/08.

Filed Date: 10/31/2008.

Accession Number: 20081104–0030.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 12, 2008.

Docket Numbers: CP07–208–003.

Applicants: Rockies Express Pipeline LLC.

Description: Rockies Express Pipeline LLC submits Abbreviated application for limited amendment of the certificate of public convenience and necessity issued May 30, 2008.

Filed Date: 10/31/2008.

Accession Number: 20081031–5074.

Comment Date: 5 p.m. Eastern Time on Friday, November 14, 2008.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E8–26615 Filed 11–6–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–431–000]

Columbia Gas Transmission Corporation; Notice of Availability of the Environmental Assessment for the Proposed Ohio Storage Expansion Project

October 31, 2008.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared this environmental assessment (EA) on the natural gas storage facilities proposed by Columbia Gas Transmission Corporation (Columbia) in the above-referenced docket. Columbia's proposal (the Ohio Storage Expansion Project) would add additional storage and transmission capabilities to its existing Crawford (Fairfield and Hocking Counties, Ohio)

and Weaver Storage Fields (Ashland and Holmes Counties, Ohio).

The EA was prepared to satisfy the requirements of the National Environmental Policy Act of 1969. The staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The EA assesses the potential environmental effects of the construction and operation of the proposed Ohio Storage Expansion Project. The purpose of the project is to provide an additional 103,400 dekatherms per day of storage deliverability for service in the eastern United States and to increase storage capacity at these fields by 6.7 billion cubic feet of natural gas.

The EA has been placed in the public files of the FERC. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street, NE., Room 2A, Washington, DC 20426.

Copies of the EA have been mailed to federal, state, and local agencies; newspapers and libraries in the project area; parties to this proceeding; and those who have expressed an interest in this project by returning the Mailing List Form attached to the February 22, 2008 *Notice of Intent to Prepare an Environmental Assessment for the Proposed Ohio Storage Expansion Project and Request for Comments on Environmental Issues.*

Any person wishing to comment on the EA may do so. To ensure consideration prior to a Commission decision on the proposal, it is important that we receive your comments as specified below. Please carefully follow these instructions below to ensure that your comments are received in time and properly recorded.

- Send an original and two copies of your comments to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1A, Washington, DC 20426;
- Label one copy of the comments for the attention of Gas Branch 1, PJ–11.1;
- Reference Docket No. CP08–431–000; and
- Mail your comments so that they will be received in Washington, DC on or before December 1, 2008.

The Commission strongly encourages electronic filing of any comments. See Title 18 of the Code of Federal Regulations, Part 385.2001(a)(1)(iii) and the instructions on the Commission's Internet Web site at *http://www.ferc.gov* under the link to ''*Documents and Filings*'' and ''e-Filing.'' eFiling is a file attachment process and requires that you prepare your submission in the same manner as you would if filing on paper, and save it to a file on your hard drive. New eFiling users must first create an account by clicking on ''*Sign up*'' or ''*eRegister.*'' You will be asked to select the type of filing you are making. This filing is considered a ''Comment on Filing.'' In addition, there is a ''*Quick Comment*'' option available, which is an easy method for interested persons to submit text only comments on the project. The *Quick-Comment User Guide* can be viewed at *http://www.ferc.gov/docs-filing/efiling/quick-comment-guide.pdf.* Quick Comment does not require a FERC eRegistration account: However, you will be asked to provide a valid e-mail address. All comments submitted under either eFiling or the Quick Comment option are placed in the public record for the specified docket or project number(s).

Comments will be considered by the Commission but will not serve to make the commentor a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214). Only intervenors have the right to seek rehearing of the Commission's decisions. Anyone may intervene in this proceeding based on this EA. You must file your request to intervene as specified above.[1] You do not need intervenor status to have your comments considered.

Additional information about the project is available from the Commission's Office of External Affairs at 1–866–208–FERC or on the FERC Internet Web site (*http://www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number exluding the last three digits in the docket number field (i.e., CP08–431). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, contact (202) 502–8659. The eLibrary link on the FERC Internet Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notifications of these filings, document summaries, and direct links to the documents. Go to the eSubscription link on the FERC Internet Web site for more information or to subscribe to this service.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–26582 Filed 11–6–08; 8:45 am]

BILLING CODE 6717–01–P

[1] Interventions may also be filed electronically via the Internet in lieu of paper. See the previous discussion of filing comments electronically.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP08–96–000]

Arlington Storage Company, LLC; Notice of Availability of the Environmental Assessment for the Proposed Thomas Corners Storage Project

October 31, 2008.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) on the natural gas pipeline facilities proposed by Arlington Storage Company, LLC (ASC) in the above-referenced docket.

The EA was prepared to satisfy the requirements of the National Environmental Policy Act of 1969 (NEPA). The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

Three New York State agencies cooperated in the development of this EA. These agencies include the New York State Department of Environmental Conservation, New York State Department Agriculture and Markets, and the New York State Historic Preservation Office. These state agencies provided input for the preparation of this EA.

The EA assesses the potential environmental effects of the construction and operation of ASC's proposed Thomas Corners Storage (TCS) Project which includes all of the facilities described below in Steuben County, New York. ASC proposes to convert an abandoned natural gas production field into a new storage field referred to as the Thomas Corners Storage Field. The facilities to be constructed at the storage field are referred to as the Thomas Corners

Storage Facility (TCS Facility) and would consist of:

- Drilling up to 10 injection/withdrawal wells from a common well pad;
- Drilling two observation wells within the common well pad, if two former production wells located near the TCS Facility cannot be converted into observation wells;
- Constructing about 1.70 miles of gathering pipeline; and
- Constructing and operating a compressor station (Thomas Corners Storage Compressor Station) housing two gas-powered nominal 3,785-horsepower reciprocating engines within the TCS Facility on its western side.

The TCS Facility would have a total working gas capacity of about 7.0 Bcf and would occupy about a 27.0-acre site.

ASC also proposes to:

- Construct about 8.09 miles of 12-inch-diameter pipeline, called the Thomas Corners West Lateral;
- Use an existing 7.50-mile-long, 8-inch-diameter pipeline, called the Thomas Corners South Lateral;
- Construct a 0.19-mile-long extension on the Thomas Corners South Lateral; and
- Construct three meter and regulator stations and interconnections with Columbia Gas Transmission Corporation, Tennessee Gas Pipeline Company, and Corning Natural Gas Company.

The Thomas Corners Storage Field would have a total working gas capacity of about 7 billion cubic feet (Bcf) of natural gas within an abandoned natural gas production field. The purpose of the project is to provide highly flexible services natural gas storage services for two interstate gas transmission systems and a local distribution company.

The EA has been placed in the public files of the FERC. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street, NE., Room 2A, Washington, DC 20426, (202) 502–8371.

Copies of the EA have been mailed to federal, state, and local agencies; public interest groups; interested individuals; newspapers and libraries in the project area; Native America groups; and parties to this proceeding. Any person wishing to comment on the EA may do so. To ensure consideration prior to a Commission decision on the proposal, it is important that we receive your comments before the date specified below.

Please note that the Commission strongly encourages electronic filing of any comments or interventions or protests to this proceeding. See Title 18 of the Code of Federal Regulations, § 385.2001(a)(1)(iii) and the instructions on the Commission's Internet Web site at *http://www.ferc.gov* under the link to ''Documents and Filings'' and ''eFiling.'' eFiling is a file attachment process and requires that you prepare your submission in the same manner as you would if filing on paper, and save it to a file on your computer's hard drive. New eFiling users must first create an account by clicking on ''Sign up'' or ''eRegister.'' You will be asked to select the type of filing you are making. This filing is considered a ''Comment on Filing.'' In addition, there is a ''*Quick Comment*'' option available, which is an easy method for interested persons to submit text only comments on a project. The Quick-Comment User Guide can be viewed at *http://www.ferc.gov/docs-filing/efiling/quick-comment-guide.pdf.* Quick Comment does not require a FERC eRegistration account; however, you will be asked to provide a valid e-mail address. All comments submitted under either eFiling or the Quick Comment option are placed in the public record for the specified docket.

If you are filing written comments, please carefully follow these instructions to ensure that your comments are received in time and properly recorded:

- Send an original and two copies of your comments to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1A, Washington, DC 20426.
- Reference Docket No. CP08–96–000;
- Label one copy of the comments for the attention of the Gas Branch 1, PJ–11.1; and
- Mail your comments so that they will be received in Washington, DC on or before December 1, 2008.

Comments will be considered by the Commission but will not serve to make the commentor a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).[1] Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your comments considered.

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC or on the FERC Internet Web site (*http://www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number excluding the last three digits in the Docket Number field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries and direct links to the documents. To register for this service, go to the eSubscription link on the FERC Internet Web site (*http://www.ferc.gov/esubscribenow.htm*).

Kimberly D. Bose,

Secretary.

[FR Doc. E8–26580 Filed 11–6–08; 8:45 am]

BILLING CODE 6717–01–P

[1] Interventions may also be filed electronically via the Internet in lieu of paper. See the previous discussion on filing comments electronically.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR08–23–001]

Worsham-Steed Gas Storage, L.P.; Notice of Compliance Filing

October 31, 2008.

Take notice that on October 27, 2008, Worsham-Steed Gas Storage, L.P. filed a Statement of Operating Conditions for both gas storage and transportation service pursuant to section 284.123(e) of the Commission's regulations and to comply with the Commission's letter order issued on September 25, 2008, in Docket No. PR08–23–000.

Any person desiring to participate in this proceeding must file a motion to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of

Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on November 7, 2008.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–26581 Filed 11–6–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP08–350–000]

Southern Star Central Gas Pipeline, Inc.; Revised Notice of Informal Settlement Conference

October 31, 2008.

Take notice that an informal settlement conference will be convened in this proceeding commencing at 1 p.m. on Wednesday, November 12, 2008. The conference will continue through close of business Friday, November 14, 2008, if necessary at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, for the purpose of exploring the possible settlement of the above-referenced dockets.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined by 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an e-mail to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or (202) 208–1659 (TTY), or send a FAX to (202) 208–2106 with the required accommodations.

For additional information, please contact James Keegan at (202) 502–8158, *James.Keegan@ferc.gov.*

Kimberly Bose,

Secretary.

[FR Doc. E8–26579 Filed 11–6–08; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2009–0799; FRL–8389–8]

Certain New Chemicals; Receipt and Status Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from October 6, 2008 through October 17, 2008, consists of the PMNs pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

DATES: Comments identified by the specific PMN number or TME number, must be received on or before December 8, 2008.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2009–0799, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2009–0799. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2009–0799. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects

or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the docket are listed in the docket index available in regulations.gov. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT:

Colby Lintner, Regulatory Coordinator, Environmental Assistance Division, Office of Pollution Prevention and Toxics (7408M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitter of the premanufacture notices addressed in the action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Why is EPA Taking this Action?

Section 5 of TSCA requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a PMN or an application for a TME and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from October 6, 2008 through October 17, 2008, consists of the PMNs pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

III. Receipt and Status Report for PMNs

This status report identifies the PMNs or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period. If you are interested in information that is not included in the following tables, you may contact EPA as described in Unit I. to access additional non-CBI information that may be available.

In Table I of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the PMNs received by EPA during this period: the EPA case number assigned to the PMN; the date the PMN was received by EPA; the projected end date for EPA's review of the PMN; the submitting manufacturer; the potential uses identified by the manufacturer in the PMN; and the chemical identity.

I. 22 PREMANUFACTURE NOTICES RECEIVED FROM: 10/06/08 TO 10/17/08

Case No.	Received Date	Projected Notice End Date	Manufacturer/Importer	Use	Chemical
P–09–0003	10/03/08	12/31/08	Gelest, Inc.	(G) Monomer for use in cured fabrication of an article	(S) 2-propenoic acid, 2-methyl-, (dimethylphenylsilyl)methyl

I. 22 PREMANUFACTURE NOTICES RECEIVED FROM: 10/06/08 TO 10/17/08—Continued

Case No.	Received Date	Projected Notice End Date	Manufacturer/Importer	Use	Chemical
P–09–0004	10/03/08	12/31/08	CBI	(G) Rubber additive	(G) Isocyanate polymer
P–09–0005	10/03/08	12/31/08	CBI	(G) Resin	(G) Substituted phenol, polymer with 2-(chloromethyl)oxirane 1,3-diisocyanatomethylbenzene, 2-ethylhexanoate (ester), cyclized, reaction products with diethylenetriamine and 2-(methylamino) ethanol
P–09–0006	10/06/08	01/03/09	Archer daniels midland company	(G) Petrochemical replacement	(S) Canola oil, oleic acid-high. Extractives and their physically modified derivatives. it consists primarily of the glycerides of oleic fatty acid. (*Brassica napus* and *Brassica campestris*, hybrid).
P–09–0007	10/06/08	01/03/09	Archer Daniels Midland Company	(G) Petrochemical replacement	(S) Safflower oil, oleic acid-high. Extractives and their physically modified derivatives. It consists primarily of the glycerides of oleic fatty acid. (*Carthamus tinctorius hybrid*).
P–09–0008	10/08/08	01/05/09	Hi-Tech Color, Inc.	(S) Inkjet ink ingredient	(S) Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with 1,3-dioxolan-2-one, 1,6-hexanediol, hydrazine, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane and 1,5-pentanediol, ethanolamine-blocked, compounds with triisopropanolamine
P–09–0009	10/08/08	01/05/09	CBI	(G) Chemical intermediate	(G) Glycolate ester
P–09–0010	10/09/08	01/06/09	CBI	(G) 1 part of a 2-part polyurethane adhesive	(G) Polyurethane pre-polymers of polymeric mdi and polyether polyols
P–09–0011	10/09/08	01/06/09	CBI	(G) Resin modifier for unsaturated resins	(G) Unsaturated urethane acrylate
P–09–0012	10/09/08	01/06/09	CBI	(S) Chemical intermediate	(S) Magnesium, chloroethenyl-
P–09–0013	10/09/08	01/06/09	Para-Chem, Inc. /Standard Division	(G) Binder	(G) Acrylate, polymers with butyl acrylate, methyl methacrylate, styrene.
P–09–0014	10/09/08	01/06/09	Firmenich Inc.	(S) Aroma for use in fragrance mixtures, which in turn are used in perfumes, soaps, cleansers, etc.	(S) Oils, *Iris germanica*. Extractives and their physically modified derivatives. *Iris germanica*.
P–09–0015	10/09/08	01/06/09	CBI	(G) Adhesion promoter in polyurethane adhesive/sealant.	(G) Isocyanate silane adduct
P–09–0016	10/10/08	01/07/09	CBI	(G) Coating component	(G) Fluoroethylene vinyl copolymer
P–09–0017	10/14/08	01/11/09	The Dow Chemical Company	(G) Polymeric intermediate	(G) Diphenyl isocyanate diol prepolymer
P–09–0018	10/14/08	01/11/09	The Dow Chemical Company	(G) Polymeric intermediate	(G) Diphenyl isocyanate diol prepolymer
P–09–0019	10/14/08	01/11/09	CBI	(S) Epoxy resin for filament winding; epoxy resin for electrical encapsulation-motors, generators	(G) 4-cyclohexene-1,2-bis(2-oxiranylmethyl) ester
P–09–0020	10/14/08	01/11/09	CBI	(G) Coating intermediate	(G) Heterocyclic alklether substituted silane triol
P–09–0021	10/14/08	01/11/09	CBI	(G) Resin (open, non-dispersive)	(G) Polyurethane thermoplastic
P–09–0022	10/15/08	01/12/09	CBI	(G) Coating	(G) Alkyl oxiranes, polymer with alkyl triol, polymer with polyalkylene oxides and alkyl isocyanate
P–09–0023	10/15/08	01/12/09	CBI	(G) Coating	(G) Alkyl oxiranes, polymer with alkyl triol, polymer with polyalkylene oxides and alkyl isocyanate
P–09–0024	10/15/08	01/12/09	Evonik Degussa Corporation	(S) Extrusion of tubing systems; injection molded semi-finished articles	(G) Polymer of alkanedioic acid and alkanediamine

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the Notices of Commencement to manufacture received:

II. 19 NOTICES OF COMMENCEMENT FROM: 10/06/08 TO 10/17/08

Case No.	Received Date	Commencement Notice End Date	Chemical
P–03–0487	10/07/08	12/19/03	(S) 2-propenenitrile, polymer with 1,3-butadiene, 3-carboxy-1-cyan0-1-methylpropyl-terminated, reaction products with 2,2′-[(1-methylethylidene)bis[(2,6-dibromo-4,1-phenylene)oxymethylene]]bis[oxirane]-4,4′-(1-methylethylidene)bis[2,6-dibromophenol] polymer, dimethacrylates (esters)
P–07–0171	10/09/08	10/06/08	(G) Polyoxyalkylene siloxane
P–07–0446	10/03/08	09/19/08	(G) Fluoroalkyl acrylate copolymer
P–07–0589	10/09/08	09/17/08	(G) Substituted dibasic ester
P–07–0590	10/09/08	09/18/08	(G) Substituted dibasic ester
P–07–0591	10/09/08	09/17/08	(G) Substituted dibasic ester
P–07–0592	10/09/08	09/17/08	(G) Substituted dibasic ester
P–07–0593	10/09/08	09/17/08	(G) Substituted dibasic ester
P–07–0724	10/10/08	09/22/08	(G) Substituted benzene polymer, aminomethylated
P–08–0222	10/10/08	10/01/08	(G) Fluoroalkyl acrylate copolymer
P–08–0411	10/03/08	09/12/08	(G) Carbohydrate polymer with 2,5-furandione and 2-propenoic acid, sodium salt, hydrogen peroxide- and peroxydisulfuric acid ([(ho)s(o)2]202) sodium salt (1:2)-initiated
P–08–0413	10/03/08	09/12/08	(G) Carbohydrate polymer with 2,5-furandione, methyl 2-methyl-2-propenoate, 2-propenoic acid, sodium 4-ethenylbenzenesulfonate (1:1) and sodium 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-1-propanesulfonate (1:1), sodium salt, hydrogen peroxide- and peroxydisulfuric acid ([(ho)s(o)2]202) sodium salt (1:2)-initiated
P–08–0416	10/03/08	09/12/08	(G) Carbohydrate polymer with 1-methyl hydrogen (2*Z*)-2-butenedioate, 1,2-propanediol mono(2-methyl-2-propenoate) and 2-propenoic acid, ammonium salt, tert-bu hydroperoxide-initiated
P–08–0469	10/03/08	09/12/08	(G) Isocyanate terminated hydroxylpolyalkyl polyurethane prepolymer
P–05–0283	10/15/08	09/26/08	(G) Polyalkyl-alkoxy-polyheteroatom containing alkanoic acid
P–07–0724	10/10/08	09/22/08	(G) Substituted benzene polymer, aminomethylated
P–08–0222	10/10/08	10/01/08	(G) Fluoroalkyl acrylate copolymer
P–08–0463	10/15/08	09/28/08	(S) 2*H* pyran-2-one, tetrahydro-5-propyl
P–08–0478	10/15/08	09/29/08	(G) Acrylic polymer, polymers with acrylates and polyethylene glycol acrylate alkyl ethers

List of Subjects

Environmental protection, Chemicals, Premanufacturer notices.

Dated: October 31, 2008.

Vanessa Williams,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. E8–26494 Filed 11–6–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–8587–4]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and Section 102(2) (c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at 202–564–7146.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 6, 2008 (73 FR 19833).

Draft EISs

EIS No. 20080291, ERP No. D–AFS–J65522–CO, Colorado Roadless Areas Rulemaking, Proposes to Promulgate a State-Specific Rule to Manage Roadless Values and Characteristics, Colorado Forests with Roadless Areas include: Arapaho and Roosevelt: Grand Mesa, Uncompahgre, and Gunnison; Manti-La Sal (portion in Colorado); Pike and San Isabel; Rio Grande; Routt: San Juan; and White River National Forests, CO.

Summary: EPA expressed environmental concerns about potential impacts to air quality, especially visibility and water quality from new roads, and the number of acres at risk to the establishment of invasive plants from ground-disturbing activities within the Colorado Roadless Areas. Rating EC2.

EIS No. 20080346, ERP No. D–USN–L11039–WA, Naval Sea Systems Command (NAVSEA). Naval Undersea Warfare Center (NUWC), Keyport Complex Extension, Propose to Extend the Operational Areas, Three Distinct Range Sites: Keyport Range Site; Dabob Bay Range Complex (DBRC) Site, Quinault Underwater Tracking Range Site, Gray Harbor, Jefferson, Kitsap and Mason Counties, WA.

Summary: EPA expressed environmental concerns about impacts to water quality and critical habitat in Puget Sound and to protected resources in the Olympic Coast National Marine Sanctuary. Rating EC2.

EIS No. 20080349, ERP No. D–AFS–K65346–CA, Round Valley Fuels Reduction and Vegetation Management Project, Proposes to Reduce Fuel and Manage Vegetation, Funding, Goosenest Ranger District, Klamath National Forest, Siskiyou County, CA.

Summary: EPA's review has identified no environmental impacts requiring substantive changes to the proposed action. Rating LO.

EIS No. 20080350, ERP No. D–NOA–E91026–00, PROGRAMMATIC EIS—Fishery Management Plan for Regulating Offshore Marine Aquaculture in the Gulf of Mexico, To Increase the Maximum Sustainable Yield (MSY) and Optimum Yield (OY), Implementation.

Summary: EPA expressed environmental concern about the potential for excess nutrients to cause organic loading within the water column. Rating EC1.

Final EISs

EIS No. 20080358, ERP No. F–SFW–G99007–TX, Williamson County Regional Habitat Conservation Plan, Application for an Incidental Take Permit, Williamson County, TX.

Summary: No formal comment letter was sent to the preparing agency.

EIS No. 20080371, ERP No. F–FAA–G59005–TX, ADOPTION—Northwest Corridor Light Rail Transit Line (LRT) to Irving/Dallas/Fort Worth International Airport, Construction, Dallas County, TX.

Summary: No formal EPA comment letter was sent to the preparing agency.

EIS No. 20080400, ERP No. F–DOE–J05080–MT, MATL 230–kV Transmission Line Project, To Construct, Operate, Maintain, and Connects a 230–kV Electric Transmission Line, Issuance of Presidential Permit for Right-to-Way Grant, Cascade, Teton, Chouteau, Pondera, Toole and Glacier Counties, MT.

Summary: EPA continues to have environmental concern about water quality impacts.

EIS No. 20080384, ERP No. FS–MMS–G02016–00, Gulf of Mexico Outer Continental Shelf Oil and Gas Lease Sales: 2009–2012 Western Planning Area Sales: 210 in 2009, 215 in 2010, and 218 in 2011, and Central Planning Area Sales: 208 in 2009, 213 in 2010, 216 in 2011, and 222 in 2012, TX, LA, MS, AL and FL.

Summary: No formal comment letter was sent to the preparing agency.

Dated: November 4, 2008.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E8–26667 Filed 11–6–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–8587–3]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–1399 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 10/27/2008 Through 10/31/2008

Pursuant to 40 CFR 1506.9

EIS No. 20080440, Second Draft Supplement, COE, CA, Hamilton Wetland Restoration Project, Dredged Material Aquatic Transfer Facility, Implementation, Marin County, CA, *Comment Period Ends:* 12/22/2008, *Contact:* Cynthia Jo Fowler 415–503–6870.

EIS No. 20080441, Draft EIS, FHW, OR, Sellwood Bridge Project, Rehabilitate or Replace the Bridge Crosses the Willamette River on Southeast Tacoma Street and Oregon State Highway 43, Funding, Multnomah County, OR, *Comment Period Ends:* 12/22/2008, *Contact:* Jeffrey Graham 503–587–4727.

EIS No. 20080442, Draft Supplement, AFS, CO, White River National Forest Travel Management Plan, Updated Information for the Preferred Alternative, To Accommodate and Balance Transportation Needs, Implementation, Eagle, Garfield, Gunnison, Mesa, Moffat, Pitkin, Rio Blanco, Routt and Summit Counties, CO, *Comment Period Ends:* 01/06/2009, *Contact:* Wendy Haskins 970–945–3303.

EIS No. 20080443, Final Supplement, BLM, MT, Montana Statewide Oil and Gas, Development Alternative for Coal Bed Natural Gas Production and Amendment of the Powder River and Billings Resource Management Plans, Additional Information Three New Alternatives, Implementation, U.S. Army COE Section 404 Permit, NPDES Permit, Several Cos, MT, *Wait Period Ends:* 12/08/2008, *Contact:* Mary Bloom 406–233–2852.

EIS No. 20080444, Final EIS, NPS, HI, PROGRAMMATIC EIS—Ala Kahakai National Historic Trail Comprehensive Management Plan, To Provide Long-Term Direction for Natural and Cultural Resource, Island of Hawaii, HI, *Wait Period Ends:* 12/08/2008, *Contact:* Aric Arakaki 808–326–6012.

EIS No. 20080445, Draft EIS, FTA, CA, Berkeley/Albany Ferry Terminal Study, Proposing to Implement New Ferry Service between Berkeley/Albany and the San Francisco Ferry Building, Funding, San Francisco Water Transit Authority (WETA), Berkeley/Albany, CA, *Comment Period Ends:* 12/31/2008, *Contact:* Ray Sukys 415–744–3133.

EIS No. 20080446, Final EIS, BLM, CA, Mountain View IV Wind Energy Project, Construction and Operation, Wind Turbine Generators on Public Lands in Section 22 and 28 and Private Land Section 27, Right-of-Way Grant and Conditional Use Permit in the City of Palm Springs, CA, *Wait Period Ends:* 12/08/2008, *Contact:* Greg Hill 760–251–4848.

EIS No. 20080447, Draft EIS, AFS, WI, Camp Four Vegetation Project, Proposes Vegetation and Road Management Activities, Desired Future Condition (DFC), Medford-Park Falls Ranger District, Chequamegon-Nicolet National Forest, Price County, WI, *Comment Period Ends:* 12/22/2008, *Contact:* Ann Hoefferle 715–758–4875 Ext 24.

EIS No. 20080448, Draft EIS, NPS, AZ, Fire Management Plan, Management of Wildland and Prescribed Fire, Protection of Human Life and Property Restoration and Maintenance of Fire Dependent Ecosystems, and Reduction of Hazardous Fuels, Grand Canyon National Park, Coconino County, AZ, *Comment Period Ends:* 12/22/2008, *Contact:* Chris Marks 986–606–1050.

EIS No. 20080449, Final EIS, AFS, CA, Sugarberry Project, Proposes to Protect Rural Communities from Fire Hazards by Constructing Fuel Breaks Known as Defensible Fuel Profile Zones (DFPZs), Feather River Ranger District, Plumas National Forest, Plumas, Sierra, Yuba Counties, CA, *Wait Period Ends:* 12/08/2008, *Contact:* Sharen Parker 530–534–6500.

EIS No. 20080450, Final EIS, NOA, 00, Amendment 16 to the Fishery Management Plan for the Snapper Grouper Fishery, Additional Information to Analyze Four New Management Measures Alternatives for Gag and Vermillion Snapper, Implementation, South Atlantic Region, *Wait Period Ends:* 12/08/2008, *Contact:* Roy E. Crabtree 727–824–5305.

EIS No. 20080451, Draft EIS, COE, CA, University of California (UC) Merced Campus and University Community Project, Development of a Major Research University, To Allow for the Discharge of Fill Material into 76.7 Acres of Wetlands, U.S. Army COE Section 404 Permit, Merced County, CA, *Comment Period Ends:* 01/05/2009, *Contact:* Nancy Haley 916–557–7731.

EIS No. 20080452, Final EIS, GSA, DC, Department of Homeland Security Headquarters at the St. Elizabeths West Campus, To Consolidate Federal Office Space on a Secure Site, Washington, DC, *Wait Period Ends:* 12/08/2008, *Contact:* Denise Decker 202–538–5643.

EIS No. 20080453, Final EIS, FTA, 00, Access to the Region's Core Project, Additional Information on the Build Alternative, To Increase Trans-Hudson Commuter Rail Capacity, Improve System Safety and Reliability between Secaucus Junction Station in NJ and midtown Manhattan, Funding, Hudson County, NJ, and New York County, NY, *Wait Period Ends:* 12/08/

2008, *Contact:* Donald Burns 212–668–2182.

EIS No. 20080454, Final EIS, OSM, 00, Black Mesa Project, Revisions to the Life-of-Mine Operation and Reclamation for the Kayenta and Black Mesa Surface-Coal Mining Operations, Right-of-Way Grant, Mohave, Navajo, Coconino and Yavapai Counties, AZ, and Clark County, NV, *Wait Period Ends:* 12/08/2008, *Contact:* Dennis Winterringer 303–293–5030.

Amended Notices

EIS No. 20080296, Final EIS, FHW, TX, Grand Parkway (State Highway 99) Selected the Preferred Alternative Alignment, Segment F–2 from SH 249 to IH 45, Right-of-Way Permit and U.S. Army COE Section 404 Permit, Harris County, TX, *Wait Period Ends:* 11/26/2008, *Contact:* Justin Ham 512–536–5963. Revision to FR Notice Published 08/08/2008. Extending Wait Period from 11/07/2008 to 11/26/2008.

EIS No. 20080333, Draft EIS, IBR, CO, Windy Gap Firming Project, Construct a New Water Storage Reservoir To Deliver Water to Front Range and West Slope Communities and Industries, Funding, NPDES and U.S. Army COE Section 404 Permit, Grand and Larimer Counties, CO, *Comment Period Ends:* 12/29/2008, *Contact:* Will Tully 970–962–4368. Revision to FR Notice Published 08/29/2008: Extending Comment Period 10/28/2008 to 12/29/2008.

EIS No. 20080416, Final EIS, BLM, OR, Western Oregon Bureau of Land Management Districts of Salem, Eugene, Roseburg, Coos Bay, and Medford Districts, and the Klamath Falls Resource Area of the Lakeview District, Revision of the Resource Management Plans, Implementation, OR, *Wait Period Ends:* 11/17/2008, *Contact:* Jerry Hubbard 503–808–6115. Revision of FR Notice Published 10/17/2008: Correction to Wait Period from 12/01/2008 to 11/17/2008.

Dated: November 4, 2008.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E8–26605 Filed 11–6–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8738–6]

Proposed CERCLA Administrative Cost Recovery Settlement; City of Waterbury, CT, Chase Brass & Copper Site, Watertown, CT

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement; request for public comment.

SUMMARY: In accordance with Section 122(i) of the Comprehensive Environmental Response Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement for recovery of past costs concerning the Chase Brass & Copper Superfund Site in Watertown, Connecticut with the following settling party: City of Waterbury, Connecticut. The settlement requires the settling party to pay $75,000 to the Hazardous Substance Superfund. The settlement includes a covenant not to sue for the settling party pursuant to Section 107(a) of CERCLA, 42 U.S.C. 9607(a). For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate.

The Agency's response to any comments received will be available for public inspection at One Congress Street, Boston, MA 02114–2023.

DATES: Comments must be submitted by December 8, 2008.

ADDRESSES: Comments should be addressed to Mary Jane O'Donnell, Chief, ME/VT/CT Superfund Section, U.S. Environmental Protection Agency, Region I, One Congress Street, Suite 1100 (HBT), Boston, Massachusetts 02114–2023 (Telephone No. 617–918–1371) and should refer to: In re: Chase Brass & Copper Superfund Site, U.S. EPA Docket No. 01–2008–0010.

FOR FURTHER INFORMATION CONTACT: A copy of the proposed settlement may be obtained from Mary Jane O'Donnell, Chief, ME/VT/CT Superfund Section, U.S. Environmental Protection Agency, Region I, One Congress Street, Suite 1100 (HBT), Boston, Massachusetts 02114–2023 (Telephone No. 617–918–1371; E-mail *odonnell.maryjane@epa.gov*).

Dated: September 8, 2008.

James T. Owens, III,

Director, Office of Site Remediation and Restoration, Region 1.

[FR Doc. E8–26670 Filed 11–6–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8739–5]

State Program Requirements; Approval of Application by Alaska To Administer the National Pollutant Discharge Elimination System (NPDES) Program; Alaska

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On October 31, 2008, the Regional Administrator for the Environmental Protection Agency, Region 10 (EPA), approved the application by the State of Alaska to administer and enforce an Alaska version of the National Pollutant Discharge Elimination System (NPDES) program, pursuant to section 402 of the Clean Water Act (CWA or ''the Act''). The State will administer the approved Alaska Pollutant Discharge Elimination System (APDES) program through the Alaska Department of Environmental Conservation (ADEC) regulating discharges of pollutants into waters of the United States under its jurisdiction. EPA has approved the State's implementation plan that transfers the administration of specific program components from EPA to the State over a three year period from the date of program approval, subject to continuing EPA oversight and enforcement authority, in place of the NPDES program previously administered by EPA in Alaska. Upon approval of the Alaska program, the Regional Administrator notified the State, signed the Memorandum of Agreement between EPA and ADEC, and will suspend issuance of NPDES permits in Alaska in accordance with the State's approved schedule to transfer NPDES program authority. EPA retains NPDES permitting authority and primary enforcement responsibility for: the bio-solids program; facilities operating in the Denali National Park and Preserve pursuant to Alaska Statehood Act Section 11; facilities discharging in Indian Country as defined in 18 U.S.C. 1151; facilities operating outside state waters (three miles offshore); and facilities with CWA section 301(h) waivers. This approval includes an implementation plan that transfers the

administration of specific program components from EPA to the State over a three year period from the date of program approval. In making its decision, EPA considered and addressed the comments and issues raised during the public comment period, public testimony at three public hearings, and comments expressed by tribes during the requested government-to-government tribal consultations.

DATES: Pursuant to 40 CFR 123.61(c), the APDES program was approved and became effective on October 31, 2008.

FOR FURTHER INFORMATION CONTACT: Michael Lidgard, Office of Water and Watersheds, U.S. Environmental Protection Agency, Region 10, 1200 6th Avenue, Suite 900, Mail Stop OWW–130, Seattle, WA 98101–3140, (206) 553–1755, *lidgard.michael@epa.gov;* or Sharon Morgan, Alaska Department of Environmental Conservation, P.O. Box 111800, 410 Willoughby Avenue, Suite 303, Juneau, AK 99811–1800, (907) 465–5530, *sharon.morgan@alaska.gov.* The State's program application, supporting documentation and EPA's response to comments can be viewed and downloaded from the EPA Web site, *http://www.epa.gov/r10earth/waterperimits,* and the State's program application can also be viewed from the ADEC's Web site, *http://www.dec.state.ak.us/water/npdes/npdes.htm.*

SUPPLEMENTARY INFORMATION: The Alaska program application was described in the **Federal Register** (73 FR 34746) published on June 18, 2008, in which EPA requested comments. Notice of Alaska's program application was published in four State of Alaska newspapers on June 18, 2008. Combined NPDES educational workshops and public hearings on the Alaska program application were held in Fairbanks, Alaska, on July 21, 2208, in Juneau, Alaska, on July 22, 2008, and in Anchorage, Alaska, on July 23, 2008. EPA held government-to-government tribal consultations as requested in Dillingham, Alaska, on May 12, 2008, in Kotzebue, Alaska, on August 5, 2008, in Sitka, Alaska, on September 11, 2008, and in Bethel, Alaska, on September 30, 2008. Additionally, EPA held government-to-government consultation teleconferences as requested by the Loudon Tribal Council of Galena, Alaska, on May 8, 2008; and with Sun'aq Tribe of Kodiak, Alaska, on October 3, 2008.

Section 402(c)(1) of the CWA provides that ninety days after a State has submitted an application to administer the NPDES program, EPA's authority to issue such permits is suspended unless EPA disapproves or approves the State's application or EPA and the State mutually agree to extend this 90-day statutory review period in accordance with 40 CFR 123.21(b)(1) and 123.61(b). EPA Region 10 determined that the APDES program application received on May 1, 2008, along with revisions received up to June 9, 2008, were administratively complete pursuant to 40 CFR 123.21. On June 10, 2008, a letter of completeness and confirmation of the mutual agreement to extend the statutory review period was sent to the Commissioner of ADEC.

In accordance with section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act, EPA completed a ''Determination of No Adverse Effect on Essential Fish Habitat of Alaska's APDES Program Authorization,'' August 2008. On August 28, 2008, EPA sent the National Marine Fisheries Service a courtesy copy of the no effect determination.

A. Scope of APDES Program

The State of Alaska is applying to administer the NPDES permitting, compliance and enforcement programs for individual and general permits, as well as for the pretreatment and stormwater programs in Alaska. The State did not apply to regulate the disposal of sewage sludge (Bio-Solids Program) in Alaska. EPA retains NPDES permitting authority and primary enforcement responsibility over the Bio-Solids Program in accordance with section 405 of the Act and 40 CFR part 503.

Additionally, EPA will retain NPDES permitting authority and primary enforcement responsibility over the following: operations in the Denali National Park and Preserve pursuant to Alaska Statehood Act section 11; NPDES facilities discharging in Indian Country as defined in 18 U.S.C. 1151; facilities operating outside state waters (three miles offshore); and facilities with CWA section 301(h) waivers.

The State of Alaska has been approved to assume responsibility for the NPDES programs in phases, pursuant to the CWA section 402(n)(4). Alaska's application meets the requirements for such a phased approach. In accordance with CWA section 402(n)(4), EPA may approve a phased permit program covering administration of a major component that represents a significant and identifiable part of the NPDES program.

The State will administer the NPDES program by phases and agrees to make all reasonable efforts to assume such administration by the deadlines. Specifically, ADEC's approval includes a schedule for EPA to transfer permit, compliance, and enforcement responsibility for the NPDES program to DEC over three years from the APDES program approval date, October 31, 2008. The following schedule identifies the phasing plan that the approved APDES program will administer for its permitting, compliance, and enforcement activities associated with each major component: Phase I, at program approval the APDES program will include Domestic Discharges, Timber Harvesting, Seafood Processing Facilities, and Hatcheries. Phase II, one year from program approval, the APDES program will include Federal Facilities, Stormwater Program (excluding the Bio-Solids Program), Pretreatment Program, and miscellaneous non-domestic discharges. Phase III, two years from program approval, the APDES program will include Mining. Phase IV, three years from program approval, the APDES program will include Oil and Gas, Cooling Water intakes and dischargers, Munitions, and all other remaining facilities.

Pursuant to CWA section 402(d), in specified circumstances EPA retains the right to object to APDES permits proposed by ADEC and, if the objections are not resolved, to issue the permits itself. As part of operating the approved program, ADEC generally will have the lead responsibility for enforcement. However, EPA will retain its full statutory enforcement authorities under CWA sections 308, 309, 402(i) and 504. Thus, EPA may continue to bring federal enforcement action under the CWA in response to any violation of the CWA, as appropriate. In particular, if EPA determines that the State has not taken timely and/or appropriate enforcement action against a violator in Alaska, EPA may take its own enforcement action.

Additional details about the scope and summary of the APDES program application can be found in the **Federal Register** (73 FR 34746) published on June 18, 2008. Additionally, the APDES program is described in documents the State submitted in accordance with 40 CFR 123.21, which include a letter from the Governor requesting program approval; a Memorandum of Agreement (MOA) for execution by ADEC and EPA; a Program Description outlining the procedures, personnel, and protocols that will be relied on to implement the State's permitting, compliance, and enforcement program; a Statement signed by the Attorney General that describes the State's legal authority to administer a program equivalent to the federal NPDES program; and a

description of the State's Continuing Planning Process.

B. Public Comments

The EPA received numerous public comments concerning the Alaska APDES program. Several comments urged the EPA to approve the State's program. Supporters of approval felt the State had met all of the CWA requirements and that the program would benefit from being operated by ADEC though increased accessibility, resources, and familiarity with Alaska conditions. Comments were received that urged EPA to not approve the authorization request based on grounds that the application did not meet CWA requirements, including the lack of an adequate state enforcement program. Numerous Tribal governments and communities expressed concerns that once Alaska receives authorization, government-to-government tribal consultation with EPA would no longer be required and Tribes would lose an avenue for providing input into permit decisions. Some Tribes assert EPA's trust responsibilities to Tribes prohibit program approval until all Tribal concerns are addressed. All public comments are addressed in the EPA Response to Comments document dated October 31, 2008, and can be viewed and downloaded from the EPA Web site, *http://www.epa.gov/r10earth/waterpermits.htm.*

C. Obtaining Copies of Documents

To obtain copies of documents contact Audrey Washington, Office of Water and Watersheds, U.S. Environmental Protection Agency, Region 10, 1200 6th Avenue, Suite 900, Mail Stop OWW–130, Seattle, WA 98101–3140, (206) 553–0523, *washington.audrey@epa.gov;* or Sharon Morgan, Alaska Department of Environmental Conservation, P.O. Box 111800, 410 Willoughby Avenue, Suite 303, Juneau, AK 99811–1800, (907) 465–5530, *sharon.morgan@alaska.gov.*

D. Notice of Decision

I hereby provide public notice that EPA has taken final action authorizing Alaska to administer and implement the approved Alaska Pollutant Discharge Elimination System (APDES) program through the Alaska Department of Environmental Quality (ADEC) regulating discharges of pollutants into waters of the United States under its jurisdiction.

Authority: This action is taken under the authority of section 402 of the Clean Water Act as amended, 42 U.S.C. 1342.

Dated: October 31, 2008.

Elin D. Miller,

Regional Administrator, EPA, Region 10.

[FR Doc. E8–26486 Filed 11–6–08; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ELECTION COMMISSION

Sunshine Act Notices

AGENCY: Federal Election Commission.

DATE AND TIME: Friday, November 7, 2008 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED: Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C. Matters concerning participation in civil actions or proceedings or arbitration. Internal personnel rules and procedures or matters affecting a particular employee.

PERSON TO CONTACT FOR INFORMATION: Mr. Robert Biersack, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. E8–26420 Filed 11–6–08; 8:45 am]

BILLING CODE 6715–01–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than November 24, 2008.

A. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. First National Bank of Sparta Profit Sharing Plan; David Hauskins; Roger Deterding; and Mary Lou Bauer, each as Trustees of the Plan, together with David Hauskins; Mary Hauskins; The Roger L. Deterding Declaration of Trust; Roger L. Deterding as Trustee; The Nancy K. Deterding Declaration of Trust; Nancy K. Deterding as Trustee, all of Sparta, Illinois, and Mary Lou Bauer, Red Bud, Illinois, to gain control of First Bancorp of Sparta, Ltd., and thereby indirectly acquire control of First National Bank of Sparta, both of Sparta, Illinois.

Board of Governors of the Federal Reserve System, November 4, 2008.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E8–26601 Filed 11–6–08; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/.*

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 4, 2008.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Bank Applications Officer) 33 Liberty Street, New York, New York 10045–0001:

1. Morgan Stanley, to acquire up to 9.9 percent of the voting shares of Heritage Bank, N.A. (in organization), both of New York, New York.

B. Federal Reserve Bank of Chicago (Burl Thornton, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. First Community Financial Partners, Inc., Joliet, Illinois, to acquire at least 50.1 percent of the voting shares of Burr Ridge Bank and Trust (in organization), Burr Ridge, Illinois.

2. Golden Eagle Bancorp, Inc., to become a bank holding company by acquiring 100 percent of the voting shares of Golden Eagle Community Bank, both of Woodstock, Illinois.

In connection with this application, Applicant also has applied to engage in extending credit and servicing loans, pursuant to section 225.28(b)(1) of Regulation Y.

C. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. Independent Bank Group, Inc., to acquire by merger 100 percent of Independent Bank Group Central Texas, Inc., both of McKinney, Texas, and thereby indirectly acquire voting shares of Independent Bank, Waco, Texas.

Board of Governors of the Federal Reserve System, November 4, 2008.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E8–26603 Filed 11–06–08; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. E8-25509) published on page 63711 of the issue for Monday, October 27, 2008.

Under the Federal Reserve Bank of Kansas City heading, the entry for Lindoe, Inc., Ordway, Colorado, is revised to read as follows:

A. Federal Reserve Bank of Kansas City (Todd Offenbacker, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. Lindoe, Inc., Ordway, Colorado, to acquire up to 100 percent of the voting shares of Southern Colorado National Bancorporation, Inc., and thereby indirectly acquire voting shares of Southern Colorado National Bank, both of Pueblo, Colorado.

Comments on this application must be received by November 24, 2008.

Board of Governors of the Federal Reserve System, November 4, 2008.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E8–26602 Filed 11–6–08; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–09–09AC]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Occupational Injuries and Illnesses Among Emergency Medical Services (EMS) Workers: A NEISS-Work Telephone Interview Survey—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Studies have reported that EMS workers have higher rates of non-fatal injuries and illnesses as compared to the general worker population. As EMS professionals are tasked with protecting the health of the public and treating urgent medical needs, it follows that understanding and preventing injuries and illnesses among EMS workers will have a benefit reaching beyond the workers to the general public.

As mandated in the Occupational Safety and Health Act of 1970 (Pub. L. 91–596), the mission of NIOSH is to conduct research and investigations on occupational safety and health. Related to this mission, the purpose of this project is to conduct research that will provide a detailed description of non-fatal occupational injuries and illnesses incurred by EMS workers. This project will bridge a gap of limited existing EMS worker injury and illness surveillance identified in a 2007 National Highway Traffic Safety Administration, (NHTSA) report. The project will use two related data sources. The first source is data abstracted from medical records of EMS workers treated in a nationally stratified sample of emergency departments. These data are routinely collected by the occupational supplement to the National Electronic Injury Surveillance System (NEISS-Work). The second data source, for which NIOSH is seeking OMB approval, is responses to telephone interview surveys of the injured and ill EMS workers identified within NEISS-Work.

The proposed telephone interview surveys will supplement NEISS-Work data with an extensive description of EMS worker injuries and illnesses, including worker characteristics, injury types, injury circumstances, injury outcomes, and use of personal protective equipment. Previous reports describing occupational injuries and illnesses to EMS workers provide limited details on specific regions or sub-segments of the population and many are outdated. As compared to these earlier studies, the scope of the telephone interview data will be broader as it includes sampled cases nationwide and has no limitations in regards to type of employment (i.e., volunteer versus career). Results from the telephone interviews will be weighted and reported as national estimates.

The sample size for the telephone interview survey is estimated to be approximately 175 EMS workers annually for the proposed four year duration of the study. This estimate is based on the number of EMS workers identified in previous years of NEISS-Work data and a 50% response rate that is comparable to the rate of previously conducted National Electronic Injury

Surveillance System telephone interview studies. Each telephone interview will take approximately 20 minutes to complete, resulting in an annualized burden estimate of 58 hours. Using the routine NEISS-Work data, an analysis of all identified EMS workers will be performed to determine if there are any differences between the telephone interview responder and non-responder groups.

This project is a collaborative effort between the Division of Safety Research in the NIOSH and the Office of Emergency Medical Services in the National Highway Traffic Safety Administration. Both agencies have a strong interest in improving surveillance of EMS worker injuries and illnesses to provide the information necessary for effectively targeting and implementing prevention efforts and, consequently, reducing occupational injuries and illnesses among EMS workers. The Consumer Product Safety Commission (CPSC) will also contribute to this project as they are responsible for coordinating the collection of all NEISS-Work data and for overseeing the collection of all telephone interview data.

There is no cost to respondents other than their time.

Estimated Annualized Burden Hours

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
EMS workers	175	1	20/60	58

Dated: November 3, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–26644 Filed 11–6–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–08–07BF]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC, or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Formative Research on Lung Cancer Screening—New—Division of Cancer Prevention and Control (DCPC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The value of screening for lung cancer is a topic of scientific debate with important medical and economic consequences. Although chest x-rays (CXR) have been widely used for lung cancer screening, studies have shown that CXR with or without sputum cytology does not reduce mortality from lung cancer. Studies are currently underway to provide more information about the effectiveness of other types of screening tests, such as computed tomography (CT) scans and spiral CT scans.

CDC proposes to conduct formative research to gather information from adult health care consumers and primary care physicians about experiences and practices related to lung cancer screening. Information will be collected over a two-year period. Of particular interest are long-term heavy smokers aged 40–70 who are considered high-risk for lung cancer. Information to be collected concerns their knowledge, attitudes, and behaviors related to preventive lung cancer screening and testing. Eight in-person focus groups involving an average of nine health care consumers will be conducted in each year of the study. In addition, in-depth follow-up interviews will be conducted by telephone with a limited subset of health care consumers who report experience with screening tests such as spiral computed tomography (CT).

Information will also be collected through focus groups composed of primary care physicians. Potential respondents will indicate their interest in participating by completing and returning a mailed screening form. Focus groups involving physicians will be conducted by telephone and will also collect information about knowledge, attitudes, and behaviors related to preventive cancer screening and testing. Four focus groups involving physicians will be conducted in each year of the study with an average of six respondents participating in each focus group. Two alternates will be recruited for each physician focus group in order to assure the participation of the targeted number of physician respondents.

The results of this formative research project will be used to inform future research and educational efforts and to develop lung cancer screening and testing interventions.

There are no costs to respondents except their time. The total estimated annualized burden hours are 193.

Estimated Annualized Burden Hours

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Care Consumers	Health Care Consumer Screener Form	192	1	2/60
	Moderator's Guide for Health Care Consumer Focus Groups.	72	1	2
	Guide for In-Depth Interviews with Health Care Consumers.	8	1	1
Physicians	Physician Response Form	64	1	5/60

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
	Moderator's Guide for Physician Focus Groups.	24	1	1.25

Dated: November 3, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–26646 Filed 11–6–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Board on Medical Rehabilitation Research.

Date: December 8–9, 2008.

Time: December 8, 2008, 8:30 a.m. to 5 p.m.

Agenda: NICHD Director's Report presentation, NCMRR Director's Report presentation and various reports on Medical Research Initiatives.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Time: December 9, 2008, 8:30 a.m. to 12 p.m.

Agenda: Other business dealing with NABMRR Board.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Ralph M Nitkin, PhD, Director, B.S.C.D., Biological Sciences and Career Development, NCMRR, Eunice Kennedy Shriver National Institute of Child Health & Human Development, NIH, DHHS, 6100 Executive Boulevard, Room 2A03, Bethesda, MD 20892–7510, (301) 402–4206, *nitkinr@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nichd.nih.gov/about/ncmrr.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 30, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–26434 Filed 11–6–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Novel Therapeutics for Prion Diseases.

Date: December 11, 2008.

Time: 3:30 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institution on Aging, Gateway Building, 7201 Wisconsin Avenue, Room 2C212, Bethesda, MD 20814 (Telephone Conference Call).

Contact Person: Ramesh Vemuri, PhD, Chief, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C–212, Bethesda, MD 20892, 301–402–7700, *rv23r@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 28, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–26331 Filed 11–6–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis; Panel Criminal Justice Drug Abuse Treatment (CJ–DATS).

Date: November 19, 2008.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mark Swieter, PhD, Chief, Training and Special Projects Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6101 Executive Boulevard, Suite 220, Bethesda, MD 20892–8401, (301) 435–1389, *ms80x@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and

Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 30, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–26435 Filed 11–6–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Drug Testing for Clinical Trials.

Date: December 2, 2008.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Courtyard by Marriott Rockville, 2500 Research Boulevard, Rockville, MD 20850.

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301) 435–1439, *lf33c.nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Non-Clinical ADME Studies.

Date: December 11, 2008.

Time: 9 a.m. to 6 p.m.

Agenda: To review and evaluate contract proposals.

Place: Courtyard by Marriott Rockville, 2500 Research Boulevard, Rockville, MD 20850.

Contact Person: Minna Liang, PhD, Scientific Review Officer, Training and Special Projects Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, 6101 Executive Blvd., Room 220, MSC 8401, Bethesda, MD 20852, 301–435–1432, *liangm@nida.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 30, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–26436 Filed 11–6–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, NIH.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, NIH.

Date: December 5, 2008.

Time: 8:30 a.m. to 5 p.m.

Agenda: Among the topics proposed for discussion are: (1) NIH Director's Report; (2) NIH Director's Council of Public Representatives Liaison Report; (3) Work Group on Participant and Data Protection for Gene-Wide Association Studies; and (4) Report from NIH Blue Ribbon Panel on the National Emerging Infectious Disease Lab at Boston University Medical Center.

Place: National Institutes of Health, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Penny W. Burgoon, PhD, Senior Assistant to the Deputy Director, Office of the Director, National Institutes of Health, 1 Center Drive, Building 1, Room 109, Bethesda, MD 20892, 301–451–5870, *burgoonp@od.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.nih.gov/about/director/acd.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: October 28, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–26330 Filed 11–6–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

Agency Information Collection Activities: Extension of an Existing Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection For Review; Secure Communities IDENT/IAFIS Interoperability State and Local Agency Assessment; OMB Control No. 1653–0040.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), will be submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until January 6, 2009.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), Joseph M. Gerhart, Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, 500 12th Street, SW., Room 3138, Washington, DC 20024; (202) 732–6337.

Comments are encouraged and will be accepted for sixty days until January 6, 2009. Written comments and suggestions from the public and affected agencies concerning the proposed

collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of currently approved information collection.

(2) *Title of the Form/Collection:* Secure Communities IDENT/IAFIS Interoperability State and Local Agency Assessment.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form 70–003 and Form 70–004, U.S. Immigration and Customs Enforcement.

Affected public who will be asked or required to respond, as well as a brief abstract: Primary: State and Local Correctional Facilities. 8 U.S.C. 1231(a) gives the Department of Homeland Security (DHS) Immigration and Customs Enforcement (ICE) authority to remove criminal aliens who have been ordered as such. DHS/ICE is improving community safety by transforming the way the federal government cooperates with state and local law enforcement agencies to identify, detain, and remove all criminal aliens held in custody. Secure Communities (SC) revolutionizes immigration enforcement by using technology to share information between law enforcement agencies and by applying risk-based methodologies to focus resources on assisting all local communities remove high-risk criminal aliens. In order for the Secure Communities Initiative to meet its goals, ICE must collect detailed business requirements and input from its state and local law enforcement partners. ICE will interview law enforcement officials at a combined 7,000 state and local jails across the United States as part of the Secure Communities Initiative. The collection instruments are transitioning from the currently approved paper based format to the implementation of technology permitting electronic submissions of responses. This assessment determines the fingerprint procedures and technological capabilities of state and local jails governance, as well as basic jail booking statistics. This information is used in order to prioritize local sites and deliver the implementation strategy of the Secure Communities Initiative.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 7,000 responses at 20 minutes (0.3333333333333333 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 2,334 annual burden hours.

Comments and/or questions; requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information should be directed to: Joseph M. Gerhart, Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, 500 12th Street, SW., Room 3138, Washington, DC 20024; (202) 732–6337.

Dated: November 3, 2008.

Joseph M. Gerhart,

Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. E8–26542 Filed 11–6–08; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5186–N–45]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7266, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Rita, Division of Property Management, Program Support Center, HHS, room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Coast Guard:* Commandant, United States Coast Guard, Attn: Teresa Sheinberg, 2100 Second St, SW., Rm 6109, Washington, DC 20593–0001; (202) 267–6142; *Energy:* Mr. Mark Price, Department of Energy, Office of Engineering and Construction Management, 1000 Independence Ave., SW., Washington, DC 20585; (202) 586–5422; *GSA:* Mr. John Smith, Deputy Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th & F Streets, NW., Washington, DC 20405; (202) 501–0084; *Navy:* Mrs. Mary Arndt, Acting Director, Department of the Navy, Real Estate Services, Naval Facilities Engineering Command, Washington Navy Yard, 1322 Patterson Ave., SE., Suite 1000, Washington, DC 20374–5065; (202) 685–9305; (These are not toll-free numbers).

Dated: October 30, 2008.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

Title V, Federal Surplus Property Program

Federal Register Report for 11/07/2008

Suitable/Available Properties

Building

North Carolina

Federal Building
241 Sunset Ave.
Asheboro Co: Randolph NC 27203
Landholding Agency: GSA
Property Number: 54200840007
Status: Excess
GSA Number: 4–G–NC–0746–2AB
Comments: 6935 sq. ft., needs rehab, presence of asbestos/possible lead paint, most recent use office, covenant included noting building's National Register eligibility

Oregon

3 Bldgs/Land
OTHR–B Radar
Cty Rd 514
Christmas Valley OR 97641
Landholding Agency: GSA
Property Number: 54200840003
Status: Excess
GSA Number: 9–D–OR–0768
Comments: 14000 sq. ft. each/2626 acres, most recent use—radar site, right-of-way

U.S. Customs House
220 NW. 8th Ave.
Portland OR
Landholding Agency: GSA
Property Number: 54200840004
Status: Excess
GSA Number: 9–D–OR–0733
Comments: 100,698 sq. ft., historical property/National Register, most recent use—office, needs to be brought up to meet earthquake code and local bldg codes, presence of asbestos/lead paint

Suitable/Available Properties

Building

Texas

Federal Center (Bldg 11A)
501 West Felix St.
Fort Worth TX 76115
Landholding Agency: GSA
Property Number: 54200840005
Status: Excess
GSA Number: 7–G–TX–0767AF
Comments: 8324 sq. ft., most recent use—office, off-site use only

Land

Arizona

SRP Ditch
24th St. & Jones Ave.
Phoenix AZ 85040
Landholding Agency: GSA
Property Number: 54200840001
Status: Surplus
GSA Number: AZ–0849–AA
Comments: approx. 4131 sq. ft. unimproved land, floodplain

Suitable/Available Properties

Land

Wyoming

Cody Wyoming Property
Hwy 20
Park WY
Landholding Agency: GSA
Property Number: 54200840006
Status: Surplus
GSA Number: 7–I–WY–0547
Comments: 2.1 acres

Unsuitable Properties

Building

Alaska

Bldg. 10
LORAN Station
Carroll Inlet AK
Landholding Agency: Coast Guard
Property Number: 88200840001
Status: Excess
Reasons: Extensive deterioration, Not accessible by road

Unsuitable Properties

Building

California

5 Bldgs.
Lawrence Livermore Natl Lab
1481, 1527, 1884, 1885, 1927
Livermore CA
Landholding Agency: Energy
Property Number: 41200840001
Status: Excess
Reasons: Extensive deterioration

Bldgs. 3577, 3982, 4128
Lawrence Livermore Natl Lab
Livermore CA
Landholding Agency: Energy
Property Number: 41200840002
Status: Excess
Reasons: Secured Area

Bldgs. 453, 454, 508, 509
Naval Air Station
Lemoore CA
Landholding Agency: Navy
Property Number: 77200840003
Status: Unutilized
Reasons: Extensive deterioration, Secured Area, within 2000 ft. of flammable or explosive material

Unsuitable Properties

Building

California

Bldgs. 950, 952, 994
Naval Air Station
Lemoore CA
Landholding Agency: Navy
Property Number: 77200840004
Status: Unutilized
Reasons: Secured Area

Connecticut

Bldgs. 105, 285
Naval Submarine Base
Groton Co: New London CT 06349
Landholding Agency: Navy
Property Number: 77200840005
Status: Excess
Reasons: Secured Area

Tennessee

Bldgs. 01, 02
Naval Surface Warfare
Memphis TN 38118
Landholding Agency: Navy
Property Number: 77200840007
Status: Underutilized
Reasons: Secured Area

Unsuitable Properties

Building

Texas

Bldgs. 04–024, 04–027, 04–029
Pantex Plant
Amarillo TX
Landholding Agency: Energy
Property Number: 41200840003
Status: Unutilized
Reasons: Secured Area, within 2000 ft. of flammable or explosive material

Bldgs. 09–013, 09–125
Pantex Plant
Amarillo TX
Landholding Agency: Energy
Property Number: 41200840004
Status: Unutilized
Reasons: Secured Area, within 2000 ft. of flammable or explosive material

5 Bldgs.
Pantex Plant
Amarillo TX
Landholding Agency: Energy
Property Number: 41200840005
Status: Unutilized
Directions: 09–095, 09–126, 09–132, 09–132A, 09–134
Reasons: Secured Area, within 2000 ft. of flammable or explosive material

Unsuitable Properties

Building

Texas

Bldg. 11–027
Pantex Plant
Amarillo TX
Landholding Agency: Energy
Property Number: 41200840006
Status: Unutilized
Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

4 Bldgs.
Pantex Plant
Amarillo TX
Landholding Agency: Energy
Property Number: 41200840007
Status: Unutilized
Directions: 12–R–009B, 12–0245, 12–041SS, 12–075A
Reasons: Within 2000 ft. of flammable or explosive material, Secured Area

Virginia

Bldg. 3186
Naval Amphibious Base
Little Creek Co: Norfolk VA
Landholding Agency: Navy
Property Number: 77200840006
Status: Unutilized
Reasons: Secured Area

Unsuitable Properties

Land

North Dakota

11 Missile Launch Facilities
Grand Forks ND
Landholding Agency: GSA
Property Number: 54200840002
Status: Surplus
GSA Number: 7–D–ND–0500
Reasons: Contamination

[FR Doc. E8–26321 Filed 11–6–08; 8:45 am]
BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA 660–07–5101–ER]

Notice of Availability of Final Environmental Impact Statement/ Environmental Impact Report (EIS/EIR) for the Proposed Mountain View IV Wind Energy Project

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA, 42 U.S.C. 4321 *et seq.*) and the Federal Land Policy and Management Act of 1976 (FLPMA, 43 U.S.C. 1701 *et seq.*), the Bureau of Land Management (BLM), with the City of Palm Springs, has prepared a Final Environmental Impact Statement/ Environmental Impact Report (EIS/EIR) for the proposed Mountain View IV Wind Energy Project and by this notice is announcing the availability of the document. The BLM is the lead Federal agency for the preparation of this EIS and the City of Palm Springs is the lead State of California agency for the preparation of this EIR.

DATES: The document will be available for 30 days following publication of a Notice of Availability (NOA) of this document, in the **Federal Register**, by the Environmental Protection Agency (EPA). The BLM will not issue a final decision on the proposal for a minimum of 30 days following publication of EPA's NOA.

ADDRESSES: A copy of the Final EIS/EIR for the Proposed Mountain View IV Wind Energy Project is available for review at the BLM Palm Springs-South Coast Field Office, 690 W. Garnet Avenue, North Palm Springs, California, during regular business hours of 7:45 a.m. to 4:30 p.m., Monday through Friday, except holidays, and at the Palm Springs Public Library located at 300 South Sunrise Way, Palm Springs, CA 92262. Copies are also available via the Internet at *http://www.blm.gov/ca/palmsprings*. Electronic (on CD–ROM) or paper copies may also be obtained by contacting the BLM at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: For further information contact Greg Hill, Bureau of Land Management, Palm Springs-South Coast Field Office, (760) 251–4840, or by e-mail at *Greg_Hill@ca.blm.gov*.

SUPPLEMENTARY INFORMATION: Mountain View Power Partners IV, LLC has applied for a right-of-way on public lands and a conditional use permit on private lands to construct a wind energy generating facility in the Coachella Valley, in Riverside County. The project site is west of Indian Avenue and is within the corporate boundary of the City of Palm Springs and within the planning area for the draft Coachella Valley Multiple Species Habitat Conservation Plan. Operations are expected to last approximately 30 years. The proposed project would install a total of approximately 42 to 50 wind turbines on public and private lands, with a total generating capacity of approximately 49 megawatts. Related structures would include access roads, a 34.5–kV powerline and an electrical substation. If approved, the wind energy generating facility on public lands would be authorized in accordance with Title V of FLPMA and the Federal regulations at 43 CFR part 2800. The proposed project would take approximately 7 months to construct. A Notice of Intent To Prepare an EIS/EIR was published in the **Federal Register** on June 5, 2006, and invited comments on issues which may have been relevant to preparation of the document. A public scoping meeting was held on June 27, 2006 in the City of Palm Springs. The Draft EIS/EIR was released for public review, with a 45-day comment period, on February 23, 2007. Following release of the Draft EIS/EIR, a public meeting was held to solicit additional comments on the document. Two comment letters were submitted on the Draft EIS/EIR. No comments contained in these letters resulted in substantive changes being made to the Draft EIS/EIR in preparing the Final EIS/EIR.

The BLM will consider any comments submitted during this period to determine whether they identify significant new circumstances or information relevant to environmental concerns bearing upon the proposed action. The BLM will prepare a Record of Decision (ROD) for the proposed project after the 30-day period following publication of the NOA. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your

personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

John Kalish,

Field Manager, Palm Springs-South Coast Field Office.

[FR Doc. E8–26476 Filed 11–6–08; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR 930.0000.L6350.0000.DQ0000; HAG–09–0022]

Notice of Availability of the Final Environmental Impact Statement for the Revision of the Resource Management Plans of the Western Oregon Bureau of Land Management Districts of Salem, Eugene, Roseburg, Coos Bay, and Medford, and the Klamath Falls Resource Area of the Lakeview District; Amendment

AGENCY: Bureau of Land Management, Interior.

ACTION: Amended Notice.

SUMMARY: This is an amended notice for Environmental Impact Statement (EIS) No. 20080416, Final EIS, Bureau of Land Management (BLM), Oregon (OR), Western Oregon BLM Districts of Salem, Eugene, Roseburg, Coos Bay, and Medford Districts, and the Klamath Falls Resource Area of the Lakeview District, Revision of the Resource Management Plans (RMP), Implementation, OR, which originally published in the **Federal Register** on October 17, 2008 [73 FR 61905]. This amended notice reflects a decision by the BLM to offer a protest period on the proposed revision of the Western Oregon RMPs. Any person who participated in the planning process and has an interest which is or may be adversely affected by the approval of the proposed RMPs may protest such approval. A protest period is not a comment period. A valid protest addresses only those issues which were submitted for the record during the planning process and contains a concise statement explaining why the decision to adopt the proposed plan would violate an applicable statute, regulation or BLM policy.

DATES: The protest shall be filed (postmarked or delivered) by December 8, 2008. E-mailed and faxed protests will not be accepted as valid protests unless the protesting party also provides the original letter by either regular mail (USPS) or overnight delivery service postmarked by the close of the protest period. Under these conditions, the BLM will consider the e-mailed or faxed protest as an advance copy and will afford it full consideration. If you wish to provide the BLM with such advance notification, please direct faxed protests to the attention of Brenda Hudgens-Williams—BLM protest coordinator at 202–208–5010, and e-mailed protests to: *Brenda_Hudgens-Williams@blm.gov*.

ADDRESSES: You may send your protest to one of the following addresses:

- USPS Delivery Service: Director (210), Attention: Brenda Hudgens-Williams—Western Oregon Plans Revisions, P.O. Box 66538, Washington, DC 20035
- Overnight Delivery Service (not USPS): Director (210), Attention: Brenda Hudgens-Williams—Western Oregon Plans Revisions, 1620 L Street NW., Suite 1075, Washington, DC 20036

SUPPLEMENTARY INFORMATION: The protest shall be in writing and shall be filed with the Director. The protest shall contain:

- The name, mailing address, telephone number and interest of the person filing the protest;
- A statement of the issue or issues being protested;
- A statement of the part or parts of the plan or amendment being protested;
- A copy of all documents addressing the issue or issues that were submitted during the planning process by the protesting party or an indication of the date the issue or issues were discussed or provided for the record; and
- A concise statement explaining why the decision to adopt the proposed plan would violate an applicable statute, regulation or BLM policy.

Concerns that have not been raised previously in the planning process, concerns that are not germane to the planning process, and/or statements that merely reflect disagreement, express opinions, or make demands or allegations without the support of a concise statement on why a decision to adopt the proposed plan is in error will not be further analyzed and will be considered invalid protests.

- The Director shall promptly render a decision on all valid protests and will send his written decision to the protesting party by certified mail, return receipt requested.
- The decision of the Director shall be the final decision of the Department of the Interior.

FOR FURTHER INFORMATION, CONTACT: Jerry Hubbard, Public Affairs Specialist, Bureau of Land Management, Oregon State Office, 333 S.W. 3rd Ave., Portland, Oregon 97208, Telephone (503) 808–6115.

Dated: November 3, 2008.

Edward W. Shepard,

State Director, Oregon/Washington.

[FR Doc. E8–26672 Filed 11–6–08; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–020–1310–DT 050E]

Notice of Availability of the Final Supplement to the Montana Statewide Oil and Gas Environmental Impact Statement and Proposed Amendment of the Powder River and Billings Resource Management Plans (RMPs)

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: By Order of the U.S. District Court for the District of Montana, dated April 5, 2005, and pursuant to the *Federal Land Policy and Management Act of 1976* and the *National Environmental Policy Act of 1969*, the Bureau of Land Management (BLM) has prepared a Final Supplement to the Montana Statewide Oil and Gas Environmental Impact Statement and Proposed Amendment (Proposed SEIS/Amendment) of the Powder River and Billings Resource Management Plans (RMPs).

ADDRESSES: Copies of the Proposed SEIS/Amendment have been sent to affected federal, state, and local government agencies; to tribal governments; and to interested parties. Copies of the Proposed SEIS/Amendment are available for public inspection at the BLM Miles City Field Office, 111 Garryowen Road, Miles City, Montana; and at the BLM Montana State Office, 5001 Southgate Drive, Billings, Montana. You may also view the Proposed SEIS/Amendment on the Internet at *http://www.blm.gov/eis/mt/milescity_seis/*.

FOR FURTHER INFORMATION CONTACT: Mary Bloom, Project Manager, by telephone at (406) 233–2852; by mail at 111 Garryowen Road, Miles City, MT 59301; or by e-mail at *Mary_Bloom@blm.gov*.

SUPPLEMENTARY INFORMATION: The Powder River and Billings RMP areas comprise approximately 1.5 million acres of BLM-managed surface and 5 million acres of BLM-managed mineral

estate. There are approximately 3.2 million acres of BLM-managed oil and gas. The Powder River RMP area includes Powder River and Treasure Counties, and portions of Big Horn, Carter, Custer, and Rosebud Counties. The Billings RMP area includes Carbon, Golden Valley, Musselshell, Stillwater, Sweet Grass, Wheatland, and Yellowstone Counties and the remaining portion of Big Horn County. The Proposed SEIS/Amendment supplements the 2003 *Montana Statewide Final Oil and Gas Environmental Impact Statement and Proposed Amendment of the Powder River and Billings Resource Management Plans* (Statewide Document).

The Statewide Document was approved on April 30, 2003. Several lawsuits were filed against the BLM's decisions. Two of the lawsuits resulted in an April 5, 2005, ruling by the U.S. District Court ordering the BLM to prepare the SEIS/Amendment to consider a phased development alternative for coal bed natural gas (CBNG) production in the Billings and Powder River RMP areas.

Topics addressed in the Proposed SEIS/Amendment include those provided or recommended by the U.S. District Court: Phased CBNG development, the inclusion of the proposed Tongue River Railroad in the cumulative impact analysis, and a discussion on how private water well mitigation agreements help alleviate the impacts of methane migration and groundwater drawdown. The Notice of Intent to plan for the Draft SEIS/Amendment was published in the **Federal Register** in Volume 70 FR Number 150, p. 45417, August 5, 2005.

The Draft SEIS/Amendment analyzed three new alternatives (F, G and H) to consider phased CBNG development. Under Alternative F, the BLM would limit the number of Federal applications for permit to drill (APD) approved each year cumulatively and in each fourth-order watershed. The BLM would also limit the percentage of disturbance within identified crucial wildlife habitat. Further, the BLM would place a limit on the volume of untreated water discharged to surface waters from Federal CBNG wells within each fourth-order watershed.

Under Alternative G, development of CBNG on Federal leases in the Billings and Powder River RMP areas would be done following the same management actions as described under Alternative F. However, while the BLM would limit the number of Federal APDs approved each year cumulatively, development would be limited to a low range of predicted wells based on the Statewide Document's Reasonably Foreseeable Development scenario.

Alternative H, the BLM's preferred alternative, contained three key components. First, a phased development approach would be implemented where a CBNG proposal would be reviewed against four filters or screens to determine if the proposal needed to be modified. Second, this alternative would include extensive requirements that an operator must meet when submitting a project Plan of Development (POD). Third, mitigation measures, and subsequent modifications to existing operations via adaptive management, would be considered and applied to each POD, as appropriate.

The 90-day public comment period on the Draft SEIS/Amendment ended May 2, 2007. During the comment period, the EPA notified the BLM of air analysis deficiencies in the Draft SEIS/Amendment. As a result, the BLM prepared a draft supplement to the Draft SEIS/Amendment to demonstrate that predicted visibility effects in Class I and II areas could be mitigated. The 90-day public comment period for the additional air quality analyses ended March 13, 2008.

Public comments on the Draft SEIS/Amendment and supplemental air analyses were considered in the preparation of the Proposed SEIS/Amendment. Public comments resulted in changes to the Air Quality and Wildlife screens in the Draft SEIS/Amendment (Alternative H). The Air Quality Screen was modified to allow for better monitoring of air quality. The BLM also received comments on climate change, which have been addressed in the Proposed SEIS/Amendment. Consideration of climate change analysis did not result in any additional changes to the Air Quality Screen. The Wildlife Screen was modified to include population threshold levels for pronghorn, mule deer, and sage-grouse habitat. If the BLM management of habitat results in declines in the populations of these species, based on the established threshold levels, the BLM would implement mitigation measures to minimize impacts to wildlife habitat and maintain wildlife populations. The Wildlife Screen was also modified to include provisions that would allow for the implementation of protective measures for other species' habitats.

The Assistant Secretary, Land and Minerals Management, in the Department of the Interior is the responsible official for this proposed plan amendment on public lands. The *Federal Land Policy and Management Act* and its implementing regulations provide land use planning authority to the Secretary, as delegated to the Assistant Secretary. Because the Record of Decision will be signed by the Assistant Secretary, Land and Minerals Management, it will be the final decision for the Department of the Interior. This decision is not subject to administrative review (protest) under the BLM or the Department of the Interior regulations (43 CFR 1610.5–2).

The BLM has initiated activities to coordinate and consult with the Montana Governor. Prior to the issuance of the Record of Decision and approval of the proposed land use plan amendment, the Governor will be given the opportunity to identify any inconsistencies between the Proposed SEIS/Amendment and state or local plans and to provide recommendations in writing during the 60-day consistency review period required by the BLM land use planning regulations (43 CFR 1610.3–2).

Gene R. Terland,

State Director.

[FR Doc. E8–26473 Filed 11–6–08; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Folsom Dam Safety of Dams Mormon Island Auxiliary Dam (MIAD) Modification, California

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of intent to prepare an Environmental Impact Statement/Environmental Impact Report (EIS/EIR) and notice of public scoping meetings.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA) and the California Environmental Quality Act (CEQA), the Bureau of Reclamation, the lead Federal agency, and the Sacramento Area Flood Control Agency (SAFCA), acting as the lead State agency, will prepare a joint EIS/EIR for the proposed Folsom Dam Safety of Dams MIAD Modification (Proposed Action). The purpose of the Proposed Action is to reduce the seismic and static risk of failure of MIAD. In this way, Reclamation will achieve the existing standards for dam safety and reduce the risk of injury to those people living and working downstream of the Folsom Dam complex.

DATES: A series of scoping meetings will be held to solicit public input on the scope of the environmental document, alternatives, concerns, and issues to be

addressed in the EIS/EIR. The scoping meeting dates are:

- Tuesday, December 2, 2008. 1 p.m. to 4 p.m., Folsom, CA.
- Tuesday, December 2, 2008. 6 p.m. to 9 p.m., Folsom, CA.
- Thursday, December 4, 2008. 6 p.m. to 9 p.m., El Dorado Hills, CA.

Written comments on the scope of the EIS/EIR will be accepted until January 3, 2009.

ADDRESSES: The public scoping meetings will be held at:

- Folsom: Folsom Community Center, 52 Natoma Street, Folsom, CA 95630.
- El Dorado Hills: El Dorado Hills Community Services District, 1021 Harvard Way, El Dorado Hills, CA 95762.

Written comments on the scope of the EIS/EIR document should be sent to Ms. Elizabeth Vasquez, Central California Area Office, Bureau of Reclamation, 7794 Folsom Dam Road, Folsom, CA 95630–1799; or e-mailed to *FolsomDamMods@mp.usbr.gov*.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth Vasquez, Central California Area Office, Bureau of Reclamation, at the CCAO general telephone number 916–988–1707, e-mail at: *FolsomDamMods@mp.usbr.gov*.

SUPPLEMENTARY INFORMATION:

Background

The March 2007 Folsom Dam Safety and Flood Damage Reduction EIS/EIR (Folsom DS/FDR EIS/EIR) included NEPA/CEQA analysis of modifying MIAD. The analysis in the Folsom DS/FDR EIS/EIR considered several methods to modify MIAD to achieve Reclamation's risk standards for dam safety. The May 2007 *Record of Decision Folsom Dam Safety of Dams and Security Upgrades Project* documented that the preferred alterative for MIAD modification was to place an overlay and seepage control filters on the downstream (terrestrial) side of MIAD and reinforce the MIAD foundation using a construction technique known as jet grouting. At that time, some of the required permits and consultations (Endangered Species Act, Fish and Wildlife Coordination Act, and Sec 106 of the National Historic Preservation Act) were also obtained. Subsequent investigations into the feasibility of the MIAD Modification Project as conceived in the Folsom DS/FDR EIS/EIR have indicated that the design of the MIAD Modification Project will need to be changed to achieve Reclamation's existing risk standards for dam safety. Specifically, the utilization of jet grouting to stabilize the foundation of MIAD is unlikely to meet those risk standards.

The purpose of the Proposed Action is to reduce the seismic and static risk of failure of MIAD. In this way, Reclamation will achieve the existing standards for dam safety and reduce the risk of injury to those people living and working downstream of the Folsom Dam complex. This proposed project is a feature of the Folsom Dam Safety of Dams Project, and the analysis will tier from the March 2007 NEPA/CEQA environmental analysis, the Folsom DS/FDR EIS/EIR.

At this time, there are no known or possible Indian trust assets or environmental justice issues associated with the Proposed Action.

Special Assistance for Public Scoping Meetings

If special assistance is required to participate in the public hearings, please contact Ms. Elizabeth Vasquez at 916–989–7192, TDD 916–989–7285, or e-mail *evasquez@mp.usbr.gov*. Please notify Ms. Vasquez as far in advance as possible to enable Reclamation to secure the needed services. If a request cannot be honored, the requestor will be notified. A telephone device for the hearing impaired (TDD) is available at 916–989–7285.

Public Disclosure

Before including your name, address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: October 28, 2008.

Michael Chotkowski,

Acting Regional Environmental Officer, Mid-Pacific Region.

[FR Doc. E8–26634 Filed 11–6–08; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Black Mesa Project Final Environmental Impact Statement, OSM–EIS–033

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of availability of the final environmental impact statement for the Black Mesa Project.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (we or OSM), as lead Federal agency, announces the availability of the final environmental impact statement (EIS) for the proposed Black Mesa Project. The proposed project consists of Peabody Western Coal Company's (Peabody's) operation and reclamation plans for coal mining at the Black Mesa Complex near Kayenta, Arizona.

DATES: The waiting period for OSM's and the Bureau of Land Management's (BLM's) records of decision on the proposed project ends on December 8, 2008.

FOR FURTHER INFORMATION CONTACT: OSM, Western Region, P.O. Box 46667, Denver, CO 80201, Dennis Winterringer, Black Mesa Project EIS Leader, telephone (303) 293–5048 or by e-mail at *BMKEIS@osmre.gov*.

SUPPLEMENTARY INFORMATION: In 2006, under the National Environmental Policy Act of 1969 (NEPA), we prepared and made available for public review a draft EIS analyzing the effects of the Black Mesa Project. The Environmental Protection Agency (EPA) published the notice of availability on December 1, 2006 (71 FR 69562). The proposed project consisted of (1) Peabody's operation and reclamation plans for coal mining at the Black Mesa Complex near Kayenta, Arizona; (2) Black Mesa Pipeline Incorporated's (BMPI's) coal slurry preparation plant at the Black Mesa Complex; (3) BMPI's reconstruction of the 273-mile-long coal slurry pipeline across northern Arizona from the coal slurry preparation plant to the Mohave Generating Station in Laughlin, Nevada; and (4) the Mohave Generation Station co-owners' construction and operation of a water supply system consisting of water wells in the Coconino aquifer (C aquifer) near Leupp, Arizona, and of a water supply pipeline running 108 miles across the Navajo and Hopi Reservations from the wells to the coal slurry preparation plant. Peabody proposed to continue supplying coal to the Navajo Generating Station and the Mohave Generating Station. The coal slurry preparation plant, coal-slurry pipeline, and Coconino aquifer water-supply system were associated with supplying coal to the Mohave Generating Station.

Since the draft EIS was issued, the scope of the proposed project has been reduced to Peabody's operation and reclamation plans for coal mining at the Black Mesa Complex for supplying coal

to the Navajo Generating Station. The proposed project no longer includes the originally-proposed project components associated with supplying coal to the Mohave Generating Station, although the final EIS continues to analyze them in one of the EIS alternatives.

OSM is the lead Federal agency preparing the EIS. The BLM, EPA, Navajo Nation, Hopi Tribe, Hualapai Tribe, County of Mohave, Arizona, and City of Kingman, Arizona are cooperating agencies.

The preferred alternative in the final EIS is for OSM to approve the permit application submitted by Peabody under the Surface Mining Control and Reclamation Act and for BLM to approve the mining plan submitted by Peabody under Secretarial Order No. 3087, Amendment No. 1 (February 7, 1983), and the Tribal Lands Leasing Act (25 U.S.C. 396a).

The final EIS analyzes the potential direct, indirect, and cumulative impacts of approval of the proposed project and alternative actions on the physical, biological, and human environments. The final EIS is not a decision document. OSM will use it to make an informed decision on the permit application. In accordance with the Council on Environmental Quality's regulation at 40 CFR 1506.10(b)(2), the BLM and OSM records of decision can be made no sooner than 30 days after EPA's weekly **Federal Register** notice announcing that the Black Mesa Project EIS has been filed with it. OSM is timing this notice to coincide with the date of publication of the EPA notice.

You may view and download a copy of the final EIS on the OSM Internet Web site at *http://www.wrcc.osmre.gov/WR/BlackMesaEIS.htm*. Limited numbers of compact disk and paper copies of the final EIS are available by contacting the person listed in **FOR FURTHER INFORMATION CONTACT.**

Dated: October 22, 2008.

Allen D. Klein,

Regional Director, Western Region, OSM.

[FR Doc. E8–26382 Filed 11–6–08; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–317P]

Controlled Substances: Proposed Aggregate Production Quotas for 2009

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed year 2009 aggregate production quotas.

SUMMARY: This notice proposes initial year 2009 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: Comments or objections must be received on or before December 8, 2008.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–317P'' on all written and electronic correspondence. Written comments should be sent to the DEA Headquarters, Attn: DEA **Federal Register** Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The proposed year 2009 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2009 to provide adequate supplies of each substance for: The estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

In determining the proposed year 2009 aggregate production quotas, the Deputy Administrator considered the following factors: Total actual 2007 and estimated 2008 and 2009 net disposals of each substance by all manufacturers; estimates of 2008 year-end inventories of each substance and of any substance manufactured from it and trends in accumulation of such inventories; product development requirements of both bulk and finished dosage form manufacturers; projected demand as indicated by procurement quota applications filed pursuant to 21 CFR 1303.12; and other pertinent information.

Pursuant to 21 CFR 1303, the Deputy Administrator of the DEA will adjust aggregate production quotas and individual manufacturing quotas allocated for the year based upon 2008 year-end inventory and actual 2008 disposition data supplied by quota recipients for each basic class of schedule I or II controlled substance.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA of 1970 (21 U.S.C. 826), and delegated to the Administrator of the DEA by 28 CFR 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby proposes that the year 2009 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic class—Schedule I	Proposed 2009 quotas (g)
2,5-Dimethoxyamphetamine	2
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2
3-Methylfentanyl	2
3-Methylthiofentanyl	2
3,4-Methylenedioxyamphetamine (MDA)	25
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	10
3,4-Methylenedioxymethamphetamine (MDMA)	20
3,4,5-Trimethoxyamphetamine	2

Basic class—Schedule I	Proposed 2009 quotas (g)
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	2
4-Methoxyamphetamine	27
4-Methylaminorex	2
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2
5-Methoxy-3,4-methylenedioxyamphetamine	2
5-Methoxy-N,N-diisopropyltryptamine	5
Acetyl-alpha-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
Alpha-ethyltryptamine	2
Alphameprodine	2
Alphamethadol	2
Alpha-methylfentanyl	2
Alpha-methylthiofentanyl	2
Aminorex	2
Benzylmorphine	2
Betacetylmethadol	2
Beta-hydroxy-3-methylfentanyl	2
Beta-hydroxyfentanyl	2
Betameprodine	2
Betamethadol	2
Betaprodine	2
Bufotenine	3
Cathinone	3
Codeine-N-oxide	602
Diethyltryptamine	2
Difenoxin	50
Dihydromorphine	2,549,000
Dimethyltryptamine	3
Gamma-hydroxybutyric acid	21,940,000
Heroin	20
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	1
Lysergic acid diethylamide (LSD)	10
Marihuana	4,500,000
Mescaline	7
Methaqualone	5
Methcathinone	4
Methyldihydromorphine	2
Morphine-N-oxide	605
N,N-Dimethylamphetamine	7
N-Ethylamphetamine	2
N-Hydroxy-3,4-methylenedioxyamphetamine	2
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	16
Para-fluorofentanyl	2
Phenomorphan	2
Pholcodine	2
Psilocybin	7
Psilocyn	7
Tetrahydrocannabinols	312,500
Thiofentanyl	2
Trimeperidine	2 g

Basic class—Schedule II	Proposed 2009 quotas (g)
1-Phenylcyclohexylamine	2
Alfentanil	8,000
Alphaprodine	2
Amobarbital	3
Amphetamine (for sale)	17,000,000
Amphetamine (for conversion)	5,000,000
Cocaine	247,000
Codeine (for sale)	39,605,000
Codeine (for conversion)	65,000,000
Dextropropoxyphene	106,000,000

Basic class—Schedule I	Proposed 2009 quotas (g)
Dihydrocodeine	1,200,000
Diphenoxylate	947,000
Ecgonine	83,000
Ethylmorphine	2
Fentanyl	1,428,000
Glutethimide	2
Hydrocodone (for sale)	55,000,000
Hydromorphone	3,300,000
Isomethadone	2
Levo-alphacetylmethadol (LAAM)	3
Levomethorphan	5
Levorphanol	10,000
Lisdexamfetamine	6,200,000
Meperidine	8,600,000
Metazocine	1
Methadone (for sale)	25,000,000
Methadone Intermediate	26,000,000
Methamphetamine	3,130,000
[680,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,405,000 grams for methamphetamine mostly for conversion to a schedule III product; and 45,000 grams for methamphetamine (for sale)]	
Methylphenidate	50,000,000
Morphine (for sale)	35,000,000
Morphine (for conversion)	100,000,000
Nabilone	5,502
Noroxymorphone (for sale)	10,000
Noroxymorphone (for conversion)	9,000,000
Opium (powder)	1,050,000
Opium (tincture)	230,000
Oripavine	15,000,000
Oxycodone (for sale)	70,000,000
Oxycodone (for conversion)	3,400,000
Oxymorphone (for sale)	2,000,000
Oxymorphone (for conversion)	12,000,000
Pentobarbital	28,000,000
Phenazocine	1
Phencyclidine	20
Phenmetrazine	2
Phenylacetone	1
Racemethorphan	2
Remifentanil	500
Secobarbital	67,000
Sufentanil	10,300
Thebaine	126,000,000

The Deputy Administrator further proposes that aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR 1308.11 and 1308.12 be established at zero.

All interested persons are invited to submit their comments in writing or electronically regarding this proposal following the procedures in the **ADDRESSES** section of this document. A person may object to or comment on the proposal relating to any of the above-mentioned substances without filing comments or objections regarding the others. If a person believes that one or more of these issues warrant a hearing, the individual should so state and summarize the reasons for this belief.

In the event that comments or objections to this proposal raise one or more issues which the Deputy Administrator finds warrant a hearing, the Deputy Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the issues to be heard and setting the time for the hearing.

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

This action does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this action does not have federalism implications warranting the application of Executive Order 13132.

The Deputy Administrator hereby certifies that this action will have no significant impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are necessary to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

This action meets the applicable standards set forth in Sections 3(a) and

3(b)(2) of Executive Order 12988 Civil Justice Reform.

This action will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This action will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated: October 31, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–26609 Filed 11–6–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated July 29, 2008, and published in the **Federal Register** on August 6, 2008, (73 FR 45780), Wildlife Laboratories, 1401 Duff Drive, Suite 400, Fort Collins, Colorado 80524, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Etorphine Hydrochloride (9059), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance for sale to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Wildlife Laboratories to import the basic class of controlled substance is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Wildlife Laboratories to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Dated: October 30, 2008.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E8–26598 Filed 11–6–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

November 3, 2008.

The Department of Labor (DOL) hereby announces the submission of the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of this ICR, with applicable supporting documentation; including among other things a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAMain* or by contacting Amy Hobby on 202–693–4553 (this is not a toll-free number)/e-mail: *DOL_PRA_PUBLIC@dol.gov*.

Interested parties are encouraged to send comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Employment and Training Administration (ETA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–7316/Fax: 202–395–6974 (these are not toll-free numbers), e-mail: *OIRA_submission@omb.eop.gov* within 30 days from the date of this publication in the **Federal Register**. In order to ensure the appropriate consideration, comments should reference the OMB Control Number (see below).

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Employment and Training Administration.

Type of Review: Extension without change of an existing OMB Control Number.

Title of Collection: Labor Condition Application for H–1B, H–1B1, and E–3 Nonimmigrants.

OMB Control Number: 1205–0310.

Agency Form Number(s): ETA–9035, ETA–9035CP, ETA–9035E, and WH–4.

Affected Public: Businesses or other for-profits, not-for-profit institutions.

Total Estimated Number of Respondents: 77,500.

Total Estimated Annual Burden Hours: 368,991.

Total Estimated Annual Costs Burden: $0.

Description: The application form and other information collection instruments are to be used by employers seeking to use nonimmigrants (H–1B, H–1B1, E–3) in specialty occupations and as fashion models or by those who want to report violations. The collection of information will permit the Department to meet its statutory responsibilities for program administration, management, and oversight. For additional information, see related notice published at 73 FR 36357 on June 26, 2008.

Darrin A. King,

Departmental Clearance Officer.

[FR Doc. E8–26544 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF LABOR

Office of the Secretary

Senior Executive Service; Appointment of Members to the Performance Review Board

Title 5 U.S.C. 4314(c)(4) provides that Notice of the Appointment of an individual to serve as a member of the

Performance Review Board of the Senior Executive Service shall be published in the **Federal Register**.

The following individuals are hereby appointed to serve on the Department's Performance Review Board: John McWilliam, Felix Quintana, Corlis Sellers.

FOR FURTHER INFORMATION CONTACT: Ms. Andrea Burckman, Director, Office of Executive Resources and Personnel Security, Room C5508, U.S. Department of Labor, Frances Perkins Building, 200 Constitution Avenue, NW., Washington, DC 20210, telephone: (202) 693–7628.

Signed at Washington, DC., this 3rd day of November, 2008.

Elaine L. Chao,

Secretary of Labor.

[FR Doc. E8–26640 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–23–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

[Application Nos. and Proposed Exemptions; D–11481, Citigroup, Inc.; D–11484; Robert W. Baird & Co. Incorporated; D–11490, Raymond James & Associates, Inc.; D–11505, Northwestern Mutual Investment Services, LLC, et al.]

Notice of Proposed Exemptions

AGENCY: Employee Benefits Security Administration, Labor

ACTION: Notice of Proposed Exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, within 45 days from the date of publication of this **Federal Register** Notice. Comments and requests for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADDRESSES: All written comments and requests for a hearing (at least three copies) should be sent to the Employee Benefits Security Administration (EBSA), Office of Exemption Determinations, Room N–5700, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: Application No. _____, stated in each Notice of Proposed Exemption. Interested persons are also invited to submit comments and/or hearing requests to EBSA via e-mail or FAX. Any such comments or requests should be sent either by e-mail to: *moffitt.betty@dol.gov,* or by FAX to (202) 219–0204 by the end of the scheduled comment period. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of the Employee Benefits Security Administration, U.S. Department of Labor, Room N–1513, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Citigroup, Inc., Located in New York, New York, Exemption Application Number D–11481.

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and section 4975(c)(2) of the Internal Revenue Code of 1986, as amended (the Code), and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990).[1]

Section I. Transactions Involving Plans Described In Both Title I and Title II of ERISA

If the proposed exemption is granted, the restrictions of section 406(a)(1)(A) through (D) and section 406(b) of ERISA, and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply, effective February 1, 2008, to the following transactions, if the conditions set forth in section III have been met:

(a) The sale or exchange of an Auction Rate Security (as defined in section IV(b)) by a Plan (as defined in section IV(h)) to the Sponsor (as defined in section IV(g)) of such Plan; or

(b) A lending of money or other extension of credit to a Plan in connection with the holding of an Auction Rate Security by the Plan, from: (1) Citigroup, Inc. or an affiliate (Citigroup); (2) an Introducing Broker (as defined in section IV(f)); or (3) a Clearing Broker (as defined in section IV(d)); where the loan is: (i) Repaid in accordance with its terms; and (ii) guaranteed by the Plan Sponsor.

II. Transactions Involving Plans Described In Title II of ERISA Only

If the proposed exemption is granted, the sanctions resulting from the application of section 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply, effective February 1, 2008, to the following transactions, if the conditions set forth in section III have been met:

(a) The sale or exchange of an Auction Rate Security by a Title II Only Plan (as defined in section IV(i)) to the Beneficial Owner (as defined in section IV(c)) of such Plan; or

(b) A lending of money or other extension of credit to a Title II Only Plan in connection with the holding of

[1] For purposes of this proposed exemption, references to section 406 of ERISA should be read to refer as well to the corresponding provisions of section 4975 of the Code.

an Auction Rate Security by the Title II Only Plan, from: (1) Citigroup; (2) an Introducing Broker; or (3) a Clearing Broker; where the loan is: (i) Repaid in accordance with its terms and; (ii) guaranteed by the Beneficial Owner.

III. Conditions

(a) Citigroup acted as a broker or dealer, non-bank custodian, or fiduciary in connection with the acquisition or holding of the Auction Rate Security that is the subject of the transaction;

(b) For transactions involving a Plan (including a Title II Only Plan) not sponsored by Citigroup for its own employees, the decision to enter into the transaction is made by a Plan fiduciary who is Independent (as defined in section IV(e)) of Citigroup. Notwithstanding the foregoing, an employee of Citigroup who is the Beneficial Owner of a Title II Only Plan may direct such Plan to engage in a transaction described in section II, if all of the other conditions of this section III have been met;

(c) The last auction for the Auction Rate Security was unsuccessful;

(d) The Plan does not waive any rights or claims in connection with the loan or sale as a condition of engaging in the above-described transaction;

(e) The Plan does not pay any fees or commissions in connection with the transaction;

(f) The transaction is not part of an arrangement, agreement or understanding designed to benefit a party in interest;

(g) With respect to any sale described in section I(a) or section II(a):

(1) The sale is for no consideration other than cash payment against prompt delivery of the Auction Rate Security; and

(2) For purposes of the sale, the Auction Rate Security is valued at par, plus any accrued but unpaid interest; [2]

(h) With respect to an in-kind exchange described in section (I)(a) or section II(a), the exchange involves the transfer by a Plan of an Auction Rate Security in return for a Delivered Security, as such term is defined in section IV(j), where:

(1) The exchange is unconditional;

(2) For purposes of the exchange, the Auction Rate Security is valued at par, plus any accrued but unpaid interest;

(3) The Delivered Security is valued at fair market value, as determined at the time of the in-kind exchange by a third party pricing service or other objective source;

(4) The Delivered Security is appropriate for the Plan and a security that the Plan is otherwise permitted to hold under applicable law; [3] and

(5) The total value of the Auction Rate Security (*i.e.*, par plus any accrued but unpaid interest) is equal to the fair market value of the Delivered Security;

(i) With respect to a loan described in section I(b) or II(b):

(1) The loan is documented in a written agreement containing all of the material terms of the loan, including the consequences of default;

(2) The Plan does not pay an interest rate that exceeds one of the following three rates as of the commencement of the loan:

(A) The coupon rate for the Auction Rate Security;

(B) The Federal Funds Rate; or

(C) The Prime Rate;

(3) The loan is unsecured; and

(4) The amount of the loan is not more than the total par value of the Auction Rate Securities held by the Plan.

IV. Definitions

(a) The term ''affiliate'' means: Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(b) The term ''Auction Rate Security'' or ''ARS'' means a security:

(1) That is either a debt instrument (generally with a long-term nominal maturity) or preferred stock; and

(2) With an interest rate or dividend that is reset at specific intervals through a Dutch auction process;

(c) The term ''Beneficial Owner'' means: The individual for whose benefit the Title II Only Plan is established and includes a relative or family trust with respect to such individual;

(d) The term ''Clearing Broker'' means: A member of a securities exchange that acts as a liaison between an investor and a clearing corporation and that helps to ensure that a trade is settled appropriately, that the transaction is successfully completed and that is responsible for maintaining the paper work associated with the clearing and executing of a transaction;

(e) The term ''Independent'' means a person who is: (1) Not Citigroup or an affiliate; and (2) not a relative (as defined in ERISA section 3(15)) of the party engaging in the transaction;

(f) The term ''Introducing Broker'' means: A registered broker that is able to perform all the functions of a broker except for the ability to accept money, securities, or property from a customer;

(g) The term ''Sponsor'' means: A plan sponsor as described in section 3(16)(B) of the Act and any Affiliates;

(h) The term ''Plan'' means: Any plan described in section 3(3) of the Act and/or section 4975(e)(1) of the Code;

(i) The term ''Title II Only Plan'' means: Any plan described in section 4975(e)(1) of the Code which is not an employee benefit plan covered by Title I of ERISA;

(j) The term ''Delivered Security'' means a security that is: (1) Listed on a national securities exchange (excluding OTC Bulletin Board-eligible securities and Pink Sheets-quoted securities); or (2) a U.S. Treasury obligation; or (3) A fixed income security that has a rating at the time of the exchange that is in one of the two highest generic rating categories from an independent nationally recognized statistical rating organization (*e.g.*, a highly rated municipal bond or a highly rated corporate bond); or (4) A certificate of deposit insured by the Federal Deposit Insurance Corporation. Notwithstanding the above, the term ''Delivered Security'' shall not include any Auction Rate Security, or any related Auction Rate Security, including derivatives or securities materially comprised of Auction Rate Securities or any illiquid securities.

Summary of Facts and Representations

1. The Applicant is Citigroup, Inc. and its affiliates (hereinafter, either Citigroup or the Applicant). Citigroup is a holding company whose businesses include the provision of investment advisory and other services to IRAs and pension, profit sharing, and 401(k) plans qualified under section 401(a) of the Code. Among other things, Citigroup acts as a broker and dealer with respect

[2] This proposed exemption does not address tax issues. The Department has been informed by the Internal Revenue Service and the Department of the Treasury that they are considering providing limited relief from the requirements of sections 72(t)(4), 401(a)(9), and 4974 of the Code with respect to retirement plans that hold Auction Rate Securities. The Department has also been informed by the Internal Revenue Service that if Auction Rate Securities are purchased from a Plan in a transaction described in sections I and II at a price that exceeds the fair market value of those securities, then the excess value would be treated as a contribution for purposes of applying applicable contribution and deduction limits under sections 219, 404, 408, and 415 of the Code.

[3] The Department notes that the Act's general standards of fiduciary conduct also would apply to the transactions described herein. In this regard, section 404 requires, among other things, that a fiduciary discharge his duties respecting a plan solely in the interest of the plan's participants and beneficiaries and in a prudent manner. Accordingly, a plan fiduciary must act prudently with respect to, among other things: (1) The decision to exchange an Auction Rate Security for a Delivery Security; and (2) the negotiation of the terms of such exchange (or a cash sale or loan described above), including the pricing of such securities. The Department further emphasizes that it expects plan fiduciaries, prior to entering into any of the proposed transactions, to fully understand the risks associated with these types of transactions following disclosure by Citigroup of all relevant information.

to the purchase and sale of securities, including Auction Rate Securities. The Applicant describes Auction Rate Securities and the arrangement by which ARS are bought and sold as follows. Auction Rate Securities (or ARS) are securities (issued as debt or preferred stock) with an interest rate or dividend that is reset at periodic intervals pursuant to a process called a Dutch Auction. Investors submit orders to buy, hold, or sell a specific ARS to a broker-dealer selected by the entity that issued the ARS. The broker-dealers, in turn, submit all of these orders to an auction agent. The auction agent's functions include collecting orders from all participating broker-dealers by the auction deadline, determining the amount of securities available for sale, and organizing the bids to determine the winning bid. If there are any buy orders placed into the auction at a specific rate, the auction agent accepts bids with the lowest rate above any applicable minimum rate and then successively higher rates up to the maximum applicable rate, until all sell orders and orders that are treated as sell orders are filled. Bids below any applicable minimum rate or above the applicable maximum rate are rejected. After determining the clearing rate for all of the securities at auction, the auction agent allocates the ARS available for sale to the participating broker-dealers based on the orders they submitted. If there are multiple bids at the clearing rate, the auction agent will allocate securities among the bidders at such rate on a pro-rata basis.

2. The Applicant states that Citigroup is permitted, but not obligated, to submit orders in auctions for its own account either as a bidder or a seller and routinely does so in the auction rate securities market in its sole discretion. Citigroup may routinely place one or more bids in an auction for its own account to acquire ARS for its inventory, to prevent: (1) A failed auction (*i.e.*, an event where there are insufficient clearing bids which would result in the auction rate being set at a specified rate); or (2) an auction from clearing at a rate that Citigroup believes does not reflect the market for the particular ARS being auctioned.

3. The Applicant states that for many ARS, Citigroup has been appointed by the issuer of the securities to serve as a dealer in the auction and is paid by the issuer for its services. Citigroup is typically appointed to serve as a dealer in the auctions pursuant to an agreement between the issuer and Citigroup. That agreement provides that Citigroup will receive from the issuer auction dealer fees based on the principal amount of the securities placed through Citigroup.

4. The Applicant states further that Citigroup may share a portion of the auction rate dealer fees it receives from the issuer with other broker-dealers that submit orders through Citigroup, for those orders that Citigroup successfully places in the auctions. Similarly, with respect to ARS for which broker-dealers other than Citigroup act as dealer, such other broker-dealers may share auction dealer fees with Citigroup for orders submitted by Citigroup.

5. According to the Applicant, since February 2008, a minority of auctions have cleared, particularly involving municipalities. As a result, Plans holding Auction Rate Securities may not have sufficient liquidity to make benefit payments, mandatory payments and withdrawals and expense payments when due.[4]

6. The Applicant represents that, in certain instances, Citigroup may have previously advised or otherwise caused a Plan to acquire and hold an Auction Rate Security and thus may be considered a fiduciary to the Plan so that a loan to the Plan by Citigroup may violate section 406(a) and (b) of ERISA; in addition, a sale between a Plan and its sponsor or an IRA and its Beneficial Owner violates section ERISA section 406 and/or section 4975(c)(1) of the Code.[5] The Applicant is therefore requesting relief for the following transactions, involving all employee benefit plans: (1) The sale or exchange of an Auction Rate Security from a Plan to the Plan's Sponsor; and (2) a lending of money or other extension of credit to a Plan in connection with the holding of an Auction Rate Security from: Citigroup, an Introducing Broker, or a Clearing Broker, where the subsequent repayment of the loan is made in accordance with its terms and is guaranteed by the Plan Sponsor.

7. The Applicant is requesting similar relief for plans covered only by Title II of ERISA. In this regard, the Applicant is requesting relief for: (1) The sale or exchange of an Auction Rate Security from a Title II Only Plan to the Beneficial Owner of such Plan; and (2) a lending of money or other extension of credit to a Title II Only Plan in connection with the holding of an Auction Rate Security from: Citigroup; an Introducing Broker; or a Clearing Broker; where the subsequent repayment of the loan is made in accordance with its terms and is guaranteed by the Beneficial Owner.

8. The Applicant represents that the proposed transactions are in the interests of the Plans. In this regard, the Applicant states that the exemption, if granted, will provide Plan fiduciaries with liquidity notwithstanding changes that occurred in the Auction Rate Securities markets. The Applicant also notes that, other than for Plans sponsored by the Applicant, the decision to enter into a transaction described herein will be made by a Plan fiduciary who is independent of Citigroup.

9. The proposed exemption contains a number of safeguards designed to protect the interests of each Plan. With respect to the sale of an Auction Rate Security by a Plan, the Plan must receive cash equal to the par value of the Security, plus any accrued interest. The sale must also be unconditional, other than being for payment against prompt delivery. For in-kind exchanges covered by the proposed exemption, the security delivered to the Plan (*i.e.*, the Delivered Security) must be: (1) Listed on a national securities exchange (excluding OTC Bulletin Board-eligible securities and Pink Sheets-quoted securities); or (2) a U.S. Treasury obligation; or (3) a fixed income security that has a rating at the time of the exchange that is in one of the two highest generic rating categories from an independent nationally recognized statistical rating organization (*e.g.*, a highly rated municipal bond or a highly rated corporate bond); or (4) a certificate of deposit insured by the Federal Deposit Insurance Corporation. The Delivered Security must also be appropriate for the Plan, and a security that the Plan is permitted to hold under applicable law. The proposed exemption further requires that the Delivered Security be valued at its fair market value, as determined at the time of the exchange from a third party pricing service or other objective source, and must equal the total value of the Auction Rate Security being exchanged (*i.e.*, par value, plus any accrued interest).

10. With respect to a loan to a Plan holding an Auction Rate Security, such loan must be documented in a written agreement containing all of the material terms of the loan, including the

[4] The Department notes that Class Exemption 80–26 (45 FR 28545 (Apr. 29, 1980), as amended at 71 FR 17917 (Apr. 7, 2006)) permits interest-free loans or other extensions of credit from a party in interest to a Plan if, among other things, the proceeds of the loan or extension of credit are used only—(1) for the payment of ordinary operating expenses of the Plan, including the payment of benefits in accordance with the terms of the Plan and periodic premiums under an insurance or annuity contract, or (2) for a purpose incidental to the ordinary operation of the Plan.

[5] The relief contained in this proposed exemption does not extend to the fiduciary provisions of section 404 of the Act.

consequences of default. Further, the Plan may not pay an interest rate that exceeds one of the following three rates as of the commencement of the loan: The coupon rate for the Auction Rate Security; the Federal Funds Rate; or the Prime Rate. Additionally, such loan must be unsecured and for an amount that is no more than the total par value of Auction Rate Securities held by the affected Plan.

11. Additional conditions apply to each transaction covered by the exemption, if granted. Among other things, the Plan may not pay any fees or commissions in connection with the transaction and the transaction may not part of an arrangement, agreement, or understanding designed to benefit a party in interest. The exemption expressly prohibits any waiver of rights or claims by a Plan in connection with the sale or exchange of an Auction Rate Security by a Plan, or a lending of money or other extension of credit to a Plan holding an Auction Rate Security.

12. In summary, the Applicant represents that the transactions described herein satisfy the statutory criteria set forth in section 408(a) of the Act and section 4975(c)(2) of the Code because:

(1) Any sale will be:

(A) For no consideration other than cash payment against prompt delivery of the Auction Rate Security; and

(B) At par, plus any accrued but unpaid interest;

(2) Any in-kind exchange will be unconditional, other than being for payment against prompt delivery, and will involve Delivered Securities that are:

(A) Appropriate for the Plan;

(B) Listed on a national securities exchange (but not OTC Bulletin Board-eligible securities and Pink Sheets-quoted securities); U.S. Treasury obligations; fixed income securities; or certificates of deposit; and

(C) Securities that the Plan is permitted to hold under applicable law; and,

(3) Any loan will be:

(A) Documented in a written agreement containing all of the material terms of the loan, including the consequences of default;

(B) At an interest rate not in excess of: the coupon rate for the Auction Rate Security, the Federal Funds Rate, or the Prime Rate;

(C) Unsecured; and

(D) For an amount that is not more than the total par value of Auction Rate Securities held by the affected Plan.

Notice to Interested Persons

The Applicant represents that the potentially interested participants and beneficiaries cannot all be identified and therefore the only practical means of notifying such participants and beneficiaries of this proposed exemption is by the publication of this notice in the **Federal Register**. Comments and requests for a hearing must be received by the Department not later than 45 days from the date of publication of this notice of proposed exemption in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chris Motta of the Department, telephone (202) 693–8540. (This is not a toll-free number.)

Robert W. Baird & Co. Incorporated, Located in Milwaukie, Wisconsin, Exemption Application Number D–11484.

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and section 4975(c)(2) of the Internal Revenue Code of 1986, as amended (the Code), and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990).[6]

Section I. Transactions Involving Plans Described in Both Title I and Title II of ERISA

If the proposed exemption is granted, the restrictions of section 406(a)(1)(A) through (D) and section 406(b) of ERISA, and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply, effective February 1, 2008, to the following transactions, if the conditions set forth in section III have been met:

(a) The sale or exchange of an Auction Rate Security (as defined in section IV (b)) by a Plan (as defined in section IV(h)) to the Sponsor (as defined in section IV (g)) of such Plan; or

(b) A lending of money or other extension of credit to a Plan in connection with the Plan's holding of an Auction Rate Security, from: (1) Robert W. Baird & Co. Incorporated or any of its current or future affiliates or subsidiaries (Baird); (2) an Introducing Broker (as defined in section IV (f)); or (3) a Clearing Broker (as defined in section IV (d)); where the loan is: (i) Repaid in accordance with its terms; and (ii) guaranteed by the Plan Sponsor.

[6] For purposes of this proposed exemption, references to section 406 of ERISA should be read to refer as well to the corresponding provisions of section 4975 of the Code.

II. Transactions Involving Plans Described in Title II of ERISA Only

If the proposed exemption is granted, the sanctions resulting from the application of section 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply, effective February 1, 2008, to the following transactions, if the conditions set forth in section III have been met:

(a) The sale or exchange of an Auction Rate Security by a Title II Only Plan (as defined in section IV(i)) to the Beneficial Owner (as defined in section IV(c)) of such Plan; or

(b) A lending of money or other extension of credit to a Title II Only Plan in connection with the Plan's holding of an Auction Rate Security, from: (1) Baird; (2) an Introducing Broker; or (3) a Clearing Broker; where the loan is: (i) Repaid in accordance with its terms and; (ii) guaranteed by the Beneficial Owner.

III. Conditions

(a) Baird acted as a broker or dealer, non-bank custodian, or fiduciary in connection with the acquisition or holding of the Auction Rate Security that is the subject of the transaction;

(b) For transactions involving a Plan (including a Title II Only Plan) not sponsored by Baird for its own employees, the decision to enter into the transaction is made by a Plan fiduciary who is Independent (as defined in section IV (e)) of Baird. Notwithstanding the foregoing, an employee of Baird who is the Beneficial Owner of a Title II Only Plan may direct such Plan to engage in a transaction described in section II, if all of the other conditions of this section III have been met;

(c) The last auction for the Auction Rate Security was unsuccessful;

(d) The Plan does not waive any rights or claims in connection with the loan or sale as a condition of engaging in the transaction;

(e) The Plan does not pay any fees or commissions in connection with the transaction;

(f) The transaction is not part of an arrangement, agreement or understanding designed to benefit a party in interest;

(g) With respect to any sale described in section I (a) or section II (a):

(1) The sale is for no consideration other than cash payment against prompt delivery of the Auction Rate Security; and

(2) For purposes of the sale, the Auction Rate Security is valued at par, plus any accrued but unpaid interest; [7]

(h) With respect to an in-kind exchange described in section (I)(a) or section II(a), the exchange involves the transfer by a Plan of an Auction Rate Security in return for a Delivered Security, as such term is defined in section IV(j), where:

(1) The exchange is unconditional;

(2) For purposes of the exchange, the Auction Rate Security is valued at par, plus any accrued but unpaid interest;

(3) The Delivered Security is valued at fair market value, as determined at the time of the in-kind exchange by a third party pricing service or other objective source;

(4) The Delivered Security is appropriate for the Plan and a security that the Plan is otherwise permitted to hold under applicable law; [8] and

(5) The total value of the Auction Rate Security (*i.e.*, par plus any accrued but unpaid interest) is equal to the fair market value of the Delivered Security;

(i) With respect to a loan described in section I(b) or II(b):

(1) The loan is documented in a written agreement containing all of the material terms of the loan, including the consequences of default;

(2) The Plan does not pay an interest rate that exceeds one of the following three rates as of the commencement of the loan:

(A) The coupon rate for the Auction Rate Security;

(B) The Federal Funds Rate; or

(C) The Prime Rate;

(3) The loan is unsecured; and

(4) The amount of the loan is not more than the total par value of the Auction Rate Securities held by the Plan.

IV. Definitions

(a) The term ''affiliate'' means any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(b) The term ''Auction Rate Security'' or ''ARS'' means a security:

(1) That is either a debt instrument (generally with a long-term nominal maturity) or preferred stock; and

(2) with an interest rate or dividend that is reset at specific intervals through a Dutch auction process;

(c) The term ''Beneficial Owner'' means: The individual for whose benefit the Title II Only Plan is established and includes a relative or family trust with respect to such individual;

(d) The term ''Clearing Broker'' means: A member of a securities exchange that acts as a liaison between an investor and a clearing corporation and that helps to ensure that a trade is settled appropriately, that the transaction is successfully completed and that is responsible for maintaining the paper work associated with the clearing and executing of a transaction;

(e) The term ''Independent'' means a person who is: (1) Not Baird or an affiliate; and (2) not a relative (as defined in ERISA section 3(15)) of the party engaging in the transaction;

(f) The term ''Introducing Broker'' means: A registered broker that is able to perform all the functions of a broker except for the ability to accept money, securities, or property from a customer;

(g) The term ''Sponsor'' means: A plan sponsor as described in section 3(16)(B) of the Act and any Affiliates;

(h) The term ''Plan'' means: Any plan described in section 3(3) of the Act and/or section 4975(e)(1) of the Code;

(i) The term ''Title II Only Plan'' means: Any plan described in section 4975(e)(1) of the Code which is not an employee benefit plan covered by Title I of ERISA;

(j) The term ''Delivered Security'' means a security that is: (1) Listed on a national securities exchange (excluding OTC Bulletin Board-eligible securities and Pink Sheets-quoted securities); or (2) a U.S. Treasury obligation; or (3) A fixed income security that has a rating at the time of the exchange that is in one of the two highest generic rating categories from an independent nationally recognized statistical rating organization (*e.g.*, a highly rated municipal bond or a highly rated corporate bond); or (4) A certificate of deposit insured by the Federal Deposit Insurance Corporation. Notwithstanding the above, the term ''Delivered Security'' shall not include any Auction Rate Security, or any related Auction Rate Security, including derivatives or securities materially comprised of Auction Rate Securities or any illiquid securities.

Summary of Facts and Representations

1. The applicant is Baird (hereinafter, either the Applicant or Baird), an employee-owned wealth management, capital markets, asset management and private equity firm headquartered in Milwaukie, Wisconsin. Baird is a registered broker-dealer and a member of the Financial Industry Regulatory Authority. Baird is also a registered investment advisor, providing investment advice and asset management services to clients that include plans described in section 3(3) of the Act and/or section 4975(e)(1) of the Code.

2. The Applicant describes Auction Rate Securities (ARS), and the arrangement by which ARS are bought and sold, as follows. Auction Rate Securities are securities (issued as debt or preferred stock) with an interest rate or dividend that is reset at periodic intervals pursuant to a process called a Dutch Auction. Investors submit orders to buy, hold, or sell a specific ARS to a broker-dealer selected by the entity that issued the ARS. The broker-dealers, in turn, submit all of these orders to an auction agent. The auction agent's functions include collecting orders from all participating broker-dealers by the auction deadline, determining the amount of securities available for sale, and organizing the bids to determine the winning bid. If there are any buy orders placed into the auction at a specific rate, the auction agent accepts bids with the lowest rate above any applicable minimum rate and then successively higher rates up to the maximum applicable rate, until all sell orders and orders that are treated as sell orders are filled. Bids below any applicable minimum rate or above the applicable maximum rate are rejected. After determining the clearing rate for all of the securities at auction, the auction agent allocates the ARS available for sale to the participating broker-dealers based on the orders they submitted. If there are multiple bids at the clearing rate, the auction agent will allocate securities among the bidders at such rate on a pro-rata basis.

3. The Applicant states that Baird is permitted, but not obligated, to submit

[7] This proposed exemption does not address tax issues. The Department has been informed by the Internal Revenue Service and the Department of the Treasury that they are considering providing limited relief from the requirements of sections 72(t)(4), 401(a)(9), and 4974 of the Code with respect to retirement plans that hold Auction Rate Securities. The Department has also been informed by the Internal Revenue Service that if Auction Rate Securities are purchased from a Plan in a transaction described in sections I and II at a price that exceeds the fair market value of those securities, then the excess value would be treated as a contribution for purposes of applying applicable contribution and deduction limits under sections 219, 404, 408, and 415 of the Code.

[8] The Department notes that the Act's general standards of fiduciary conduct also would apply to the transactions described herein. In this regard, section 404 requires, among other things, that a fiduciary discharge his duties respecting a plan solely in the interest of the plan's participants and beneficiaries and in a prudent manner. Accordingly, a plan fiduciary must act prudently with respect to, among other things, (1) The decision to exchange an Auction Rate Security for a Delivered Security; and (2) the negotiation of the terms of such exchange (or a cash sale or loan described above), including the pricing of such securities. The Department further emphasizes that it expects plan fiduciaries, prior to entering into any of the proposed transactions, to fully understand the risks associated with these types of transactions following disclosure by Baird of all relevant information.

orders in auctions for its own account either as a bidder or a seller and routinely does so in the auction rate securities market in its sole discretion. In this regard, Baird may routinely place one or more bids in an auction for its own account to acquire ARS for its inventory, to prevent: (1) a failed auction (*i.e.*, an event where there are insufficient clearing bids which would result in the auction rate being set at a specified rate); or (2) an auction from clearing at a rate that Baird believes does not reflect the market for the particular ARS being auctioned.

4. The Applicant states that for many ARS, Baird has been appointed by the issuer of the securities to serve as a dealer in the auction and is paid by the issuer for its services. Baird is typically appointed to serve as a dealer in the auctions pursuant to an agreement between the issuer and Baird. That agreement provides that Baird will receive from the issuer auction dealer fees based on the principal amount of the securities placed through Baird.

5. The Applicant states further that Baird may share a portion of the auction rate dealer fees it receives from the issuer with other broker-dealers that submit orders through Baird, for those orders that Baird successfully places in the auctions. Similarly, with respect to ARS for which broker-dealers other than Baird act as dealer, such other broker-dealers may share auction dealer fees with Baird for orders submitted by Baird.

6. According to the Applicant, since February 2008, a minority of auctions have cleared, particularly involving municipalities. As a result, Plans holding Auction Rate Securities may not have sufficient liquidity to make benefit payments, mandatory payments and withdrawals and expense payments when due.[9] The Applicant is therefore requesting relief for the following transactions, involving all employee benefit plans: (1) The sale or exchange of an Auction Rate Security from a Plan to the Plan's Sponsor; and (2) a lending of money or other extension of credit to a Plan in connection with the holding of an Auction Rate Security from: Baird, an Introducing Broker, or a Clearing Broker, where the subsequent repayment of the loan is made in accordance with its terms and is guaranteed by the Plan Sponsor.

7. The Applicant is requesting similar relief for plans covered only by Title II of ERISA. In this regard, the Applicant is requesting relief for: (1) The sale or exchange of an Auction Rate Security from a Title II Only Plan to the Beneficial Owner of such Plan; and (2) a lending of money or other extension of credit to a Title II Only Plan in connection with the holding of an Auction Rate Security from: Baird; an Introducing Broker; or a Clearing Broker; where the subsequent repayment of the loan is made in accordance with its terms and is guaranteed by the Beneficial Owner.

8. The Applicant states that relief from section 406(a) and (b) of ERISA is necessary since: (1) Baird may have previously advised or otherwise caused a Plan to acquire and hold the Auction Rate Security that is the subject of the transaction;[10] and (2) the sale of an Auction Rate Security from a Plan to its sponsor (or from an IRA to its Beneficial Owner) violates section ERISA section 406 and/or section 4975(c)(1) of the Code.

9. The Applicant represents that the proposed transactions are in the interests of the Plans. In this regard, the Applicant states that the exemption, if granted, will provide Plan fiduciaries with liquidity notwithstanding changes that occurred in the Auction Rate Securities markets. The Applicant also notes that, other than for Plans sponsored by the Applicant, the decision to enter into a transaction described herein will be made by a Plan fiduciary who is independent of Baird.

10. The proposed exemption contains a number of safeguards designed to protect the interests of each Plan. With respect to the sale of an Auction Rate Security by a Plan, the Plan must receive cash equal to the par value of the Security, plus any accrued interest. The sale must also be unconditional, other than being for payment against prompt delivery. For in-kind exchanges covered by the proposed exemption, the security delivered to the Plan (*i.e.*, the Delivered Security) must be: (1) Listed on a national securities exchange (excluding OTC Bulletin Board-eligible securities and Pink Sheets-quoted securities); or (2) a U.S. Treasury obligation; or (3) a fixed income security that has a rating at the time of the exchange that is in one of the two highest generic rating categories from an independent nationally recognized statistical rating organization (*e.g.*, a highly rated municipal bond or a highly rated corporate bond); or (4) a certificate of deposit insured by the Federal Deposit Insurance Corporation. The Delivered Security must also be appropriate for the Plan, and a security that the Plan is permitted to hold under applicable law. The proposed exemption further requires that the Delivered Security be valued at its fair market value, as determined at the time of the exchange from a third party pricing service or other objective source, and must equal the total value of the Auction Rate Security being exchanged (*i.e.*, par value, plus any accrued interest).

11. With respect to a loan to a Plan holding an Auction Rate Security, such loan must be documented in a written agreement containing all of the material terms of the loan, including the consequences of default. Further, the Plan may not pay an interest rate that exceeds one of the following three rates as of the commencement of the loan: The coupon rate for the Auction Rate Security; the Federal Funds Rate; or the Prime Rate. Additionally, such loan must be unsecured and for an amount that is no more than the total par value of Auction Rate Securities held by the affected Plan.

12. Additional conditions apply to each transaction covered by the exemption, if granted. Among other things, the Plan may not pay any fees or commissions in connection with the transaction and the transaction may not part of an arrangement, agreement, or understanding designed to benefit a party in interest. The exemption also expressly prohibits any waiver of rights or claims by a Plan in connection with the sale or exchange of an Auction Rate Security by a Plan, or a lending of money or other extension of credit to a Plan holding an Auction Rate Security.

13. In summary, the Applicant represents that the transactions described herein satisfy the statutory criteria set forth in section 408(a) of the Act and section 4975(c)(2) of the Code because:

(1) Any sale will be:

(A) For no consideration other than cash payment against prompt delivery of the Auction Rate Security; and

(B) At par, plus any accrued but unpaid interest;

(2) Any in-kind exchange will be unconditional and will involve Delivered Securities that are:

(A) Appropriate for the Plan;

(B) Listed on a national securities exchange (but not OTC Bulletin Board-eligible securities and Pink Sheets-

[9] The Department notes that Class Exemption 80–26 (45 FR 28545 (Apr. 29, 1980), as amended at 71 FR 17917 (Apr. 7, 2006)) permits interest-free loans or other extensions of credit from a party in interest to a Plan if, among other things, the proceeds of the loan or extension of credit are used only—(1) for the payment of ordinary operating expenses of the Plan, including the payment of benefits in accordance with the terms of the Plan and periodic premiums under an insurance or annuity contract, or (2) for a purpose incidental to the ordinary operation of the Plan.

[10] The relief contained in this proposed exemption does not extend to the fiduciary provisions of section 404 of the Act.

quoted securities); U.S. Treasury obligations; fixed income securities; or certificates of deposit; and

(C) Securities that the Plan is permitted to hold under applicable law; and,

(3) Any loan will be:

(A) Documented in a written agreement containing all of the material terms of the loan, including the consequences of default;

(B) At an interest rate not in excess of: The coupon rate for the Auction Rate Security, the Federal Funds Rate, or the Prime Rate;

(C) Unsecured; and

(D) For an amount that is not more than the total par value of Auction Rate Securities held by the affected Plan.

Notice to Interested Persons

The Applicant represents that the potentially interested participants and beneficiaries cannot all be identified and therefore the only practical means of notifying such participants and beneficiaries of this proposed exemption is by the publication of this notice in the **Federal Register**. Comments and requests for a hearing must be received by the Department not later than 45 days from the date of publication of this notice of proposed exemption in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chris Motta of the Department, telephone (202) 693–8540. (This is not a toll-free number.)

Raymond James & Associates, Inc., Located in St. Petersburg, Florida, Exemption Application Number D–11490.

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and section 4975(c)(2) of the Internal Revenue Code of 1986, as amended (the Code), and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990).[11]

Section I. Transactions Involving Plans Described In Both Title I and Title II of ERISA

If the proposed exemption is granted, the restrictions of section 406(a)(1)(A) through (D) and section 406(b) of ERISA, and the taxes imposed by section 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply, effective February 1, 2008, to the following transactions, if the conditions set forth in section III have been met:

(a) The sale or exchange of an Auction Rate Security (as defined in section IV(b)) by a Plan (as defined in section IV(h)) to the Sponsor (as defined in section IV(g)) of such Plan; or

(b) A lending of money or other extension of credit to a Plan in connection with the Plan's holding of an Auction Rate Security, from: (1) Raymond James & Associates, Inc. or any of its current or future affiliates or subsidiaries (Raymond James); (2) an Introducing Broker (as defined in section IV(f)); or (3) a Clearing Broker (as defined in section IV(d)); where the loan is: (i) repaid in accordance with its terms; and (ii) guaranteed by the Plan Sponsor.

II. Transactions Involving Plans Described In Title II of ERISA Only

If the proposed exemption is granted, the sanctions resulting from the application of section 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code, shall not apply, effective February 1, 2008, to the following transactions, if the conditions set forth in section III have been met:

(a) The sale or exchange of an Auction Rate Security by a Title II Only Plan (as defined in section IV(i)) to the Beneficial Owner (as defined in section IV(c)) of such Plan; or

(b) A lending of money or other extension of credit to a Title II Only Plan in connection with the Plan's holding of an Auction Rate Security, from: (1) Raymond James; (2) an Introducing Broker; or (3) a Clearing Broker; where the loan is: (i) repaid in accordance with its terms and; (ii) guaranteed by the Beneficial Owner.

III. Conditions

(a) Raymond James acted as a broker or dealer, non-bank custodian, or fiduciary in connection with the acquisition or holding of the Auction Rate Security that is the subject of the transaction;

(b) For transactions involving a Plan (including a Title II Only Plan) not sponsored by Raymond James for its own employees, the decision to enter into the transaction is made by a Plan fiduciary who is Independent (as defined in section IV(e)) of Raymond James. Notwithstanding the foregoing, an employee of Raymond James who is the Beneficial Owner of a Title II Only Plan may direct such Plan to engage in a transaction described in section II, if all of the other conditions of this section III have been met;

(c) The last auction for the Auction Rate Security was unsuccessful;

(d) The Plan does not waive any rights or claims in connection with the loan or sale as a condition of engaging in the transaction;

(e) The Plan does not pay any fees or commissions in connection with the transaction;

(f) The transaction is not part of an arrangement, agreement or understanding designed to benefit a party in interest;

(g) With respect to any sale described in section I(a) or section II(a):

(1) The Sale is for no consideration other than cash payment against prompt delivery of the Auction Rate Security; and

(2) For purposes of the sale, the Auction Rate Security is valued at par, plus any accrued but unpaid interest;[12]

(h) With respect to an in-kind exchange described in section (I)(a) or section II(a), the exchange involves the transfer by a Plan of an Auction Rate Security in return for a Delivered Security, as such term is defined in section IV(j), where:

(1) The exchange is unconditional;

(2) For purposes of the exchange, the Auction Rate Security is valued at par, plus any accrued but unpaid interest;

(3) The Delivered Security is valued at fair market value, as determined at the time of the in-kind exchange by a third party pricing service or other objective source;

(4) The Delivered Security is appropriate for the Plan and a security that the Plan is otherwise permitted to hold under applicable law;[13] and

[11] For purposes of this proposed exemption, references to section 406 of ERISA should be read to refer as well to the corresponding provisions of section 4975 of the Code.

[12] This proposed exemption does not address tax issues. The Department has been informed by the Internal Revenue Service and the Department of the Treasury that they are considering providing limited relief from the requirements of sections 72(t)(4), 401(a)(9), and 4974 of the Code with respect to retirement plans that hold Auction Rate Securities. The Department has also been informed by the Internal Revenue Service that if Auction Rate Securities are purchased from a Plan in a transaction described in sections I and II at a price that exceeds the fair market value of those securities, then the excess value would be treated as a contribution for purposes of applying applicable contribution and deduction limits under sections 219, 404, 408, and 415 of the Code.

[13] The Department notes that the Act's general standards of fiduciary conduct also would apply to the transactions described herein. In this regard, section 404 requires, among other things, that a fiduciary discharge his duties respecting a plan solely in the interest of the plan's participants and beneficiaries and in a prudent manner. Accordingly, a plan fiduciary must act prudently with respect to, among other things: (1) The decision to exchange an Auction Rate Security for a Delivered Security; and (2) the negotiation of the terms of such exchange (or a cash sale or loan described above), including the pricing of such securities. The Department further emphasizes that it expects plan fiduciaries, prior to entering into any of the proposed transactions, to fully understand

(5) The total value of the Auction Rate Security (*i.e.*, par plus any accrued but unpaid interest) is equal to the fair market value of the Delivered Security;

(i) With respect to a loan described in section I(b) or II(b):

(1) The loan is documented in a written agreement containing all of the material terms of the loan, including the consequences of default;

(2) The Plan does not pay an interest rate that exceeds one of the following three rates as of the commencement of the loan:

(A) The coupon rate for the Auction Rate Security;

(B) The Federal Funds Rate; or

(C) The Prime Rate;

(3) The loan is unsecured; and

(4) The amount of the loan is not more than the total par value of the Auction Rate Securities held by the Plan.

IV. Definitions

(a) The term ''affiliate'' means any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(b) The term ''Auction Rate Security'' or ''ARS'' means a security:

(1) That is either a debt instrument (generally with a long-term nominal maturity) or preferred stock; and

(2) with an interest rate or dividend that is reset at specific intervals through a Dutch auction process;

(c) The term ''Beneficial Owner'' means: The individual for whose benefit the Title II Only Plan is established and includes a relative or family trust with respect to such individual;

(d) The term ''Clearing Broker'' means: A member of a securities exchange that acts as a liaison between an investor and a clearing corporation and that helps to ensure that a trade is settled appropriately, that the transaction is successfully completed and that is responsible for maintaining the paper work associated with the clearing and executing of a transaction;

(e) The term ''Independent'' means a person who is: (1) Not Raymond James or an affiliate; and (2) not a relative (as defined in ERISA section 3(15)) of the party engaging in the transaction;

(f) The term ''Introducing Broker'' means: A registered broker that is able to perform all the functions of a broker except for the ability to accept money, securities, or property from a customer;

(g) The term ''Sponsor'' means: A plan sponsor as described in section 3(16)(B) of the Act and any Affiliates;

(h) The term ''Plan'' means: Any plan described in section 3(3) of the Act and/or section 4975(e)(1) of the Code;

(i) The term ''Title II Only Plan'' means: Any plan described in section 4975(e)(1) of the Code which is not an employee benefit plan covered by Title I of ERISA;

(j) The term ''Delivered Security means a security that is: (1) Listed on a national securities exchange (excluding OTC Bulletin Board-eligible securities and Pink Sheets-quoted securities); or (2) a U.S. Treasury obligation; or (3) a fixed income security that has a rating at the time of the exchange that is in one of the two highest generic rating categories from an independent nationally recognized statistical rating organization (*e.g.*, a highly rated municipal bond or a highly rated corporate bond); or (4) a certificate of deposit insured by the Federal Deposit Insurance Corporation. Notwithstanding the above, the term ''Delivered Security'' shall not include any Auction Rate Security, or any related Auction Rate Security, including derivatives or securities materially comprised of Auction Rate Securities or any illiquid securities.

Summary of Facts and Representations

1. The applicant is Raymond James (hereinafter, either the Applicant or Raymond James), a Florida-based entity that provides a range of financial services to clients that include plans described in section 3(3) of the Act and/or section 4975(e)(1) of the Code. Raymond James additionally acts as a broker and dealer with respect to the purchase and sale of securities, including Auction Rate Securities.

2. The Applicant describes Auction Rate Securities (ARS), and the arrangement by which ARS are bought and sold, as follows. Auction Rate Securities are securities (issued as debt or preferred stock) with an interest rate or dividend that is reset at periodic intervals pursuant to a process called a Dutch Auction. Investors submit orders to buy, hold, or sell a specific ARS to a broker-dealer selected by the entity that issued the ARS. The broker-dealers, in turn, submit all of these orders to an auction agent. The auction agent's functions include collecting orders from all participating broker-dealers by the auction deadline, determining the amount of securities available for sale, and organizing the bids to determine the winning bid. If there are any buy orders placed into the auction at a specific rate, the auction agent accepts bids with the lowest rate above any applicable minimum rate and then successively higher rates up to the maximum applicable rate, until all sell orders and orders that are treated as sell orders are filled. Bids below any applicable minimum rate or above the applicable maximum rate are rejected. After determining the clearing rate for all of the securities at auction, the auction agent allocates the ARS available for sale to the participating broker-dealers based on the orders they submitted. If there are multiple bids at the clearing rate, the auction agent will allocate securities among the bidders at such rate on a pro-rata basis.

3. The Applicant states that Raymond James is permitted, but not obligated, to submit orders in auctions for its own account either as a bidder or a seller and routinely does so in the auction rate securities market in its sole discretion. In this regard, Raymond James may routinely place one or more bids in an auction for its own account to acquire ARS for its inventory, to prevent: (1) A failed auction (*i.e.*, an event where there are insufficient clearing bids which would result in the auction rate being set at a specified rate); or (2) an auction from clearing at a rate that Raymond James believes does not reflect the market for the particular ARS being auctioned.

4. The Applicant states that for many ARS, Raymond James has been appointed by the issuer of the securities to serve as a dealer in the auction and is paid by the issuer for its services. Raymond James is typically appointed to serve as a dealer in the auctions pursuant to an agreement between the issuer and Raymond James. That agreement provides that Raymond James will receive from the issuer auction dealer fees based on the principal amount of the securities placed through Raymond James.

5. The Applicant states further that Raymond James may share a portion of the auction rate dealer fees it receives from the issuer with other broker-dealers that submit orders through Raymond James, for those orders that Raymond James successfully places in the auctions. Similarly, with respect to ARS for which broker-dealers other than Raymond James act as dealer, such other broker-dealers may share auction dealer fees with Raymond James for orders submitted by Raymond James.

6. According to the Applicant, since February 2008, a minority of auctions have cleared, particularly involving municipalities. As a result, Plans holding Auction Rate Securities may not have sufficient liquidity to make benefit payments, mandatory payments and withdrawals and expense payments

the risks associated with these types of transactions following disclosure by Raymond James of all relevant information.

when due.[14] The Applicant is therefore requesting relief for the following transactions, involving all employee benefit plans: (1) The sale or exchange of an Auction Rate Security from a Plan to the Plan's Sponsor; and (2) a lending of money or other extension of credit to a Plan in connection with the holding of an Auction Rate Security from: Raymond James, an Introducing Broker, or a Clearing Broker, where the subsequent repayment of the loan is made in accordance with its terms and is guaranteed by the Plan Sponsor.

7. The Applicant is requesting similar relief for plans covered only by Title II of ERISA. In this regard, the Applicant is requesting relief for: (1) The sale or exchange of an Auction Rate Security from a Title II Only Plan to the Beneficial Owner of such Plan; and (2) a lending of money or other extension of credit to a Title II Only Plan in connection with the holding of an Auction Rate Security from: Raymond James; an Introducing Broker; or a Clearing Broker; where the subsequent repayment of the loan is made in accordance with its terms and is guaranteed by the Beneficial Owner.

8. The Applicant states that relief from section 406(a) and (b) of ERISA is necessary since: (1) Raymond James may have previously advised or otherwise caused a Plan to acquire and hold the Auction Rate Security that is the subject of the transaction;[15] and (2) the sale of an Auction Rate Security from a Plan to its sponsor (or from an IRA to its Beneficial Owner) violates section ERISA section 406 and/or section 4975(c)(1) of the Code.

9. The Applicant represents that the proposed transactions are in the interests of the Plans. In this regard, the Applicant states that the exemption, if granted, will provide Plan fiduciaries with liquidity notwithstanding changes that occurred in the Auction Rate Securities markets. The Applicant also notes that, other than for Plans sponsored by the Applicant, the decision to enter into a transaction described herein will be made by a Plan fiduciary who is independent of Raymond James.

10. The proposed exemption contains a number of safeguards designed to protect the interests of each Plan. With respect to the sale of an Auction Rate Security by a Plan, the Plan must receive cash equal to the par value of the Security, plus any accrued interest. The sale must also be unconditional, other than being for payment against prompt delivery. For in-kind exchanges covered by the proposed exemption, the security delivered to the Plan (*i.e.*, the Delivered Security) must be: (1) Listed on a national securities exchange (excluding OTC Bulletin Board-eligible securities and Pink Sheets-quoted securities); or (2) a U.S. Treasury obligation; or (3) a fixed income security that has a rating at the time of the exchange that is in one of the two highest generic rating categories from an independent nationally recognized statistical rating organization (*e.g.*, a highly rated municipal bond or a highly rated corporate bond); or (4) a certificate of deposit insured by the Federal Deposit Insurance Corporation. The Delivered Security must also be appropriate for the Plan, and a security that the Plan is permitted to hold under applicable law. The proposed exemption further requires that the Delivered Security be valued at its fair market value, as determined at the time of the exchange from a third party pricing service or other objective source, and must equal the total value of the Auction Rate Security being exchanged (*i.e.*, par value, plus any accrued interest).

11. With respect to a loan to a Plan holding an Auction Rate Security, such loan must be documented in a written agreement containing all of the material terms of the loan, including the consequences of default. Further, the Plan may not pay an interest rate that exceeds one of the following three rates as of the commencement of the loan: The coupon rate for the Auction Rate Security; the Federal Funds Rate; or the Prime Rate. Additionally, such loan must be unsecured and for an amount that is no more than the total par value of Auction Rate Securities held by the affected Plan.

12. Additional conditions apply to each transaction covered by the exemption, if granted. Among other things, the Plan may not pay any fees or commissions in connection with the transaction and the transaction may not be part of an arrangement, agreement, or understanding designed to benefit a party in interest. The exemption also expressly prohibits any waiver of rights or claims by a Plan in connection with the sale or exchange of an Auction Rate Security by a Plan, or a lending of money or other extension of credit to a Plan holding an Auction Rate Security.

13. In summary, the Applicant represents that the transactions described herein satisfy the statutory criteria set forth in section 408(a) of the Act and section 4975(c)(2) of the Code because:

(1) Any sale will be:

(A) For no consideration other than cash payment against prompt delivery of the Auction Rate Security; and

(B) At par, plus any accrued but unpaid interest;

(2) Any in-kind exchange will be unconditional and will involve Delivered Securities that are:

(A) Appropriate for the Plan;

(B) Listed on a national securities exchange (but not OTC Bulletin Board-eligible securities and Pink Sheets-quoted securities); U.S. Treasury obligations; fixed income securities; or certificates of deposit; and

(C) Securities that the Plan is permitted to hold under applicable law; and,

(3) Any loan will be:

(A) Documented in a written agreement containing all of the material terms of the loan, including the consequences of default;

(B) At an interest rate that is not in excess of: The coupon rate for the Auction Rate Security, the Federal Funds Rate, or the Prime Rate;

(C) Unsecured; and

(D) For an amount that is not more than the total par value of Auction Rate Securities held by the affected Plan.

Notice to Interested Persons

The Applicant represents that the potentially interested participants and beneficiaries cannot all be identified and therefore the only practical means of notifying such participants and beneficiaries of this proposed exemption is by the publication of this notice in the **Federal Register**. Comments and requests for a hearing must be received by the Department not later than 45 days from the date of publication of this notice of proposed exemption in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Chris Motta of the Department, telephone (202) 693–8540. (This is not a toll-free number.)

Northwestern Mutual Investment Services, LLC, Located in Milwaukee, Wisconsin, Exemption Application Number D–11505.

[14] The Department notes that Class Exemption 80–26 (45 FR 28545 (Apr. 29, 1980), as amended at 71 FR 17917 (Apr. 7, 2006)) permits interest-free loans or other extensions of credit from a party in interest to a Plan if, among other things, the proceeds of the loan or extension of credit are used only—(1) for the payment of ordinary operating expenses of the Plan, including the payment of benefits in accordance with the terms of the Plan and periodic premiums under an insurance or annuity contract, or (2) for a purpose incidental to the ordinary operation of the Plan.

[15] The relief contained in this proposed exemption does not extend to the fiduciary provisions of section 404 of the Act.

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and section 4975(c)(2) of the Internal Revenue Code of 1986, as amended (the Code), and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990).[16]

Section I. Transactions

If the proposed exemption is granted, the restrictions of section 406(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (D) of the Code, shall not apply, effective September 30, 2008, to the sale (the Sale) by a Plan (as defined in section II(d)) of an Auction Rate Security (as defined in section II(b) to Northwestern Mutual Investment Services, LLC (NMIS), provided that the following conditions are met:

(a) The Plan acquired the Auction Rate Security (ARS) in connection with brokerage services provided by NMIS;

(b) The last auction for the ARS was unsuccessful;

(c) The Sale is made in connection with a written offer by NMIS (the Offer) containing all of the material terms of the Sale;

(d) The Sale is for no consideration other than cash payment against prompt delivery of the ARS;

(e) The amount of the Sale is equal to the greater of:

(1) The fair market value of the ARS as of the date of the Sale, as determined by a qualified, independent appraiser; or

(2) The sum of the price paid by the Plan for the ARS and any accrued but unpaid interest;[17]

(f) The Plan does not waive any rights or claims in connection with the Sale;

(g) The decision to accept the Offer or retain the ARS is made by a Plan fiduciary or Plan participant or IRA owner, who (in all cases) is Independent (as defined in section II(c)) of NMIS;[18]

(h) Neither NMIS nor any affiliate exercises investment discretion or renders investment advice [within the meaning of 29 CFR 2510.3–21(c)] with respect to the decision to accept the Offer or retain the ARS;

(i) The Plan does not pay any commissions or transaction costs with respect to the Sale;

(j) The Sale is not part of an arrangement, agreement or understanding designed to benefit a party in interest to the Plan;

(k) NMIS and its affiliates, as applicable, maintain, or cause to be maintained, for a period of six (6) years from the date of the Sale such records as are necessary to enable the persons described below in paragraph (l)(i), to determine whether the conditions of this proposed exemption, if granted, have been met, except that—

(i) No party in interest with respect to a Plan which engages in a Sale, other than NMIS and its affiliates, as applicable, shall be subject to a civil penalty under section 502(i) of the Act or the taxes imposed by section 4975(a) and (b) of the Code, if such records are not maintained, or not available for examination, as required, below, by paragraph (l)(i); and

(ii) A separate prohibited transaction shall not be considered to have occurred solely because, due to circumstances beyond the control of NMIS or its affiliates, as applicable, such records are lost or destroyed prior to the end of the six-year period;

(l)(i) Except as provided below in paragraph (l)(ii), and notwithstanding any provisions of subsections (a)(2) and (b) of section 504 of the Act, the records referred to above in paragraph (k) are unconditionally available at their customary location for examination during normal business hours by—

(A) Any duly authorized employee or representative of the Department, the Internal Revenue Service, or the U.S. Securities and Exchange Commission; or

(B) Any fiduciary of any Plan that engages in a Sale, or any duly authorized employee or representative of such fiduciary; or

(C) Any employer of participants and beneficiaries and any employee organization whose members are covered by a Plan that engages in the Sale, or any authorized employee or representative of these entities; or

(D) Any IRA owner, participant or beneficiary of a Plan that engages in a Sale, or duly authorized employee or representative of such IRA owner, participant or beneficiary;

(ii) None of the persons described above in paragraph (l)(i)(B)–(D) shall be authorized to examine trade secrets of NMIS, or commercial or financial information which is privileged or confidential; and

(iii) Should NMIS refuse to disclose information on the basis that such information is exempt from disclosure, NMIS shall, by the close of the thirtieth (30th) day following the request, provide a written notice advising that person of the reasons for the refusal and that the Department may request such information.

Section II. Definitions

(a) The term ''affiliate'' means: Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(b) The term ''Auction Rate Security'' or ''ARS'' means a security:

(1) That is either a debt instrument (generally with a long-term nominal maturity) or preferred stock; and

(2) with an interest rate or dividend that is reset at specific intervals through a Dutch auction process;

(c) The term ''Independent'' means a person who is: (1) Not NMIS or an affiliate; and (2) not a relative (as defined in ERISA section 3(15)) of the party engaging in the transaction; and

(d) The term ''Plan'' means: any plan described in section 3(3) of the Act and/or section 4975(e)(1) of the Code.

Summary of Facts and Representations

1. The applicant is Northwestern Mutual Investment Services, LLC (hereinafter, either the Applicant or NMIS), a subsidiary of the Northwestern Mutual Life Insurance Company. NMIS is a Wisconsin-based securities brokerage company offering investment products and services in the United States. NMIS makes available brokerage accounts, mutual funds, custodial accounts, individual retirement accounts, money market accounts, and insurance products, among others, and offers advisory and account services. The Applicant represents that, on September 17, 2008, ratings agency Standard & Poor's (S&P) confirmed in a public announcement that Northwestern Mutual remains one of the strongest companies in the life insurance industry and continues to maintain S&P's best

[16] For purposes of this proposed exemption, references to section 406 of ERISA should be read to refer as well to the corresponding provisions of section 4975 of the Code.

[17] In the event that the fair market value of an ARS exceeds the sum of its par value plus any accrued, but unpaid, interest as of the date of the Sale, NMIS will credit the difference to the Plan, with interest equal to the Federal Funds rate plus 125 basis points.

[18] The Department notes that the Act's general standards of fiduciary conduct also would apply to the transactions described herein. In this regard, section 404 requires, among other things, that a fiduciary discharge his duties respecting a plan solely in the interest of the plan's participants and beneficiaries and in a prudent manner. Accordingly, a plan fiduciary must act prudently with respect to, among other things, the decision to engage (or to not engage) in a Sale. The Department further emphasizes that it expects a plan fiduciary, prior to entering into a Sale (or, alternately, prior to deciding to retain an ARS), to fully understand the risks associated with such a decision, following disclosure by NMIS of all relevant information.

possible insurance financial strength rating (AAA).

2. The Applicant states that in early 2006, NMIS began effecting, as broker, the purchase and sale of ARS on behalf of clients including plans described in section 3(3) of the Act and/or section 4975(e)(1) of the Code (*i.e.*, the Plans). In this regard, the Applicant states that, as of September 10, 2008, Plans with respect to which NMIS was the broker of record collectively held $17.6 million in ARS (IRAs held approximately $15.225 million in ARS; qualified pension or profit sharing plans held approximately $2.05 million in ARS; and SEP-IRA's held approximately $350,000 in ARS). The Applicant describes ARS as nominal long-term debt instruments or preferred shares with short-term interest or dividend rates regularly reset at periodic Dutch auctions. According to the Applicant, NMIS's role in the ARS market has been solely as a broker. The Applicant represents that neither NMIS nor its affiliates have been an issuer, market-maker, underwriter, dealer or auction agent of or for ARS.

3. The Applicant states that, in February 2008, auctions for ARS began to fail as both investors and the investment banks that previously had acted as bidders of last resort declined to bid. The Applicant represents that, to the best of its information and belief, due to the failure of the primary market for ARS as well as the lack of any secondary market for the securities, there were no available unrelated purchasers for the ARS held by the Plans. In view of the foregoing, on September 30, 2008, NMIS made the Offer to the Plans. In this regard, on that date, NMIS sent a written communication to the Plans outlining its offer to purchase ARS with respect to which NMIS was the broker of record. The Offer provides that, if a Plan fiduciary (or Plan participant or IRA owner) that is independent of NMIS so directs, NMIS will purchase each Plan's ARS for the greater of: (a) The fair market value of the ARS as determined by a qualified, independent appraiser; or (b) the price at which the ARS was purchased by the Plan, plus any accrued but unpaid interest. Plans will be able to accept the Offer at any time during the period September 30, 2008 through November 30, 2008, and Plans will not be compelled to accept the Offer since acceptance must occur solely by an independent fiduciary's affirmative consent. The Applicant states that neither NMIS nor its affiliates will provide investment advice or exercise investment discretion with regard to any Sale.

4. The Applicant states that an independent appraiser will determine the fair market value of the ARS for purposes of each Sale. The Applicant represents that the independent appraiser will be experienced in valuing securities such as ARS and will not have received from NMIS, Northwestern Mutual or their affiliates, gross income for its most recent fiscal year that exceeds five percent of the independent appraiser's annual gross income from all sources for the prior fiscal year. That Applicant states that the appraiser's determination of the fair market value of the ARS on any Sale date will be valid as of the date of such Sale. In the event the appraiser determines that the fair market value of an ARS exceeds the sum of its par value plus any accrued interest, NMIS will credit the difference to the Plan, with interest at the Federal Funds rate plus 125 basis points.

5. The proposed exemption contains a number of additional safeguards designed to protect the interests of each Plan. In this regard, each Sale will involve an ARS for which the last Dutch auction was unsuccessful. Additionally, each Sale will be for no consideration other than cash payment against prompt delivery of the ARS. Affected Plans will not waive any rights or claims in connection with a Sale, and will not bear any commissions or transaction costs with respect to such Sale. Each Sale will not be a part of an arrangement, agreement or understanding designed to benefit a party in interest to the Plan.

6. The Applicant states that the Sales are in the interest of the Plans. In this regard, that Applicant states that the Sales will provide the Plans with liquid funds for reinvestment that may not exist if the Plans remain invested in the ARS. The Applicant represents also that the requested exemption will be administratively feasible since the Sales will be one-time transactions for cash involving specific, identifiable securities. The Applicant represents further that the transactions will occur during a fixed period at a set price to be verified by an independent appraiser, and will not require monitoring by the Department.

7. In summary, the applicant represents that the transaction satisfied the statutory criteria of section 408(a) of the Act and section 4975(c)(2) of the Code because, among other things:

(a) Each Sale will be for no consideration other than cash payment against prompt delivery of the ARS;

(b) Each affected Plan will receive the greater of:

(1) The fair market value of the ARS as of the date of the Sale, as determined by a qualified, independent appraiser, or

(2) The sum of the price at which the ARS was purchased by the Plan, plus any accrued but unpaid interest;

(c) A Plan will not be required to waive any rights or claims in connection with any Sale;

(d) The decision to accept the Offer (or retain the ARS) will be made by a Plan fiduciary or Plan participant or IRA owner, who (in all cases) is independent of NMIS;

(e) Plans will not bear any commissions or transaction costs with respect to the Sale; and

(f) In no event will any Sale be part of an arrangement, agreement or understanding designed to benefit a party in interest.

Notice to Interested Persons

Written notice will be provided to a representative of each Plan. The notice shall contain a copy of the proposed exemption as published in the **Federal Register** and an explanation of the rights of interested parties to comment regarding the proposed exemption. Such notice will be provided by personal or express delivery within 15 days of the issuance of the proposed exemption. Any written comments must be received by the Department from interested persons within 45 days of the publication of this proposed exemption in the **Federal Register**.

For Further Information Contact: Chris Motta of the Department, telephone (202) 693–8554. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which, among other things, require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries, and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC this 3rd day of November 2008.

Ivan Strasfeld,

Director of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. E8–26565 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,000]

Chrysler LLC, Manufacturing Truck and Activity Division, Jefferson North Assembly Plant, Including On-Site Leased Workers From Technical Engineering Consultants, Inc., Detroit, MI; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on March 28, 2008, applicable to workers of Chrysler LLC, Manufacturing Truck and Activity Division, Jefferson North Assembly Plant, Detroit, Michigan. The notice was published in the **Federal Register** on April 11, 2008 (73 FR 19899).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers assemble Jeep Commanders and Jeep Grand Cherokees.

New information shows that leased workers of Technical Engineering Consultants, Inc. were employed on-site at the Detroit, Michigan location of Chrysler LLC, Manufacturing Truck and Activity Division, Jefferson North Assembly Plant. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include leased workers of Technical Engineering Consultants, Inc. working on-site at the Detroit, Michigan location of the subject firm.

The intent of the Department's certification is to include all workers employed at Chrysler LLC, Manufacturing Truck and Activity Division, Jefferson North Assembly Plant who were adversely affected by increased imports.

The amended notice applicable to TA–W–63,000 is hereby issued as follows:

All workers of Chrysler LLC, Manufacturing Truck and Activity Division, Jefferson North Assembly Plant, including on-site leased workers from Technical Engineering Consultants, Inc., Detroit, Michigan, who became totally or partially separated from employment on or after March 12, 2007, through March 28, 2010, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC this 29th day of October 2008.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–26535 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–62,273B]

Delphi Corporation, Brake Hose Division, Including On-Site Leased Workers From Bartech, Acro and Securitas Security Services, Dayton, OH; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on April 25, 2008, applicable to workers of Delphi Corporation, Brake Hose Division, including on-site leased workers from Bartech and Acro, Dayton, Ohio. The notice was published in the **Federal Register** on May 13, 2008 (73 FR 27560).

At the request of the petitioners, the Department reviewed the certification for workers of the subject firm. The workers of the Brake Hose Division produce brake hose for the automotive industry. New information shows that workers leased from Securitas Security Services were employed on-site at the Dayton, Ohio location of Delphi Corporation, Brake Hose Division. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Securitas Security Services working on-site at the Brake Hose Division, Dayton, Ohio location of the subject firm.

The amended notice applicable to TA–W–62,273B is hereby issued as follows:

All workers of Delphi Corporation, Brake Hose Division, including on-site leased workers from Bartech, Acro and Securitas Security Services, Dayton, Ohio, who became totally or partially separated from employment on or after October 8, 2006, through April 25, 2010, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC, this 30th day of October 2008.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–26534 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–62,273; TA–W–62,273A]

Delphi Corporation, Automotive Holdings Group Division, Including On-Site Leased Workers From Bartech, Acro and Securitas Security Services, Dayton, OH; Delphi Corporation, Disc Pads Division, Including On-Site Leased Workers From Bartech, Acro and Securitas Security Services, Dayton, OH; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on December 21, 2007, applicable to workers of Delphi Corporation, Automotive Holdings Group Division, including on-site leased workers from Bartech and Acro, Dayton, Ohio and Delphi Corporation, Disc Pads Division, including on-site leased workers from Bartech and Acro, Dayton, Ohio. The notice was published in the **Federal Register** on January 16, 2008 (73 FR 2943).

At the request of the petitioners, the Department reviewed the certification for workers of the subject firm. The workers of the Automotive Holdings Group Division produce mounts and the workers of the Disc Pads Division produce disc pads. New information shows that workers leased from Securitas Security Services were employed on-site at the Dayton, Ohio location of Delphi Corporation, Automotive Holdings Group Division and the Disc Pads Division. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Securitas Security Services working on-site at the Automotive Holdings Group Division and the Disc Pads Division, Dayton, Ohio location of the subject firm.

The amended notice applicable to TA-W–62,273 and TA-W–62,273A are hereby issued as follows:

Workers engaged in employment related to the production of mounts at Delphi Corporation, Automotive Holdings Group Division, including on-site leased workers from Bartech, Acro and Securitas Security Services, Dayton, Ohio (TA–62,273), and workers engaged in employment related to the production of disc pads at Delphi Corporation, Disc Pads Division, including on-site leased workers from Bartech, Acro and Securitas Security Services, Dayton, Ohio (TA–W–62,273A), who became totally or partially separated from employment on or after October 8, 2006, through December 21, 2009, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC this 30th day of October 2008.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–26533 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,878]

Gerber Scientific, Inc., Gerber Scientific International, Inc., South Windsor, CT; Including Employees of Gerber Scientific, Inc., Gerber, Scientific International, Inc., South Windsor, CT, Working in the Following Locations: Ta–W–63,878c, Lexington, MI; Ta–W–63,878d, Liberty, KY; Ta–W–63,878e, Franklin, IN; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on August 27, 2008, applicable to workers of Gerber Scientific, Inc., South Windsor, Connecticut. The notice was published in the **Federal Register** on September 12, 2008 (73 FR 53045). The certification was amended on September 19, 2008 to include workers located in Broadway, Virginia and Coraopolis, Pennsylvania. The notice was published in the **Federal Register** on September 24, 2008 (73 FR 55138).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of computer controlled systems for manufacturing apparel, soft goods, lenses for eyewear and signs.

New information shows that worker separations have occurred involving employees of the South Windsor, Connecticut location of Gerber Scientific, Inc., Gerber Scientific International, Inc. working in Lexington, Michigan; Liberty, Kentucky and Franklin, Indiana. Mr. David Burks, Mr. Mark Lawless and Mr. Steve Peo provided engineering and sales support function services for the production of computer controlled systems for manufacturing apparel, soft goods, lenses for eyewear and signs produced at the South Windsor, Connecticut location of the subject firm.

Information also shows that workers separated from employment at the subject firm had their wages reported under a separate unemployment insurance (UI) tax account for Gerber Scientific International, Inc.

Accordingly, the Department is amending this certification to properly reflect these matters.

The intent of the Department's certification is to include all workers of Gerber Scientific, Inc., Gerber Scientific International, Inc., South Windsor, Connecticut who were adversely affected by increased imports of computer controlled systems for manufacturing apparel, soft goods, lenses for eyewear and signs following a shift in production to China.

The amended notice applicable to TA–W–63,878 is hereby issued as follows:

All workers of Gerber Scientific, Inc., Gerber Scientific International, Inc., South Windsor, Connecticut, (TA–W–63,878), including employees in support of Gerber Scientific, Inc., Gerber Scientific International, Inc., South Windsor, Connecticut, working in Lexington, Michigan (TA–W–63,878C), Liberty, Kentucky (TA–W–63,878D) and Franklin, Indiana (TA–W–63,878E, who became totally or partially separated from employment on or after August 14, 2007, through August 27, 2010, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC this 29th day of October 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–26539 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,747]

Hynix Semiconductor Manufacturing America, Inc., Including On-Site Leased Workers From Securitas Security Systems and Global Tech Building Services Corp., Eugene, OR; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and Section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on August 20, 2008, applicable to workers of Hynix Semiconductor Manufacturing America, Inc., Eugene, Oregon. The notice was published in the **Federal Register** on September 3, 2008 (73 FR 51529).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of Dynamic Random Access Memory (DRAM) wafers.

New information shows that leased workers of Securitas Security Systems and Global Tech Building Services Corp. were employed on-site at the Eugene, Oregon location of Hynix Semiconductor Manufacturing America, Inc. The Department has determined that these workers were sufficiently under the control of the subject firm.

Based on these findings, the Department is amending this certification to include leased workers of Securitas Security Systems and Global Tech Building Services Corp. working on-site at the Eugene, Oregon location of the subject firm.

The intent of the Department's certification is to include all workers employed at Hynix Semiconductor Manufacturing America, Inc. who were adversely affected by increased imports following a shift in production of Dynamic Random Access Memory (DRAM) wafers to South Korea.

The amended notice applicable to TA–W–63,747 is hereby issued as follows:

All workers of Hynix Semiconductor Manufacturing America, Inc. including on-site leased workers from Securitas Security Systems and Global Tech Building Services Corp., Eugene, Oregon, who became totally or partially separated from employment on or after July 24, 2007, through August 20, 2010, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC this 30th day of October 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–26538 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than November 17, 2008.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than November 17, 2008.

The petitions filed in this case are available for inspection at the Office of the Director, Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room C–5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 29th day of October 2008.

Erin Fitzgerald,

Director, Division of Trade Adjustment Assistance.

APPENDIX

[TAA petitions instituted between 10/20/08 and 10/24/08]

TA–W	Subject firm (Petitioners)	Location	Date of institution	Date of petition
64246	Borg Warner Morse Tech (Wkrs)	Ithaca, NY	10/20/08	10/14/08
64247	Guilford (Comp)	Fuquay-Varina, NC	10/20/08	10/17/08
64248	Freudenberg (Comp)	Durham, NC	10/20/08	10/17/08
64249	Gates Corporation (Comp)	Moncks Corner, SC	10/20/08	10/17/08
64250	Findlay Industries (Wkrs)	Chesterfield, MO	10/20/08	10/17/08
64251	Sperian Fall Protection (Wkrs)	Franklin, PA	10/20/08	10/06/08
64252	Lear Corporation (Union)	Wentzville, MO	10/21/08	10/20/08
64253	Amkor Technology, Inc. (Comp)	Morrisville, NC	10/21/08	10/16/08
64254	ITW CIP (State)	Waterbury, CT	10/21/08	10/20/08
64255	Hoffman/New Yorker, Inc. (Comp)	Dushore, PA	10/21/08	10/17/08
64256	STMicroelectronics (Comp)	Phoenix, AZ	10/21/08	10/17/08
64257	Vanguard Furniture Co., Inc. (Wkrs)	Conover, NC	10/21/08	10/01/08

APPENDIX—Continued

[TAA petitions instituted between 10/20/08 and 10/24/08]

TA–W	Subject firm (Petitioners)	Location	Date of institution	Date of petition
64258	Irwin Research and Development (Wkrs)	Yakima, WA	10/21/08	10/16/08
64259	Kim Ro Manufacturing, Inc. (Wkrs)	Trezevant, TN	10/21/08	10/17/08
64260	Glatfelter's Ohio Operation (USW)	Chillicothe, OH	10/21/08	10/17/08
64261	Reed Elsevier/Lexis Nexis (Wkrs)	Miamisburg, OH	10/21/08	10/16/08
64262	Classic Components Corporation (State)	Torrence, CA	10/22/08	09/28/08
64263	Celanese Emulsions Corporation (Union)	Meredosia, IL	10/22/08	10/09/08
64264	General Motors Corporation—Pittsburgh Metal Center (UAW)	West Mifflin, PA	10/22/08	10/22/08
64265	Cooper Crouse-Hinds, Cooper Interconnect (Comp)	LaGrange, NC	10/22/08	10/16/08
64266	Environmental Business Services/Katun Corporation (State)	Austin, TX	10/22/08	10/21/08
64267	Stevens Linen Associates, Inc. (01571)	Dudley, MA	10/22/08	10/21/08
64268	Eagle Ottawa LLC (Comp)	Waterloo, IA	10/23/08	10/22/08
64269	SD Summit Design, Inc. (State)	Montebello, CA	10/23/08	10/22/08
64270	Thermo Fisher Scientific, Lab Vision Fremont, Mfg. Dept. (Wkrs)	Fremont, CA	10/23/08	10/22/08
64271	Knight Colotex (Comp)	Lisbon Falls, ME	10/23/08	10/10/08
64272	Nielsen Co. (formerly AC Nielsen Co.) (Wkrs)	Fond du Lac, WI	10/23/08	10/21/08
64273	Century Furniture Casegoods (Comp)	Hickory, NC	10/24/08	10/23/08
64274	Item-Eyes Apparel (UNITE)	New York, NY	10/24/08	10/23/08
64275	Reynolds Foil, Inc. (Comp)	Richmond, VA	10/24/08	10/21/08
64276	American Safety Razor (IUE)	Verona, VA	10/24/08	10/01/08
64277	Louisiana-Pacific Corporation (State)	Athens, GA	10/24/08	10/23/08
64278	Purcell Systems (Wkrs)	Spokane Valley, WA	10/24/08	10/13/08

[FR Doc. E8–26532 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,713]

Canterbury Printing Company of Rome Incorporated, Rome, New York; Notice of Negative Determination on Reconsideration

On September 17, 2008, the Department issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of Canterbury Printing Company of Rome Incorporated, Rome, New York (subject firm). The Department's Notice of affirmative determination was published in the **Federal Register** on September 24, 2008 (73 FR 55137). Workers produce printed materials including postcards, calendars, and journals.

The Department's determination regarding the subject workers' eligibility to apply for Trade Adjustment Assistance (TAA) and Alternative Trade Adjustment Assistance (ATAA) was based on the Department's findings that, during the relevant period, there were no increased imports by the subject firm or its major declining customer or a shift of production by the subject firm to a foreign country.

In the request for administrative reconsideration, the Graphic Communications Conference of the International Brotherhood of Teamsters Union, Local 503–M, alleged that increased imports contributed to the closure of the subject firm.

In order to apply for TAA, petitioners must meet the worker group eligibility requirements for directly-impacted (primary) workers under Section 222(a) the Trade Act of 1974, as amended. The eligibility requirements can be met by satisfying either Section (a)(2)(A) or Section (a)(2)(B).

Under Section (a)(2)(A), the following criteria must be met:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated; and

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision.

Under Section (a)(2)(B), the following criteria must be met:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated; and

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States; or

2. The country to which the workers' firm has shifted production of the articles is a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

During the reconsideration investigation, the Department confirmed that the subject firm closed permanently in July 2008. Therefore, the Department affirms that the first two criteria of Section 222(a)(2)(A) have been met.

Based on the allegations in the request for reconsideration, the scope of the reconsideration investigation is limited to whether or not the third criteria in Section 222(a)(2)(A) has been met (increased imports of articles like or directly competitive with those produced by the subject firm contributed importantly to the workers' separation and to subject firm sales or production declines).

During the reconsideration investigation, the Department confirmed that the subject firm did not import printed material or articles like or

directly competitive with printed material.

On reconsideration, the Department contacted the subject firm's major declining customer that was surveyed during the initial investigation, and confirmed that the customer did not import articles like or directly competitive with the printed material produced by the subject firm. The customer also stated that it ceased purchasing from the subject firm because it transferred to a Web-based publication. The move from the print medium to an electronic medium was due to the interactive nature of the electronic medium and the customer's advertisers' demands.

During the reconsideration investigation, the Department contacted a previously-unidentified customer of the subject firm and was informed that this customer did not award the subject firm the contract for printing its 2008 catalogue of products. Although the customer did consider awarding the contract to a Chinese company, the contract was awarded to a domestic company.

During the reconsideration investigation, the Department obtained information regarding the printing industry in general. The information indicates that the rise of the digital media—and the attending changes in technology (such as new equipment and computer programs), operating procedures (like ''on demand'' or ''short run'' printing), and customers' demands (including access to Internet links and ''pop up'' advertisements)—is the major factor in the decline in the printing industry. The fast-paced changes in this industry brought about by the ever-changing nature of the digital media, compounded by aging infrastructure and the higher postage costs, have contributed to the closure of companies unable to adapt to the changing environment.

Based on findings in the initial investigation and the reconsideration investigation, the Department determines that increased imports did not contribute importantly to the subject workers' separations and subject firm sales/production declines. Therefore, the Department affirms that Section 222(a)(2)(A)(C) has not been met.

In order for the Department to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA), the subject worker group must be certified eligible to apply for Trade Adjustment Assistance (TAA). Since the subject workers are denied eligibility to apply for TAA, the workers cannot be certified eligible for ATAA.

Conclusion

After careful reconsideration, I affirm the original notice of negative determination of eligibility to apply for worker adjustment assistance for workers and former workers of Canterbury Printing Company of Rome Incorporated, Rome, New York.

Signed at Washington, DC this 27th day of October 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–26537 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,574]

Albany International Research Company, Mansfield, MA; Notice of Negative Determination Regarding Application for Reconsideration

By application postmarked September 30, 2008, a company official requested administrative reconsideration of the Department's negative determination regarding eligibility to apply for Trade Adjustment Assistance (TAA), applicable to workers and former workers of the subject firm. The denial notice was signed on August 18, 2008 and published in the **Federal Register** on September 3, 2008 (73 FR 51530).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The negative TAA determination issued by the Department for workers of Albany International Research Company, Mansfield, Massachusetts was based on the finding that imports of prototype fabrics did not contribute importantly to worker separations at the subject plant and there was no shift of production to a foreign country during the relevant period. The ''contributed importantly'' test is generally demonstrated through a survey of the workers' firm's declining domestic customers. In this instance, the subject firm did not sell prototype fabrics to outside domestic customers, thus a survey was not conducted. The subject firm did not import prototype fabrics into the United States during the relevant period.

In the request for reconsideration the petitioner states that employment at the subject facility will be negatively impacted by a shift in a portion of Research and Development work to England. According to the company official, the shift will be taking place on December 31, 2008.

When assessing eligibility for TAA, the Department exclusively considers import impact during the relevant time period (one year prior to the date of the petition). Events occurring on December 31, 2008 are outside of the relevant time period as established by the petition date of June 19, 2008, and thus cannot be considered in this investigation.

Should conditions change in the future, the company is encouraged to file a new petition on behalf of the worker group which will encompass an investigative period that will include these changing conditions.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed in Washington, DC, this 22nd day of October 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–26536 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,962]

GE Consumer and Industrial Lighting, Willoughby Lucalox Plant, Willoughby, OH; Notice of Negative Determination Regarding Application for Reconsideration

By application dated October 10, 2008, IUE–CWA, Local 84707 requested administrative reconsideration of the Department's negative determination regarding eligibility to apply for Trade Adjustment Assistance (TAA), applicable to workers and former workers of the subject firm. The denial notice was signed on September 24,

2008 and published in the **Federal Register** on October 8, 2008 (73 FR 58982).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The negative TAA determination issued by the Department for workers of GE Consumer and Industrial Lighting, Willoughby Lucalox Plant, Willoughby, Ohio was based on the finding that imports of ceramic metal halide (CMH) high-intensity discharge lamps did not contribute importantly to worker separations at the subject plant and there was no shift of production to a foreign country during the relevant period. The ''contributed importantly'' test is generally demonstrated through a survey of the workers' firm's declining domestic customers. In this instance, the subject firm did not sell ceramic metal halide (CMH) high-intensity discharge lamps to domestic customers, thus a survey was not conducted. The subject firm did not import ceramic metal halide (CMH) high-intensity discharge lamps into the United States during the relevant period.

In the request for reconsideration the petitioner states that ''General Electric Company will begin buying Arc Chambers as early as the start of second quarter next year 2009 from China.''

When assessing eligibility for TAA, the Department exclusively considers import impact during the relevant time period (one year prior to the date of the petition). Events occurring in 2009 are outside of the relevant time period as established by the petition date of August 18, 2008, and thus cannot be considered in this investigation.

Should conditions change in the future, the company is encouraged to file a new petition on behalf of the worker group which will encompass an investigative period that will include these changing conditions.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed in Washington, DC, this 27th day of October 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–26540 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–64,073]

Broan Nutone Storage Solutions, Cleburne, TX; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on September 18, 2008, in response to a worker petition filed by a company official on behalf of workers of Broan Nutone Storage Solutions, Cleburne, Texas.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 28th day of October 2008.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–26541 Filed 11–6–08; 8:45 am]

BILLING CODE 4510–FN–P

OFFICE OF NATIONAL DRUG CONTROL POLICY

Paperwork Reduction Act; Notice of Intent To Collect; Comment Request

AGENCY: Office of National Drug Control Policy (ONDCP).

ACTION: ONDCP provides opportunity for public comment concerning the collection of information gathered for the purpose of developing and tracking anti-drug advertising for the National Youth Anti-Drug Media Campaign.

SUMMARY: This action proposes the renewal of three existing data collection instruments used in the production of ONDCP's National Youth Anti-Drug Media Campaign advertising and Media Campaign tracking.

SUPPLEMENTARY INFORMATION:

I. Purpose

The National Youth Anti-Drug Media Campaign is in the process of renewing three data collection instruments. These data collection instruments—pre-production qualitative (or ''focus group'') testing of creative advertising concepts (OMB 3201–0011), pre-broadcast quantitative (or ''copy'') testing of developed advertising (OMB 3201–0006) and a tracking study to measure advertising effectiveness (OMB 3201–0010)—are critical to the continuity and improvement of the Media Campaign and are key contributors to the downturn in drug abuse.

Type of Collections: OMB 3201–0011—Qualitative Research—Focus groups; OMB 3201–0006—Copytesting—15-minute mall intercept interviews; OMB 3201–0010—Tracking Study—15-minute mall intercept interviews.

Title of Collection: See above.

Frequency: OMB 3201–0011—Qualitative Research—Quarterly; OMB 3201–0006—Copytesting—Quarterly; OMB 3201–0010—Tracking Study—Weekly.

Affected Public: Teenagers and adult influencers of teenagers.

Estimated Burden: OMB 3201–0011—Qualitative Research—$11,600; OMB 3201–0006—Copytesting—$16,500; OMB 3201–0010—Tracking Study—$21,000.

II. Special Issues for Comment

ONDCP especially invites comments on: (a) Ways to enhance information quality, utility, and clarity of the collection instruments; and (b) ways to ease the burden on respondents, including the use of automated collection techniques or other forms of information technology.

Comments: Address comments within 60 days to Mark Krawczyk, Executive Office of the President, Office of National Drug Control Policy, Washington, DC 20503; by e-mail at *MKrawczyk@ondcp.eop.gov*; or, by fax at (202) 395–0858. For further information, contact Mr. Krawczyk at (202) 395–6720.

Signed in Washington, DC, on November 3, 2008.

Daniel R. Petersen,

Assistant General Counsel.

[FR Doc. E8–26553 Filed 11–6–08; 8:45 am]

BILLING CODE 3180–02–P

NUCLEAR REGULATORY COMMISSION

Luminant Generation Company LLC; Notice of Receipt and Availability of Application for a Combined License

On September 19, 2008, Luminant Generation Company LLC filed with

The Nuclear Regulatory Commission (NRC, the Commission) pursuant to Section 103 of the Atomic Energy Act and Title 10 of the Code of Federal Regulations (10 CFR) Part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants,'' an application for a combined license (COL) for two United States—Advanced Pressurized Water Reactors nuclear power plants at the Comanche Peak site located near Glen Rose, Texas. The reactors are to be identified as Comanche Peak Nuclear Power Plant, Units 3 and 4.

An applicant may seek a COL in accordance with Subpart C of 10 CFR Part 52. The information submitted by the applicant includes certain administrative information such as financial qualifications submitted pursuant to 10 CFR 52.77, as well as technical information submitted pursuant to 10 CFR 52.79.

Subsequent **Federal Register** notices will address the acceptability of the tendered COL application for docketing and provisions for participation of the public in the COL review process.

A copy of the application is available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland, and via the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* The accession number for the application transmittal letter is ML082680250. Future publicly available documents related to the application will also be posted in ADAMS. Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the NRC Public Document Room staff by telephone at 1–800–397–4209 or 301–415–4737, or via e-mail at *pdr@nrc.gov.* The application is also available at *http://www.nrc.gov/reactors/new-licensing/col.html.*

Dated at Rockville, Maryland, this 3rd day of November 2008.

For the Nuclear Regulatory Commission.

Stephen Raul Monarque,

Project Manager, US–APWR Projects Branch, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. E8–26608 Filed 11–6–08; 8:45 am]

BILLING CODE 7590–01–P

Office of Personnel Management

[OMB Control No. 3206–0230; Standard Form [SF] 2817]

Proposed Information Collection; Request for Comment on an Existing Information Collection

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) intends to submit to the Office of Management and Budget (OMB) a request for review of an existing information collection. This information collection, ''Life Insurance Election'' (OMB Control No. 3206–0230; SF 2817), is used by Federal employees and assignees (those who have acquired control of an employee/annuitant's coverage through an assignment or ''transfer'' of the ownership of the life insurance). Clearance of this form for use by active Federal employees is not required according to the Paperwork Reduction Act (Pub. L. 98–615). The Public Burden Statement meets the requirements of 5 CFR 1320.8(b)(3). Therefore, only the use of this form by assignees, i.e., members of the public, is subject to the Paperwork Reduction Act.

Comments are particularly invited on whether this information is necessary for the proper performance of functions of the Office of Personnel Management, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Approximately 100 SF 2817 forms are completed annually by assignees. This form takes approximately 15 minutes to complete. The annual estimated burden is 25 hours.

For copies of this proposal, contact Cyrus S. Benson by telephone at (202) 606–4808, by FAX (202) 606–0910, or by e-mail to *Cyrus.Benson@opm.gov.* Please include a mailing address with your request.

DATES: Comments on this proposal should be received within 60 calendar days of the date of this publication.

ADDRESSES: Send or deliver comments to: Christopher N. Meuchner, Life Insurance & Long Term Care Group, Center for Retirement and Insurance Services, U.S. Office of Personnel Management, 1900 E Street, NW.—Room 2H22, Washington, DC 20415–3661.

For Information Regarding Administrative Coordination Contact: Cyrus S. Benson, Team Leader, Publications Team, RIS Support Services/Support Group, 1900 E Street, NW.—Room 4H28, Washington, DC 20415, (202) 606–0623.

Office of Personnel Management.

Howard Weizmann,

Deputy Director.

[FR Doc. E8–26560 Filed 11–6–08; 8:45 am]

BILLING CODE 6325–38–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 18f–3, SEC File No. 270–385, OMB Control No. 3235–0441.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Section 18(f)(1) [1] of the Investment Company Act of 1940 [2] (the ''Investment Company Act'' or ''Act'') prohibits registered open-end management investment companies (''funds'') from issuing any senior security. Rule 18f–3 under the Act [3] exempts from section 18(f)(1) a fund that issues multiple classes of shares representing interests in the same portfolio of securities (a ''multiple class fund'') if the fund satisfies the conditions of the rule. In general, each class must differ in its arrangement for shareholder services or distribution or both, and must pay the related expenses of that different arrangement.

The rule includes one requirement for the collection of information. A multiple class fund must prepare, and

[1] 15 U.S.C. 80a–18(f)(1).

[2] 15 U.S.C. 80a.

[3] 17 CFR 270.18f–3.

fund directors must approve, a written plan setting forth the separate arrangement and expense allocation of each class, and any related conversion features or exchange privileges (''rule 18f–3 plan'').[4] Approval of the plan must occur before the fund issues any shares of multiple classes and whenever the fund materially amends the plan. In approving the plan, a majority of the fund board, including a majority of the fund's independent directors, must determine that the plan is in the best interests of each class and the fund as a whole.

The requirement that the fund prepare and directors approve a written rule 18f–3 plan is intended to ensure that the fund compiles information relevant to the fairness of the separate arrangement and expense allocation for each class, and that directors review and approve the information. Without a blueprint that highlights material differences among classes, directors might not perceive potential conflicts of interests when they determine whether the plan is in the best interests of each class and the fund. In addition, the plan may be useful to Commission staff in reviewing the fund's compliance with the rule.

There are approximately 5,300 multiple class funds offered by 1,120 registrants.[5] Based on a review of typical rule 18f–3 plans, the Commission's staff estimates that the 1,120 registrants together make an average of 560 responses each year to prepare and approve a written rule 18f–3 plan, requiring approximately 10 hours per response and a total of 5,600 burden hours per year in the aggregate.[6] The staff estimates that preparation of the rule 18f–3 plan may require 6 hours of the services of an attorney employed by the fund, at a cost of approximately $295 per hour for professional time,[7] and approval of the plan may require 4 hours of the services of the board of directors, at a cost of approximately $2000 per hour.[8] The staff therefore estimates that the aggregate annual cost of complying with the paperwork requirements of the rule is approximately $5,471,200 ((6 hours × 560 responses × $295 = $991,200) + (4 hours × 560 responses × $2000 = $4,480,000)).

The estimated annual burden of 5,600 hours represents a decrease of 110 hours over the prior estimate of 5,710 hours. The decrease in burden hours is attributable to a change in the estimate of the number of responses that are submitted pursuant to the rule.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act. The estimate is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. Complying with this collection of information requirement is mandatory. Responses will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Written comments are invited on: (a) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burdens of the collections of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burdens of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Lewis W. Walker, Acting Director/CIO, Securities and Exchange Commission, C/O Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312; or send an e-mail to: *PRA_Mailbox@sec.gov*.

Dated: October 30, 2008.

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–26572 Filed 11–6–08; 8:45 am]

BILLING CODE 8011–01–P

[4] Rule 18f–3(d).

[5] This estimate is based on data from Form N–SAR, the semi-annual report that funds file with the Commission. In previous years, the staff estimated that each multiple class fund prepared and approved a rule 18f–3 plan. However, the staff has revised this estimate to reflect its belief that most registrants prepare and approve a single rule 18f–3 plan for all series funds offered by the registrants.

[6] The estimate reflects the assumption that each registrant prepares and approves a rule 18f–3 plan every two years when issuing a new fund or new class or amending a plan (or that 560 of all 1,120 registrants prepare and approve a plan each year). The estimate assumes that the time required to prepare a plan is 6 hours per plan (or 3360 hours for 560 registrants annually), and the time required to approve a plan is an additional 4 hours per plan (or 2240 hours for 560 registrants annually).

[7] This hourly rate estimate is derived from annual salaries reported in: Securities Industry and Financial Markets Association, Management and Professional Earnings in the Securities Industry (2007), modified to account for an 1800-hour work year and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead.

[8] This hourly rate estimate is derived from fund representatives.

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549–0213.

Extension:

Rule 30b2–1, SEC File No. 270–213, OMB Control No. 3235–0220.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit the existing collection of information to the Office of Management and Budget for extension and approval.

Rule 30b2–1 (17 CFR 270.30b2–1) under the Investment Company Act of 1940 (15 U.S.C. 80a) requires the filing of four copies of every periodic or interim report transmitted by or on behalf of any registered investment company to its stockholders.[1] This requirement ensures that the Commission has information in its files to perform its regulatory functions and to apprise investors of the operational and financial condition of registered investment companies.[2]

Registered management investment companies are required to send reports to stockholders at least twice annually. In addition, each registered investment company is required to file with the Commission Form N–CSR (17 CFR 274.128), certifying the financial statements.[3] The annual burden of filing the reports is included in the burden estimate for Form N–CSR; however, we are requesting one burden hour remain in inventory for administrative purposes.

The burden estimate for rule 30b2–1 is made solely for the purposes of the Act and is not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms.

Written comments are invited on: (a) Whether the proposed collection of

[1] Most filings are made via the Commission's electronic filing system; therefore, paper filings under Rule 30b2–1 occur only in exceptional circumstances. Electronic filing eliminates the need for multiple copies of filings.

[2] Annual and periodic reports to the Commission become part of its public files and, therefore, are available for use by prospective investors and stockholders.

[3] Rule 30b2–1(a) [17 CFR 270.30b2–1(a)].

information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Lewis W. Walker, Acting Director/CIO, Securities and Exchange Commission, C/O Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312; or send an e-mail to: *PRA_Mailbox@sec.gov*.

Dated: October 30, 2008,

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–26573 Filed 11–6–08; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58888; File No. SR–NYSEArca–2008–100]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Rules 6.100 and 6.82

October 30, 2008.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on October 20, 2008, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange''), filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NYSE Arca proposes to amend its rules governing Allocation of Options Issues and Lead Market Maker (''LMM'') Evaluations. The Exchange proposes to eliminate Rule 6.100 and revise Rule 6.82. The text of the proposed rule change is available on the Exchange's Web site at *http://www.nyse.com,* at the Exchange's principal office and at the Public Reference Room of the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to delete certain obsolete provisions of Rule 6.100. The Exchange then proposes to incorporate the remaining relevant provisions of Rule 6.100 into a revised Rule 6.82, so that all relevant provisions related to LMM issue allocation reside within one consolidated rule. Finally, the Exchange proposes to add new relevant provisions to Rule 6.82 and logically renumber the Rule.

History

Rule 6.100 was originally adopted from Options Floor Procedural Advice (''OFPA'') [4] B13, issued on April 2, 1988, which described Trading Crowd evaluations and the process for allocating option issues. On October 3, 1996, the Exchange revised OFPA–B13 to describe the process for evaluating LMMs for purposes of allocating option issues. OFPA–B13 was ultimately incorporated into the Exchange's rules, as part of SR–PCX–1999–48.[5]

Prior to the Exchange's conversion to its Lead Market Maker system (a conversion which is now 100% complete), options issues, or classes of options, on NYSE Arca were allocated to either a Trading Crowd, consisting of a group of individual Market Makers, or to LMMs. An allocation to a Trading Crowd simply designated the physical post on the trading floor where a particular issue would trade. Traditionally, a Market Maker's Appointment was generally limited to issues allocated to a particular Trading Crowd.[6] The allocation did not convey any specific rights, nor confer any specific obligations on any individual Market Maker of the crowd, other than those already specified in NYSE Arca 6.37.[7] A Market Maker's obligations, conveyed as a condition of his or her Appointment, are not affected due to the allocation, or reallocation of an options issue. An allocation of a particular class of options to an LMM, which in turn becomes part of that Market Maker's Appointment, does however guarantee certain rights, in return for fulfilling certain obligations. Presently, these obligations and rights are detailed, in part, in Rule 6.82.

By the end of the period in which the Exchange allocated issues to both LMMs and Trading Crowds, the Exchange determined that most issues that were allocated to an LMM (as opposed to a Trading Crowd) had tighter bid/ask spreads, offered more liquidity and were generally thought to offer a better product for public investors. As a result, since 1999, all option issues on the Exchange have been allocated exclusively to LMMs.[8] Presently, there are no issues allocated to a Trading Crowd.

Delete Obsolete Provisions of Rule 6.100

Rule 6.100(b)–(c). The Exchange proposes to eliminate Rules 6.100(b)–(c) that relate solely to Trading Crowd questionnaires and evaluations. As described above, since options issues are no longer allocated to Trading Crowds, these rules are obsolete and unnecessary.

Rule 6.100(d)–(g). The Exchange proposes to eliminate Rules 6.100(d)–(g)

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] OFPAs were previously issued by the Exchange as a way of distributing information such as committee decisions, policies and procedures, and rule interpretations. Such information is now conveyed through the issuance of Regulatory Bulletins.

[5] *See* Securities Exchange Act Release No. 44345 (May 23, 2001), 66 FR 30037 (June 4, 2001) (approval notice for SR–PCX–1999–48).

[6] Market Maker Appointments are governed by NYSE Arca Rule 6.35. Since the advent of electronic access to the Exchange in 2003, a Market Maker's ''Appointment'' is no longer necessarily bound by the physical layout of the Trading Floor.

[7] *See* NYSE Arca Rule 6.37 (Obligations of Market Makers).

[8] It should be noted that in mid-2007 the Exchange received approval to designate certain option issues as ''non-LMM'' issues. *See* Securities Exchange Act Release No. 56001 (July 2, 2007), 72 FR 37557 (July 10, 2007) (SR–NYSEArca–2007–34). To qualify for non-LMM status, the option issues must be highly liquid, highly active issues that have sufficient participation by OTP Holders that there is no need for an LMM. By their very definition, non-LMM issues are not allocated to an LMM, nor are they allocated to a Trading Crowd. The proposed changes described herein do not encompass or otherwise impact non-LMM issues.

that establish certain procedures related to informal meetings regarding LMM evaluations. The Exchange, however, will retain certain procedures related to informal hearings regarding LMM evaluations. As set forth more fully below, in a revised Rule 6.82(g), the Exchange may afford LMMs an opportunity to informal hearings prior to a final determination regarding their performance—consistent with the current rule. The Exchange will also afford LMMs an opportunity to appeal allocation decisions pursuant to the Exchange's formal appeals process codified in Rule 10.14.

Delete Obsolete Provisions of Rule 6.82

Rule 6.82(a)(1) *Lead Market Maker Defined.* The Exchange proposes to remove the reference to ''nominee.'' The concept of nominee, as it pertains to the definition of LMMs, is obsolete and unnecessarily confusing. To clarify who must be registered with the Exchange as a Market Maker, the Exchange is replacing the reference to ''nominee'' and will refer instead to individuals trading on behalf of the LMM, as follows: Each individual trading on behalf of an LMM must be registered with the Exchange as a Market Maker or Market Maker Authorized Trader.

Rule 6.82(e)(1) *Allocation.* The Exchange proposes to delete the obsolete and unnecessary reference to ''trading crowd''. The Exchange also proposes to remove the reference to ''Rule 6.100'' and replace it with a reference to ''subparagraph (g) of this Rule''. As described more fully below, this change relates to the Exchange's effort to consolidate all provisions relating to issue allocation into one rule.

Rule 6.82(e)(2) *Transfer of Issues.* The Exchange proposes removing the reference to ''nominees.'' The reference to nominees is historic and obsolete. Since issues are allocated to LMMs and not to nominees, this restriction on transferring issues between nominees is both confusing and unnecessary.

Rule 6.82(e)(3) *Evaluation of LMMs.* The Exchange proposes to eliminate this provision and replace it with a revised Rule 6.82(g), which will incorporate Rule 6.82(e)(3) as well as certain provision of Rule 6.100. As set forth more fully below, the revised Rule 6.82(g) will clarify the performance standards by which LMMs will be evaluated, the process by which LMMs will be evaluated, and the LMMs' right to appeal such evaluation.

Rule 6.82(f)(1) *Reallocation.* The Exchange proposes to remove obsolete references to Trading Crowds and Nominees. The Exchange is not otherwise amending or altering the substance of this rule.

Rule 6.82(f)(2) *Continued Quality and Service.* The Exchange proposes to eliminate Rule 6.82(f)(2), which governs the reallocation of issues to the Market Maker system (Trading Crowd). Since option issues are no longer allocated to Trading Crowds, this provision is obsolete and unnecessary.

Rule 6.82(f)(3) *LMM Compensation.* The Exchange also proposes to eliminate Rule 6.82(f)(3), which states that in the event an LMM has an option issue(s) reallocated, the Exchange may award compensation to that LMM based on various factors. Option issues are generally reallocated in situations where LMMs either fail to meet certain performance standards or have been otherwise disqualified to act as an LMM by the Exchange. As a result, the Exchange has determined that compensating LMMs in these circumstances is not appropriate and therefore proposes to eliminate this provision.

Rule 6.82(g) Review of Exchange Decisions. The Exchange proposes remove Rule 6.82(g), which generally sets forth that a LMM may appeal allocation decisions pursuant to Rule 10. In its place, the Exchange proposes to add new Rule 6.82(b)(5), which affords LMMs an opportunity to appeal allocation decisions pursuant to the Exchange's formal appeals process codified in Rule 10.14.

Move the Remaining Relevant Provisions of Rule 6.100 to Rule 6.82

NYSE Arca proposes to move the remaining relevant portions of Rule 6.100 to new Rule 6.82(g). This will eliminate all text associated with Rule 6.100. The Exchange also proposes to amend certain procedures contained in Rule 6.82 and eliminate confusing references to historic practices as detailed below.

The Exchange proposes moving Rule 6.100(a) *Evaluation of Options Trading Crowd Performance* to new Rule 6.82(g)(1) and renaming the Rule: *Evaluation of Lead Market Maker Performance.* In addition to renumbering and renaming the rule, the Exchange will clarify the performance standards by which LMMs will be evaluated, the process by which LMMs will be evaluated, and the LMMs' right to appeal such evaluation. Upon revision, this provision will combine, in one rule, certain relevant aspects of Rule 6.82(e)(3), as well as certain relevant provisions of Rule 6.100. Relevant criteria such as quality of markets and adherence to ethical standards remain. On the other hand, items such as competition among Market Makers, which was a criterion used solely in connection with allocating issues to a Trading Crowd is no longer relevant and will be deleted. In addition, all references to Trading Crowd evaluations and questionnaires will be removed since they are obsolete an unnecessary.[9]

Add New Relevant Provisions to Rule 6.82

Rule 6.82(b)(5) *Appeals.* As Described above, the Exchange proposes adding this new provision which replaces Rule 6.82(g)(1) and affords LMMs an opportunity to appeal allocation decisions pursuant to the Exchange's formal appeals process codified in Rule 10.14.

Rule 6.82(g)(1)(A). The Exchange proposes adding new Rule 6.82(g)(1)(A), which explains how NYSE Arca market share shall be calculated. A minimum percentage of total national market volume shall be established at the time an issue is allocated and will be identified on the Request for Issue Allocation form that an LMM is required to complete.[10] Failure to maintain the minimum percentage of national volume identified and agreed to at the time the issue is allocated to the LMM will be considered a failure to meet minimum performance standards.

Rule 6.82(g)(1)(B). The Exchange proposes adding new Rule 6.82(g)(1)(B), which states that the Exchange will provide LMMs with information related to their national market share in each of their allocated issues. According to the new provision, LMMs shall have the ability to meet with Exchange staff, upon request, to discuss such findings.

Rule 6.82(g)(1)(C). The Exchange proposes adding new Rule 6.82(g)(1)(C), which outlines the informal hearing process the Exchange may undertake in the event an LMM has failed to meet performance standards pursuant Rule 6.82(g)(1). This section is generally consistent with current Rule 6.100(e)–(f) and (h).

[9] The Exchange notes that while Market Makers will no longer be evaluated for purposes of participating in a Trading Crowd, Market Makers will continue to be evaluated as a condition of their Appointment under Rule 6.35(j). The Exchange will periodically evaluate LMMs, in practice this may be as frequent as monthly and no less than semiannually. The Exchange notes, that pursuant to Rule 6.41, the Exchange provides Market Makers, on a monthly basis, with statistical reports designed to measure trading volume and participation in trading activity in each option issue traded on the Exchange.

[10] Presently, the standard minimum acceptable total national market volume is 5%. The Exchange determines this minimum acceptable percentage based on NYSE Arca's percentage of total national contract volume per security.

Rule 6.82(g)(1)(D). The Exchange proposes adding new Rule 6.82(g)(1)(D), which outlines the process the Exchange will undertake in the event an LMM has failed to meet performance standards pursuant Rule 6.82(g)(1), including the right to appeal pursuant to Rule 10.14.

Conclusion

NYSE Arca Rules 6.100 and 6.82 contain numerous obsolete and outdated provisions. The Exchange proposes eliminating those obsolete provisions of Rules 6.100 and 6.82 and renumbering the remaining relevant provisions of Rule 6.100 as part of the newly reconstituted Rule 6.82. The Exchange also proposes to add new relevant rules pertaining to the allocation of option issues and the evaluation of LMMs. Taken together, these changes will simplify and clarify the Exchange's rules regarding option issues allocation.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) [11] of the Act, in general, and furthers the objectives of Section 6(b)(5),[12] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system. The Exchange proposes eliminating obsolete provisions of Rules 6.100 and 6.82 while adding new relevant rules pertaining to the allocation of option issues and the evaluation of LMMs. Taken together, these changes will simplify and clarify the Exchange's rules regarding option issues allocation.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [13] and Rule 19b–4(f)(6) thereunder.[14] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and Rule 19b–4(f)(6)(iii) thereunder.[16]

The Exchange further asserts that the proposed changes simply serve to clarify the rules of NYSE Arca regarding option issues allocation by eliminating obsolete provisions of Rules 6.100 and 6.82 while adding new relevant rules pertaining to the allocation of option issues and the evaluation of LMMs. For the foregoing reasons, the Exchange has designated this rule filing as a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2008–100 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2008–100. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the self-regulatory organization. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2008–100 and should be submitted on or before November 28, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–26571 Filed 11–6–08; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b-4(f)(6).

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6)(iii). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied the pre-filing requirement.

[17] 17 CFR 240.19b–4(f)(6).

[18] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11514]

Arkansas Disaster #AR–00026

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Arkansas (FEMA—1804—DR), dated 10/22/2008.

Incident: Tropical Storm Ike.

Incident Period: 09/13/2008 through 09/23/2008.

Effective Date: 10/22/2008.

Physical Loan Application Deadline Date: 12/22/2008.

Economic Injury (EIDL) Loan Application Deadline Date: 07/22/2009.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 10/22/2008, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Carroll, Clay, Craighead, Greene, Hempstead, Howard, Izard, Lafayette, Lawrence, Little River, Madison, Miller, Newton, Randolph, Sharp, Van Buren.

The Interest Rates are:

	Percent
Other (Including Non-Profit Organizations) With Credit Available Elsewhere	5.250
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage and for economic injury is 11514.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–26589 Filed 11–6–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11505 and #11506]

California Disaster #CA–00093

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of California dated 10/28/2008.

Incident: June 2008 Dry Lightning Wildfires.

Incident Period: 06/08/2008 through 08/20/2008

Effective Date: 10/28/2008.

Physical Loan Application Deadline Date: 12/29/2008.

Economic Injury (EIDL) Loan Application Deadline Date: 07/28/2009.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Butte, Monterey, Santa Cruz.

Contiguous Counties:

California: Colusa, Fresno, Glenn, Kings, Plumas, San Benito, San Luis Obispo, San Mateo, Santa Clara, Sutter, Tehama, Yuba.

The Interest Rates are:

	Percent
Homeowners with Credit Available Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.687
Businesses with Credit Available Elsewhere	8.000
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Other (Including Non-Profit Organizations) with Credit Available Elsewhere	5.250
Businesses and Non-Profit Organizations without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 11505 5 and for economic injury is 11506 0.

The State which received an EIDL Declaration # is California.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: October 28, 2008.

Sandy K. Baruah,

Acting Administrator.

[FR Doc. E8–26578 Filed 11–6–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11516]

Florida Disaster #FL–00038

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Florida (FEMA–1806–DR), dated 10/27/2008.

Incident: Hurricane Gustav.

Incident Period: 08/31/2008 through 09/07/2008.

Effective Date: 10/27/2008.

Physical Loan Application Deadline Date: 12/26/2008.

Economic Injury (EIDL) Loan Application Deadline Date: 07/27/2009.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 10/27/2008, private non-profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Bay, Escambia, Franklin, Gulf, Okaloosa, Santa Rosa.

The Interest Rates are:

	Percent
Other (Including Non-Profit Organizations) With Credit Available Elsewhere	5.250

	Percent
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage and for economic injury is 11516.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–26586 Filed 11–6–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11479]

Kentucky Disaster Number KY–00017

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Kentucky (FEMA–1802–DR), dated 10/09/2008.

Incident: Severe Wind Storm associated with Tropical Depression Ike.

Incident Period: 09/14/2008 through 09/15/2008.

Effective Date: 10/27/2008.

Physical Loan Application Deadline Date: 12/08/2008.

Economic Injury (EIDL) Loan Application Deadline Date: 07/09/2009.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for private non-profit organizations in the Commonwealth of Kentucky, dated 10/09/2008, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Washington.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–26592 Filed 11–6–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11489]

Louisiana Disaster Number LA–00024

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Louisiana (FEMA–1792–DR), dated 09/13/2008.

Incident: Hurricane Ike.

Incident Period: 09/11/2008 and continuing.

Effective Date: 10/30/2008.

Physical Loan Application Deadline Date: 11/12/2008.

Economic Injury (EIDL) Loan Application Deadline Date: 06/15/2009.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for private non-profit organizations in the State of Louisiana, dated 09/13/2008, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Natchitoches.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–26590 Filed 11–6–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11478]

North Carolina Disaster Number NC–00016

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of North Carolina (FEMA–1801–DR), dated 10/08/2008.

Incident: Tropical Storm Hanna.

Incident Period: 09/04/2008 through 09/15/2008.

Effective Date: 10/28/2008.

Physical Loan Application Deadline Date: 12/08/2008.

Economic Injury (EIDL) Loan Application Deadline Date: 07/08/2009.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for private non-profit organizations in the State of North Carolina, dated 10/08/2008, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: New Hanover.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–26593 Filed 11–6–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11515]

Ohio Disaster #OH–00016

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Ohio (FEMA–1805–DR), dated 10/24/2008.

Incident: Severe Wind Storm associated with Tropical Depression Ike.

Incident Period: 09/14/2008.

Effective Date: 10/24/2008.

Physical Loan Application Deadline Date: 12/23/2008.

Economic Injury (EIDL) Loan Application Deadline Date: 07/24/2009.

ADDRESSES: Submit completed loan applications to: U.S. Small Business

Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 10/24/2008, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Ashland, Brown, Butler, Carroll, Champaign, Clark, Clermont, Clinton, Coshocton, Delaware, Fairfield, Franklin, Greene, Guernsey, Hamilton, Harrison, Highland, Hocking, Holmes, Knox, Licking, Madison, Miami, Montgomery, Morrow, Perry, Pickaway, Preble, Shelby, Summit, Tuscarawas, Union, Warren.

The Interest Rates are:

	Percent
Other (Including Non-Profit Organizations) With Credit Available Elsewhere	5.250
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage and for economic injury is 11515.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–26588 Filed 11–6–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11503 and #11504]

Texas Disaster #TX–00305

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Texas dated 10/28/2008.

Incident: Severe Storms and Flooding.

Incident Period: 08/18/2008 through 08/21/2008.

Effective Date: 10/28/2008.

Physical Loan Application Deadline Date: 12/29/2008.

Economic Injury (EIDL) Loan Application Deadline Date: 07/28/2009.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Starr, Wichita.

Contiguous Counties:

Texas: Archer, Baylor, Brooks, Clay, Hidalgo, Jim Hogg, Wilbarger, Zapata.

Oklahoma: Cotton, Tillman.

The Interest Rates are:

	Percent
Homeowners With Credit Available Elsewhere	5.750
Homeowners Without Credit Available Elsewhere	2.875
Businesses With Credit Available Elsewhere	8.000
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Other (Including Non-Profit Organizations) With Credit Available Elsewhere	5.250
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 11503 6 and for economic injury is 11504 0.

The States which received an EIDL Declaration # are Texas, Oklahoma.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: October 28, 2008.

Sandy K. Baruah,

Acting Administrator.

[FR Doc. E8–26594 Filed 11–6–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11517 and #11518]

U.S. Virgin Islands Disaster #VI–00001

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the U.S. Virgin Islands dated 10/31/2008.

Incident: Hurricane Omar.

Incident Period: 10/14/2008 through 10/16/2008.

Effective Date: 10/31/2008.

Physical Loan Application Deadline Date: 12/30/2008.

Economic Injury (EIDL) Loan Application Deadline Date: 07/31/2009.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Island: Saint Croix.

The Interest Rates are:

	Percent
Homeowners with Credit Available Elsewhere	5.750
Homeowners without Credit Available Elsewhere	2.875
Businesses with Credit Available Elsewhere	8.000
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Other (Including Non-Profit Organizations) with Credit Available Elsewhere	5.250
Businesses and Non-Profit Organizations without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 11517 8 and for economic injury is 11518 0.

The Island which received an EIDL Declaration # is Saint Croix.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: October 31, 2008.

Jovita Carranza,

Deputy Administrator.

[FR Doc. E8–26591 Filed 11–6–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11508 Disaster #ZZ–00004]

The Entire United States and U.S. Territories

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of the Military Reservist Economic Injury Disaster Loan Program (MREIDL), dated 10/28/2008.

DATES: *Effective Date:* 10/28/2008.

MREIDL Loan Application Deadline Date: 1 year after the essential employee is discharged or released from active duty.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of Public Law 106–50, the Veterans Entrepreneurship and Small Business Development Act of 1999, and the Military Reservist and Veteran Small Business Reauthorization Act of 2008, this notice establishes the application filing period for the Military Reservist Economic Injury Disaster Loan Program (MREIDL).

Effective 10/28/2008, small businesses employing military reservists may apply for economic injury disaster loans if those employees are called up to active duty during a period of military conflict or have received notice of an expected call-up, and those employees are essential to the success of the small business daily operations.

The purpose of the MREIDL program is to provide funds to eligible small businesses to meet its ordinary and necessary operating expenses that it could have met, but is unable to meet, because an essential employee was called up or expects to be called up to active duty in his or her role as a military reservist. These loans are intended only to provide the amount of working capital needed by a small business to pay its necessary obligations as they mature until operations return to normal after the essential employee is released from active duty. For information/applications contact 1–800–659–2955 or visit *http://www.sba.gov*.

Applications for the Military Reservist Economic Injury Disaster Loan Program may be filed at the above address.

The Interest Rate for eligible small businesses is 4.000.

The number assigned is 11508 0.

(Catalog of Federal Domestic Assistance Number 59002)

James E. Rivera,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. E8–26583 Filed 11–6–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #11513]

U.S. Virgin Islands Disaster #VI–00002

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the U.S. Virgin Islands (FEMA–1807–DR), dated 10/29/2008.

Incident: Hurricane Omar.

Incident Period: 10/14/2008 through 10/16/2008.

Effective Date: 10/29/2008.

Physical Loan Application Deadline Date: 12/29/2008.

Economic Injury (EIDL) Loan Application Deadline Date: 07/29/2009.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 10/29/2008, private non-profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Saint Croix, Saint Thomas.

The Interest Rates are:

	Percent
Other (Including Non-Profit Organizations) with Credit Available Elsewhere	5.250
Businesses and Non-Profit Organizations without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 11513.

(Catalog of Federal Domestic Assistance Number 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–26587 Filed 11–6–08; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Privacy Act of 1974: System of Records

AGENCY: Department of Transportation (DOT), Office of the Secretary.

ACTION: Notice to add a system of records.

SUMMARY: DOT proposes to add a system of records under the Privacy Act of 1974. The system is DOT's implementation of the Department of Interior's (DOI's) Federal Personnel and Payroll System (FPPS). The system of records consists of human resources (HR) and payroll data moved from DOT's legacy HR and payroll systems to FPPS as well as new data added to FPPS. This system would not duplicate any other DOT system of records.

DATES: *Effective Date*: This notice will be effective, without further notice, on December 17, 2008, unless modified by a subsequent notice to incorporate comments received by the public. Comments must be received by December 17, 2008 to be assured consideration.

ADDRESSES: Send comments to Habib Azarsina, Departmental Privacy Officer, S–80, United States Department of Transportation, Office of the Secretary of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590 or *habib.azarsina@dot.gov.*

FOR FURTHER INFORMATION CONTACT: Habib Azarsina, Departmental Privacy Officer, S–80, United States Department of Transportation, Office of the Secretary of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590; telephone 202.366.1965, or *habib.azarsina@dot.gov.*

SUPPLEMENTARY INFORMATION: The DOT system of records notice subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, as proposed to be added, is available from the above mentioned address and appears below:

SYSTEM NUMBER:

DOT/ALL 19.

SYSTEM NAME:

Federal Personnel and Payroll System (FPPS).

SECURITY CLASSIFICATION:

Unclassified, sensitive.

SYSTEM LOCATION:

This system of record is in the National Business Center, U.S. Department of the Interior, 7301 West Mansfield Avenue, MS D–2400, Denver, CO 80235–2230.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Prospective, present, and former employees in the Office of the Secretary of Transportation, OST; Federal Aviation Administration, FAA; Federal Highway Administration, FHWA; Federal Railroad Administration, FRA; Federal Transit Administration, FTA; Maritime Administration, MARAD; National Highway Traffic Safety Administration, NHTSA; Office of the Inspector General, OIG; St. Lawrence Seaway Development Corporation, SLSDC; Federal Motor Carrier Safety Administration, FMCSA; Pipeline and Hazardous Materials Safety Administration, PHMSA; Research and Innovative Technology Safety Administration, RITA; and the Surface Transportation Board, STB.

CATEGORIES OF RECORDS IN THE SYSTEM:

Employee name, Social Security number, and organizational code; pay rate and grade, retirement, and location data; length of service; pay, leave, time and attendance, allowances, and cost distribution records; deductions for Medicare or FICA, savings bonds, FEGLI, union dues, taxes, allotments, quarters, charities, health benefits, and Thrift Savings Fund contributions; awards, shift schedules, pay differentials, IRS tax lien data, commercial garnishments, child support and/or alimony wage assignments; and related payroll and personnel data. Also included is information on debts owed to the Government as a result of overpayment, refunds owed, or a debt referred for collection on a transferred employee. The payroll, attendance, retirement, and leave records described in this notice form a part of the information contained in DOI's integrated Federal Personnel Payroll System (FPPS). Personnel, but not payroll, records contained in the system are covered under the Government-wide system of records notice published by the Office of Personnel Management (OPM/GOVT–1).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 5101, *et seq.*; 31 U.S.C. 3512.

PURPOSE(S):

The purpose for collecting the data in the FPPS System of Records is to control and facilitate payment of salaries to DOT civilian employees.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The primary uses of the records are for fiscal operations for payroll, attendance, leave, insurance, tax, retirement, budget, and cost accounting programs; and to prepare related reports to other Federal agencies including the Department of the Treasury and the Office of Personnel Management. Disclosures outside DOT and DOI may be made:

(1) To the Department of the Treasury for preparation of payroll (and other) checks and electronic funds transfers to Federal, State, and local government agencies, non-governmental organizations, and individuals.

(2) To the Internal Revenue Service and to State, local, tribal, and territorial governments for tax purposes.

(3) To the Office of Personnel Management in connection with programs administered by that office.

(4) To any other Federal agency to which an employee has transferred.

(5) To the Department of Justice, or to a court, adjudicative or other administrative body, or to a party in litigation before a court or adjudicative or administrative body, when:

(a) One of the following is a party to the proceeding or has an interest in the proceeding:

(1) The Department or any component of the Department;

(2) Any Departmental employee acting in his or her official capacity;

(3) Any Departmental employee acting in his or her individual capacity where the Department or the Department of Justice has agreed to represent the employee; or

(4) The United States, when the Department determines that the Department is likely to be affected by the proceeding; and

(b) The Department deems the disclosure to be:

(1) Relevant and necessary to the proceeding; and

(2) Compatible with the purpose for which it compiled the information.

(6) To the appropriate Federal, State, tribal, local or foreign governmental agency that is responsible for investigating, prosecuting, enforcing or implementing a statute, rule, regulation order or license, when the Department becomes aware of an indication of a violation or potential violation of the statute, rule, regulation, order or license.

(7) To appropriate Federal and State agencies to provide required reports including data on unemployment insurance.

(8) To the Social Security administration to report FICA deductions.

(9) To labor unions to report union dues deductions.

(10) To insurance carriers to report withholdings for health insurance.

(11) To charitable institutions to report contributions.

(12) To a Federal agency for the purpose of collecting a debt owed the Federal government through administrative or salary offset.

(13) To provide addresses obtained from the Internal Revenue Service to debt collection agencies for purposes of locating a debtor to collect or compromise a Federal claim against the debtor.

(18) To the Federal Retirement Thrift Investment Board with respect to Thrift Savings Fund contributions.

(19) To disclose debtor information to the Internal Revenue Service or to another Federal agency or its contractor solely to aggregate information for the Internal Revenue Service, to collect debts owed to the Federal Government through the offset of tax refunds.

(20) To disclose the names, social security numbers, home addresses, dates of birth, dates of hire, quarterly earnings, employer identifying information, and State of hire of employees to the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services for the purposes of locating individuals to establish paternity, establishing and modifying orders of child support, identifying sources of income, and for other child support enforcement actions as required by the Personal Responsibility and Work Opportunity Reconciliation Act (Welfare Reform Law, Pub. L. 104–193).

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosure pursuant to 5 U.S.C. 552a (b)(12). Disclosures may be made from this system to consumer reporting agencies as defined in the Fair Credit

Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Act of 1966 (31 U.S.C. 3701(a)(3)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM: STORAGE:

Records are maintained in manual, microfilm, microfiche, electronic, imaged and computer printout form. Current records are stored on magnetic media at DOI's central computer processing center; historic records are stored on magnetic media at DOI's central computer center. Original input documents are stored in standard office filing equipment and/or as imaged documents on magnetic media at all locations which prepare and provide input documents and information for data processing.

RETRIEVABILITY:

Records are retrieved by name, Social Security number, and organizational code.

SAFEGUARDS:

Access to all records in the system is limited to authorized personnel whose official duties require such access. Paper or micro format records are maintained in locked metal file cabinets in secured rooms. Electronic records are maintained with safeguards meeting the security requirements of 49 CFR 10.3.

RETENTION AND DISPOSAL:

The records contained in this system of records have varying retention periods as described in General Records Schedule 2, (available on-line at *http://www.nara.gov*), issued by the Archivist of the United States, and are disposed of in accordance with the National Archives and Records Administration Regulations, 36 CFR part 1228 *et seq.*

SYSTEM MANAGER(S) AND ADDRESS:

The following system manager is responsible for the payroll records contained in the Federal Personnel Payroll System (FPPS). Personnel records contained in the system fall under the jurisdiction of the Office of Personnel Management as prescribed in 5 CFR part 253 and 5 CFR part 297: Chief, FPPS Management Division, National Business Center, U.S. Department of the Interior, 7301 West Mansfield Avenue, Denver, CO 80235–2230.

NOTIFICATION PROCEDURE:

Inquiries regarding the existence of records should be addressed to the System Manager. The request must be in writing, signed by the requester, and meet the content requirements of 49 CFR 10.31.

RECORD ACCESS PROCEDURES:

A request for access may be addressed to the System Manager. The request must be in writing, signed by the requester, and meet the content requirements of 49 CFR 2.63.

CONTESTING RECORD PROCEDURES:

A petition for amendment should be addressed to the System Manager.

The request must be in writing, signed by the requester, and meet the content requirements of 49 CFR 10.41.

RECORD SOURCE CATEGORIES:

Individuals on whom the records are maintained, official personnel records of individuals on whom the records are maintained, supervisors, timekeepers, previous employers, and the Internal Revenue Service.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: November 3, 2008.

Habib Azarsina,

Departmental Privacy Officer.

[FR Doc. E8–26595 Filed 11–6–08; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2008–0164]

Agency Information Collection Activities: Notice of Request for Renewal of a Previously Approved Information Collection

AGENCY: Office of the Secretary (OST).

ACTION: Notice and request for comments.

SUMMARY: The FHWA has forwarded the information collection request described in this notice to the Office of Management and Budget (OMB) for approval of a new information collection. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on August 4, 2008. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by December 8, 2008.

ADDRESSES: You may submit comments identified by DOT DMS Docket Number FHWA–2008–0164 by any of the following methods:

Web Site: http://dms.dot.gov. Follow the instructions for submitting comments on the DOT electronic docket site.

Fax: 1–202–493–2251.

Mail: Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590.

Hand Delivery: U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Michael Koontz, 202–366–2076, Office of Natural and Human Environment, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue, Washington, DC 20590. Office hours are from 8 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

OMB: 2125–0614

Title: Annual Reporting for the Congestion Mitigation and Air Quality Improvement (CMAQ) Program.

Background: Section 1808 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users of 2005 (SAFETEA–LU) calls for an *Evaluation and Assessment of CMAQ Projects.* The statute calls for the identification and analysis of a representative sample of CMAQ projects and the development and population of a database that describes the impacts of the program both on traffic congestion levels and air quality. To establish and maintain this database, the FHWA is requesting States to submit annual reports on their CMAQ investments that cover projected air quality benefits, financial information, a brief description of projects, and several other factors outlined in the Interim Program Guidance for the CMAQ program. States are requested to provide the end of year summary reports via the automated system provided through FHWA by the first day of March of each year, covering the prior Federal fiscal year.

Respondents: 51; each State DOT, and Washington DC.

Frequency: Annually.

Estimated Average Burden per Response: 125 hours per annual report.

Estimated Total Annual Burden Hours: 6,375 hours.

Public Comments Invited: You are asked to comment on any aspect of this

information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued on: November 3, 2008.

Judith Kane,

Team Leader, Management Programs and Analysis Division.

[FR Doc. E8–26643 Filed 11–6–08; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System or Relief From the Requirements of Title 49 Code of Federal Regulations Part 236

Pursuant to Title 49 Code of Federal Regulations (CFR) Part 235 and 49 U.S.C. 20502(a), the following railroad has petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of the signal system or relief from the requirements of 49 CFR Part 236 as detailed below.

[Docket Number FRA–2008–0108]

Applicant: Port of San Francisco, Ms. Evelyn Onderdonk, P.E., Resident Engineer, Pier 1, The Embarcadero, San Francisco, California 94111.

The Port of San Francisco seeks relief from the requirements of the Rules, Standards, and Instructions, Title 49 CFR Part 236, §§ 236.312, Movable bridge, interlocking of signal appliances with bridge; 236.303, Control circuits for signals, selected through circuit controller operated by switch points or by switch locking mechanism; and 236.55, Dead section; maximum length, on the Illinois Street Bridge Project. The Port is the owner of the bridge and the railroad. The location of the bridge is in San Francisco on Illinois Street between Cargo Way and Marin Street.

Applicant's justification for relief: As to § 236.312, the Illinois Street Bridge is a non-counterweighted single leaf trunnion type bascule span rotated by hydraulic cylinders. The leaf weighs 475 kips. The bridge is opened by brute force. As such, there is no need for a mechanical locking device to hold the bridge down. Horizontal alignment of the rail is provided by the trunnion at the heel end and by friction on the toe end bearings. In addition, a toe end centering device, or lug, is provided to ensure bridge horizontal alignment in overload conditions such as moderate earthquakes and ship impacts.

As to § 236.303, trains are operating at 10 mph, regardless of the switch points' position the train engineer, per the railroad's operating procedures, will get off the engine, inspect the switch points and align if required to ensure that they are in the correct position and that no obstructions are present, push the appropriate push button, wait until a proceed signal is received, board the engine, and proceed.

As to § 236.55, there is a 70-foot dead section on the bridge. A trap circuit ensures that the bridge cannot be raised while the bridge is occupied by a train and functions as follows: ''When a train leaves the last track circuit before the dead section and enters the dead section, the track circuit on the other side of the dead section must become occupied and then unoccupied before the bridge can be raised.'' Under this system, there is a possibility that a rail car could be left within the dead section and not be detected. To protect against this possibility, operation of the bridge must occur from the roof of the bridge control house where conditions on the bridge can be observed. The bridge cannot be raised remotely. The train engineer shall use line of sight to ensure that the bridge is unobstructed before proceeding across the bridge.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

Any interested party desiring to protest the granting of an application shall set forth specifically the grounds upon which the protest is made, and it shall contain a concise statement of the interest of the party in the proceeding. Additionally, one copy of the protest shall be furnished to the applicant at the address listed above.

All communications concerning these proceedings should be identified by Docket Number FRA–2008–0108 and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue, SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://www.regulations.gov*.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Issued in Washington, DC, on November 3, 2008.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E8–26619 Filed 11–6–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

New Jersey Transit Rail

[Docket Number FRA–2008–0109]

New Jersey Transit Rail (NJTR) seeks a waiver of compliance with certain requirements of 49 CFR 238.307(c)(7) *Passenger Equipment Safety Standards*, as they pertain to inspection and gauging the coupler and draft gear arraignment during the required periodic mechanical inspection of passenger cars and unpowered vehicles used in passenger trains. The periodic mechanical inspection is required to be performed at 184-day intervals at which time the railroad would be required to uncouple the car to inspect and gauge the couplers. NJTR's request is to perform this inspection during an annual inspection and perform a visual inspection to the extent possible at 180 days.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number FRA–2008–0109) and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue, SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://www.regulations.gov*.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Issued in Washington, DC on November 3, 2008.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E8–26664 Filed 11–6–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Metro-North Railroad

[Docket Number FRA–2007–0006]

The Metro-North Railroad (Metro-North) seeks a permanent waiver of compliance from certain specific requirements in the testing protocol of the *Locomotive Safety Standards*, 49 CFR 229.129(c), as it pertains to railroad locomotive horn testing. Metro-North seeks to utilize an acoustic enclosure specially designed for the purpose of testing horns removed from the locomotives in lieu of the requirements required in CFR § 229.129(c)(4), (5) and (7). The data from the acoustic enclosure testing would be used to calculate the level to be expected at the location 100 feet in front of the locomotive as required under CFR § 229.129(c)(7).

Metro-North has requested the Acoustical Society of America to work towards a new ANSI standard that supports the approach proposed by Metro-North. Metro-North further proposes to fund the design, fabrication and pilot testing of the testing facility proposed if this waiver application is granted on a conditional basis. In addition to the requested waiver of the technical requirements described above, Metro-North is also requesting an extension of five (5) years to June 24, 2015, in which to complete the required testing of its approximately 762 train horns.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number FRA–2007–0006) and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue, SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://www.regulations.gov*.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

Issued in Washington, DC on November 3, 2008.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E8–26665 Filed 11–6–08; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34936]

Port of Moses Lake—Construction Exemption—Moses Lake, WA [STB Finance Docket No. 34936 (Sub-No. 1)]; Port of Moses Lake—Acquisition Exemption—Moses Lake, WA

AGENCY: Surface Transportation Board and Washington State Department of Transportation.

ACTION: Notice of Availability of Environmental Assessment and Request for Public Review and Comment.

SUMMARY: By petition filed on August 28, 2008, the Port of Moses Lake (Port) seeks an exemption under 49 U.S.C. 10502 from the prior approval requirements of 49 U.S.C. 10901 to construct rail lines in Grant County, Washington. In the same petition, the Port also seeks an exemption under 49 U.S.C. 10502 from the prior approval requirements of 49 U.S.C. 10901 to acquire an existing segment of rail line from Columbia Basin Railroad Company, Inc. (CBRW). The Board, through its Section of Environmental Analysis (SEA), and the Washington State Department of Transportation (WSDOT) are co-lead agencies responsible for the environmental review of the proposed rail project and the preparation of the Environmental Assessment (EA).

The proposed project, known as the Northern Columbia Basin Railroad Project, includes the construction of two new rail line segments and the acquisition and refurbishment of an existing rail segment to provide rail access to land designated and zoned for industrial uses along Wheeler Road (Road 3 NE) and at the Grant County International Airport (GCIA). The entire proposed route would extend approximately 11.5 miles.

For Segment 1, the Port proposes to construct a rail line that would allow trains to bypass downtown Moses Lake and would provide access to the industrial areas along Wheeler Road (Road 3 NE), including one of two alternatives for a bridge crossing at Parker Horn or Crab Creek. For Segment 2, the Port proposes to extend the existing track (Segment 3), which currently terminates just south of the GCIA, to the industrial lands located east of the GCIA. For Segment 3, the Port proposes to acquire and rehabilitate an existing rail line that is currently owned by CBRW. Goods to be shipped would vary depending on the specific industries that may locate along the route, but would likely consist of steel, manufactured parts, and specialty chemicals. The proposed rail route would accommodate a maximum of two trains (one round trip) per day for the foreseeable future.

Copies of the EA have been served on all interested parties and will be made available to additional parties upon request. The entire EA is also available for review on the Board's Web site (*http://www.stb.dot.gov*) by going to ''E-LIBRARY,'' clicking on the ''Decisions and Notices'' link, and then searching by the Service Date (November 7, 2008) or Docket Number (FD 34936). SEA, working with WSDOT, will consider all comments received in making its final recommendations to the Board. The Board will then consider SEA's final recommendations and the complete environmental record in making its final decision in this proceeding.

FOR FURTHER INFORMATION CONTACT: Christa Dean, Attorney and Project Manager, at (202) 245–0299; e-mail: *christa.dean@stb.dot.gov*, or Elizabeth Phinney, WSDOT Rail Environmental Manager, at (360) 705–7902; e-mail: *phinnee@wsdot.wa.gov*. Federal Information Relay Service for the hearing impaired: 1–800–877–8339.

DATES: The EA is available for public review and comment. All comments must be submitted or post-marked by December 8, 2008.

ADDRESSES: Send written comments to: Christa Dean, Surface Transportation Board, 395 E Street, SW., Room 1108, Washington, DC 20423.

Please reference STB Docket No. 34992 in all correspondence.

Comments on the EA may also be filed electronically on the Board's Web site, *http://www.stb.dot.gov*, by clicking on the ''E-FILING'' link.

Decided: November 7, 2008.

By the Board, Victoria Rutson, Chief, Section of Environmental Analysis.

Kulunie L. Cannon,

Clearance Clerk.

[FR Doc. E8–26552 Filed 11–6–08; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 35190]

Union Pacific Railroad Company—Temporary Trackage Rights Exemption—Orange County Transportation Authority

Orange County Transportation Authority (OCTA), pursuant to a written trackage rights agreement entered into between OCTA and Union Pacific Railroad Company (UP), has agreed to grant to UP temporary overhead trackage rights between milepost 165.25 at Fullerton Jct., CA, and milepost 171.00 at CP College, CA, a total distance of approximately 5.75 miles.

The transaction is scheduled to be consummated on January 5, 2009.[1] The temporary trackage rights will expire on or about January 26, 2009. The purpose of the temporary trackage rights is to facilitate maintenance work on UP lines.

As a condition to this exemption, any employee affected by the acquisition of the temporary trackage rights will be protected by the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980), and any employee affected by the discontinuance of those trackage rights will be protected by the conditions set out in *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979).

This notice is filed under 49 CFR 1180.2(d)(8). If it contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction. Any stay petition must be filed on or before November 14, 2008 (at least 7 days before the exemption becomes effective).

Pursuant to the Consolidated Appropriations Act, 2008, Public Law 110–161, section 193, 121 Stat. 1844 (2007), nothing in this decision authorizes the following activities at any solid waste rail transfer facility: collecting, storing, or transferring solid waste outside of its original shipping container; or separating or processing solid waste (including baling, crushing, compacting, and shredding). The term ''solid waste'' is defined in section 1004 of the Solid Waste Disposal Act, 42 U.S.C. 6903.

[1] The exemption is scheduled to become effective on November 22, 2008 (30 days after the exemption was filed).

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 35190, must be filed with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Gabriel S. Meyer, Union Pacific Railroad Company, 1400 Douglas Street, STOP 1580, Omaha, NE 68179.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov*.

Decided: October 31, 2008.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Jeff Herzig,

Clearance Clerk.

[FR Doc. E8–26449 Filed 11–6–08; 8:45 am]

BILLING CODE 4915–01–P

Federal Register

Friday,
November 7, 2008

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Draft Compliance Policy Guide; "Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;" Availability; Final Rule and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2002–N–0233] (formerly Docket No. 2002N–0278)

RIN 0910–AC41

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation that requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. The final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which required prior notification of imported food to begin on December 12, 2003. The final rule requires that the prior notice be submitted to FDA electronically via either the U.S. Customs and Border Protection (CBP or Customs) Automated Broker Interface (ABI) of the Automated Commercial System (ACS) or the FDA Prior Notice System Interface (FDA PNSI). The information must be submitted and confirmed electronically as facially complete by FDA for review no less than 8 hours (for food arriving by water), 4 hours (for food arriving by air or land/rail), and 2 hours (for food arriving by land/road) before the food arrives at the port of arrival. Food imported or offered for import without adequate prior notice is subject to refusal and, if refused, must be held. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft compliance policy guide (CPG) entitled ''Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.''

DATES: This rule is effective May 6, 2009.

FOR FURTHER INFORMATION CONTACT: Laura Draski, Office of Regulatory Affairs (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 866–521–2297.

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I. Background and Legal Authority

Section 307 of the Bioterrorism Act, which was enacted on June 12, 2002, amended the Federal Food, Drug, and Cosmetic Act (the act) (section 307 of the Bioterrorism Act added section 801(m) to the act (21 U.S.C. 381(m)) and amended section 301 of the act (21 U.S.C. 331)) by changing when FDA will receive certain information about imported foods by requiring the Secretary of Health and Human Services (the Secretary), after consultation with the Secretary of the Treasury,[1] to issue an implementing regulation by December 12, 2003, to require prior notification to FDA of food that is imported or offered for import into the United States. Beginning on December 12, 2003, food importers were required to provide FDA with advance notice of human and animal food shipments imported or offered for import.

FDA and CBP jointly published the proposed prior notice regulation in the **Federal Register** of February 3, 2003 (68 FR 5428), for comment (proposed rule). On October 10, 2003, FDA and CBP issued the prior notice interim final rule (IFR) (prior notice IFR) (68 FR 58974) (corrected by a technical amendment on February 2, 2004; 69 FR 4851). The IFR implemented section 307 of the Bioterrorism Act, and required that the prior notice be submitted to FDA electronically via either the CBP ABI/ACS or the FDA PNSI. The information must be submitted and confirmed electronically as facially complete by FDA for review no less than 8 hours (for food arriving by water), 4 hours (for food arriving by air or land via rail), and 2 hours (for food arriving by land via road) before the food arrives at the port of arrival. Food imported or offered for import without adequate prior notice is subject to refusal and, if refused, must be held. The IFR responded to comments from the public on the proposed rule, and established a 75-day comment period. In order to ensure that those commenting on the IFR had the benefit of FDA's outreach and educational efforts and had experience with the systems, timeframes, and data elements of the prior notice system, FDA reopened the comment period for 30 days on April 14, 2004 (69 FR 19763), and for an additional 60 days on May 18, 2004 (69 FR 28060), for a total of 165 days.

[1] Under the Homeland Security Act of 2002 (Public Law 107–296), the Secretary of the Treasury has delegated all relevant Customs revenue authorities to the Secretary of Homeland Security who has, in turn, delegated them to the Commissioner of the Bureau of Customs and Border Protection (CBP or Customs). Thus, the Secretary is issuing this final rule jointly with the Secretary of Homeland Security.

II. Summary of Significant Changes Made to the IFR

The highlights of how this final rule compares to the IFR and the rationale for certain changes are described briefly in the following paragraphs and are discussed in more detail later in the preamble.

A. What Definitions Apply to This Subpart? (§ 1.276)

We retain the following terms without change from the IFR:

- ''The act;''
- ''Calendar day;''
- ''Country from which the article originates;''
- ''FDA Country of Production;''
- ''Grower;''
- ''Port of entry;'' and
- ''United States.''

FDA made the following changes in the final rule:

- We revised the term, ''Country from which the article is shipped,'' to read, ''* * * or, in the case of food sent by international mail, the country from which the article is mailed.''
- We revised the term, ''food,'' to add the phrase, ''except as provided in paragraph (b)(5)(i) of this section,'' in the first sentence; and reworded § 1.276(b)(5)(i) to read, ''For purposes of this subpart, food does not include''.
- We added the term, ''full address,'' to the final rule. *Full address* means the facility's street name and number; suite/unit number, as appropriate; city; Province or State as appropriate; mail code as appropriate; and country.
- We revised the term, ''international mail,'' to make the sentence easier to read, and to add the phrase, ''unless such service is operating under contract as an agent or extension of a foreign mail service,'' at the end of the definition.
- We added the term, ''manufacturer,'' to the final rule. *Manufacturer* means the last facility, as that word is defined in § 1.227(b)(2), that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a *de minimis* nature. If the food undergoes further manufacturing/processing that exceeds an activity of a *de minimis* nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer.
- We revised the term, ''no longer in its natural state,'' by deleting ''waxed''

from the list of actions that render an article of food still in its natural state for purposes of this subpart.

• We revised the term, ''port of arrival'' to read ''* * * the water, air, or land port at which the article of food is imported or offered for import into the United States. For an article of food arriving by water or air, this is the port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the United States. The port of arrival may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).''

• We revised the term, ''registration number,'' by changing the phrase, ''refers to,'' to ''means,'' and by adding the phrase, ''to a facility,'' after the word, ''assigned,'' to clarify that FDA assigns registration numbers by facility.

• We revised the term, ''shipper,'' by adding the phrase, ''or express consignment operators or carriers or other private delivery service,'' after ''international mail'' to clarify that a shipper is involved with various types of transactions, and not just international mail shipments.

• We revised the term, ''you,'' to simplify the last phrase of the definition to ''i.e., the submitter or the transmitter, if any.''

B. What is the Scope of This Subpart? (§ 1.277)

We revised this provision and added ''Articles of food subject to Art. 27(3) of The Vienna Convention on Diplomatic Relations (1961), i.e., shipped as baggage or cargo constituting the diplomatic bag'' to the list of food that does not require prior notice.

C. Who is Authorized to Submit Prior Notice? (§ 1.278)

We retain this provision without change.

D. When Must Prior Notice Be Submitted to FDA? (§ 1.279)

FDA revised this provision. Section 1.279(b) of the IFR states that, except for international mail, prior notice may not be submitted more than 5 calendar days before the anticipated date of arrival at the anticipated port of arrival. We revised this section to permit prior notice submissions to be submitted no more than 15 calendar days before the anticipated date of arrival for submissions made through the PNSI and no more than 30 calendar days before the anticipated date of arrival for submission made through the ABI/ACS.

E. How Must You Submit Prior Notice? (§ 1.280)

FDA revised this provision. Under 21 CFR 1.280(a)(2) (§ 1.280(a)(2)) of the IFR, prior notice must be submitted via PNSI for articles of food that have been refused under section 801(m)(1) of the act. Under the final rule, prior notice for articles that have been refused under section 801(m) of the act must be submitted through PNSI until such time as ACS or its successor system can accommodate such transactions.

FDA also simplified the IFR provisions pertaining to system outages at § 1.280(b) through (e) by providing the outage notification at one Web address (*http://www.fda.gov*) and stating that FDA will accept prior notice submissions in the format it deems appropriate during the system(s) outage.

F. What Information Must Be in a Prior Notice? (§ 1.281)

FDA revised the following information requirements:

• Submitter: The IFR states that ''if a registration number is provided, city and country may be provided instead of the full address.'' For clarity, in the final rule, FDA has revised this phrase to state that ''if the business address of the individual submitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address.'' FDA also deleted the requirement for providing the submitter's fax number.

• Transmitter: The IFR states that ''if a registration number is provided, city and country may be provided instead of the full address.'' For clarity, in the final rule, FDA has revised this phrase to state that ''if the business address of the individual submitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address.'' FDA also deleted the requirement for providing the transmitter's fax number.

• Manufacturer, for food no longer in its natural state:

Under the IFR, the name, address, and registration number of the manufacturer must be submitted; if a registration number is provided, city and country may be provided instead of the full address. The final rule requires the name of the manufacturer and either: (1) The registration number, city and country of the manufacturer or (2) both the full address of the manufacturer and the reason the registration number is not provided. Publishing elsewhere in this issue of the **Federal Register**, the Prior Notice Final Rule Draft CPG lists the reasons to use when the registration number is not provided.

In the IFR, a registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage, and export, or further manipulation and export. We have removed this from the final rule and are requiring the registration number of the manufacturer (or the full address of the manufacturer and a reason) in all circumstances.

In the final rule, we have removed the option provided in the IFR that allows the label information in § 101.5 (21 CFR 101.5) to be submitted instead of the name, address, and registration number of the manufacturer for food sent by an individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States. FDA notes, however, that under the enforcement policy proposed in the Prior Notice Final Rule Draft CPG, FDA and CBP should typically consider not taking any regulatory action when no prior notice is submitted for food imported or offered for import for noncommercial purposes with a noncommercial shipper, irrespective of the type of carrier.

• Shipper: The IFR required the name and address of the shipper and, if the shipper is required to register, the registration number assigned to the shipper's facility; if a registration number is provided, city and country may be provided instead of the full address. The final rule requires the name and full address of the shipper, if the shipper is different from the manufacturer in order to eliminate duplicative requirements. If the address of the shipper is a registered facility, the submitter may submit the registration number of the shipper's registered facility.

In the IFR, the shipper's registration number was not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage, and export, or further manipulation and export. We have removed this from the final rule because the shipper's registration number is now optional.

• Anticipated arrival information: Under the final rule, we removed the requirement for the identity of the anticipated border crossing within the port of arrival because FDA and CBP have determined that it is no longer necessary for purposes of communication. For post-refusal submissions, actual date the article arrived is now a required data element so that FDA knows how long it has been since the refused food shipment arrived

in the United States and how to connect the refused prior notice to the post-refusal prior notice submission for shipments where a previously refused prior notice was filed.

The final rule also includes a new provision for food arriving by express consignment operator or carrier since certain information may not be available to persons who ship food using an express consignment operator or courier. If the article of food is arriving by express consignment operator or carrier, and neither the submitter nor transmitter is the express consignment operator or carrier, and the prior notice is submitted via PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the anticipated arrival information.

• The name and address of the importer, owner, and ultimate consignee: The IFR required the name and address of the importer, owner, and ultimate consignee, unless the shipment is imported or offered for import for transshipment through the United States under a Transportation and Exportation (T&E) entry. In the final rule, FDA is inserting the word ''full'' in front of ''address'' to make clear that the complete address is required. Consequently, FDA is revising the subsequent text to state that if the business address of the importer, owner, or ultimate consignee is a registered facility, then the facility's registration number also may be provided in addition to the facility's full address.

• Planned shipment information: FDA revised this provision by clarifying that the required planned shipment information is applicable by mode of transportation and when it exists. Moreover, FDA added a new provision in the final rule for the Airway Bill number/Bill of Lading number and flight number since this information is generally not available to individual submitters. The final rule provides that for food arriving by express consignment operator or carrier when neither the submitter nor transmitter is the express consignment operator or carrier, the tracking number can be submitted in lieu of the Bill of Lading or Airway Bill number and the flight number for prior notices submitted via PNSI.

FDA also revised the IFR by deleting the requirement to provide the Harmonized Tariff Schedule (HTS) code since FDA and CBP have determined that the HTS code is no longer critical for communication with CBP.

In the final rule, we deleted the requirement for the license plate number (and State or Province that issued the license) for food arriving by privately owned vehicle from the planned shipment information and added this data element to the section identifying the carrier of the article of food (§ 1.281(a)(16) and (c)(16)).

Table 2, which appears later in this preamble, summarizes the information required in a prior notice.

G. What Must You Do If Information Changes After You Have Received Confirmation of a Prior Notice From FDA? (§ 1.282)

The IFR required that for prior notices submitted via ABI/ACS, the submitter should cancel the prior notice via ACS by requesting that CBP ''delete'' the entry. FDA has revised the final rule to state that the submitter should request that CBP ''cancel'' the entry. Moreover, we changed references to ''PN System Interface'' to ''PNSI.''

H. What Happens to Food That Is Imported or Offered for Import Without Adequate Prior Notice? (§ 1.283)

The IFR stated that refused food must be moved under appropriate custodial bond. FDA has revised this paragraph in the final rule to state that the refused food must be moved under appropriate custodial bond unless immediately exported under CBP supervision. The final rule clarifies that the refused food may be held at the port or at a secure facility outside the port. FDA also changed the timeframe for notifying FDA of the hold location from within 24 hours of refusal to before the food is moved to the hold location. For clarity and consistency throughout the final rule, we are changing the phrase, ''designated location,'' to ''designated secure facility.''

Under the section describing FDA review after refusal, FDA revised the final rule by including the carrier as one of the entities who can submit a request for FDA review. FDA also revised the final rule to delete acceptance of requests for review by mail and express courier. We are limiting delivery to fax and e-mail.

I. What Are the Other Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart? (§ 1.284)

We corrected the word ''federal'' in the IFR to read ''Federal.'' We also corrected the citation to ''section 303 of the act'' in the IFR to read ''sections 301 and 303 of the act.''

J. What Happens to Food That Is Imported or Offered for Import From Unregistered Facilities That Are Required to Register Under Subpart H of This Part? (§ 1.285)

The final rule removes the provision in § 1.285(a) that if food is from a foreign manufacturer that is not registered as required and is imported or offered for import, it is subject to refusal of admission for failure to provide adequate prior notice. It also deletes the text in that provision that states that failure to provide the manufacturer's registration number renders the identity of the facility incomplete for purposes of prior notice. The final rule retains, with revisions, the provision that states that if food is from a foreign facility that is not registered and is imported or offered for import, it is subject to being placed under hold under section 801(l) of the act.

III. Comments on the IFR

FDA received 320 timely submissions in response to the IFR. To make it easier to identify comments and FDA's responses to the comments, the word ''Comment'' will appear in parentheses before the description of the comment, and the word ''Response'' will appear in parentheses before FDA's response. A summary follows which includes a description of the appropriate section in the final rule.

A. General Comments

(Comments) Most comments generally support the intent of the Bioterrorism Act and FDA's efforts to implement its provisions with the IFR. Some comments commend FDA for revising certain proposed requirements to address the needs of international trade by shortening timeframes, reducing the amount of information required to be submitted, and adding a reasonable amount of flexibility for the submission of prior notice based on the mode of transportation in the IFR. However, several comments assert that the agency has misinterpreted the Bioterrorism Act and some comments suggest that the final rule should be more consistent with the existing trade practices established in accordance with CBP.

(Response) FDA drafted the IFR in response to the comments to the proposed rule, the needs of international trade, and the continued threat of international terrorism and other significant risks to public health posed by imported food. We also drafted the final rule accordingly.

(Comments) Several comments support the graduated enforcement policy the agency used to implement the

IFR, noting that this policy facilitated the transition into compliance with the prior notice requirements. Comments ask that FDA provide a similar transition period after publication of the final rule during which time submitters may become familiar with new requirements, understand the new procedures and adjust business processes and practices.

(Response) After publication of the IFR, FDA published guidance that included a transition period during which we emphasized education to achieve compliance (the December 2003 Prior Notice Interim Final Rule CPG) (68 FR 69708, December 15, 2003). FDA agrees that implementing a graduated enforcement policy using enforcement discretion has assisted submitters to become accustomed to the new requirements. The new requirements of the final rule will not take effect until 180 days after publication. Since the final rule retains most of the requirements found in the IFR, and with the 180-day delay in effective date, we are not implementing a graduated enforcement policy for implementing the final rule.

FDA and CBP have issued elsewhere in this issue of the **Federal Register** a new CPG (hereinafter the Prior Notice Final Rule Draft CPG) that explains our proposed policies for enforcing violations of this final rule. The draft CPG describes the circumstances under which FDA and CBP should typically consider not taking any regulatory action, the types of violations FDA and CBP intend to focus on, and other enforcement policies.

(Comments) Several comments thank FDA for providing an opportunity to provide comments on the provisions of the IFR after a period of active FDA/CBP enforcement.

(Response) FDA agrees that providing several comment periods following publication of the IFR has permitted affected stakeholders an additional opportunity to offer specific and informed comments on the new requirements.

(Comments) One comment requests that FDA clarify that prior notices submitted to FDA will not be subject to public disclosure under the Freedom of Information Act (5 U.S.C. 552, *et seq.*) (FOIA) because information contained in a prior notice is confidential business information. Alternatively, the comment requests that FDA develop policies to protect confidential business information contained in prior notices from public disclosure.

(Response) FDA does not believe this is necessary. FDA already has relatively detailed regulations, in 21 CFR part 20, governing the disclosure of information under FOIA, including the disclosure of confidential business information. Likewise, the agency's general policies, procedures, and practices relating to the protection of confidential information received from third parties apply to information received under prior notice. We do not believe rules, policies, or procedures specific to prior notice are needed.

(Comments) One comment states that during the period of enforcement discretion, various ports of arrival took different approaches to enforcement and suggests that FDA ensure that all ports and all officials act in a similar fashion to achieve a consistent enforcement posture. The comment also suggests that FDA and CBP conduct ''cross-training'' of their officials staffing FDA or CBP help desks.

(Response) All prior notice field operations and procedures are directed by the FDA Prior Notice Center (PNC). The PNC works to ensure a consistent implementation and enforcement program. Since the initial implementation of the prior notice rule, FDA staff has received additional training and guidance on prior notice requirements.

(Comments) Several comments acknowledge the efforts of CBP and FDA to work together to achieve the common goal of securing the imported food supply. In particular, comments congratulate FDA for coordinating with CBP to allow transmission of FDA-required information through the ABI to CBP's ACS. In addition, comments support the integration and cooperation of both agencies in utilizing CBP's targeting system to efficiently and rapidly spot anomalies in freight crossing our borders; reducing the FDA proposed timeframes for submission of prior notice in the advance electronic information requirements; and the commissioning of CBP staff to conduct examinations and investigations. One comment requests that CBP and FDA ensure that there are adequate resources at ports of arrival to mitigate anticipated delays at border crossings when the rule is enforced. Several comments anticipated that trade would collapse on December 12, 2003, when the new regulations took effect.

(Response) FDA and CBP are continuously coordinating efforts to receive, review, and respond to prior notice submissions. We further note that trade continued without significant interruption on December 12, 2003, or anytime after that implementation date. Rather, the implementation of the prior notice requirements was relatively smooth.

(Comments) Several comments acknowledge the importance and value of FDA's educational outreach efforts to the trade industry through scheduled outreach and education sessions, port-specific flyers, foreign government training and Web site communications, especially those that summarize certain compliance data. The comments also applaud the unprecedented efforts the FDA has made in this regard.

(Response) FDA and CBP will continue outreach and education efforts as resources permit. See section III.M entitled ''Outreach and Enforcement'' later in this document for further discussion on this subject.

(Comments) Several comments commend FDA for its efforts in developing the prior notice regulation in an efficient and effective manner, reaching out to affected stakeholders for input and comment, and acknowledge the tremendous effort put forth by the agency in the development of the regulation. Other comments state that the rule lacked real world international business input and will have both business and government unable to function because of the amount of paperwork generated, which will not stop a terrorist attack. In particular, one comment notes that tracing a grower of a particular shipment is impossible in many instances.

(Response) FDA and CBP systems have been able to manage the millions of prior notice submissions received, reviewed, and responded to since December 12, 2003. The agencies strove to implement the requirements in the Bioterrorism Act in a manner that required only that information deemed necessary and appropriate to ensure FDA could meet its statutory obligation to receive, review and respond to prior notices and target those shipments needing inspection upon arrival in the United States. Based on FDA's and CBP's experience since December 2003, the agencies have revised some of the requirements in the IFR and eliminated some of the information we no longer deem necessary (e.g., HTS codes). FDA notes that the grower of a food in its natural state is required only when known.

(Comments) One comment suggests that the prior notice IFR is ''functionally redundant'' because prior notice has long been a part of FDA protocol long before the Bioterrorism Act.

(Response) While FDA agrees that most of the information required by the IFR has been submitted to FDA via CBP processes for decades, the information has not been required prior to arrival of the food, making prior notice a new, unique, and valuable process.

(Comments) One comment suggests that the IFR was unduly costly, ill-considered and generally more harmful than useful. An additional comment believes that the prior notice requirements would restrict trade more than necessary and hopes that the United States will implement the Bioterrorism Act in the least trade-restrictive manner. Another comment states that despite efforts to comply with the new requirements, massive problems seem to constantly occur. Another comment complains about accessibility to the Web site, cost and time of the submission procedures, language barriers, and complexity of the information requested.

(Response) FDA disagrees. The prior notice process, which allows submission of the required information via either ABI/ACS or PNSI, has been relatively smooth. Although there were some technical problems encountered during the early implementation phase, FDA believes that the graduated enforcement process coupled with the vigorous education and outreach efforts by both the government and the industry have supported a relatively smooth transition to the new procedures and have improved compliance with the new requirements. FDA also has considered its international trade obligations under various World Trade Organization agreements, North America Free Trade Agreement, and other international agreements throughout the rulemaking development processes for both the IFR and this final rule. Both rules are consistent with our international obligations.

(Comments) Some comments believe there is a disincentive towards product diversification when exporting articles of food to the United States because the prior notice requirements put them at a competitive disadvantage compared to shipments that originate in the United States.

(Response) The requirement for prior notice was established by Congress with the passage of the Bioterrorism Act to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Section 307 of the Bioterrorism Act requires prior notice of all food imported or offered for import into the United States. FDA is aware of the international trade obligations of the United States and has considered these obligations throughout the rulemaking process for this final rule and the IFR preceding it. Both are consistent with these international obligations. FDA and CBP have actively explored ways to reduce the burden on industry to the extent feasible while fulfilling the Bioterrorism Act mandates. Accordingly, we have made a number of changes in the final rule that minimize the impact of prior notice requirements on the food being imported or offered for import into the United States. We also note that the registration requirement applies to domestic facilities, as well as foreign facilities, and that the registration provisions in the Bioterrorism Act contain certain exclusions that apply only to foreign facilities. (See e.g., 21 CFR 1.226(a), which exempts from the requirement to register a foreign facility, if food from such facility undergoes further manufacturing/processing (including packaging) by another facility outside the United States; no similar exclusion applies to facilities within the Unites States.)

(Comments) Other comments suggest that the IFR failed to include a provision that would ensure that high risk imports arrive at ports staffed by FDA inspection personnel and notes that this could be accomplished by designating particular ports of entry for accepting high risk products or requiring importers of such products to provide longer notice to ensure adequate inspection coverage.

(Response) FDA disagrees. Section 307 of the Bioterrorism Act specifically prohibits FDA from limiting the port of entry by stating, ''Nothing in this section may be construed as a limitation on the port of entry for an article of food.'' We also disagree that certain shipments require longer timeframes for submission of prior notice to ensure adequate inspection coverage. Under a Memorandum of Understanding (MOU) between FDA and CBP, published on January 7, 2004 (69 FR 924), FDA has commissioned thousands of CBP officers in ports and other locations to conduct, on FDA's behalf, investigations and examinations of imported foods. This helps ensure that there is adequate inspection coverage, including at ports where FDA does not currently have personnel.

B. Comments on the Legal Authority

(Comments) One comment requests that FDA delegate authority to the U.S. Department of Agriculture (USDA), as it has with CBP, to enable USDA to implement prior notice requirements on products where the USDA shares jurisdiction.

(Response) FDA disagrees. FDA has not delegated its authority under section 801(m) of the act to CBP, although FDA has commissioned CBP officers in ports and other locations to conduct, on FDA's behalf, investigations and examinations of imported foods. FDA recognizes that there are some products over which both FDA and USDA have jurisdiction. For example, both FDA and USDA's Animal and Plant Health Inspection Service (APHIS) regulate the importation of fruits and vegetables into the United States, although the goal of APHIS' regulation is to safeguard U.S. agriculture and natural resources from the risks associated with the plant pests. Nonetheless, FDA does not believe that there is a need to have USDA implement the prior notice requirements for products for which we share jurisdiction, nor do we believe that doing so would lead to an efficient enforcement of the prior notice requirements. The Bioterrorism Act mandates that advance notice be given to FDA for any article of food that is being imported or offered for import into the United States and that the Secretary receive, review, and appropriately respond to such notifications. To accomplish this, FDA established the PNC that operates 24 hours a day, 7 days a week, to receive, review, and respond to these notices as they are submitted. The purpose of prior notice is to enable FDA to conduct inspections of imported foods at U.S. ports upon arrival and target foods that may pose a significant risk to public health, based on the information submitted.

Prior Notice is submitted electronically to FDA through either Customs' ABI/ACS or FDA's PNSI. Regardless of the mode of transmission, the prior notice information will undergo both a validation process and a screening in FDA's Operational and Administrative System for Import Support (OASIS) for food safety and security criteria. If the FDA system does not indicate that further evaluation of or action on the notice or article of food is necessary for prior notice, the system will transmit a message through OASIS to the ABI/ACS interface for CBP that the article of food may be conditionally released. However, if additional evaluation of the prior notice information is necessary, personnel at the FDA's PNC will access the information provided and determine if that information suggests the potential for a significant risk to public health.

FDA personnel are able to make this determination by using their experience of imported foods, utilizing the expertise within the Center for Food Safety and Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), the inspectional information obtained by the Office of Regulatory Affairs (ORA), and utilizing the expertise of CBP staff who are co-located with the PNC. If FDA determines that a potential health risk is present, FDA or CBP will

examine the food or take other appropriate action.

Evaluations of imported articles of food are made on an article-of-food by article-of-food basis. CBP and FDA are continuously working together to incorporate further intelligence gained from this process. The recent addition of USDA personnel to assist in the sharing of information affecting the safety and security of imported foods will help further this effort.

FDA does note that food items that are under the exclusive jurisdiction of the USDA are not subject to the requirements of prior notice. (See the discussion on § 1.277 (scope), discussed infra.)

(Comments) Another comment suggests that to be consistent with the Bioterrorism Act, FDA should permit an alternative to prior notice for administrative flexibility. The comments suggest that this could be accomplished by including in the final rule a provision which states, ''Other measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.''

(Response) FDA disagrees. Section 801(m) of the act requires the submission of prior notice for all food imported or offered for import into the United States, except as outlined in § 1.277(b). FDA is to use that information to determine whether it should inspect the food upon arrival in the United States. Compliance with prior notice, therefore, means providing the required information within the specified timeframes. No other ''measures'' would ''provide an equivalent level of assurance of compliance'' with the prior notice requirements.

C. What Definitions Apply to This Subpart? (§ 1.276)

Section 1.276 of the IFR provides definitions for the following terms: The act, calendar day, country from which the article originates, country from which the article is shipped, FDA Country of Production, food, grower, international mail, no longer in its natural state, port of arrival, port of entry, registration number, shipper, United States, and you. FDA received no comments on the definitions for the act, calendar day, country from which the article originates, FDA Country of Production, grower, and United States, and thus, the final rule retains the definitions for these terms that were in the IFR. Although no comments were received on the definitions for ''country from which the article is shipped,'' ''registration number,'' and ''you,'' we made minor revisions to these definitions. We also added a definition for the term, ''full address,'' although we did not get any comments on this term.

1. The Act (§ 1.276(a))

The final rule defines ''the act'' to mean ''the Federal Food, Drug, and Cosmetic Act.''

2. Calendar Day (§ 1.276(b)(1))

The final rule defines ''calendar day'' to mean ''every day shown on the calendar.''

3. Country From Which the Article Originates (§ 1.276(b)(2))

The final rule defines ''country from which the article originates'' to mean ''FDA Country of Production.''

4. Country From Which the Article is Shipped (§ 1.276(b)(3))

The final rule defines ''country from which the article is shipped'' to mean ''the country in which the article of food is loaded onto the conveyance that brings it to the United States or, in the case of food sent by international mail, the country from which the article is mailed.'' For clarity, we revised the last phrase of this definition to change, ''the country in which the article will be mailed'' to ''the country from which the article is mailed.''

5. FDA Country of Production (§ 1.276(b)(4))

The final rule defines ''FDA Country of Production'' to mean, for an article of food that is in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish, including seafood that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is in its natural state was grown, including harvested or collected and readied for shipment, in a Territory, the FDA Country of Production is the United States. For an article of food that is no longer in its natural state, the country where the article was made; except that, if an article of food is made from wild fish, including seafood, aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in a Territory, the FDA Country of Production is the United States.

6. Full Address (§ 1.276(b)(6))

The IFR did not have a definition for the term, ''full address.'' However, we added this term to the final rule for clarity since this term is used throughout the rule. The final rule defines ''full address'' to mean ''the facility's street name and number; suite/unit number, as appropriate; city; Province or State as appropriate; mail code as appropriate; and country.''

7. Grower (§ 1.276(b)(7))

The final rule defines ''grower'' to mean ''a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.''

8. Registration Number (§ 1.276(b)(13))

The final rule defines ''registration number'' to mean ''the registration number assigned to a facility by FDA under section 415 of the act (21 U.S.C. 350d) and subpart H of this part.'' FDA made a minor change in this definition in the final rule by adding the phrase ''to a facility'' after the word ''assigned'' to clarify that FDA assigns registration numbers by facility.

9. United States (§ 1.276(b)(15))

The final rule defines ''United States'' to mean ''the Customs territory of the United States (i.e., the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico), but not the Territories.''

10. You (§ 1.276(b)(16))

The final rule defines ''you'' to mean ''the person submitting the prior notice, i.e., the submitter or the transmitter, if any.'' We made a minor change to this definition by simplifying the last phrase of the definition to ''i.e., the submitter or the transmitter, if any.''

FDA received comments on the definitions for the following terms in the IFR: food, international mail, no longer in its natural state, port of arrival, and shipper. FDA also received comments that recommend that FDA include additional definitions for the following terms in the IFR: Carrier, manufacturer, trip number, and ultimate consignee. FDA responds to these comments in the following paragraphs.

11. Food (§ 1.276(b)(5))

The IFR defines ''food'' as having the meaning given in section 201(f) of the act, except that it does not include food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)) or pesticides as defined in 7 U.S.C. 136(u). Examples of food include fruits, vegetables, fish, including seafood,

dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

(Comments) One comment asks FDA to define food contact substances, which are exempt from the requirements of prior notice, to include secondary direct food additives. The comment reasons that secondary direct food additives, many of which are food processing aids, meet the criteria for food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)). The comment further reasons that secondary direct food additives meet the criteria that FDA used in the registration IFR to exclude food contact materials from the requirements of the registration IFR as they are not ''food for consumption'' in that ''they are not intentionally eaten for their taste, aroma, or nutritive value'' (68 FR 58894 at 58911).

(Response) Some secondary direct food additives meet the definition of food contact substances as given in section 409(h)(6) of the act and, therefore, would not be subject to the prior notice requirements (§ 1.276(b)(5)(i)(A)). The comment, however, asks about secondary direct food additives that are not food contact substances, for example food processing aids. The IFR concluded that food processing aids that are not food contact substances are subject to prior notice ''Whether a food processing aid or 'indirect additive' is subject to prior notice depends upon whether such a substance is 'food' under this rule. As noted, for purposes of the interim final rule, 'food' excludes 'food contact substances' as defined at section 409(h)(6) of the FD&C Act. Among other things, unlike food processing aids and 'indirect additives,' 'food contact substances' are not 'intended to have any technical effect in food,' [section 409(h)(6) of the act]. In addition, 'food' excludes pesticides as defined at 7 U.S.C. 136(u). Thus, if the substance is not a pesticide and is intended to have a technical effect in the food being processed, the substance is not exempt from the definition of 'food' under § 1.276(b)(5) in the interim final rule. This is a reasonable result in that such processing aids are intentionally and directly added to 'traditional' foods.'' (68 FR 58974 at 58986). We continue to hold this view. Thus, if a secondary direct food additive is not a food contact substance but is a food processing aid, then it would be subject to prior notice.

(Comments) Two comments ask the FDA to clarify the term, ''reasonably expected to be directed to a food use.'' One comment states that seed produced by seed companies is intended to be used for planting crops, but the production process inevitably results in remnant or culled seed that is suitable for use as animal feed (and to a far lesser degree, as food for human consumption), which generally is sold by the seed company as such. The comment states that a similar issue arises with some crops, such as onions, for which bulbs sold to farmers may also be used as feed or, in limited cases, as food if they are determined to be remnant or culled. The comment believes that FDA should provide specific limitations on the definitions of ''reasonably believes'' and ''reasonably expected'' that take into consideration that the seed produced by seed companies is intended to be used for planting crops, even though it is understood that there inevitably will be some remnant seed and culls. Without such limitations, the comment believes the rule is unreasonably broad, imposes a burden on seed companies primarily marketing seeds for planting purposes that is out of proportion to the protective goals of the act, and is subject to widely varying interpretations. Another comment notes that the seed industry's research and development activities generate very small amounts of seed that may be found ''unsuitable'' for planting and end up in the food supply, and similarly asks for clarification of the ''reasonably believes'' and ''reasonably expected'' language.

(Response) In the preamble to the IFR, we state that ''FDA will consider a product as one that will be used for food if any of the persons involved in importing or offering the product for import (e.g., submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use'' (68 FR 58974 at 58987). The purpose of this statement was to explain when an article of food would be subject to prior notice if it is capable of multiple uses. The comments, and our experience with the IFR, have shown that there is some confusion as to how to determine when a substance that is capable of a food use and a nonfood use is a ''food'' for purposes of prior notice. To clarify, we will consider such a substance to be ''food'' for the purpose of prior notice if it is reasonably likely to be directed to a food use. This should make it clearer that, as explained in the preamble to the IFR, the determination is not based on the intended use of the article (68 FR 58974 at 58987).

In one of the comments, the seed will ''inevitably'' contain remnant seed and culls that will be diverted to human or animal feed. In this case, since at the time of import, the seed is reasonably likely to be directed to a food use, prior notice is required. FDA believes this is consistent with the purpose of the Bioterrorism Act. With respect to the other comment about seeds found ''unsuitable'' for planting, there is insufficient detail in the comment to determine whether these seeds would be considered food.

Nonetheless, we note that the Prior Notice Final Rule Draft CPG, announced elsewhere in this issue of the **Federal Register**, proposes an enforcement policy regarding seeds for planting. Under the draft policy, FDA and CBP would typically consider not taking any regulatory action regarding seeds that will be used for cultivation. The policy would apply when no more than a small portion of that seed is diverted from cultivation to animal feed or other food use. It would not apply, however, where the seed is used for the production of edible sprouts, such as alfalfa seeds for the production of alfalfa sprouts.

(Comments) One comment states that the Bioterrorism Act regulations do not present a means to provide FDA with certification that any of the indicated persons (i.e., submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) do not reasonably believe that an item is reasonably expected to be directed to a food use prior to arrival at a U.S. port. The comment further states that there is no method to avoid classifying their products as anything other than those flagged as FD4 [2] articles requiring prior

[2] HTS codes are ''flagged'' in ACS as follows to indicate that products are or may be under FDA jurisdiction:

FD0—Indicates that FDA has determined the article, even though subject to FDA's laws and regulations, is acceptable for CBP release without further presentation of prior notice or other entry information to FDA.

FD1—Indicates that the article may be subject to FDA jurisdiction, including FDA review under 801(a) of the act. For products not subject to FDA jurisdiction, a filer can ''Disclaim'' product from FDA notification requirements.

FD2—Indicates that the article is under FDA jurisdiction and review of entry information by FDA under section 801(a) of the act will take place. However, the article is not ''food'' for which prior notice information is required.

FD3—Indicates that the article may be subject to prior notice under section 801(m) of the act and 21 CFR Part 1, subpart I. , e.g., the article has both food and nonfood uses.

Continued

notice, thereby providing no means to avoid refusal of the goods upon arrival because the prior notice was not filed.

(Response) FDA disagrees. FDA is continuously reviewing the FD3 and FD4 flags associated with HTS codes. The HTS codes are flagged to indicate which products will (FD4) or may (FD3) require prior notice and which product will or may require FDA review under section 801(a) of the act for admissibility; all FDA-regulated products are covered, not just foods. If you believe that an item has been incorrectly flagged, you should contact the FDA and provide a statement that explains your rationale. The designation will be reviewed and action taken to correct the flag if deemed appropriate. With respect to the comment about providing certification about the belief of the ''indicated persons,'' submitters may disclaim articles of food marked FD3 if the article is not reasonably likely to be directed to a food use by using an affirmation of compliance in ABI/ACS.

(Comments) Many comments address the FD flags associated with the HTS codes. Two comments state that they are currently importing a product that was flagged FD4, which requires that prior notice be submitted for that article. However, the item is not an article of food and the commenter would like the HTS code changed from a FD4 flag to a FD3 flag. An additional comment had concerns about multiple use products, where one use would require prior notice and another use would not. Another comment states that there is no clear methodology provided to disclaim an item beyond the initial FD3 designation. The comment recommends that the agency outline the elements of a due diligence protocol that would become part of the disclaimer process. One comment suggested that the data elements in the prior notice submission be amended to permit an affirmation that a substance is not directed for a food use. This would avoid the article of food from being refused if the prior notice was submitted for a category that required prior notice. Another comment wants FDA to develop a method that would allow the submitter or the transmitter to disclaim the need for prior notice at the time of the prior notice transmission.

(Response) If there is a concern regarding the FD flags associated with the HTS codes, you should contact FDA and provide a detailed description of why you believe the HTS code is flagged incorrectly. FDA and CBP are continuously reviewing and updating the FD flags associated with the HTS codes. If you have questions regarding whether prior notice is required for a particular article of food, contact the PNC for assistance. Furthermore, we have established procedures in place to disclaim articles of food the submitter believes does not require prior notice. This can be accommodated by ABI/ACS as an affirmation of compliance.

(Comments) One comment states that the list of HTS codes flagged for prior notice (both FD3 and FD4) (as provided by Customs Admin message 03–2605 dated October 31, 2003) contains 762 tariff numbers. The comment asks if this is a definitive list at this point, especially since FDA and CBP estimated the number to be around 2,000.

(Response) This is not a definitive list. FDA and CBP are continuously reviewing and updating the FD flags associated with the HTS codes. Guidance regarding the HTS flags is posted at *http://www.cfsan.fda.gov/~dms/htsguid3.html*. The lack of an FD3 or FD4 designation does not mean that prior notice is not required. If the article of food fits the definition of food provided in § 1.276 of the final rule, then prior notice is required for that article of food.

(Final rule) Section 1.276(b)(5) of the final rule defines ''food'' as having the meaning given in section 201(f) of the act, except that it does not include food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)) or pesticides as defined in 7 U.S.C. 136(u). Examples of food include fruits, vegetables, fish, including seafood, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

We revised this definition for clarity in the final rule by adding the phrase, ''except as provided in paragraph (b)(5)(i) of this section,'' in the first sentence; and reworded paragraph (b)(5)(i) to read, ''For purposes of this subpart, food does not include:''.

12. International Mail (§ 1.276(b)(8))

The IFR defines ''international mail'' to mean foreign national mail services. International mail does not include express carriers, express consignment operators, or other private delivery services.''

(Comments) One comment asks FDA to define international mail to include express carriers. Another comment asks FDA to clarify whether sending an item by express delivery will be considered ''international mail'' or ''express carrier.''

(Response) FDA declines to make the requested change. The IFR defines ''international mail'' to mean ''foreign national mail services'' and expressly excluded express carriers, express consignment operators, or other private delivery services from the definition. We retain this definition in the final rule but revised the wording to make the definition easier to read, and to add the phrase, ''unless such service is operating under contract as an agent or extension of a foreign mail service,'' at the end of the definition. This phrase was needed to clarify that a contractor working for a foreign mail service also is included in the definition of ''international mail.'' International mail is a function of the foreign postal organizations of sovereign countries who are members of the International Postal Union. International mail shipments generally do not utilize any of the electronic data transmission systems commonly used by express consignment carriers and private delivery services.

(Final rule) Section 1.276(b)(8) of the final rule defines ''international mail'' to mean foreign national mail services. International mail does not include express consignment operators or carriers or other private delivery services unless such service is operating under contract as an agent or extension of a foreign mail service.

13. Manufacturer (§ 1.276(b)(9))

(Comments) Two comments request that we define the word ''manufacturer.'' One of these suggests that we define ''manufacturer'' to mean the last entity to conduct a processing operation; e.g., including bottling but excluding labeling.

(Response/Final rule) As discussed in section III.H.7.a of this document, FDA agrees and has added a definition for manufacturer. Section 1.276(b)(9) of the final rule defines manufacturer as the last facility, as that word is defined in § 1.227(b)(2) (in the registration rule), that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a *de minimis* nature. If the food undergoes further manufacturing/processing that exceeds an activity of a *de minimis* nature, then the subsequent facility that performed the additional

FD4—Indicates that the article is ''food'' for which prior notice is required under section 801(m) of the act and 21 CFR Part 1, subpart I.

manufacturing/processing is considered the manufacturer.

14. No Longer in Its Natural State (§ 1.276(b)(10))

The IFR defines ''no longer in its natural state'' to mean that ''an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Crops that have been cleaned (e.g., dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, waxed, or polished are still in their natural state for purposes of this subpart. Whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of this subpart.''

(Comments) One comment asks FDA to clarify the term, ''no longer in its natural state'' by expressly stating that seed for sowing or planting that are shucked, sorted and sized remain ''in their natural state'' for purposes of prior notice. Another comment believes that activities such as trimming, washing, waxing, and packaging of produce are part of normal harvesting activities and seeks to clarify that produce that has been trimmed, washed, waxed, and/or packaged is still ''in its natural state.''

(Response) The IFR defines ''no longer in its natural state'' as meaning ''an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Crops that have been cleaned (e.g., dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, waxed, or polished are still in their natural state for purposes of this subpart. Whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of this subpart.'' In the final rule, we are deleting the word ''waxed'' in the list of activities that render the food still in their natural state because this was included in error.

After publishing the prior notice IFR, FDA issued guidance in the form of questions and answers to help clarify the prior notice requirements. In the second edition of ''Questions and Answers Regarding the Interim Final Rule on Prior Notice of Imported Food (Edition 2)'' (the prior notice question and answer guidance document) available at *http://www.cfsan.fda.gov/~pn/pnqagui2.html*, issued May 2004, under section B, Definitions, question 4.1 of the guidance, we discuss seeds. If the seed will be used only for sowing or planting, and not directed to food use, then no prior notice is required and, therefore, there is no need to determine whether the seeds are in their natural state for the purposes of prior notice.

Regarding the other comments, the definition for ''no longer in its natural state'' in the final rule already states that trimmed or washed produce is still in its natural state, if those activities are attendant to harvest or collection. This same definition states that waxing and packaging are activities that render food no longer in its natural state.

(Final Rule) Section 1.276(b)(10) of the final rule defines ''no longer in its natural state'' to mean that ''an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Crops that have been cleaned (e.g., dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, or polished or packaged are still in their natural state for purposes of this subpart. Whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of this subpart.''

15. Port of Arrival (§ 1.276(b)(11))

The IFR defines ''port of arrival'' to mean ''the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where the article of food first arrives in the United States. This port may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).''

(Comments) Two comments ask FDA to clarify what is meant by the term, ''port of arrival.'' One comment notes that notwithstanding the definition in the IFR, FDA representatives have stated that ''port of arrival'' means the first port where the articles of food are ''off-loaded'' and that if the articles remain on the vehicle or vessel, then the port of arrival definition has not been met for these and only these articles. Another comment reports being told by FDA representatives that when a ship arrives from Europe, only goods ''off loaded'' in that port must be given prior notice within the timeframes required. If the ship has food destined to be ''off loaded'' in other ports, prior notice must be filed for each port in accordance with the timeframes required by the regulations. The comments ask FDA to clarify this definition.

(Response) FDA agrees to clarify the term, ''port of arrival,'' as it is a required data element in a prior notice and important for gauging the timeframes for prior notice submission. The interim final rule defined ''port of arrival'' as ''the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where the article of food first arrives in the United States.'' In essence, the comments ask us to identify the point at which an article of food ''first arrives'' in the United States when the food is arriving by water.

The preambles to the proposed rule and IFR explained that for FDA to be able to protect U.S. consumers from terrorism or other food-related emergencies, it was important for FDA to receive prior notice before the food covered by that notice is shipped around the country and potentially lost to government oversight (68 FR 5428 at 5431 and 68 FR 58974 at 58991). The preambles concluded that prior notice must be given before the food first physically appears in the United States so that FDA can inspect the food upon arrival.

As noted in the comments, some shipments contain both food and nonfood cargo. If the carrier stops at multiple ports, the articles of food may remain on board at intermediate ports where nonfood articles are unloaded. The articles of food are then unloaded at one or more subsequent ports. When food is shipped via water and FDA has bioterrorism or other public health emergency concerns about the food, it would inspect the food at the point of unloading. This is because before the food is unloaded it would remain on the carrier either at a secured port under CBP authority or in open water, preventing intentional or unintentional diversion until unloading. The same is true for food shipped by air. When an article of food remains on board at one airport to be unloaded at a subsequent airport, FDA would not need to examine the food until the point where that food is unloaded. In contrast, when food is shipped via land, any articles of food

remaining on board would travel through the United Stated while outside of secured ports and, therefore, could be potentially lost to government oversight due to off-loading in noncontrolled areas.

Therefore, we believe that when an article of food is shipped via water or air, the article ''first arrives'' at the port where it is unloaded. When an article of food is shipped via land, the article ''first arrives'' at the port where it crosses the border. We are revising the definition of ''port of arrival'' in the final rule to clarify this distinction. We have added a statement that for an article of food arriving by water or air, the port of arrival is the port of unloading. For an article of food arriving by land, the definition now states that the port of arrival is the port where the article of food first crosses the border into the United States.

(Comments) One comment asks FDA to clarify the word ''port.'' The comment asks whether the IFR applies to U.S. Navy ships returning to ''port'' or to a U.S. Naval Base from outside U.S. territorial waters. The comment notes that U.S. Navy fleet ships always have been considered U.S. territory. The comment also notes that the CPG states that food entering and then leaving the ''port area'' is not subject to prior notice and asks FDA to clarify the term, ''port area.''

(Response) FDA clarifies that the term, ''port,'' is not defined but that ''port of arrival'' and ''port of entry'' are defined. The term, ''port,'' as used in the rule relates to ports identified by CBP. In 19 CFR 101.1 *Definitions*, ''Port and port of entry refer to any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms 'port' and 'port of entry' incorporate the geographical area under the jurisdiction of a port director.'' If CBP changes this definition in the future, we will evaluate whether § 1.276(b)(12) should be revised to incorporate those changes. Proposed policies in the Prior Notice Final Rule Draft CPG, would apply to most articles of food on U.S. Navy ships returning to ''port'' or a U.S. Naval Base from outside U.S. territorial waters. One policy states that FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for an official government purpose without prior notice, provided that a Federal Government agency is the importer of record. Another states that FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for noncommercial purposes with a noncommercial shipper without prior notice. One of the examples of foods imported or offered for import that may be covered by this policy is food in household goods, including military transfers.

(Final rule) Section 1.276 (b)(11) of the final rule defines ''port of arrival'' as ''the water, air, or land port at which the article of food is imported or offered for import into the United States. For an article of food arriving by water or air, this is the port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the United States. The port of arrival may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).''

16. Shipper (§ 1.276(b)(14))

The IFR defines ''shipper'' to mean ''the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail to the United States.''

(Comments) Two comments request that we clarify the IFR's definition of ''shipper.'' One comment asks whether the shipper is the person who physically loads the shipment for its final journey to the United States, the company that has the business contract to export the food to the U.S. importer, or someone in the middle who removes the shipment from temporary storage for the initial phase of its entire journey to the United States. Another comment asks for clarification as to who is the shipper when the producer's shipping platform is involved in the shipment—the transporter who takes responsibility for the whole shipment or the producer's own facility (assuming that neither would be classified as ''manufacturer'')?

(Response) In the IFR, we defined ''shipper'' based upon the description of shipper as it is discussed in CBP's proposed rule ''Required Advance Electronic Presentation of Cargo Information'' (July 23, 2003, 68 FR 43574 at 43577). We have decided to continue to use this definition in the final rule. In the examples cited in the comments above, the shipper is considered to be the entity that arranges or directs the shipment to be sent to the United States, irrespective of who physically transports it. In the first example it would be the company having the business contract to export the food; in the second, assuming that the producer is sending the food to a firm in the United States, they (the producer) would be the shipper. It should also be noted that a firm may be both a shipper and a manufacturer with respect to the same product if the product is shipped from the point of manufacture to the United States. Moreover, we have added the phrase, ''or express consignment operators or carriers or other private delivery service,'' after the term, ''international mail,'' in the definition of ''shipper'' to clarify that a shipper is involved with various types of transactions, and not just international mail shipments.

(Final rule) Section 1.276(b)(14) of the final rule defines shipper to mean ''the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail or express consignment operators or carriers or other private delivery service to the United States.''

17. Comments Requesting Additional Definitions

(Comments) Several comments request that we define additional terms in the final rule, including: ''trip number,'' ''carrier,'' and ''ultimate consignee.''

(Response) FDA disagrees. FDA believes these terms are sufficiently clear based on our experience since the initial implementation of the prior notice IFR. FDA intends to interpret the ''ultimate consignee'' consistent with CBP's use of that term in regards to the entry of merchandise, which is contained in paragraph 6.3 of Customs Directive No. 3550–079A, June 27, 2001. As stated in that CBP Directive, ''if the merchandise has not been sold or consigned to a U.S. party at the time of entry or release, then the Ultimate Consignee at the time of entry or release is defined as the proprietor of the U.S. premises to which the merchandise is to be delivered.''

18. Summary of the Final Rule

Section 1.276 of the final rule defines the following terms: The act, calendar day, country from which the article originates, country from which the article is shipped, FDA Country of Production, food, full address, grower, international mail, manufacturer, no longer in its natural state, port of arrival, port of entry, registration number, shipper, United States, and you.

D. What is the Scope of this Subpart? (§ 1.277)

Section 1.277(a) of the IFR states that the prior notice requirements apply to all food for humans and other animals that is imported or offered for import into the United States. This covers food for use, storage, or distribution in the United States, and includes food for gifts, trade and quality assurance/quality control samples, food for transshipment through the United States to another country, food for future export, and food for use in a U.S. Foreign Trade Zone (FTZ).

Section 1.277(b) of the IFR sets out the exclusions from prior notice. It excludes food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States (i.e., for consumption by themselves, family and friends, not for sale or other distribution); food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States; food that is imported then exported without leaving the port of arrival until export; and meat food products, poultry products, and egg products that, at the time of importation, are subject to the exclusive jurisdiction of USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

FDA received many comments about § 1.277(b), which are addressed in order of the exclusions covered in the IFR: Food for an individual's personal use when carried by or otherwise accompanying an individual; homemade food; food that is imported for immediate exportation; and foods under exclusive USDA/Food Safety and Inspection Service jurisdiction. The comments concerning requests for additional exclusions from the scope of the prior notice requirements are addressed by issue, beginning with general comments/requests.

1. Food for an Individual's Personal Use When Accompanied at Arrival

Section 1.277(b)(1) of the IFR excludes food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States. The IFR explains that in this situation there was no ''shipper'' as that term is used in section 801(m) of the act.

(Comments) One comment requests that FDA expand the exemption for food carried in to the United States for personal use to include all food products carried in personal baggage; or to allow declaration of entry to be made through existing general CBP entry declaration procedures.

(Response) FDA disagrees. Prior notice is not required for food that is carried by or otherwise accompanies an individual entering the United States (e.g., food that is in his or her carry-on or checked baggage) when the food is for that individual's personal use (§ 1.277(b)(1)). This means that the food is for consumption by the individual or by the individual's family and friends and is not for sale or other distribution. If the food carried by or otherwise accompanying an individual is for commercial purposes, then prior notice requirements apply.

As we explained in the IFR preamble, we do not believe that Congress intended for us to characterize travelers bringing food back from their travels in their personal baggage for their own use as ''shippers'' for purposes of section 801(m) of the act. When there is a commercial purpose involved, there is a ''shipper,'' i.e., the person or entity on whose behalf the traveler is bringing in the food. Thus, by its terms, section 801(m) of the act requires that food carried by or otherwise accompanying an individual arriving in the United States that is not for personal use be subject to prior notice. Moreover, we explained that we would potentially create a loophole that would defeat the purpose of the prior notice rule if we were to exempt all food products carried in personal baggage.

(Final rule) Section 1.277(b)(1) of the final rule continues to state that the rule does not apply to food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States.

2. Homemade Food Sent as Personal Gift

Section 1.277(b)(2) of the IFR excludes food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States.

(Comments) No comments were received about this issue.

(Final rule) Section 1.277(b)(2) is retained without change.

3. Food Imported Then Exported Without Leaving Port of Arrival Until Export

Section 1.277(b)(3) of the IFR excludes food that is imported then exported without leaving the port of arrival until export.

(Comments) One comment states that if food moves for immediate export [3] (IE) out of the same port, it is not subject to prior notice. However, if the food moves on a T&E entry, prior notice is required. The comment provides a scenario where a shipment arrives at Los Angeles Harbor and then moves to Los Angeles Airport for export. Los Angeles Harbor and Los Angeles Airport are separate ports and each has its own port code assigned by CBP. The comment states that CBP considers this an IE entry. Similarly, the comment questioned if FDA considers this an IE entry as well, or if it is considered a T&E entry that requires prior notice.

(Response) If the food arrives in and is exported from the same port, then it is not subject to prior notice. FDA considers a port to be the same as defined by CBP in 19 CFR 101.1; i.e., the term ''port'' incorporates the geographical area under the jurisdiction of a port director. The geographical boundaries of the port of Los Angeles-Long Beach are described in 19 CFR 101.3(b)(1). While Los Angeles Harbor and Los Angeles Airport are separate for CBP management purposes, they are considered to be within the same port. Accordingly, IE entries may be filed for movements between Los Angeles Harbor and Los Angeles Airport followed by exportation of the goods. Similarly, because such movements would not leave the port of arrival until export, prior notice would not be required.

(Comments) One comment suggests that articles of food imported and admitted into a FTZ in or adjacent to the port of arrival as ''zone restricted status'' merchandise, and then exported from the port of arrival under an IE entry, are sufficiently similar to an IE entry that the same restrictions as for an IE entry would apply if the food were refused admission under 801(m) of the act. The comment, therefore, recommends that these articles should be exempt from the prior notice requirements.

(Response) The fact that food is for admission into an FTZ does not, by itself, mean that the food is not subject to the requirements of the prior notice regulation (§ 1.277(a)). In the first instance described in the comments, where the article of food is imported and admitted into an FTZ located in the port of arrival and then exported from the port of arrival, prior notice is not required (§ 1.277(b)(3)). In the second instance, where the article of food is imported and admitted into an FTZ

[3] Food that is brought to a U.S. port but is then directly exported from that port of arrival is entered under a CBP IE entry and subject to the limitations of an IE bond. In essence, this food may not leave the port of arrival until export.

located adjacent to the port of arrival and then exported, prior notice would be required since the food has left the port of arrival before export and may not be subject to the limitations of an IE bond. An FTZ adjacent to the port of arrival is considered to be outside the port of arrival, and therefore not sufficiently similar to those IE entries that have never left the port of arrival.

(Comments) Several comments ask that FDA exempt the airline industry's food service from the requirements of prior notice. The comments assert that there is no danger to the American public from this operation. One comment suggests that leftover unopened cans of soda, unopened small bottles of liquor (to be held in bonded storage) or other ''dry-stores'' items on flights inbound to the United States and intended for use on later flights should be exempt from prior notice. In addition, the comment states that it is not possible to determine at ''wheels up'' what will remain upon landing in the United States. One comment states that it is impossible to provide detailed information about leftover soda and liquor on incoming international aircraft. One comment proposes the addition of the following exception to § 1.277(b): ''Food that is imported by a shipper operating an aircraft in international air transportation, then exported by the same shipper, [as] long as such food remains on board the aircraft at all times from import to export.''

(Response) If the aircraft food is consumed on the international flight or discarded and is not entered into the United States for use, storage, or distribution or remains on board and is exported from the same port into which it arrived, it is outside the scope of the regulation and prior notice is not required. By contrast, prior notice is required for in-flight food that is moved out of the port of arrival to caterers for use on other international or domestic flights (§ 1.277).

(Comments) One comment questions whether wines manufactured in a foreign country and present on a passenger ship that may cruise or dock in the United States Territorial Sea require prior notice.

(Response) If the wine remains on the ship, it does not require prior notice (§ 1.277(b)(3)). However, if the wine is offloaded from the ship and leaves the port of arrival in the United States, prior notice would be required.

(Comments) One comment asks that if wines are loaded onto a passenger ship at a U.S. port, but such an article of food has been previously imported into the U.S. to be exported or transshipped, does the prior notice for such an article of food require the manufacturer's registration number.

(Response) Prior notice is required for food imported or offered for import into the United States before arrival and not when the food is loaded onto a passenger ship in the United States.

(Final rule) Section 1.277(b)(3) is retained without change in the final rule and excludes food that is imported then exported without leaving the port of arrival until export.

4. Food Under the Exclusive Jurisdiction of USDA

The IFR in § 1.277(b)(4), (b)(5), and (b)(6) excludes: Meat food products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*); poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 et seq); and egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 et seq). The IFR explains that these are excluded as directed in the Bioterrorism Act.

(Comments) Comments state that live animals including cattle, pig, chickens, etc. require prior notice, whereas prior notice is not required for products exclusively regulated by the Federal Meat Inspection Act. The comments recommend that animals regulated exclusively by USDA/Veterinary Services such as live cattle, pigs, and chickens be exempt from prior notice because USDA examines them upon importation. One comment further suggests that live animals requiring prior notice should be those animals regulated by FDA, such as turtles, game animals, etc. Another comment asks whether prior notice is required for livestock sent to the United States for recreational purposes, but after a number of years are expected to be slaughtered and enter the food chain as pet food. One comment asks that FDA exempt breeder livestock not imported for immediate slaughter and remove ''FD3'' flags from HTS codes that cover breeder livestock to avoid confusion at the ports of arrival regarding applicability of prior notice requirements.

(Response) FDA disagrees. Live animals, such as poultry and cattle, are food for purposes of prior notice (§ 1.276(b)(5)(ii)) if the article of food is reasonably likely to be directed to a food use (see discussion supra on the definition of food in section III.C.11). Note that live food animals are not excluded from prior notice under section 801(m)(3)(B) of the act and § 1.277(b)(4) or (b)(5) because live food animals do not fall within the exclusive jurisdiction of USDA under the Federal Meat Inspection Act or Poultry Products Inspection Act. If the live animals are imported for a nonfood use (i.e., as a pet, for show purposes, racing) and are not reasonably likely to be directed to a food use, then prior notice is not required. USDA/Veterinary Services inspects imported live animals for animal health, not human health, purposes. An FD3 flag associated with breeder livestock means that the livestock may be subject to prior notice requirements. If the live animal is not reasonably likely to be directed to a food use, then the HTS code may be disclaimed because prior notice is not required.

(Comments) Some comments had a concern regarding USDA-regulated products. One comment noted that USDA-regulated products were excluded from the FDA prior notice rule, but that an HTS codes document released on November 20, 2003, highlights a number of products that are regulated by USDA. Another comment questions why cattle imported for slaughter are coded FD4 and all other cattle are coded FD3 when the importation of cattle is under the responsibility and jurisdiction of USDA.

(Response) Only items that are under the exclusive jurisdiction of the USDA are excluded from the requirements of prior notice. Articles of food that are jointly regulated by FDA and USDA are subject to the requirements of prior notice. Live animals raised for food, even though not in their final, edible form, are considered to be food under the act. *United States* v. *Tomahara Enterprises Ltd.*, Food Drug Cosm. L. Rep. (CCH) 38,217 (N.D.N.Y. 1983) (live calves intended as veal are food) and *United States* v. *Tuente Livestock*, 888 F. Supp. 1416 (S.D. Ohio 1995) (live hogs are food).

(Final rule) Section 1.277(b)(4), (b)(5), and (b)(6) of the final rule are retained without change and exclude meat food products that at the time of importation are subject to the exclusive jurisdiction of the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*); poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

5. Additional Exclusions Requested—General

(Comments) One comment states that cough drops containing OTC (over-the-counter) Monograph active ingredients are regulated as an over-the-counter drug by the FDA, and therefore, are not subject to prior notice. However, CBP categorizes all cough drops, including ones regulated as drugs by the FDA, as candy subject to regulation by FDA as food. Therefore, due to this classification by CBP, cough drops would require prior notice. In addition, another comment asks if pharmaceuticals, such as over-the-counter drugs, are exempt from prior notice requirements.

(Response) CBP classification does not identify foods requiring prior notice. However, CBP and FDA have worked together to provide indicators; i.e., flags associated with HTS codes to indicate which articles being imported may require prior notice submission. The FD3 flag indicates that the products categorized by that HTS code may require prior notice submission; those products categorized in those HTS codes flagged as FD3 that do not require prior notice submission may be disclaimed by the filer upon entry. On the other hand, the FD4 flag indicates that the products categorized by that HTS code require prior notice submission. FDA has published guidance regarding these flags and has published a list of the HTS codes with FD3 and FD4 flags. The guidance is posted at *http://www.cfsan.fda.gov/~dms/htsguid3.html* and the list of codes is posted at *http://www.cfsan.fda.gov/~pn/htscodes.html*.

The comment asks about such articles containing OTC monograph active ingredients. HTS Code 3004909176 (cough and cold preparations) would apply to, among other articles, cough suppressants that contain OTC monograph active ingredients. This HTS Code is not flagged for either FD3 or FD4, meaning that prior notice would not be required. Candies, which are food, would fall under different HTS Codes and would be subject to prior notice.

(Comments) One comment recommends that FDA's food category codes for raw materials could be made more complete to cover the range of materials known to be used in products marketed as foods. The comment states that there are numerous CBP ''Customs Codes'' that do not contain the appropriate FD3 or FD4 codes and that this causes confusion among the industry with some groups interpreting the lack of an FDA code as meaning that that food ingredient was exempt from prior notice, even if the ingredient is known to be used in food. Other comments assume that ingredients lacking an FD3 or FD4 code that are best known as being active ingredients in drugs, but are also used in dietary supplements, are exempt from prior notice. The comment recommends that these codes should be made as complete as possible and that FDA should indicate that ingredients without a FD3 or FD4 code may still require prior notice.

(Response) FDA and CBP continuously evaluate the HTS codes in order to attach the appropriate FD3 and FD4 designations. However, the lack of an FD3 or FD4 designation does not mean that prior notice is not required. If the article fits the definition of food provided in § 1.276 of the final rule, then prior notice is required for that article of food. If you believe that an item has been incorrectly flagged, or is not currently flagged, but should be, you should contact the FDA and provide a statement with your suggestion and basis for the flag designation.

(Comments) One comment believes that there is a conflict between the registration (21 CFR part 1, subpart H) and prior notice IFRs, where the former is based upon the intended use of food (i.e., consumption), and the latter applies to ''all'' food. The comment states that this has caused difficulties with the import process by: (1) Requiring foreign facilities to register in order to meet the prior notice requirements and (2) requiring drug and device establishments to register as food facilities in order to facilitate importation of intra-company articles. The comment believes this places an undue burden on drug and device establishments and hampers the importation process for articles not intended for use in food, as well as for food articles not intended for consumption. The comment suggests that section § 1.277 be changed to read: ''This subpart applies to all food intended for consumption by humans and other animals * * *.'' In addition, the comment suggests that the HTS codes be modified to allow articles designated with a FD3 or FD4 code to be disclaimed, with rationale, depending on their intended use.

(Response) FDA disagrees. FDA disagrees with changing § 1.277 to read that prior notice is only required for food that is intended for consumption. In the preamble to the IFR, FDA noted that the determination of whether a substance is ''food'' is not a question of intended use (See 68 FR 58974 at 58987). Moreover, we do not believe that there is a conflict between the registration and prior notice requirements. Under the registration rule, in general, a facility engaged in the manufacturing/processing, packaging, or holding of food for consumption in the United States must be registered. Regardless of whether the facility that manufactured the food manufactured it for consumption in the United States, section 801(l) of the act prohibits food that is from an unregistered foreign facility from being delivered for distribution in the United States until the facility is registered. Thus, if the owners, operators, or agents in charge of facilities want to ensure these types of food are not subject to being held under section 801(l) of the act, they can register in accordance with section 415 of the act (21 U.S.C. 350d) (and if the food is for consumption in the United States, they must register unless the facility qualifies for an exemption). An importer can likewise ensure that food is not subject to being held under section 801(l) of the act by not importing or offering for import food that is from an unregistered foreign facility.

Throughout this preamble to the final rule, we often use the phrase ''food is subject to being held'' in describing our enforcement of the registration requirement through prior notice. Under section 801(l) of the act, ''[i]f an article of food is being imported or offered for import into the United States, and such article is from a foreign facility for which a registration has not been submitted to the Secretary under section 415, *such article shall be held at the port of entry for the article*, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so registered'' (emphasis added). In this situation, the article of food is being prevented from moving forward past the port of arrival because the food is from a foreign facility that has not registered. This situation is distinct from a situation where, after FDA reviews the prior notice information, the food is held upon arrival for examination because it may pose a significant risk to public health, usually referred to as a ''BT Hold.'' In addition, we do not believe that prior notice places an undue burden on the drug and medical device industry. Items designated with a FD4 code are all believed to be used exclusively in food, and therefore, require prior notice. Articles designated by a FD3 code can have food and nonfood uses. These items do not require prior notice if the use of the article does not fit the definition of food provided in § 1.276 of

the final rule and may be disclaimed by the filer as such upon entry.

(Comments) One comment states that there is no facility registration requirement for transshippers; however, goods processed under CBP's Form CF7512 (T&Es and ITs) require a prior notice to be filed. The comment notes that this cannot be accomplished without the corresponding facility registration number. In addition, T&Es and ITs do not have a designated submitter. The comment requests that T&E and IT transactions be exempt from prior notice.

(Response) FDA disagrees that T&E or IT transactions should be exempt from the requirements of prior notice. These articles of food leave the port of arrival prior to exportation from the United States or for subsequent movement through the United States prior to entry.

Under § 1.281(a)(9) of the IFR, a shipper's (transshipper's) registration number was not required for a facility associated with an article of food if the article is imported for transshipment. Under the final rule, if the shipper's identity is provided, the shipper's registration number is optional. Therefore, the absence of a shipper's registration number should not prevent submission of a prior notice under either the IFR or final rule. Moreover, FDA disagrees with the comment's implication that a prior notice requires a designated submitter. Under § 1.278 of the IFR and final rule, a prior notice may be submitted by any person with knowledge of the required information.

(Comments) Several comments request that FDA generally exempt Canada and Mexico from submitting prior notice for food shipments. One comment requests that FDA exempt Canada, in keeping with the nature of cooperation and shared security risks between the United States and Canada, in particular the 30 point border plan. The comment reasons that Canadian origin food is easily traceable through existing Canadian registration requirements, while already meeting or exceeding United States standards in some instances. The comment further notes that the legislation acknowledges the largest threat is from offshore, yet the regulations most severely hit continental trade between the United States, Canada, and Mexico. One comment suggests that the exemption could be limited to shipments of food which are under similar security controls, especially small quantity shipments of fish imported via package delivery. Another comment asks that FDA exempt goods being imported into the United States from companies which are inspected by the Canadian Food and Inspection Agency.

(Response) FDA disagrees. While we welcome any additional information that supports our ability to quickly review prior notice submissions and determine which food to inspect at U.S. ports of arrival, the Bioterrorism Act does not provide for blanket exclusions based on the country from which the food is shipped or the country in which the food originates. FDA currently is reviewing flexible alternative programs (e.g., CBP's Customs-Trade Partnership Against Terrorism (C–TPAT), which was adopted into law (still as a voluntary system) by Subtitle B of Title II of the SAFE Port Act of 2006 (Public Law 109–347), and Free and Secure Trade (FAST) (a voluntary program authorized under 19 U.S.C. 1411)) to determine their potential for streamlining the prior notice review process, but notes that these programs do not meet or affect the requirement to submit prior notice. Moreover, FDA notes that many shipments from Canada and Mexico into the United States in fact are transshipments from other countries, which prior notice submissions identify with the FDA Country of Production data element.

(Comments) One comment suggests that FDA create a relational database to give unique identification numbers to an importer's specific items. The comment states that this would speed submission, reduce time to enter the data, and increase compliance with the regulation. The comment reasons that most food importers will bring in the same product, in the same package, from the same country, over and over. Another comment suggests that a single weekly summary of all shipments by a company to individual consumers or a summary of orders received should be adequate for this type of commerce.

(Response) FDA disagrees. Not all importers consistently import the same types of food. The Bioterrorism Act requires submission of prior notice before an article of food is imported or offered for import into the United States. A weekly summary as suggested by the comment would not meet this requirement, as such a summary would not provide prior (advance) notice before the article of food is imported or offered for import. FDA notes, however, that a number of the software programs that customs brokers use to file prior notice and entry submissions with ABI/ACS do allow for repetitive information to be saved on the filer's computer and used for future shipments, as appropriate. Similarly, FDA's PNSI has been designed to accommodate repetitive information, such that the basic prior notice information that will repeat on each prior notice can be created and saved for use on subsequent prior notices. A separate prior notice confirmation number is generated for each article of food or recipient.

(Comments) One comment requests that FDA exempt highly perishable food products. The comment states that highly perishable food products, such as ice cream, must be delivered in a timely manner. A delay in the delivery schedule due to holdups at the border could potentially ruin these products, and customers inconvenienced by the time delay may choose to stop importing them. A number of comments request that FDA exempt fresh produce. Several comments note that produce is already carefully monitored by CBP and placed on automatic quarantine for mandatory inspection at the first port of arrival by USDA/CBP. Other comments state that produce is already subject to 100 percent USDA inspection and approval prior to release. Another comment requests that produce be exempt from the requirement of prior notice because it already meets the requirements of the Bioterrorism Act. The comment reasons that the purpose of the prior notification to FDA is to provide FDA with the information necessary to make a decision (prior to arrival) for a possible physical inspection. The comment states that the CBP Agriculture Specialist performs the physical inspection (or reviews original documentation that confirms ''pre-inspection''). Therefore, the comment reasons, importations of fresh produce are already meeting the requirements of the Bioterrorism Act. The comments further state that because prior notice is already given for produce, the new procedure created by this new legislation will only increase costs and cause extreme hardship for small business. An additional comment states that their shipments are subject to four levels of inspection: County, State, Federal, Customs and ''Bio Terrorist'' and reasons that the redundancy is wasteful.

(Response) FDA disagrees. Highly perishable foods, like all other foods that are covered by the final rule, are subject to prior notice requirements. The timeframes are sufficiently short, allowing for submission of prior notice as soon as 2, 4, or 8 hours before arrival in the United States depending on mode of transportation. While the Bioterrorism Act provides for an exclusion for certain types of food, such as meat and meat food products subject to USDA's exclusive jurisdiction, it does not exclude perishable foods generally

or foods jointly regulated by USDA and FDA.

As we explained in the IFR preamble, merely obtaining existing information about the food from other agencies would not guarantee that FDA has the information required by section 801(m) of the act's prior notice requirements because there is wide variation in the purposes and information required by other government programs (68 FR 58974 at 58992). Moreover, our ability to respond to bioterrorism incidents or other food-related emergencies in a timely manner may be more difficult if the information is not easily accessible.

(Comments) One comment recommends that the rule be amended to include an exemption from prior notice for organizations that are importing FD4 materials for nonfood uses.

(Response) FDA disagrees. Items designated with an FD4 code are all believed to be used exclusively in food, and therefore, food encompassed by an HTS code that is flagged FD4 is subject to prior notice requirements. Moreover, as discussed previously, FDA provided extensively its rationale for not limiting the prior notice requirements to food for consumption in the United States. (See 68 FR 58974 at 58990 and 58991.) As FDA noted in the IFR, Congress did not explicitly limit the prior notice requirement to articles of food that are intended for consumption in the United States even though it could have done so as shown in section 415 of the act (requirement to register food facilities). If anyone believes that an HTS code has been flagged FD4 in error, they can inform FDA and, if we agree, we will change the flag accordingly.

(Comments) Two comments request that FDA exempt small businesses.

(Response) FDA disagrees. Prior notice is required for all FDA-regulated food that is imported or offered for import. The Bioterrorism Act does not provide for exclusions based upon the size or nature of the firms or facilities associated with that importation.

(Comments) One comment asks FDA to permit an exemption from prior notice, by importer number, to be recognized in ACS at the time of entry transmission, to importers who demonstrate that their products will not reasonably be expected to be directed to a food use.

(Response) FDA disagrees. Prior notice requirements are associated with food, not the person manufacturing, growing, shipping, importing, or owning the food. A product is food for purposes of prior notice if the article of food is reasonably likely to be directed to a food use. Prior notice is required for each article of food imported or offered for import, and food imported or offered for import by or for select importers will not be excluded from prior notice requirements. If an importer does not import articles of food, then no ''exemption'' would be needed since prior notice would not apply to such imports. The FD flags associated with HTS codes are designed to help identify which products will require prior notice. If an import is marked FD3 but it is not food subject to prior notice, the importer can disclaim this import and prior notice would not need to be submitted.

6. Additional Exclusions Requested—Special Programs (C–TPAT/FAST) and Flexible Alternatives

In the explanation of the reduced timeframes and the relationship of special programs to those timeframes, FDA stated in the IFR that the ''interim final rule provides for greatly reduced timeframes for foods based on mode of transportation. These timeframes are what FDA has determined are the minimum timeframes necessary to allow it to satisfy the statutory mandate that the timeframes give the agency the time it needs to 'receive, review, and respond' to prior notices. However, FDA is also interested in exploring flexible alternatives for submission of prior notice for foods or firms covered by programs of other agencies, such as C–TPAT, or imported by other agencies.'' (68 FR 58974 at 58995).

FDA and CBP reopened the comment period for the IFR in the **Federal Register** of April 14, 2004 (69 FR 19763). On page 19764 of that publication, FDA and CBP wrote ''In the prior notice [interim final rule], we expressed interest in exploring flexible alternatives for submission of prior notice for foods or firms covered by programs of other agencies, such as CBP's Customs-Trade Partnership Against Terrorism (C–TPAT) and the Free and Secure Trade (FAST) program, or food imported by other government agencies (68 FR 58974 at 58995). C–TPAT is a government/business initiative to increase cargo security while improving the flow of trade. Under this program, businesses must conduct comprehensive self-assessments of their supply chain using the security guidelines developed jointly with CBP, and they must familiarize companies in their supply chain with the guidelines and the program. These businesses must provide CBP with specific and relevant information about their supply chains and security practices and procedures. As C–TPAT members, companies may become eligible for expedited processing and reduced inspections, but are not exempt from advance electronic information requirements. (See CBP's advance electronic information rule). FAST, an acronym for Free and Secure Trade between the United States and Canada, and the United States and Mexico, is an expedited-clearance system designed to improve border security without slowing the flow of legitimate trade across the northern and southern U.S. borders. FAST processing is available to importers, carriers and foreign manufacturers (southern border) who participate in C–TPAT and who use a FAST-registered driver. The initiative builds on the same concepts that drove the rapid, post-9/11 construction and implementation of C–TPAT. FDA and CBP plan to assess the feasibility of including the FAST timeframes in FDA's prior notice final rule, as well as other flexible alternatives raised by comments.

To assist in this assessment, FDA and CBP requested comments on several questions, including three regarding special programs (69 FR 19763 at 19764):

C–TPAT/FAST Questions:

(1) Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C–TPAT and FAST? If so, how should this be accomplished?

(2) If the timeframe for submitting prior notice for food arriving by land via road is reduced to 1 hour consistent with the timeframe in the advance electronic information rule, would a shorter timeframe be needed for members of FAST?

(3) Should the security and verification processes in C–TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?

The comments received addressing these issues are discussed in the following paragraphs in order of the questions posed in the **Federal Register** notice, beginning with comments addressing general issues regarding C–TPAT and FAST.

a. *General comments*. (Comments) Numerous comments address special trade programs, such as C–TPAT and FAST. These comments recommend that FDA and CBP modify these CBP programs to reflect the criteria required by FDA and to develop integrated data elements for low risk FAST/C–TPAT shipments, which would meet both agencies' requirements. The comments believe it is necessary to have harmonization between FDA and CBP for ''low-risk'' shippers.

Many comments contend that the IFR does not take into account the Canada-United States Smart Border Plan (SBP). A key element of the SBP is the FAST bilateral arrangements. Under the C–TPAT and the Canadian Partnerships in Protection (PIP) programs, companies approved by both countries have invested in specific counter-terrorism and supply-chain integrity measures, and are therefore, accorded more expedited treatment at the Canada-U.S. border in recognition of the lower risk they present.

The comments recommend that FDA recognize foods imported under these programs as low risk and to afford them benefits, such as reduced information requirements for each shipment; reduced timeframes for providing prior notice; reduced clearance time at the border; and reduced number of verifications of information. The comments further urge FDA and CBP to permit importers who are participants in C–TPAT and FAST to comply with their prior notice obligations in a manner that does not undermine the benefits of participation in these programs. The comments contend that C–TPAT and FAST improve U.S. security on a number of levels, including reducing the risk of bioterrorism, and help to focus limited border resources on higher risk cargo. The comments suggest that FDA and CBP therefore should be careful not to remove incentives for participation in these programs by making importation of food items more cumbersome than other types of entries. Otherwise, the comments contend prior notice will dilute a key advantage offered to FAST/C–TPAT participants, thereby weakening the incentive to join the program. The companies participating in these programs have made a substantial commitment to improving security by putting in place appropriate security systems, and submitting to periodic review of those systems by CBP.

The comments believe that these programs strengthen FDA's ability to meet the objectives of the prior notice rule. They contend that this is achieved in two ways: (1) Through the rigorous security screening that participants must comply with in order to obtain a low-risk status; and (2) by removing low-risk shipments from the queue, FAST/C–TPAT work to shrink the number of shipments that must be screened, thereby ''freeing up'' FDA officials to focus limited resources on higher risk shipments.

One comment states that a firm having to manage its systems to track C–TPAT products and non-C–TPAT products will incur increased complexity, increased cost, and will be subject to making errors. This comment suggests that firms who routinely send products across the border could provide prior notice on a quarterly basis. The facility would track the number of shipments each quarter and update FDA with any changes to the anticipated amounts. These shipments would be permitted to cross the border without waiting, but still could be subjected to FDA or CBP inspection.

Another comment questions the cost, benefits, etc. of these programs for small companies. In addition, a few comments address the creation of similar programs and/or the expansion of the current programs. One comment requests that FDA permit the use of Line Release (i.e., an automated system designed to release and track repetitive shipments) for food shipments arriving by rail. The comment states that their member railroads participate in C–TPAT and it would be discriminatory to permit the use of an expedited clearance system for motor carriers, but not rail transportation.

One comment urges FDA to begin working with all interested parties to identify criteria for qualification and participation in a program like C–TPAT, FAST, and others as it applies to prior notice. The comment suggests that participation might hinge on the submission and verification of documentation evidencing the implementation of, and continued adherence to, validated supply chain risk management techniques. The comment believes that there would be mutual benefits of such a program. FDA could reallocate its resources to closer review and examination of shipments from those importers that do not participate in the program and, thus, have not demonstrated the same level of commitment to food safety and shipment security as participating importers do. Program participants would benefit from the agency's recognition of their commitment to safety and security, which presumably would be reflected in more efficient and timely processing of their entries at the border. In that regard, the comment suggests that the agency consider extending to participating low risk importers the option of submitting a single prior notice for all entries in a mixed load container or truck. FDA product codes for all line entries would continue to be available to FDA through FDA's existing OASIS system.

Another comment hopes that the multiple U.S. agencies (FDA, Department of Homeland Security, and USDA) could collectively address this issue and develop a protocol for food products that are currently ineligible for any FAST benefits.

A few comments request that C–TPAT should be open to all foreign operators willing to participate and that companies participating in C–TPAT should be exempt from the procedures under the Bioterrorism Act. These comments encourage partnerships between the U.S. and E.U. similar to C–TPAT, which would facilitate trade in food and feed between the E.U. and U.S. and avoid delays at the U.S. border, especially with respect to perishable products. In addition, one comment suggests that food transporters should be allowed eligibility in C–TPAT and FAST to ensure that all transporters operate on a level playing field.

One comment notes that C–TPAT is not currently offered to Canadian manufacturers unless they are an Importer of Record for U.S. Customs' purposes.

Finally, one comment expresses concern that any motor carrier who is not Pre-Arrival Processing System (PAPS)-certified may be required to present the prior notice confirmation number upon arrival at the border, even if prior notice was submitted through ACS. The comment states that truck drivers are generally unable to obtain the prior notice confirmation number prior to arrival given the short distance between Canada and the United States and the fact that prior notice is not generally submitted until after the trucker has left with the load. The comment states that requiring PAPS authorization as a way to avoid delays is to mandate that truck companies become C–TPAT certified or otherwise comply with the designation requirements. The comment notes that this is not possible, sometimes for cost reasons alone. The comment also has similar concerns regarding the PAPS-program at the Southern border.

(Response) While FDA welcomes the additional information provided by C–TPAT and FAST, these programs would require relatively significant changes to be useful in helping us carry out the prior notice program. The purpose of prior notice is to help identify food that potentially poses a significant health risk to the American public and to deploy resources to the port of arrival so that inspections can be conducted before the shipment enters the United States. Information about the manufacturing facility is used in conducting this risk assessment. The C–TPAT assessment, however, does not always include the food manufacturing/processing operations. Even when it does, C–TPAT focuses on security risks

whereas the prior notice program considers all health and safety risks to the food, such as unintentional contamination. Moreover, unlike PNC reviewers, the CBP Supply Chain Specialists who conduct the validation assessments for C–TPAT are not necessarily trained in assessing the potential risks associated to food products and neither FDA nor CBP has the resources to fund the extensive training that would be required to do so. Because knowing that a firm participates in C–TPAT does not assist FDA in conducting its food safety review, we have decided not to provide special treatment in terms of reduced prior notice information requirements or reduced timeframes based on C–TPAT participation.

It is important to note that participation in C–TPAT does not affect the information requirements of CBP's advance electronic information rules; the same information is required regardless of C–TPAT participation. However, successful participation in C–TPAT does affect the frequency of CBP cargo and trade examination. FDA likewise uses a risk-based approach in selecting foods for examination at the border for security and food safety reasons. FDA, thus, is continuing to explore with CBP and industry use of these programs in making decisions regarding which products to inspect for the purposes of admissibility (801(a) decisions).

Comments addressing which foreign operators are eligible for participation in FAST and C–TPAT are outside the scope of this rule. CBP stated in a document entitled ''Frequently Asked Questions Regarding Minimum Security Criteria for Importers,'' dated March 25, 2005, (CBP's March 25, 2005, Frequently Asked Questions (FAQ) document) (available at *http://www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/security_criteria/criteria_importers/questions.xml* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**)), that ''C–TPAT remains a voluntary, incentive based partnership. However, once a company commits to the C–TPAT program, there are specific program requirements that must be adhered to by the company to qualify for C–TPAT benefits, which are significant. C–TPAT importers are six times less likely to undergo a security related cargo examination, and four times less likely to be subject to a trade related examination, than non-C–TPAT members. These significantly fewer cargo examinations help save importers time and money, while leading to a more predictable supply chain. CBP continues to explore additional benefits, which can be afforded members who meet or exceed the minimum-security criteria.''

The document also states that ''CBP employs a risk management approach in screening and targeting, and such shipments, as well as those from unknown or less established entities, receive higher scrutiny from CBP. The agency does not disclose ATS targeting rules.''

(Comments) Several comments suggest that FDA should not establish a duplicative program, but should incorporate additional factors or criteria necessary for prior notice into existing programs.

(Response) FDA agrees that it is generally preferable not to establish duplicative programs. Thus, while we have determined not to provide C–TPAT members with special treatment in terms of reduced prior notice information requirements or reduced timeframes, we will continue exploring use of these programs in making decisions regarding which products to inspect for the purposes of admissibility (801(a) decisions).

b. *Special programs.*

i. *Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C–TPAT and FAST? If so, how should this be accomplished?*

(Comments) Numerous comments assert that businesses that participate in the C–TPAT and FAST programs should be eligible for processing/transmission benefits. These comments contend that importers, carriers and drivers who have been approved for C–TPAT and FAST already have been deemed to be ''low risk'' by CBP. Importers and carriers have had to demonstrate supply chain security controls, and drivers have been subjected to rigorous background screening. Companies have made the security investments and have bolstered their operations to provide the requisite security and integrity of their trade transactions. The federal governments of the United States and Canada have encouraged FAST participation on the grounds that it will mean expedited border crossings and reduced information requirements. By allowing food to move through the FAST ''stream'' in the same manner as other products, FDA would demonstrate the commitment to harmonization that industry has long encouraged and would provide an incentive for additional participation in the C–TPAT and FAST programs. In addition, the comments noted that if the primary benefits of the C–TPAT program were removed, FDA would create a disincentive for C–TPAT participation that would ultimately reduce the security of the articles covered by the Bioterrorism Act. Finally, the comments note that these benefits are necessary to avoid duplication and inconsistent application of prior notice requirements for shipments that meet the stringent FAST criteria.

(Response) FDA continues to use a risk-based approach for determining which foods to inspect for the purposes of admissibility. FDA will continue to work with CBP and acknowledges that the additional information provided by C–TPAT participation could be helpful in this risk-based assessment. In CBP's March 25, 2005, FAQ document cited previously, CBP states that ''[u]nsolicited shipments will understandably lie outside the capability of the importer to ensure security. CBP employs a risk management approach in screening and targeting, and such shipments, as well as those from unknown or less established entities, receive higher scrutiny from CBP.'' FDA agrees with this statement.

(Comments) Numerous comments provide suggestions on how to accomplish processing/transmission benefits for C–TPAT and FAST participants. Many of the comments cite a need for better harmonization and streamlining between FDA and CBP. Suggestions from the comments include:

- Enhance coordination between CBP and FDA, allowing trained CBP/FDA officers to process food shipments through the FAST lane, and allowing FAST importers using a FAST driver and carrier importing food and/or feed products to submit prior notice to both the CBP and FDA through the existing CBP/FDA interface.
- Allow for integrated targeting processes, including a reduction in the risk targeting factors for food shipments, as well as other product categories, which would translate into expedited processing, reduced exams and other benefits for food import shipments under the program.
- Integrate the CBP and FDA data systems to allow for one filing of the required information. The C–TPAT certification process delves into the critical aspects of a company's handling and documentation procedures, and requires a company to demonstrate it has good process controls in place throughout the supply chain.
- Modify the CBP and FDA systems for the receipt of advance notice and prior notice to ''flag'' importation under

C–TPAT and FAST. These notices should receive priority attention for entry and clearance purposes.

• Establish an MOU between FDA and CBP to allow the sharing of necessary information with the understanding of the program applicant.

• Implement a shorter prior notice timeframe for C–TPAT members.

• Reduce data element reporting by virtue of having successfully passed the C–TPAT validation process. Product information (HTS code, product code, manufacturer's registration numbers, etc.) should be part of the pre-filed information profiles under FAST.

Finally, one comment suggests the following:

(1) A statement of proof of acceptance (e.g., copy of acceptance letter from CBP) into the C–TPAT and/or FAST programs;

(2) A detailed statement/description of policies and procedures in place for meeting FDA prior notice requirements. This submission should follow the format of the supply chain questionnaire information submitted to CBP as part of the C–TPAT application process and should be considered as an addendum to the original submission; and

(3) FDA should notify the importer in writing of: (a) its acceptance/agreement with the importer's FDA prior notice procedures; or (b) additional questions to be answered or data to be provided to meet FDA requirements for acceptance into the FDA prior notice ''C–TPAT/FAST'' program.

(Response) As we discussed previously, we have determined not to provide C–TPAT members with special treatment in terms of reduced prior notice information requirements or reduced timeframes. FDA, however, is continuing to explore with CBP and industry use of these programs in making decisions regarding which products to inspect for the purposes of admissibility (801(a) decisions).

ii. *If the timeframe for submitting prior notice for food arriving by land via road is reduced to 1 hour consistent with the timeframe in the advance electronic information rule, would a shorter timeframe be needed for members of FAST?* (Comments) One comment suggests that the timeframe for submitting prior notice of one hour is fine, even for express deliveries. Another comment believes that reducing the timeframes for submission of prior notice would not sufficiently expedite the clearance of product for participants of FAST. However, an overwhelming majority of the comments favor reducing the timeframe for FAST participants to 30 minutes. Under the CBP Advance Electronic Information Rule, the time element for FAST participants is 30 minutes. The comments state that to have two different time standards for the same mode of transportation only serves to create confusion. The comments believe that any harmonization of FDA and CBP security programs would assist the orderly flow of trade at the border crossing points.

The comments contend that the key premise behind the FAST program is that low-risk parties should receive expedited treatment at the border, freeing up enforcement resources to concentrate on parties of higher or unknown risk, which is why the timeframes CBP adopted are shorter for FAST than for other shipments. If FDA adopted the 30 minute timeframe, it would demonstrate a commitment to harmonizing with CBP, and prevent a situation whereby FAST requirements vary depending on the type of commodity being transported. Finally, one comment believes that to ensure consistency with FAST and CBP's Automated Commercial Environment (ACE),[4] prior notice should be required and calculated from the port of entry and not the first point of arrival, as is currently the case.

(Response) Harmonized timeframes could facilitate the orderly flow of trade traffic at the borders. Advance screening of consistent information also would aid in reducing the review time. However, as we discuss later in section II.F of this document (''When must prior notice be submitted to FDA? (§ 1.279)''), we are maintaining the timeframes that are in the IFR. These timeframes represent the minimum amount of time FDA needs to meet the statutory responsibility to receive, review, and respond to prior notice submissions. Our assessment of the timeframes and review times showed that we would not be able to reduce the timeframes to correspond to those used by CBP for land and air shipments.

iii. *Should the security and verification processes in C–TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?* (Comments) Four comments respond that the security/verification processes of C–TPAT/FAST should be modified for food. Fourteen comments respond that the process should not be modified for food. Most comments suggest that the current validation processes are sufficient and caution that additional FDA inspection would be redundant. Many of these comments state that C–TPAT is a well-thought-out program and that with its current security profile requirements and present followup verification systems, the program is already well suited to handle human and animal food shipments. The comments suggest that FDA should rely on CBP's successful programs and avoid ''recreating the wheel'' or imposing new and potentially inconsistent criteria on food companies. The comments further contend that food safety and product integrity is already an integral part of the industry's own internal policies, which have always been concerned and accountable for the safety and security of their products without regard to the more recent border security program. Therefore, companies certified under C–TPAT have made the critical security investments and have bolstered their operations to provide the requisite security and integrity of their trade transactions, regardless of the commodities (food or nonfood products) that are shipped. Another comment stresses that FDA should not impose additional conditions of participation for FAST members because the requirements for FAST participation imposed by CBP provide adequate assurance that expedited clearance is appropriate.

(Response) FDA agrees with the statement in CBP's March 25, 2005, FAQ document that says ''For C–TPAT to ensure its continued viability, effectiveness, and relevance, the program must continue to evolve—as the terrorist threat and the nature of global trade evolves. The impetus for strengthening the existing security guidelines is to provide more detail to the membership on the expectations of the program, and to assist CBP in defining a more consistent baseline for minimal program requirements and better-defined C–TPAT benefits.'' The issue of how to modify the processes is discussed in the next comments and responses.

(Comments) Numerous comments provide suggestions on how to modify the security/verification processes of C–TPAT/FAST. These include:

• FDA should investigate security plans with actual physical inspections of the facilities prior to allowing participation in the programs.

• FDA should verify that other countries' regulatory systems for food production and safety are equivalent to those of the United States. The agency should also perform on-site audits and inspection of production facilities

[4] The ACE system will replace the current ABI/ACS, as well as combine other CBP entry functions and transactions. Prior Notice submissions will be compatible with ACE.

before a food manufacturer or carrier can be certified.

• It should be mandatory for food manufacturers to provide notice concerning any changes in the manufacturing processes or supplies, as well as those that may affect physical and personnel security. In addition, the current requirements that manufacturers periodically review the security commitment of their service providers to detect weakness or potential weaknesses in security should be altered to require that: (1) The review is conducted on an annual basis and (2) a certification that the review has been conducted.

• FDA and CBP should work together, along with the trade community, to identify potential areas where the C–TPAT security and verification processes can or should be modified. CBP and FDA should coordinate these processes to address the additional concerns of the FDA in order to allow C–TPAT/FAST members expedited processing of food and feed shipments in addition to CBP shipments.

• C–TPAT requirements should encompass any industry and food specific security measures into C–TPAT's checklist.

• These processes must be more comprehensive. There are no questions on the Supply Chain Security Profile Questionnaire to specify the type of freight being hauled. In addition, there are no opportunities in the questionnaire to indicate different locations to which a company is shipping regularly, or insurance a company has to cover those states.

(Response) FDA notes that CBP has continued to expand the C–TPAT program, which now includes minimum security criteria for importers who participate in C–TPAT. FDA also notes that as of July 10, 2006, CBP has received over 11,000 C–TPAT applications of which 6,089 have been certified and 2,973 have been validated (certified members provide a complete security profile that is screened by CBP, while validated members also undergo a complete validation of their security profile that includes an on-site visit to the company to review the submitted security profile, followed by a physical verification of security measures). There are limited resources at this time to add new significant program requirements to meet FDA's needs under the Bioterrorism Act and verify that those procedures have been incorporated. The two agencies will continue to explore the feasibility of the approaches recommended in the comments in the future.

c. *Flexible alternatives*. In the **Federal Register** document to reopen the comment period, FDA and CBP also requested comment on the following questions regarding flexible alternatives (69 FR 19763 at 19764):

• If timeframes are reduced in FDA's prior notice final rule, would other flexible alternatives for participants in FAST or for food imported by other agencies be needed?

• In considering flexible alternatives for food imported by other government agencies, what factors or criteria should FDA consider when examining alternatives? Should participation be voluntary? If so, should FDA consider inspection of companies in the supply chain from the manufacturer to those who may hold the product, including reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities as a condition of participation?

• In considering flexible alternatives for submission of prior notice, should FDA consider additional means of ensuring that all companies subject to the Registration of Food Facilities Interim Final Rule ((68 FR 58894, October 10, 2003) (21 CFR part 1, subpart H)), have an updated registration on file with FDA that has been verified?

• Are there conditions of participation that FDA should consider; e.g., inspections of companies in the supply chain from the manufacturer to those who may hold the product, or reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities?

• Should the food product category be considered as a criteria or element of expedited prior notice processing or other flexible alternatives? If so, should certain foods be excluded from expedited prior notice processing? If so, what should be the basis for determining which foods should be excluded?

• If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?

• Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?

This section will address the comments to each of those questions introduced in the **Federal Register** of April 14, 2004, beginning with general comments.

(Comments) One comment said that if the final rule is refined, then it is not necessary to offer additional flexible alternatives. Several comments state that any flexible alternatives should be incorporated into existing programs because the duplication of security programs and division of limited resources are not in the best interest of our security goals and the protection of public health.

(Response) FDA believes that additional flexible alternatives should be incorporated into existing programs when appropriate and feasible. FDA will continue to work with CBP and acknowledges that the additional information provided by other programs such as C–TPAT could be helpful for purposes of admissibility decisions.

i. *If timeframes are reduced in FDA's prior notice final rule, would other flexible alternatives for participants in FAST or for food imported by other agencies be needed?* (Comments) Several comments encourage incorporation of prior notice requirements into the C–TPAT and FAST programs. Most comments caution that additional requirements should not be added as separate programs, but that FDA should recognize participants in the existing programs for expedited review and processing of prior notice. One comment further suggests that participation in C–TPAT and FAST should also ensure expedited 801(a) admissibility processing. Another comment suggests that CBP be solely responsible for administering both the FDA and CBP requirements of C–TPAT and FAST.

(Response) As we discussed previously, we have determined not to provide C–TPAT members with special treatment in terms of reduced prior notice information requirements or reduced timeframes. FDA, however, is continuing to explore with CBP and industry use of these programs in making decisions regarding which products to inspect for the purposes of admissibility (801(a) decisions).

FDA disagrees with the comment's suggestion that CBP be solely responsible for administering both the FDA and CBP requirements for these programs, as the expertise related to food safety and possible additional participation requirements that address food safety resides in FDA. Accordingly, FDA and CBP will continue to consider how to administer FAST and C–TPAT programs so that they could apply to FDA regulated products.

ii. *In considering flexible alternatives for food imported by other government agencies, what factors or criteria should FDA consider when examining alternatives? Should participation be voluntary? If so, should FDA consider*

inspection of companies in the supply chain from the manufacturer to those who may hold the product, including reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities as a condition of participation? (Comments/Response) There were no comments addressing flexible alternatives for food imported by other government agencies. However, FDA has considered imported shipments of foods for official U.S. federal government use and our draft policy for enforcing prior notice in these situations is contained in the Prior Notice Final Rule Draft CPG that is announced elsewhere in this issue of the **Federal Register**. Under the draft policy, FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for an official government purpose, provided that a Federal Government agency is the importer of record.

(Comments) Many comments advise that voluntary participation enhances the success of these programs.

(Response) C–TPAT is a voluntary, incentive based partnership. As we continue exploring use of the C–TPAT and FAST programs in making decisions regarding which products to inspect for the purposes of admissibility (801(a) decisions), it will be based on the assumption that participation should remain voluntary.

iii. *In considering flexible alternatives for submission of prior notice, should FDA consider additional means of ensuring that all companies subject to the Registration of Food Facilities Interim Final Rule ((68 FR 58894, October 10, 2003) (21 CFR part 1, subpart H)), have an updated registration on file with FDA that has been verified?* (Comments) Several comments reiterate that it is not necessary for FDA to provide flexible alternatives that exceed or augment CBP's existing programs, including a requirement to have an updated and verified registration on file with FDA. However, another comment believes that companies eligible to participate in low-risk programs should have an updated registration and that verification of that registration would be useful in determining low-risk status. Another comment assumes that verification of registration with FDA should have been conducted under CBP's current validation aspect of the C–TPAT program.

(Response) FDA agrees that participants designated as low risk should have an updated and verified registration of all facilities subject to 21 CFR part 1, subpart H. FDA also agrees it would be efficient to conduct the verification as part of the C–TPAT validation process, but neither FDA nor CBP has the resources to do so at this time.

iv. *Are there conditions of participation that FDA should consider; e.g., inspections of companies in the supply chain from the manufacturer to those who may hold the product, or reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities?* (Comments) Most comments suggest that other conditions, such as inspection of other companies in the supply chain would be unnecessary and a repetition of effort with little return on investment. Another comment states that to begin a process of examining the security plans and procedures of foreign food facilities would be tremendously expensive, call into question the validity of the prior notice and registration requirements already in place, and the efficacy of the targeting tools FDA employs.

(Response) We agree that adding conditions for C–TPAT participation and validating them to meet the purpose of the Bioterrorism Act would be extremely expensive and potentially only benefit a small number of those entities subject to this rule. We do not believe that this is the best use of our limited resources at this time, particularly as we have not experienced significant impacts on the flow of trade as a result of the timeframes in the rule since the IFR took effect on December 12, 2003.

v. *Should the food product category be considered as a criteria or element of expedited prior notice processing or other flexible alternatives? If so, should certain foods be excluded from expedited prior notice processing? If so, what should be the basis for determining which foods should be excluded?* (Comments) While one comment asserts that the food product category be considered an important element of expedited processing, most other comments state that no product category distinctions should be made. One comment states that to allow items imported under food product categories to qualify for expedited prior notice could easily lead to abuse of the system intended to protect us from terrorist attack. Other comments suggest that all food products be treated in the same manner and be subject to the same regulations. Most comments state that no product should be specifically included or excluded from participation, but that the criteria for participation should be focused solely on attributes of the company and a company's ability to meet the program standards set by the particular government agency.

(Response) FDA agrees in part that no product category distinctions should be made. However, FDA acknowledges that some foods are more susceptible to terrorism and food safety problems than others, regardless of the processes within the supply chain. But if we were to make product category distinctions, such actions could be disruptive to transportation (e.g., we may need to segregate products) and may make such products targets for terrorism since such products may be eligible for special (e.g., expedited) treatment.

vi. *If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?* (Comments/Response) Comments addressing phase-in of timeframes are found under the discussion of § 1.279 ''When must prior notice be submitted to FDA.''

vii. *Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?* (Comments/Response) Most comments support additional training for submitters and transmitters. Additional discussion of training is found under section III. M (Outreach and Enforcement) of this document.

7. Additional Exclusions Requested—Samples

(Comments) Numerous comments request an exclusion from the requirements of prior notice for samples used in trade fairs, market research, market testing, and laboratory analyses (i.e., quality analysis/quality control (QA/QC) samples, scientific research, compositional analyses, research and development, standard of identity confirmation testing or quality comparison testing). The comments state that QA/QC samples are clearly not destined for consumption and will never enter the food chain or be consumed by the general public, thereby placing samples in a low-risk category. In addition, the comments note that these samples are often imported in very small quantities for a specific purpose. Samples used for organoleptic analyses will be consumed in very small quantities as part of the analytic procedures in a laboratory setting. In the case of trade samples, the comments contend that although the food will be consumed, the consumption is minor and is contained within a controlled environment, such as a test kitchen or trade booth.

In addition, the comments suggest some ways in which the burdens for submitting prior notice for samples could be less cumbersome. These recommendations include:

- Exempt all samples or some subset of samples, e.g., analytical, research, consumer complaint;
- Set a limit of the quantity of samples in each shipment and do not require prior notice for quantities below this limit;
- Exempt samples from the requirement to provide the manufacturer's registration number;
- Include a field in the prior notice in which a filer can indicate that the item(s) is a sample, and eliminate certain data elements if this field is flagged (i.e., registration number);
- Allow a single prior notice without registration numbers for commingled shipments of many small sample items falling under the same or similar FDA product codes;
- Allow shippers to provide a pre-approved list of customers who may receive samples in a particular month, on a monthly basis in lieu of filing individual prior notices;
- Specify procedures in the final rule for clearly identifying samples, such as the inclusion of a statement on the airway bill of lading that says: ''Quality Evaluation and Research and Development Use Only—Resale Prohibited;'' and
- Provide a limited exemption for intra-corporate (within the same company) samples.

One comment requests that FDA exempt foods for exhibit at trade shows and food samples. The comment reasons that these foods are not intended for consumption in the United States, but are imported for ''show'' and sampling at the trade shows, not for later general consumption. The comment further reasons that the quantity involved with each shipment is minuscule, usually no more than five hundred consumer units, which is too small a quantity to pose a potential national security threat.

Another comment states that there should be a de minimus provision for samples from known shippers/importers that is ''cross-referenced'' by shipper facility registration, manufacturer facility registration, importer facility registration, low value, and low weight.

(Response) Many samples of food, including those for test marketing, are ''articles of food imported or offered for import,'' as stated in section 801(m) of the act. If, however, the samples are items that are in such early stages of research and development that they cannot yet be considered food under § 1.276(b)(5) of the final rule, they would not be subject to prior notice requirements. In addition, if the sample is in a form that is not an article of food, such as a slurry of lettuce for pesticide analysis, then prior notice requirements would not apply. But where a sample is food, as defined under prior notice, the sample is not excluded from the final rule even if it is imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption and not for resale. However, as outlined in the Prior Notice Final Rule Draft CPG, FDA's and CBP's enforcement discretion policy would apply to these foods, under which FDA and CBP should typically consider not taking any regulatory action when there is no prior notice and the food is a sample not intended for human or animal consumption.

Samples of food are considered to be for quality assurance, research or analysis purposes, rather than human or animal consumption, when they are in small quantities (i.e., quantities consistent with the quality assurance, research, or analysis purposes) and the entire sample is used up by the analysis, destroyed after analysis, or destroyed following a reasonable retention period after analysis. The analysis may include sensory examination, such as organoleptic examination for determining tea quality or detecting the presence of histamines. Evidence that an article of food is for quality assurance, research, or analysis purposes only might include, among other evidence, markings on the food and shipping documents.

FDA disagrees with the comments that suggest that prior notice should only be required for food, including samples, that is intended for consumption. In the preamble to the IFR, FDA discussed extensively its rationale for not limiting the prior notice requirements to food for consumption in the United States. (See 68 FR 58974 at 58990 and 58991.) This rationale still holds. FDA also disagrees with the comments that state samples should be exempted from prior notice if the consumption of the samples is minor and is contained within a controlled environment, such as a test kitchen or trade booth, or the quantity involved with each shipment is minuscule, such that it ''is too small a quantity to pose a potential national security threat.'' The purpose of the Bioterrorism Act is not limited to terrorist activity or other national security threats; its purpose is ''[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism *and other public health emergencies*'' [emphasis added]. (Public Law 107–188.) Moreover, we have had incidents where small quantities of samples that had been consumed caused serious illness or death. For example, in the preamble to the IFR, FDA noted that ''in the summer of 2003, FDA received a report from a poison control center in country T concerning the acute poisoning of 9 men (one died) from ingestion of an herbal fermented wine. Symptoms occurred within minutes. Reports indicated that this product may have been exported to the United States in small quantities for test marketing in restaurants. This underscores the importance of FDA receiving prior notice of all food imported or offered for import.'' (68 FR 58974 at 58993.)

8. Additional Exclusions Requested—Mail

(Comments) One comment sought better information regarding the sending of food products as international packages or bringing food products into the United States personally in their baggage.

(Response) Information on the sending of food through international mail can be found at: *http://www.cfsan.fda.gov/~pn/pnmail.html*. Food products for personal use brought into the United States that accompanies an individual are not subject to the requirements of prior notice (§ 1.277(b)(1)).

(Comment) One comment questions whether express couriers, such as EMS, FEDERAL EXPRESS, DHL, and TNT, are considered ''international mail.''

(Response) Section 1.276(b)(8) of the final rule defines international mail to mean foreign national mail services and further states that international mail does not include express consignment operators or carriers or other private delivery services unless such service is operating under contract as an agent or extension of a foreign mail service. Therefore, if food items are shipped through one of these services and the food items are not otherwise excluded from prior notice requirements, prior notice is required.

(Comments) One comment questions if the rule applies to the military postal service, which is a subsidiary of the United States Postal Service that operates overseas.

(Response) If the military post offices are located outside of the United States, as defined for the purposes of prior notice, articles of food would be subject to the requirements of prior notice (§ 1.277(a)).

(Comments) One comment states that the costs and resource implications of FDA applying this type of approach to single-piece, person-to-person,

international mailings of manufactured food products may outweigh any perceived benefits. FDA's current approach to prior notice forces the U.S. Postal Service (USPS), FDA, and CBP to dedicate substantial resources simply to attempt effective implementation of these regulations. The comment asks that FDA: (1) Exempt these single-piece, personal use mailings from prior notice; (2) allow CBP to continue using its time-tested strategies for screening and selections of items from mail shipments arriving at the first port of entry; (3) allow the delivery of mail items containing food, even if the contents are not accompanied by prior notice confirmation numbers to the U.S. address, as long as the U.S. authorities find no problem with the contents at border inspection; and (4) work in close coordination with CBP and USPS to promote more clarity of understanding on the procedures for packages where the majority of the contents are not food items. The comment states that these policies will need to be uniformly applied, and also must ensure that proper accountability is provided to the mailers and recipients whose mailed items might have been refused, seized, or destroyed.

Another comment requests an exemption for manufactured food products that are sent via international mail for noncommercial purposes. Some comments complain that the required data are very complex for the average customer and the system is not very customer-friendly, entries take a long time, and each single item has to have a separate prior notice.

A few comments state that most of the required information, such as the manufacturer's registration number, is not available to private persons, and therefore, not available to international mail and mail by express carriers. The comments note that this is particularly problematic, since FDA does not provide information on registration of facilities to private parties. The comments further note that a business relationship between the buyer of the goods (e.g., a private person), the mail service and the manufacturer will in general not be present. In addition, the comments state that to file prior notice, Internet access and knowledge of the English language is required. The comments contend that mail users will have to bear unreasonable disadvantages and unequal treatment. The comments argue that this seems disproportionate because most shipments are of low value. Therefore, the comments suggest that FDA simplify the prior notice requirements through FDA's PNSI for mail users.

In addition, the comments suggest that: (1) Private persons should be excluded from prior notice; (2) the requested information should be limited to some key-information, such as the submitter and the type of food; (3) all mail services, including express carriers, should fall under the definition of ''international mail;'' and (4) FDA should provide on their Web site dedicated information for companies and consumers about international mail, in different languages.

(Response) The act does not exempt noncommercial shipments with a noncommercial shipper. FDA explained this position in the preamble to the IFR (See 68 FR 58992) and believes that this rationale is still valid. However, under the Prior Notice Final Rule Draft CPG, when food is purchased or otherwise acquired by an individual for nonbusiness purposes and sent to an individual with a noncommercial shipper, FDA and CBP would typically consider not taking regulatory action if prior notice is not submitted. This proposed enforcement discretion policy would be continued from the Prior Notice Interim Final Rule CPG.

Express consignment operators or carriers or other private delivery services, unless such service is operating under contract as an agent or extension of a foreign mail service, are not considered international mail. (See § 1.276(b)(8) of the final rule). The IFR created a category for international mail because the rule imposed slightly different requirements for such imports. For example, given the nature of international mail imports, prior notice required the planned date of mail instead of the anticipated arrival information; it required the identification of the recipient instead of the importer, owner, and consignee; and it did not require the mode of transportation, carrier, planned shipment information, and hold information. In addition, for international mail the prior notice must be submitted before the article of food has been sent in order to allow the prior notice confirmation number to accompany the package. We do not believe these changes are relevant for shipments arriving by express consignment operators or carriers or other private delivery services. For example, if the express carrier submits the prior notice, it will be able to include the mode of transportation, carrier, and other data elements not included in the international mail category. In situations where the submitter and/or transmitter is not the express consignment operator or carrier, the final rule now allows the submission of the express consignment operator or carrier tracking number in lieu of anticipated arrival and certain planned shipment information. Thus, we do not believe the final rule should be revised to expand the definition of international mail to include express consignment operators or carriers or other private delivery services.

FDA also does not agree the prior notice requirements should not apply to low-value shipments, as neither the Bioterrorism Act nor experience with samples support this approach. See FDA's responses to comments previously under section III.D.7 of this document ''Additional Exclusions Requested—Samples'' for further discussion on this point.

(Comments) A few comments suggest that FDA modify the existing procedures for commercial shipments arriving by international mail. The comments state that complying with the requirements of FDA's prior notification procedure results in an unbearable workload for mail order companies, which sometimes mail thousands of packages at one time, with each package requiring a prior notice. The comments suggest that manufacturers submit their company information and product information for similar items once and then add the different recipients' addresses at the end.

(Response) FDA's PNSI has been designed to accommodate repetitive information so that the basic prior notice can be created and saved, and each U.S. recipient can be added at the end of each subsequent prior notice. A separate prior notice confirmation number is generated for each article of food (and recipient). Similarly, a number of the software programs that customs brokers use to file prior notice and entry submissions with ABI/ACS do allow for repetitive information to be saved on the filer's computer and used for future shipments, as appropriate.

9. Additional Exclusions Requested—Gifts

(Comments) Several comments recommend that FDA expand the exemption already provided for homemade food products sent as gifts (§ 1.277(b)(2)) or food items carried in for ''personal consumption'' (§ 1.277(b)(1)) to include all gifts, regardless of mode of transportation, that are intended for personal use. Another comment asks for clarification regarding food articles sent as gifts to persons in the United States for personal consumption. This comment believes that prior notice is only required for food articles that will be

distributed or traded in the United States.

(Response) If the food was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States, prior notice is not required (§ 1.277(b)(2)). Other food products sent by an individual and imported for noncommercial purposes with a noncommercial shipper are not excluded from prior notice requirements. FDA explained this position in the preamble to the IFR (See 68 FR 58992) and believes that this rationale is still valid. However, under the Prior Notice Final Rule Draft CPG, when gifts are shipped by an individual for nonbusiness reasons to an individual without prior notice, FDA and CBP should typically consider not taking regulatory action. This proposed policy would apply regardless of the mode of transportation.

10. Additional Exclusions Requested—Low-Value

(Comments) Many comments request a *de minimis* exemption from prior notice for all low value shipments (less than $200). The comments assert that the prior notice requirements can be quite onerous for small shipments and that low value shipments of prepared food sent from and to individuals for their personal use are of little risk to the U.S. food supply, especially relative to the individual size and large number of commercial shipments entering the country. One comment states that a low value exemption from prior notice for shipments under $200, whether for personal or commercial use, would be consistent with CBP's *de minimis* exemption. In addition, one comment states that foreign individuals shipping low value gifts to the United States will not know the Bioterrorism Act's requirements and will not be able to obtain the manufacturer's phone and registration numbers. The comment states that these numbers are not readily available to the consumer when products are purchased in small quantities. One comment requests an exemption for small dollar value mail-order sales to U.S. customers ($100 or less) since the prior notice system is difficult and costly to implement for this type of business.

(Response) FDA disagrees. Low-value shipments are clearly subject to the terms of section 801(m) of the act as they are ''articles of food imported or offered for import.'' Moreover, low-value articles of food can pose the same threat level to the U.S. food supply as do articles of food that cost more, as we explained in the IFR (68 FR 58974 at 58993). However, under the proposed enforcement discretion policy, described in the Prior Notice Final Rule Draft CPG, when food is sent by an individual for noncommercial purposes with a noncommercial shipper without prior notice, regardless of the article's value, FDA and CBP should typically consider not taking any regulatory action.

(Comments) Two comments recommend that FDA consider incorporating into the final rule a limited exemption for very small quantities of food. One of those comments considers a small quantity to be under 80 pounds or less than 100 bottles.

(Response) FDA disagrees and will not place a weight or quantity restriction on the requirements for prior notice. ''Small quantity'' shipments are clearly subject to the terms of section 801(m) of the act as they are ''articles of food imported or offered for import.'' Similar to low-value articles of food, small quantity shipments can pose the same threat level to the U.S. food supply as do articles of food that arrive in larger quantities. If we were to exempt small quantity food shipments, small quantities of poisoned food (with the potential to do a high level of damage) could be imported into the United States without prior notice, thereby negating the purpose of the Bioterrorism Act.

11. Additional Exclusions Requested—Couriers

(Comments) One comment reports that many of the express couriers refuse to do the necessary paperwork for shipments being sent via their services. Therefore, the manufacturers are required to submit prior notice. However, the manufacturer does not have the necessary information needed to complete the form, such as flight number, departure and arrival time, etc. The comment suggests that express courier shipments should be treated in the same manner as mail shipments.

(Response) FDA disagrees but has modified the rule to address the underlying concern. Food imported or offered for import via these private delivery services are subject to prior notice, which must be submitted within the timeframe of the applicable mode of transportation—water, air, or land (§ 1.279). In the prior notice CPG published in November 2004 (November 9, 2004; 69 FR 64959), FDA and CBP stated that they generally would consider not taking regulatory action if the prior notice is inadequate because it does not include the required anticipated arrival information and/or planned shipment information and if, among other criteria, the prior notice includes the shipment's tracking number in lieu of the required anticipated arrival information and/or planned shipment information. A person shipping food into the United States via an express courier will have access to the tracking number to use in lieu of the flight number or other planned shipment information. FDA has incorporated this policy in § 1.281 of the final rule, which allows the submitter and/or transmitter to submit the express consignment operator or carrier tracking number in lieu of anticipated arrival and certain planned shipment information as long as neither the submitter nor transmitter is the express consignment operator or carrier and prior notice is submitted via PNSI.

12. Additional Exclusion Requested—Gift Packs

(Comments) One comment requests clarification of the interpretation pertaining to gift baskets. The comment states it is unclear whether prior notice is based upon the description of the entire gift basket as an entity, which is currently the case for CBP entry processing, or on the individual items within the basket. One comment asks FDA to exempt gift baskets because they are ''no-risk.''

(Response) Under the final rule, a gift pack is not considered a single article of food (e.g., a gift pack consisting of four articles of food would require four prior notice submissions). This is because a gift pack is not manufactured/processed as a single product, but is packed by consolidating a variety of articles of food into a unit, with or without other nonfood articles. However, FDA and CBP are proposing to continue their enforcement discretion policy for gift packs, which the agencies first announced in their March 2005 CPG (March 4, 2005; 70 FR 10657). Under that policy, ''FDA and Customs Border Protection (CBP) staff should typically consider not taking regulatory action if there is a prior notice violation because a single prior notice is submitted for a gift pack and the identity of the facility that packed the gift pack is submitted in lieu of the identity of the manufacturer(s), provided that the gift pack is purchased or otherwise acquired by an individual and imported or offered for import for nonbusiness purposes.''

There is no CBP rule or regulation, nor is there a General Rule of Interpretation (GRI) under which gift packs are classified. In the case of ''gift packs'' that contain multiple products,

CBP tries to classify the gift pack using the concept of a set. That is, if the products included in a gift pack are part of a common activity, the gift pack may be classified under the HTS code that is most applicable. However, CBP does not consider eating to be a common activity, even when all items in a gift pack are to be consumed. Therefore, unless there has been an applicable CBP ruling, entries of gift packs should be declared to CBP using the HTS code for each item included within the gift pack. This principle applies even when there are food and nonfood items in the pack (e.g., a soup mug and a can of soup) as well as for make-your-own gift packs (e.g., if you created a gift pack by personally selecting individual items from a list of available products).

13. Additional Exclusions Requested—Household Goods and Unaccompanied Baggage

(Comments) Many comments suggest that the final rule exempt unaccompanied food that is included in a shipment of personal household goods, if the food is owned by and intended to be consumed by the shipper of the household goods, their family or friends, and if the food is not to be offered for sale or distribution. In addition, several comments suggest that food contained in unaccompanied baggage should be exempt from the requirements of prior notice. The comments state that the owner of the food never changes, and that there is no sale or transfer of the goods. The comments believe that shipping food items contained in household goods or unaccompanied baggage to the United States is equivalent to carrying the items in baggage for personal use. The comments further state that household goods are even more personal than food accompanying a traveler because although it travels from one personal residence to another, it remains part of the same household or home. The comments suggest that FDA not require as many data elements for these types of shipments, and allow a minimum amount of food/consumables to be imported without prior notice. The comments believe that it will be unnecessarily tedious and exhaustive for individuals to input the required information into the FDA PNSI, and that it is unreasonable to ask individuals to destroy or leave behind hundreds of dollars of canned goods.

Additionally, one comment suggests that persons on duty in the United States as members of the armed forces of a North Atlantic Treaty Organization (NATO) or Partnership for Peace or civilian component attached to or employed by NATO Headquarters, Supreme Allied Commander Transformation Atlantic and their immediate families be granted an exemption from prior notice. The comment contends that these individuals have undergone an intense screening process prior to being selected for a NATO position. One comment requests that FDA exempt Department of Defense active duty military and civilian personnel unaccompanied baggage and household good shipments.

(Response) Section 801(m) of the act does not authorize an exclusion from prior notice for food imported as part of unaccompanied baggage or food included as part of a shipment of personal household goods. Therefore, food contained in household goods and accompanied baggage are subject to prior notice requirements.

However, a proposed enforcement discretion policy in the Prior Notice Final Rule Draft CPG would apply to most or all of the household goods and unaccompanied baggage shipments described in the comments. Under the proposed policy, FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for noncommercial purposes with a noncommercial shipper without prior notice. We consider food in household goods, including military and civilian transfers, to be food imported or offered for import for a noncommercial purpose. This enforcement discretion policy would be a continuation of the policy in effect since FDA issued the June 2004 Prior Notice Interim Final Rule CPG (June 29, 2004, 69 FR 38906).

14. Additional Exclusions Requested—Noncommercial Use

(Comments) One comment asserts that shipments for personal consignment when sent from a business are, by definition, noncommercial, due to the fact they are purchased for personal use and not for resale. The comment suggests that FDA define noncommercial shipments to include any consignment to an individual for personal, noncommercial use, as exempt from the requirements of prior notice, regardless of whether the shipper is a business entity or an individual.

(Response) FDA disagrees. As we described in the IFR, there is no basis in the statute for an exemption based on shipments that are for personal use, regardless of whether the shipper is a commercial or noncommercial (i.e., an individual) entity (68 FR 58974 at 58992). However, we are proposing an enforcement discretion policy in the Prior Notice Final Rule Draft CPG for food imported or offered for import for noncommercial purposes with a noncommercial shipper without prior notice, irrespective of the type of carrier. Under the proposed policy, FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for noncommercial purposes with a noncommercial shipper without prior notice. The noncommercial shipper, under this policy, would be an individual (e.g., the individual delivers the food to a post office or common carrier for delivery to self, family member, or friend for nonbusiness purposes).

When a business ships a food, it is for a commercial or business purpose. The situation as described in this comment, therefore, would not meet the criteria covered by the enforcement discretion policy since the shipper is a business.

(Comments) One comment requests that private persons should be excluded from the requirements of prior notice. The comment states that commercially-produced food imported for the personal use of an individual, even if included in a shipment of personal effects, should not require prior notice.

(Response) Section 801(m) of the act does not authorize a broad exclusion from prior notice for food imported or offered for import by private persons. Therefore, food that is commercially produced that is imported for the personal use of an individual, as described in the comment, would be subject to this final rule.

However, we are proposing an enforcement discretion policy in the Prior Notice Final Rule Draft CPG for food imported or offered for import for noncommercial purposes with a noncommercial shipper, irrespective of the type of carrier without prior notice. Under the proposed policy, FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for noncommercial purposes with a noncommercial shipper without prior notice. This policy would cover the food described in the comment, commercially produced food imported for the personal use of an individual, as long as the shipper is noncommercial. This enforcement policy would continue the policy initially announced in our June 2004 Prior Notice Interim Final Rule CPG. The draft CPG describes a noncommercial purpose as one where the food is purchased or otherwise acquired by an individual for nonbusiness purposes, and a noncommercial shipper is one where the shipper is an individual (e.g., the individual delivers the food to a post

office or common carrier for delivery to self, family member, or friend for nonbusiness purposes, i.e., not for sale, resale, barter, business use, or commercial use). Examples of foods imported or offered for import that may be covered by this noncommercial category are: (1) Food in household goods, including military and civilian transfers; (2) food purchased by a traveler and mailed or shipped to the traveler's U.S. address by the traveler, not the commercial establishment; and (3) gifts purchased at a commercial establishment and shipped by the purchaser, not the commercial establishment.

(Comments) One comment suggests that older wines already owned by a U.S. individual and imported solely for personal consumption be exempt from prior notice. Another comment provides an example of an individual who owns a wine cellar overseas and arranges for cases of wine to be sent to him/herself in the United States for personal consumption.

(Response) As discussed previously, there is no basis in section 801(m) of the act to exclude food imported or offered for import for personal use. Although this importation is subject to the provisions of this final rule, if the wine is imported or offered for import by an individual for noncommercial purposes and shipped by himself to himself using a noncommercial shipper without prior notice, the proposed enforcement discretion policy in the Prior Notice Final Rule Draft CPG would apply. Under the proposed policy, FDA and CBP generally should typically consider not taking regulatory action when an article of food is imported or offered for import for noncommercial purposes with a noncommercial shipper without prior notice.

(Comments) One comment suggests that small shipments of nominal value for personal, noncommercial use should be exempted from the requirements of prior notice. The comment states that the express industry handles many of these shipments now, which include purchases from a growing number of Internet-based sellers. The comment asserts that these small shipments for personal use do not qualify as a risk to the domestic food supply, and should be exempt from prior notice.

(Response) As we discussed previously, section 801(m) of the act does not authorize an exclusion for small quantity or low-value shipments. FDA notes that under the Prior Notice Final Rule Draft CPG, FDA and CBP should typically consider not taking regulatory action when an article of food is imported or offered for import for noncommercial purposes, such as small shipments for personal use, with a noncommercial shipper without prior notice. However, this proposed enforcement discretion policy would not extend to situations where the shipper is a commercial entity (e.g., a retail store, an Internet company, etc.).

15. Additional Exclusions Requested—U.S. Goods Returned

(Comments) A few comments request exemptions for unadulterated U.S. goods being returned. The comments state that these items do not pose an adequate threat to the nation's food supply. In addition, these comments indicate that it is not possible to provide the manufacturer's registration number for merchandise that was manufactured in the United States and then exported overseas, where the merchandise can be purchased and then shipped back to the United States. The comments state that the original manufacturer in the United States will not provide their registration number in these scenarios.

(Response) FDA disagrees. As discussed in the IFR, FDA believes that, for the purpose of section 801(m) of the act, the phrase ''imported or offered for import into the United States'' applies to articles of food of U.S. origin that are ''reimported'' back into the United States (68 FR 58974 at 58990). FDA believes that this interpretation, and the underlying rationale for it, are still valid. We also believe, as explained in the IFR, that section 801(m) of the act does not authorize us to exclude ''low-risk'' food shipments from prior notice requirements (68 FR 58974 at 58993).

The inability to submit the manufacturing facility's registration number is not a valid reason for excluding such a shipment from prior notice requirements. However, we are revising § 1.281(a)(6) of the final rule to provide flexibility in submitting the identity of the manufacturer. In addition to the name of the manufacturer, the submitter may submit either the registration number, city, and country of the manufacturer, or both the full address of the manufacturer and the reason why the registration number is not provided.

(Comments) One comment requests that FDA provide clear direction whether prior notice is required for food shipments of U.S. products that are returned to the United States after refusal by a foreign government.

(Response) FDA requires prior notice for an article of food that has been exported from the U.S. and is being ''reimported'' back into the U.S., as we consider such a shipment as being ''imported or offered for import into the United States'' (§ 1.277(a)), regardless of whether it was initially a U.S. export that was refused by a foreign government. We would require prior notice for these shipments even if entry is not required by CBP. In these cases, we recommend that prior notice be submitted via PNSI.

16. Additional Exclusions Requested—In-Transit Shipments

(Comments) Several comments request that in-transit shipments be excluded from the prior notice requirements. The comments express concern that submitting prior notice for such shipments presents a tremendous burden on industry. Companies may seek to avoid the potential cost and disruption by diverting freight to other routes rather than use transshipment facilities through U.S. territory for destinations in Mexico and Canada.

The comments note that requiring prior notice for shipments not intended for consumption in the United States appears to be beyond the statutory authority provided by the Bioterrorism Act. The comments reason that in-transit shipments are under strict CBP regulations and control by the carrier with respect to movement and are secured by a bond, and thus, the food cannot be diverted to enter the U.S. food supply.

(Response) FDA disagrees. The IFR contains FDA's rationale and legal support for determining that for the purpose of section 801(m) of the act, the phrase, ''imported or offered for import into the United States,'' applies to articles of food of U.S. origin that are ''reimported'' back into the United States, as well as to food that transits the United States (See 68 FR 58974 at 58990). FDA continues to believe this determination is correct and is not convinced it should be revised. Moreover, the comment implies that these shipments should be exempt from prior notice requirements since the shipments are under strict CBP control and are secured by a bond, i.e., that these shipments are low-risk. However, section 801(m) of the act does not authorize an exemption for articles of food that are ''low risk'' or covered by programs of other agencies, such as CBP or foreign government regulatory authorities.

(Comments) One comment requests that the final rule exempt foreign-to-foreign transit mail; i.e., mail shipments that simply transit the United States for delivery in a third country. The comment reasons that these items are not intended for U.S. consumption (i.e., not intended for a U.S. recipient); represent the transfer of universal

service obligation mail between sovereign governmental entities; and are items from foreign mailers who would not know when to submit the required prior notice data as they do not always know whether their mail dispatches will be transiting the United States.

(Response) As we explained in the IFR and elsewhere in this notice, food that is not intended for U.S. consumption is still within the scope of ''imported or offered for import'' (68 FR 58974 at 58991) and is subject to prior notice requirements. However, we understand that in the case of foreign-to-foreign mail, the sender does not have control over the transportation route that the foreign-to-foreign shipment will transit. Therefore, we are proposing an enforcement discretion policy in the Prior Notice Final Rule Draft CPG that would address this situation. Under that policy, FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import via international mail without prior notice and there is no U.S. recipient.

(Comments) Comments filed by express carriers request that FDA exempt all non-U.S. destination shipments from the requirement to provide prior notice. The comments note that the shipment is in the custody of the express carrier at all times and the risk of diversion from the highly-controlled environment in which express shipments move, particularly in-bond shipments, is low. The comments also reason that foreign shippers and foreign consignees do not submit the required prior notice data because they are, by design, not aware that their shipments will transit the United States on their way to a third country because express carriers do not disclose flight routes of packages either to shippers or consignees due to security concerns. If prior notice must be submitted, express carriers will be required to make the customers aware of routes, nullifying this simple but effective security precaution.

(Response) As described in the previous comment, prior notice applies to food imported or offered for import notwithstanding that the food is not intended for U.S. consumption. However, we recognize that, when shipping via express carrier or other private delivery service, the sender does not have control over the transportation route that the foreign-to-foreign shipment will transit. For example, a person in Europe intends to mail an article of food to South America via an express carrier. This person has no control over the package entering the United States if the express carrier, for example, chooses to consolidate shipments going to South America in Florida. The proposed enforcement discretion policy in the Prior Notice Final Rule Draft CPG states that FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import and the carrier is an express consignment operator or carrier; neither the submitter nor transmitter is the express consignment operator or carrier; and the importer, owner, or recipient/consignee is not located in the United States.

(Comments) Several comments request that FDA exempt shipments of food that move from Canada to Canada under bond by rail through Northern Maine. These comments note that such shipments moving by rail in bond cannot be delivered to points within the United States, must move from Canada to Canada, and that the food products in trailers on rail cars cannot be diverted to enter the U.S. food supply. The comments state that having to submit prior notice puts the U.S. rail carriers at a competitive disadvantage when competing for Canadian rail business. Other comments request that FDA exempt shipments of food that move from Canada to Canada by marine and trucking companies. The comments reason that their Canada to Canada in-transit shipments move in sealed containers and that providing detailed information for products that are never going to enter the U.S. food supply is a hardship to U.S. businesses.

(Response) FDA disagrees. The Bioterrorism Act does not create any exemptions for this situation and therefore, there is no basis for excluding such business operations from prior notice requirements. The preamble to the IFR provides our rationale for determining that food that transits the United States falls under the scope of this rule (68 FR 58974 at 58990) and we continue to hold this view. Moreover, the comment implies that these shipments should be exempt from prior notice requirements because they pose a relatively low risk by moving by rail, in bond, and/or under seal. Even if such food shipments are a low risk, as discussed elsewhere in this notice, section 801(m) of the act does not authorize a ''low risk'' exemption. However, the proposed guidance in the Prior Notice Final Rule Draft CPG (which would continue the policy established in the March 2005 revision to the Prior Notice Interim Final Rule CPG) addresses imported food arriving from and exiting to the same country. It describes the situations and conditions under which FDA and CBP should typically consider not taking regulatory action when prior notice is not submitted.

(Comments) Another comment suggests that the FDA work cooperatively with CBP such that transshipments that follow the CBP transshipment procedures are not required to enter additional information for FDA prior notice purposes, and that shipments that may pose a risk are identified through the CBP process. The comment also states that the current requirements in the agreement for secure in-transit procedures could be modified to meet the objective of the prior notice IFR to prevent the entry of products that have been intentionally adulterated. Shipments that follow the proposed secure in-transit procedures would not be distributed in the United States and would be of minimal risk to human or animal security and safety. The comment also suggests that FDA can achieve certainty of safety of overseas shipments that are transiting to the United States through Canada by conducting examinations at the first point of arrival in North America and through the expansion of existing bilateral harmonized risk screening and lockout sharing systems to accommodate additional high-risk commodities.

(Response) CBP's secure in transit procedures cannot substitute for the submission of prior notice for in transit shipments because they do not meet the requirements of the Bioterrorism Act, such as providing FDA with certain specified information. The information in a prior notice is necessary for FDA to determine whether it should examine the food at the U.S. port of arrival. In addition, section 801(m) of the act does not authorize an exemption for articles of food that are covered by programs of other agencies, such as CBP, even if those programs would ''prevent the entry of products that have been intentionally adulterated.''

(Comments) One comment notes that there are many ocean containers crossing into the United States for transshipment purposes and prior notice is not being submitted. The comment asks how to ensure that ocean containers that arrive in Canada or Mexico and cross into the United States by rail have prior notice submitted in a timely fashion, or submitted at all, when shippers are not always aware of when the containers are due to cross or on which train.

(Response) FDA addressed this issue in the IFR when it allowed any person with knowledge of the required information to submit prior notice. In

§ 1.285 of the proposed prior notice rule (68 FR 5428, February 3, 2003), FDA provided that a purchaser or importer of an article of food who resides or maintains a place of business in the United States or an agent thereof was authorized to submit prior notice. FDA further proposed that if the article of food is imported for in-bond movement through the United States for export, the prior notice must be submitted by the arriving carrier or, if known, the carrier making the in-bond entry. Many comments to the proposed rule objected to the limitation that only a person who resides or maintains a place of business in the United States can submit the prior notice. In addition, comments pointed out that under some circumstances, the U.S. importer or purchaser or carrier would not have all the information required by prior notice, but that other entities, e.g., the foreign manufacturer/ processor, shipper, or exporter, would have the required information. Many comments stated that entities other than U.S. firms or carriers should be allowed to submit prior notice.

In response, FDA modified this provision in the IFR and removed the restriction on who can submit prior notice. Accordingly, § 1.278 of the IFR provides that any person with knowledge of the required information may submit prior notice to FDA. FDA has retained this provision in the final rule.

17. Additional Exclusions Requested—Diplomatic Pouch

We have determined that prior notice does not apply to food in diplomatic pouches because Art. 27(3) of The Vienna Convention on Diplomatic Relations (1961) states that: ''The diplomatic bag shall not be opened or detained.''

(Final Rule) Section 1.277(b)(7) of the final rule adds a new exclusion to the rule: ''Articles of food subject to Art. 27(3) of The Vienna Convention on Diplomatic Relations (1961), i.e., shipped as baggage or cargo constituting the diplomatic bag.''

18. Additional Exclusions Requested—Seeds for Planting

(Comments) One comment requests that FDA exempt imported seed that is destined solely for planting purposes, even if small amounts found unsuitable for planting will end up in the food supply. The comment also requests that the FD3 flags be removed from HTS codes that cover seed for sowing or planting or, alternatively, to clarify that FD3 flagged HTS codes may be ''disclaimed'' at entry.

(Response) Whether seeds are subject to prior notice depends on whether the seeds meet the definition of food. Some seeds, such as sesame seeds for baking or as a garnish, are food for which prior notice must be submitted to FDA before the seed is imported or offered for import into the United States. Some seeds are capable of both food and nonfood uses, such as seeds that are sometimes processed into cooking oil and other times processed into industrial-use oil. As discussed elsewhere in this document, FDA considers such seed to be food for the purpose of prior notice if the seed is reasonably likely to be directed to a food use. Even when seed is for a nonfood use, such as seeds for growing flowers, if a small portion of that seed is reasonably likely to be directed for use in animal feed, prior notice would be required. Because seeds, including seeds for planting, may be subject to prior notice under section 801(m) of the act, we believe they are properly flagged as FD3.

Nonetheless, we note that the draft Prior Notice Final Rule CPG, announced elsewhere in this issue of the **Federal Register**, proposes an enforcement policy regarding seeds for planting. Under the draft policy, FDA and CBP should typically consider not taking any regulatory action regarding seeds that will be used for cultivation if they are imported or offered for import without prior notice. The policy would apply when no more than a small portion of that seed is diverted from cultivation to animal feed or other food use. It would not apply, however, where the seed is used for the production of edible sprouts, such as alfalfa seeds for the production of alfalfa sprouts.

E. Who is Authorized to Submit Prior Notice? (§ 1.278)

Section 1.278 of the IFR states that prior notice may be submitted by any person with knowledge of the required information and identifies this person as the submitter. The IFR also states that the submitter also may use another person to transmit the required information on his/her behalf and identifies the person who transmits the information as the transmitter. The IFR also states that the submitter and transmitter may be the same person.

(Comments) Several comments note that carriers often do not have access to the information required to classify articles in the FDA system (the commercial invoice and packing list) because it is proprietary information that the owners of the goods will not want to give to intermediaries in the transportation chain. Also, there is confusion regarding who is responsible for submitting prior notice. This causes particular problems for carriers of in-bond cargo transiting the United States. The comment suggests that exempting in-bond shipments from prior notice would allow carriers to move the shipment without having to submit prior notice and permit the broker at the port of entry, who does get the necessary documents, to properly submit the prior notice. (Response) FDA disagrees that there is confusion regarding who is responsible for submitting prior notice. The IFR and this final rule expressly state in § 1.278 that any person with knowledge of the required information may submit the prior notice. FDA provided this flexibility as to who could submit prior notice in response to comments that FDA received on the proposed rule, which urged FDA not to limit who could file prior notice to either a purchaser or importer of an article of food who resides or maintains a place of business in the United States or an agent thereof, or to the arriving carrier or the carrier making the in-bond entry if the article of food is imported for in-bond movement through the United States for export. (See 68 FR 58974 at 58994.) Comments to the proposed rule also pointed out that under some circumstances, the U.S. importer or purchaser or carrier would not have all the information required by prior notice, but that other entities, e.g., the foreign manufacturer/ processor, shipper, or exporter, would have the required information. Many comments stated that entities other than U.S. firms or carriers should be allowed to submit prior notice. In response, FDA modified this provision in the IFR and removed the limitation on who can submit prior notice.

(Response) FDA disagrees that there is confusion regarding who is responsible for submitting prior notice. The IFR and this final rule expressly state in § 1.278 that any person with knowledge of the required information may submit the prior notice. FDA provided this flexibility as to who could submit prior notice in response to comments that FDA received on the proposed rule, which urged FDA not to limit who could file prior notice to either a purchaser or importer of an article of food who resides or maintains a place of business in the United States or an agent thereof, or to the arriving carrier or the carrier making the in-bond entry if the article of food is imported for in-bond movement through the United States for export. (See 68 FR 58974 at 58994.) Comments to the proposed rule

also pointed out that under some circumstances, the U.S. importer or purchaser or carrier would not have all the information required by prior notice, but that other entities, e.g., the foreign manufacturer/processor, shipper, or exporter, would have the required information. Many comments stated that entities other than U.S. firms or carriers should be allowed to submit prior notice. In response, FDA modified this provision in the IFR and removed the limitation on who can submit prior notice.

Accordingly, § 1.278 of the IFR provides that any person with knowledge of the required information may submit prior notice to FDA. FDA noted in the preamble to the IFR that any person may now take responsibility for submitting prior notice for a particular article of food, as long as that person can provide all the required information. This person is referred to as the submitter in the IFR. The IFR also states that the submitter may use another person to transmit the required information to FDA. For ease of reference, the person who transmits the prior notice is referred to as the transmitter in the IFR. FDA has retained these provisions in the final rule. FDA further notes that to the extent that there is confusion, the parties to the transaction may want to consider a means for identifying which party is responsible for submitting prior notice as part of their business arrangements (e.g., within their contract).

(Comments) Several comments note that problems arise because the IFR creates no particular obligation on any particular party within the distribution system to submit prior notice. One comment states that because prior notice can be submitted by any person who has the information, there are many cases of duplicate prior notices filed by different parties for the same shipment. Another comment suggests that FDA select one party to be responsible, suggesting the appropriate party would be either the exporter or the importer-broker.

(Response) Please see the response to the previous comments. FDA's proposed rule did specify a limited class of individuals who could provide prior notice and this limitation received significant adverse comment. Accordingly, both the IFR and this final rule provide that any person with knowledge of the required information may submit the prior notice (§ 1.278). FDA notes that the parties to a transaction can elect to take steps among them to identify which party should submit the prior notice and ensure that the party submitting prior notice has the appropriate and correct information.

(Comments) One comment suggests that it is improper for a carrier to require the shipper to submit prior notice when the shipper is not shipping goods into the United States, but the carrier unilaterally moves the goods through their hub in the United States, thereby causing the shipment to enter the United States. Another comment notes that the data elements required in a prior notice are not available to the shipper, inferring that it is not possible for a shipper to submit prior notice.

(Response) Neither the IFR nor this final rule specifies who must file prior notice. Rather, the rule provides that any person with knowledge of the required information may submit prior notice to FDA. Accordingly, it is not for FDA to say whether it is proper for a carrier to require a shipper to submit prior notice as a condition of shipment, as that is a matter between two contracting parties. We note that the Prior Notice Final Rule Draft CPG proposes an enforcement policy for foreign-to-foreign mail. Under the proposed policy, if there is no prior notice FDA and CBP should typically consider not taking any regulatory action in the case of international mail where the recipient is not in the United States since the sender does not have control over the transportation route that the foreign-to-foreign mail will transit.

(Comments) One comment asks whether there are any prior notice obligations to fulfill if the exporter is not required to register with the FDA under the Bioterrorism Act (21 CFR part 1, subpart H).

(Response) Prior notice and registration are separate obligations under different regulations and with differing applicability. For example, registration applies to facilities that manufacture, process, pack or hold food that will be consumed by humans or animals in the United States. By comparison, prior notice generally applies to FDA-regulated food being imported or offered for import into the United States, regardless of whether it will be consumed in the United States and regardless of whether the exporter must register.

(Comments) One comment asks for clarification of the legal responsibility of the submitter.

(Response) Among the requirements of the final rule, the prior notice information must be accurate and timely. As described in § 1.283, if an article of food is imported or offered for import and the notice is inaccurate or untimely, the food is subject to refusal of admission. Other consequences under the act for those who fail to comply with the prior notice requirements, such as by submitting inaccurate or untimely notice, are described in § 1.284.

(Final rule) Section 1.278 of the final rule states that prior notice may be submitted by any person with knowledge of the required information and identifies this person as the submitter. The final rule also states that the submitter may use another person to transmit the required information on his/her behalf and identifies the person who transmits the information as the transmitter. The final rule also states that the submitter and transmitter may be the same person.

F. When Must Prior Notice Be Submitted to FDA? (§ 1.279)

Section 801(m)(2)(A) of the act states that FDA shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, and any timeframe FDA adopts in the final rule must be justified under this standard. Section 1.279(a) of the IFR requires FDA to receive prior notice and confirm it for review no less than 2 hours before arriving at the port of arrival by land via road, no less than 4 hours before arriving at the port of arrival by air and land via rail, and no less than 8 hours before arriving at the port of arrival by water. We explained in the preamble to the IFR that the ''interim final rule provides for greatly reduced timeframes for foods [from what we had proposed] based on mode of transportation. These timeframes are what FDA has determined are the minimum timeframes necessary to allow it to satisfy the statutory mandate that the timeframes give the agency the time it needs to 'receive, review, and respond' to prior notices.'' (68 FR 58974 at 58995)

Under § 1.279(b) of the IFR, prior notice may not be submitted more than 5 calendar days before arrival, except in the case of food imported or offered for import by international mail. Under § 1.279(c) of the IFR, if the article of food is arriving by international mail, the prior notice must be submitted before the food is sent to the United States.

Section 1.279(d) of the IFR provides that the time of submission is fixed and the prior notice time will start for purposes of determining if prior notice is timely when the prior notice submission is confirmed by FDA for

review. FDA will confirm a prior notice once all required information has been submitted and confirmed as facially complete. For example, if the information submitted failed to include an FDA Product Code, the system will not provide a confirmation for that prior notice. The transmitter has an opportunity to correct the rejected information. When the information is corrected, transmitted, and determined to be facially valid, the system will then notify the transmitter and provide the prior notice confirmation number.

Under § 1.279(e) of the IFR, the prior notice confirmation number must accompany any article of food arriving by international mail. Under § 1.279(f), a copy of the confirmation (with the prior notice confirmation number) must accompany any article of food carried by or otherwise accompanying an individual (unless excluded under § 1.277(b)(1)), and be provided to CBP or FDA upon arrival. Additionally, under § 1.279(g) the prior notice confirmation number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when arriving in the United States and must be provided to CBP and FDA upon arrival.

We further stated in the IFR's preamble that we also were interested in exploring flexible alternatives for submission of prior notice for foods or firms covered by programs of other agencies, such as C–TPAT, or imported by other agencies. We explained that FDA and CBP would publish a plan, including an implementation schedule, to achieve the goal of a uniform, integrated system, and to coordinate timeframes for import prior notice information while fulfilling the Bioterrorism Act mandates for air and truck modes of transportation with timeframes finalized by CBP when they finalize their rule entitled ''Required Advance Electronic Presentation of Cargo Information'' (the Advance Electronic Information Rule) (68 FR 58995). On December 5, 2003, CBP issued the Advance Electronic Information Rule (68 FR 68140), which requires CBP to receive, by way of a CBP-approved electronic data interchange system, information pertaining to cargo before the cargo is either brought into or sent from the United States by any mode of commercial transportation (water, air, rail, or truck). The cargo information required is that which is reasonably necessary to enable high-risk shipments to be identified for purposes of ensuring cargo safety and security and preventing smuggling under the laws enforced and administered by CBP. The Advance Electronic Information Rule implements the provisions of section 343(a) of the Trade Act of 2002, as amended by the Maritime Transportation Security Act of 2002. The relevant timeframes provided in the Advance Electronic Information Rule are as follows:

- For arrival by land via road at ports that are fully equipped to accommodate CBP's Advance Electronic Information Rule, no later than 1 hour prior to the arrival of the truck at the border, or for Free and Secure Trade (FAST) participants, 30 minutes;
- For arrival by land via rail at ports that are fully equipped to accommodate CBP's Advance Electronic Information Rule, no later than 2 hours prior to the arrival of the train at the border; For arrival by air, no later than the departure time (''wheels up'') of the aircraft from any foreign port or place in North America, including locations in Mexico, Central America, South America (from north of the Equator only), the Caribbean, and Bermuda, and from other areas into ports that are fully equipped to accommodate CBP's Advance Electronic Information Rule no later than 4 hours prior to the arrival of the aircraft in the United States.

On April 14, 2004, FDA and CBP announced their ''Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes'' (69 FR 19765), which the agencies amended in August 2004 (*http://www.cfsan.fda.gov/~pn/pnplan2.html*). As stated in the plan regarding the agencies' assessment of reduced timeframes ''FDA and CBP continuously are assessing the completeness of prior notice submissions received as well as the amount of time necessary to receive, review, and respond to those submissions requiring a human review. However, that process is not yet complete, as we are currently operating under the enforcement policies outlined in the Prior Notice Compliance Policy Guide (CPG). See Compliance Policy Guide Sec. 110.310—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. (Issued December 15, 2003, and revised June and August 2004; *http://www.fda.gov/ora* under Compliance References.) We currently do not receive prior notice for all shipments.''

In our plan, we also stated that we would assess existing procedures and staffing needed to receive, review, and respond to the prior notices submitted in accordance with the Prior Notice IFR; identify what changes to work practices and staffing would be necessary to determine if FDA could continue to receive, review, and respond to all prior notice submissions with reduced timeframes for land and air consistent with CBP's rule; and implement necessary changes and make appropriate adjustments to ensure we could receive, review, and respond to all prior notice submissions with reduced timeframes before issuing the final rule, consistent with our obligation to ensure that any timeframe selected is sufficient to receive, review, and respond to prior notice submissions, as set out in section 801(m)(2)(A) of the act. We also emphasized that ''the evaluation of whether to reduce the timeframes for prior notice review will depend on the level of compliance industry achieves during the assessment. If we are unable to make such an assessment, our intended timeframe for issuing a prior notice final rule may be delayed.''

Comments received on the prior notice IFR addressed the timeframes required in the IFR, as well as integration of those timeframes with the timeframes covered by CBP's advance electronic information rule. Comments also covered the IFR's requirement that prior notice must be submitted at least 5 days prior to arrival. We respond to the issue of timeframes for submitting prior notice here, and respond to the other questions raised in our Joint Implementation Plan and April 14, 2004, reopening of the comment period later in this preamble.

1. IFR Timeframes (2, 4, and 8 hours)

(Comments) One comment asks FDA to permit prior notice to be submitted at the port of entry, instead of at the port of arrival, in order to align the prior notice process with long-standing, existing CBP clearance processes and infrastructures at the port of entry. The comment reasons that since according to FDA's own estimates, 80 to 90 percent of prior notice data will be filed by the ABI filer, it is logical that prior notice should be filed at the same port where clearance entry is filed. The comment also suggests that FDA may want to consider a two-step process for submitting prior notice, under which the CBP ''ACI data'' is accepted as the first step, filed at port of arrival as part of the ''ACI data,'' followed by complete prior notice in its current form, filed as a second step at the port of entry, i.e., concurrent with the clearance entry. Another comment suggests that to ensure consistency with ACE, the prior notice should be required and calculated from the port of entry and not the first point of arrival, as is currently the case.

Another comment recommends that to fully achieve the FDA-CBP goal of coordinating timeframes, FDA should adopt the ''point of entry,'' rather than the ''point of arrival'' in the United States to measure the timeliness of the prior notice filing. CBP's ''point of entry'' is well known to importers and its use for purposes of the Bioterrorism Act not only will alleviate unnecessary confusion, but also will facilitate the stream of U.S. commerce without compromising food safety.

The comment also states that with the growing partnership between FDA and CBP, FDA's concern regarding limited personnel should no longer be an issue now that FDA and CBP collectively are using their respective enforcement officials for this joint endeavor.

(Response) FDA discussed the ''port of entry/port of arrival'' issue extensively in the preamble to the IFR and is not persuaded by the comments that its initial position should be changed (See 68 FR 58974 at 58988). The Bioterrorism Act established that prior notice be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed 5 days. That means that prior notice must be submitted before the article of food arrives in the United States. Moreover, we explained in the IFR that the overall purpose of the Bioterrorism Act is to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies, thereby making essential the ability to examine or hold a suspect article of food when it first arrives at a port of entry in the United States, rather than later at the port where CBP will process the entry. Thus, the final rule uses the term ''port of arrival'' rather than ''port of entry'' as the food may not arrive at the port of entry until long after it has arrived in the United States. In addition, CBP's advance electronic information rule also requires notice in advance of ''arrival'' in the United States, and not at ''entry.''

The IFR and final rule define ''port of arrival'' and ''port of entry.'' Neither, however, use the terms ''point of arrival'' or ''point of entry.'' FDA could not find reference to ''point of entry'' in CBP rules or regulations.

FDA does agree that FDA's staffing at certain U.S. ports is much less of an issue. Under an MOU between FDA and CBP signed by the respective commissioners of both agencies on December 3, 2003, FDA has commissioned thousands of CBP officers in ports and other locations to conduct, on FDA's behalf, investigations and examinations of imported foods. This unprecedented FDA-CBP collaboration significantly strengthens the implementation of the Bioterrorism Act to ensure the security of imported foods, particularly with respect to implementing the prior notice rule. Building on FDA's and CBP's long history of close cooperation, the MOU upgrades the two agencies' teamwork in training, day-to-day operations, and information sharing. As part of the MOU, FDA and CBP have provided specialized training for the commissioned CBP employees who carry out this work, and both agencies have expanded their existing cooperative arrangements to directly share information affecting the safety and security of imported foods, including co-locating FDA's PNC with CBP staff. Although the FDA and CBP partnership benefits the prior notice process in many ways, this partnership does not mean that the PNC no longer would have staffing concerns such that the prior notice timeframes could be reduced, as the comment implies. Please see the discussion later in this document regarding ''Integration of FDA and CBP timeframes'' for further discussion on reducing timeframes.

(Comments) One comment noted that the time difference between their country and the United States makes it difficult for the agent to start submitting prior notice immediately upon the receipt of necessary information. Therefore, some food transported by air, as well as by water, has actually missed the appointed timeframe. The comment requests that prior notice be accepted until immediately before the arrival of the food.

(Response) FDA disagrees. FDA's PNSI is available 24 hours a day to submit prior notice. The timeframes established in the final rule are the minimum amount of time that FDA needs to receive, review, and respond to prior notice submissions.

2. Integration of FDA and CBP Timeframes

(Comments) One comment states that ''no shorter timeframes should be allowed.'' However, the remainder of the comments addressing consistency of timeframes between FDA and CBP recommend that FDA timeframes for imported food arriving by air and land be reduced and be consistent with those set forth by CBP in their advanced electronic information rule. No comments recommend aligning the prior notice timeframe for imported food arriving by water with the CBP advanced electronic information rule timeframe of 24 hours prior to loading on the vessel. The reasons for recommending that prior notice timeframes be the same as CBP's advanced electronic information timeframes for food arriving by air and land are that it would minimize the complexity of the process by presenting a more streamlined flow of information and avoid unnecessary duplication, result in fewer errors, provide better compliance rates, allow for fewer disruptions at the border, significantly reduce the burden on the trade community without creating additional security risks, and allow operators at close border points to load and verify truck loads and travel routes prior to submitting notice. One comment suggested that there is no basis for concluding that more time is needed for food shipments than for other shipments. Another comment states that utilizing one system and one set of timelines should provide adequate notice to FDA and improve compliance with the prior notice requirements.

(Response) The timeframes established in the final rule represent the minimum amount of time FDA needs to meet our statutory responsibility to receive, review, and respond to prior notice submissions. In accordance with our Joint Implementation Plan, we evaluated the feasibility of conducting prior notice reviews in a reduced time period in an effort to more closely harmonize the submissions with CBP timeframes. As part of our assessment, we analyzed data regarding prior notices we received in the first 9.75 months of fiscal year (FY) 2005—specifically from prior notices received and responded to by the PNC between October 1, 2004, and July 23, 2005. Based on the results of our assessment, in the final rule we have maintained the timeframes that are in the IFR:

- If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival;
- If the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival;
- If the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival; and
- If the article of food is arriving by water, no less than 8 hours before arriving at the port of arrival.

FDA and CBP established these timeframes for the IFR based on the information available at the time. By necessity, though, these decisions regarding timeframes were not informed

by actual experience in operating the prior notice program. We now have that experience, and the information gained during our assessment shows that the minimum timeframes for submitting prior notices contained in the IFR closely match the minimum time necessary for FDA to receive, review, and respond to the prior notices. During the assessment period, FDA was able to receive, review, and respond to almost all notices within the established timeframes. In a relatively small number of situations, FDA was not able to make a decision regarding whether to inspect the food at the port of arrival by the end of the timeframe. In these situations, when the food arrived at the port of arrival, it was delayed while FDA completed its review. The number of such shipments, however, has been relatively low, and the resulting impact on government resources and the flow of traffic at ports has not been significant. Thus, we do not believe we should increase the timeframes to account for this relatively small number of outliers whose review takes longer than the IFR's timeframes.

Our assessment also shows that, because the IFR's timeframes closely match the minimum time necessary for FDA to receive, review, and respond to the prior notices, those timeframes could not be significantly reduced. If we were to change the timeframes to be consistent with those of CBP's advance electronic information rule, not only would this go against the statutory standard for setting the timeframes, but it would also significantly increase the number of shipments where FDA would not be able to decide whether it should examine the food at the port of arrival by the end of the timeframe. Based on current and projected staffing levels in the PNC, such shipments would be delayed at the port of arrival until FDA has either completed its review or decided to examine or not examine the food at the port of arrival without the benefit of a complete review. FDA could expend additional resources to increase capacity to review and reduce the timeframe, but it would be at considerable cost to assist a small number of shipments that have difficultly meeting these timeframes. In the nearly 4 years since the end of the transition enforcement period for the interim final rule, very few shipments have arrived without prior notice and as such, the timeframes are both reasonable, and economically efficient. The prior notice review process, information from our assessment, and the consequences of reducing the timeframes for conducting the prior notice review are discussed in more detail below.

To implement the Prior Notice IFR, FDA established the PNC that operates 24 hours a day, 7 days a week, all days of the year to receive, review, and adequately responds to these notices as they are submitted. PNC staff is also responsible for responding in real-time (by e-mail, fax, or telephone) to inquiries they receive from affected parties about pending prior notices and/or operational issues.

The purpose of prior notice is to help identify food that potentially poses a significant health risk to the American public and to deploy resources to the port of arrival so that inspections can be conducted before the shipment ever enters the United States. Regardless of whether a prior notice is submitted electronically to FDA through CBP's ABI/ACS or FDA's PNSI, the prior notice information undergoes a validation process and is then screened against food safety and security criteria.

If the results of our initial validation indicate that the prior notice requirements have been met and the results of our screening indicate that the shipment does not appear to be a potential bioterrorism or significant public health threat, the submission is considered to have satisfied prior notice requirements and the associated article of food is allowed to proceed for further processing, including FDA admissibility review under section 801(a) of the act. Alternatively, if the results of the initial screening of the prior notice information indicate there is a potential bioterrorism or other significant public health threat, the prior notice undergoes additional intensive review by the PNC using other databases and sources of information to determine whether the article of food should be held at the port of arrival for examination or should be allowed to proceed into 801(a) status for admissibility review. PNC personnel make this determination using their experience with imported foods and the expertise within FDA's CFSAN for human food or FDA's CVM for animal feed, the inspectional information obtained by FDA's ORA, and the expertise of CBP. FDA's goal is to complete its review within the 2, 4, or 8 hour timeframe for submitting prior notice so that the review is complete before the shipment arrives at the port of arrival. If the intensive review takes longer than the timeframe and the shipment arrives at the port of arrival, then FDA may delay the shipment at the port of arrival until its review is completed. FDA could increase staffing at the PNC in order to decrease timeframes, but the effect has diminishing returns. When a shipment must undergo intensive review, PNC staff members are reviewing databases and sorting through information to determine whether the shipment poses a potential threat. Reviewing one source of information leads to other sources of information to investigate. It would not necessarily be effective to expend, for example, five staff members on one intensive review at the start because not all sources of information for review are known at the beginning of an intensive review. Doubling or tripling staff, as discussed in Option 2B of the Final Regulatory Impact Analysis of this document, also would result in a significant amount of unused office space and equipment during the slowest time periods. Staffing at increased levels at all times would result in wasteful unproductive staff waiting for shipments to arrive.

Moreover, the constant unpredictability of the submission times for high risk prior notices requiring the shortest timeframe review (2 hours for food arriving by land via road) is a significant issue. The exact busiest times are variable, and are very difficult to predict on a daily basis. In addition, PNC targeting for high risk shipments also varies based on contemporaneous targeting intelligence and changing risk assessment strategies. Having constant two to three times the number of staff to cover those short bursts of time when the highest volume of high risk shipments, with the lowest timeframes are at their peak would be inefficient and wasteful.

In addition, it has been suggested that the PNC reduce their time frames and hold only those shipments it needs more time to review. There are two very significant reasons why this would be impractical. First, from a security perspective, doing so would result in holding only potential high risk shipments at the border and would make PNC targeting strategies widely visible and predictable to both those involved in legitimate trade, and those with nefarious pursuits looking to exploit weaknesses in U.S. food cargo security. Second, the holding of high risk shipments at the port would cause logistical challenges for port operators, and would almost certainly have a negative impact on all food and nonfood shipments processed through those ports. In contrast, with the current PN timeframes which have been in place for more than 4½ years, these logistical challenges have been almost nonexistent, and PNC targeting strategies are virtually transparent to the import trade.

The other factor to consider is the tremendous growth of imported foods year to year (approximately 14 percent growth over the past 4 years), which far exceeds what FDA projected in the IFR. FDA has been able to maintain the existing timeframes without adversely impacting trade. Given that we continue to expect imports to increase in volume, FDA does not believe that reducing timeframes is warranted. For all the above reasons, FDA believes that its current and projected staffing levels are sufficient and appropriate, and the timeframes are both reasonable, and economically efficient.

FDA receives approximately 167,000 prior notices each week. The distribution of prior notices by mode of transportation during our assessment that were flagged by the initial screening and that received an intensive prior notice review by the PNC is as follows:

TABLE 1.—PROPORTION OF PRIOR NOTICES FLAGGED AT THE INITIAL SCREENING, BY MODE OF TRANSPORTATION

Truck	27.6%
Car	2.9%
Air	17.6%
Rail	0.8%
Sea	39.2%
Mail	11.1%
Other	0.8%

As indicated, a significant portion (approximately 31 percent) of the prior notices reviewed by the PNC on a daily basis are land/road border entries, which under the IFR are subject to submission timeframes of at least 2 hours before arrival. On average, during the assessment period, the PNC conducted intensive security reviews on 225 to 250 prior notices per day from all modes of transportation, which means that, on average, the PNC conducted intensive security reviews on about 77 prior notices (31 percent of 250) each day that are subject to the 2–hour timeframe. Moreover, the prior notices are not evenly distributed over an 8 hour shift or 24–hour day. The actual dispersal pattern of the prior notice submissions is not uniform; an overwhelming majority of prior notice submissions arrive between a certain 12–hour period.

The amount of time the PNC has needed for its intensive review has ranged from 20 minutes to 315 minutes (5 hours and 25 minutes) from when FDA received the prior notice and confirmed it for review. Using data collected on articles of food arriving by land via truck and car during our assessment period, the PNC expended an average of 61 minutes to receive, review, and make a decision on whether or not a shipment should be refused or held for examination under section 801(m) of the act, or allowed to proceed into 801(a) status for admissibility review. The PNC completed about 99 percent of its intensive reviews of prior notices submitted for land/road border arrivals within 120 minutes of receiving and confirming the prior notice for review. Only about 57 percent of the intensive reviews were completed within 1 hour. Reviews for the remaining 43 percent (8,900 prior notices for the assessment period, or more than 10,000 for FY 2005) took longer. If the timeframe were set at 1 hour for these articles of food instead of the IFR's 2 hours, the PNC would have had to either delay the food at the port of arrival until it completed its review or decide whether to examine the food at the port or arrival without the benefit of a complete review, based on current and projected staffing levels in the PNC.

FDA does not have data to accurately analyze the impact of changing the timeframe to 30 minutes for FAST participants because FAST membership is not one of the data elements that we currently require in a prior notice submission. FDA instead did the analysis based on the total number of prior notices submitted that the PNC could review based on a timeframe of 30 minutes. The PNC completed less than 10 percent of its intensive reviews of prior notices submitted for land/road border arrivals within 30 minutes of receiving and confirming the prior notice for review. If the timeframe for all articles of food arriving by land by truck and car during our assessment period had been 30 minutes (i.e., the timeframes for FAST participants) instead of 2 hours, the PNC would not have completed approximately 68 percent of its intensive reviews (over 14,000 during the assessment period, which equates to approximately 16,000 for FY 2005 of the land/road border prior notices) within the applicable timeframe. As a result, the PNC would have had to either delay the food at the port of arrival until it completed its review or decide whether to examine the food at the port of arrival without the benefit of a complete review, based on current and projected staffing levels in the PNC. This assessment is an overestimate of the number of articles of food that would be eligible for FAST timeframes, as we do not know how many articles of food arriving in the United States subject to the prior notice requirements are from FAST and C–TPAT participants. Moreover, there are other impediments to integrating prior notice with the C–TPAT and FAST programs. These are discussed in section III.D.6 of this document (''Additional Exclusions Requested—Special Programs (C–TPAT/FAST) and Flexible Alternatives'').

We also conducted a similar assessment on prior notices submitted for articles of food arriving by air between October 1, 2004, and July 23, 2005. The IFR requires prior notices for these shipments to be submitted and confirmed for review at least 4 hours before the food arrives at the U.S. port of arrival. If the timeframes for articles of food arriving by air during our assessment period had been reduced to ''wheels up,'' the PNC would not have completed approximately 21 percent of the intensive prior notice reviews for articles of food with flight times less than 3 hours. These articles of food (2,700 for our assessment period, or an estimated 3,230 for FY 2005) also would have been subject to cargo delays and/or increased cargo examinations, based on current and projected staffing levels in the PNC.

Neither FDA nor CBP have sufficient personnel or resources to accommodate the number of additional cargo delays and/or food shipment examinations that would result under either 60- or 30-minute timeframes for articles of food arriving by land by road. This would include the significant additional personnel and resources needed to track, facilitate, and coordinate the evaluation and/or examination of the delayed cargo. Coordination of the handling of delayed shipments is a resource intensive process that can last for multiple days per shipment, and includes communicating with both FDA and CBP personnel at the border, and the brokers/filers and importers involved in the shipment.

To handle the extra work, the PNC would need to shift its personnel based on current and projected staffing levels in the PNC, resulting in fewer staff being available to review prior notices for all categories of shipments including shipments arriving by water. The PNC's current approximate average time for the PNC intensive review for shipments arriving by water is 5 hours, which is within the 8 hour submission timeframe. We would expect, based on our assessment, that the time taken away from prior notice review work for the increase in coordination due to the increase in delays and examinations for

land and air shipments would increase the time needed to complete intensive review of prior notices for shipments arriving by water by 25 percent at the minimum. As a result, over 7,000 shipments by water during our assessment period (estimated as 7,370 for FY 2005) would have been delayed at the port of arrival while the PNC completed its intensive review and determined whether the shipment in fact presented a significant health threat, based on current and projected staffing levels in the PNC.

In setting the timeframes, the act provides that we may consider, among other considerations, the effect on commerce (section 801(m)(2)(A) of the act). Assuming current and projected PNC resources, lowering the timeframes to 60 or 30 minutes would likely result in delays at the border, not only for those shipments delayed for intensive review longer than the timeframe, but also for other shipments passing through the port, especially at the busiest land border ports where traffic lanes, parking, and inspection facilities are extremely limited. In some ports, the lack of holding facilities could result in an increase in trucks being turned around at the border. As we have mentioned above, there have been a relatively small number of situations where FDA was not able to make a decision regarding whether to inspect the food at the port of arrival by the end of the timeframe, causing a small number of shipments to be delayed when it arrived at the port of arrival. Since the impact of these small number of delays on trade has not been significant, continuing to maintain that the current IFR timeframes is the most efficient use of resources.

Thus, based on current and projected resources and other high-priority activities FDA is addressing, reducing the timeframes would lead to an increase in delays at the ports of arrival, causing FDA to shift some resources away from conducting intensive reviews of prior notices so they can conduct the coordination and other activities necessary for these delayed shipments. The shift in resources away from conducting intensive reviews would, in turn, further increase the number of shipments that are delayed because FDA has not been able to finish its intensive review within the applicable submission timeframe. This ultimately would cause a delay in getting cargo to its final destination, which would have an adverse impact on trade.

Moreover, the number of prior notices identified for intensive review has increased over time, as intelligence and other risks are identified. We expect the number of intensive reviews to continue to increase relative to the assessment period, resulting in even more food shipments that would be delayed or held for examination under shortened timeframes.

We did not get any comments asking us to coordinate the timeframes for articles of food arriving by water in our prior notice rule (8 hours before arrival) with those in CBP's rule (24 hours before arrival). We received one comment asking us to reduce the time for articles arriving by water. We stated in the preamble to the IFR ''In determining the actual timeframes for submission of prior notice for each mode of transportation, FDA considered the need to provide sufficient time for the agency to review and respond to the information submitted, as well as the current ability of the food industry to provide the information required within the stated timeframe given the differences in lead time before arrival among different modes of transportation. We determined that information for shipments whose transport time is measured in days or weeks (e.g., ocean shipments) is available further in advance of arrival than shipments whose transport time is measured in hours (e.g., land and air shipments.) Staggered prior notice submission timeframes will allow FDA reviewers to direct additional resources to shipments with short transport times and to defer review of shipments with longer transport times. Based on these considerations, FDA established the prior notice timeframes in the interim final rule to associate with the mode of transportation.'' (69 FR at 58995). We continue to hold this view for shipments arriving by water in light of our assessment for articles of food arriving by land and air.

For all of the previously stated reasons, we did not reduce the timeframes for submitting prior notice in the final rule for any mode of transportation, as these timeframes still are the minimum amount of time FDA needs to fulfill its statutory obligation to receive, review and respond to prior notices while having the minimal impact on trade.

(Comments) One comment suggests that it would be preferable for FDA to harmonize the prior notice timelines to the future ACE transmission timelines, ensuring consistency and compliance of the trade community and efficiencies in both agency and industry workforces.

(Response) FDA agrees that timeframes for submission of prior notice may be further evaluated in light of new trade programs such as ACE, when it is implemented and in effect. CBP is planning to bring its ACE system on line in the next few years, which will accommodate prior notice submissions and eliminate or change ABI/ACS and PNSI prior notice submissions. FDA will continue to assess and pursue the integration of timeframes as policies, processes, and strategic IT systems are improved. FDA believes that the most opportune time for coordinating timeframes will coincide with the startup of CBP's ACE. We will determine at that time or after ACE is operational whether the prior notice timeframes should and can be reduced further. Until that time, the timeframes for submission of prior notice will remain the same in the final rule as issued under the IFR (see § 1.279).

3. Phase-In of FDA and CBP Timeframes

When FDA reopened the comment period for the IFR on April 14, 2004 (see 69 FR 19763), FDA asked Flexible Alternative Question 6: ''If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?''

(Comments) Most comments recommend integration of the phase-in of reduced timeframes in association with CBP's schedule to promote consistency between the programs, reduce errors, and minimize disruption of supply chains through conflicting requirements. However, one comment, in addition to recommending adherence to CBP's phase-in schedule, also notes that they would not want FDA to delay adopting a reduced timeframe for submitting prior notice merely because CBP is not yet ready to implement the counterpart provisions of its advance notice programs. In addition, they state that the deadlines are minimum periods, and any shipper can provide more notice of imports, to FDA, CBP or both, than the minimum timeframes in either regulation. They recommend that FDA should shorten its lead times to match those in the CBP regulations, even if the CBP requirements are not yet in place. Another comment states that the phase-in plan, which is a port-by-port implementation according to a time schedule, would be very problematic to industry. The comment further explains that systems and operations do not necessarily have the flexibility to switch on by individual site or location and the current plan would introduce complication and confuse the trade community. The comment recommends further discussion with CBP and FDA as to development of a more viable and achievable implementation plan.

(Response) This issue is moot, as the final rule retains the timeframes

established in the IFR, for the previously stated reasons.

4. Prior Notice Confirmation Number

(Comments) One comment asks for clarification regarding when the prior notice confirmation number is required to accompany the food.

(Response) The prior notice confirmation number must accompany any article of food arriving by international mail, when the food is carried by or otherwise accompanying an individual, or when the prior notice was submitted via FDA's PNSI.

Under § 1.279(e), the prior notice confirmation number must accompany any article of food arriving by international mail. Under § 1.279(f), a copy of the confirmation (with the prior notice confirmation number) must accompany any article of food carried by or otherwise accompanying an individual (unless excluded under § 1.277 (b)(1)), and be provided to CBP or FDA upon arrival. Additionally, under § 1.279(g) the prior notice confirmation number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when arriving in the United States and must be provided to CBP and FDA upon arrival.

(Comments) One comment asked FDA to confirm whether it is sufficient for an ocean carrier to have the prior notice confirmation number on arrival or whether they are required to have the actual prior notice confirmation also.

(Response) Under § 1.279(e), the prior notice confirmation number must accompany any article of food arriving by international mail. Additionally, under § 1.279(g) the prior notice confirmation number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when arriving in the United States and must be provided to CBP and FDA upon arrival. Therefore, although a prior notice confirmation number is required, the final rule does not require that the actual prior notice confirmation has to be supplied for food arriving by ocean carrier.

(Comments) One comment states that when food arrives in the United States, the carrier should present a copy of the prior notice confirmation and the food to CBP. The comment asks if the submitter should send the prior notice confirmation to the carrier company or to the vessel that transported the food to the United States.

(Response) As stated previously, § 1.279(e) requires the prior notice confirmation number to accompany any article of food arriving by international mail. Additionally, under § 1.279(g) the prior notice confirmation number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when arriving in the United States and must be provided to CBP and FDA upon arrival. How persons importing or offering for import food into the United States choose to comply with this requirement is a private matter (e.g., persons may decide to specify these obligations in the contract between the exporting company and the carriers to ensure that the logistics are worked out in advance).

(Comments) Comments stated that the data requirements should be reassessed to simplify and make the requirements more manageable. The comment states that one data element should link all information secured by prior notice, which would be beneficial for locating shipments in the event of a possible crisis. The comments suggest that FDA use bill of lading numbers as a single reference point because all shipments that are moved are repeatedly covered by this number. This would render the prior notice confirmation number currently used redundant.

(Response) FDA does not agree that the waybill/Bill of Lading can be used as a single reference point for all shipments instead of the prior notice confirmation number. A Bill of Lading number is not always assigned to a shipment at the time of prior notice submission. For certain shipments, such as those sent by international mail, no Bill of Lading may exist. Thus, FDA has determined that it is better to use a unique confirmation number provided by the FDA system to transmitters.

(Comments) One comment notes that a separate prior notice is required for each distinct food product and a prior notice confirmation number is returned for each prior notice. Therefore, if a shipment consists of multiple food products, the carrier would have multiple prior notice confirmations upon arrival. The comment states multiple prior notice confirmations do not align well with the commercial realities of international trade, where the focus is on the entire shipment, not the individual components. The comment recommends that FDA provide a prior notice confirmation number that encompasses the entire shipment.

(Response) FDA disagrees. The carrier could be carrying articles of food for different submitters or recipients. If it was necessary to hold an article of food, the entire shipment would be held under the above scenario suggested by the comment. Under the final rule, the article of food that is subject to a hold can be offloaded and the rest of the shipment allowed to proceed. This would not be the case if there was only one prior notice confirmation number for the entire shipment.

5. 5-Day Maximum Pre-Arrival Limitation

(Comments) Many comments requested that prior notice be allowed to be submitted more than 5 days before arrival. This would allow exporters to complete their documentation at the same time the bill of lading and health certification is usually completed in the case of food shipped by water. One comment contends that the 5 day limit does not reflect the variable and unpredictable nature of transport and does not reflect a risk-based approach to a potential bioterrorism threat. Another comment contends that the limitation of the timeframe to 5 days is problematic and is due to a misinterpretation of the statute. The comment asserts that the statutory language does not preclude a party from voluntarily providing prior notice more than 5 days in advance. The comment also maintains that 10 days prior to arrival would provide the necessary flexibility for their industry. A foreign government, apparently assuming that prior notice must be submitted by the foreign shipper or exporter, recommends that the time should be extended because it may take the shipment 2 weeks to reach a U.S. port.

(Response) In response to the concerns raised by the comments, we have revised § 1.279(b) to allow submission of prior notice more than 5 days before arrival (except for articles of food imported or offered for import by international mail). Specifically, this provision permits prior notice submissions to be submitted no more than 30 calendar days before the anticipated date of arrival for submissions made through ABI/ACS and no more than 15 calendar days before the anticipated date of arrival for submissions made through PNSI. Due to system limitations, the timeframes between ABI/ACS and PNSI are not identical. Also, because of the way ABI/ACS is programmed, when prior notice is submitted through ABI/ACS, the prior notice confirmation number cannot be provided more than 5 calendar days before the anticipated date of arrival.

Please note that if any of the prior notice information, except the anticipated arrival information, the estimated quantity, or the planned shipment information, changes after FDA has confirmed the prior notice submission for review, the prior notice must be resubmitted, as provided by § 1.282(a). The resubmission must be

confirmed by FDA for review no less than 2, 4, or 8 hours before arriving at the port of arrival, with the minimum time depending on the mode of transportation (§ 1.279(a)). If prior notice is resubmitted, the previous prior notice should be cancelled (§ 1.282(b), (c)).

6. International Mail

(Comments) There were no comments received regarding the timeframes established for prior notice covering food arriving by international mail.

(Response) FDA retained the timeframes for submission of prior notice for food arriving by international mail that are in the IFR.

(Final rule) The final rule at § 1.279(a) requires that you must submit prior notice to FDA and the prior notice submission must be confirmed by FDA for review as follows: If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival; if the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival; if the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival; or if the article of food is arriving by water, no less than 8 hours before arriving at the port of arrival.

Under § 1.279(b), except in the case of an article of food imported or offered for import by international mail, prior notice may be submitted no more than 30 calendar days before the anticipated date of arrival for submissions made through ABI/ACS and no more than 15 calendar days before the anticipated date of arrival for submissions made through PNSI.

Under § 1.279(c), if the article of food is arriving by international mail, the prior notice must be submitted before the article of food is sent to the United States.

Under § 1.279(d), FDA will provide notification that the prior notice has been confirmed for review with a reply message that contains a prior notice confirmation number. The prior notice will be considered submitted and the prior notice review time will start when FDA has confirmed the prior notice for review.

Under § 1.279(e), the prior notice confirmation number must accompany any article of food arriving by international mail. The prior notice confirmation number must appear on the Customs Declaration that accompanies the package. We provide CN22 or CN23 or a U.S. equivalent as examples of the Customs Declaration.

Under § 1.279(f), a copy of the confirmation, including the prior notice confirmation number, must accompany any article of food that is subject to this subpart when it is carried by or otherwise accompanies an individual when arriving in the United States. The copy of the confirmation must be provided to CBP or FDA upon arrival.

Under § 1.279(g), the prior notice confirmation number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when the article arrives in the United States and must be provided to CBP or FDA upon arrival.

G. How Must You Submit the Prior Notice? (§ 1.280)

Section 1.280 of the IFR required that prior notice must be submitted electronically to FDA in the English language, except that an individual's name, the name of a company, and the name of a street may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet. The IFR provided for two methods of electronic submission of prior notice: (1) The CBP ABI/ACS; or (2) FDA PNSI at *http://www.access.fda.gov*.

The IFR required submission of prior notice via FDA's PNSI for articles of food imported or offered for import by international mail, other transaction types that cannot be made through ABI/ACS, and articles of food that have been refused under section 801(m)(1) of the act and 21 CFR part 1, subpart I.

The IFR also provided for contingencies if certain systems were not working, e.g., a custom broker's or self-filer's system, ABI/ACS, PNSI, or OASIS. The IFR required that prior notice must be submitted through PNSI if a custom broker's or self-filer's system or if the ABI/ACS interface is not working. The IFR also required that prior notice must be submitted via e-mail or fax if PNSI or OASIS is not working. The IFR did not exempt any specific categories of food articles from prior notice if systems are not performing.

In August 2004, FDA and CBP published guidance covering a Contingency Plan for System Outages. This guidance can be accessed at *http://www.cfsan.fda.gov/~pn/pndguid.html*. Comments addressing contingencies will be discussed later in this section.

Comments regarding how to submit prior notice are addressed according to issue: General comments; comments about the ABI/ACS and PNSI systems, including technical issues and security of the systems; and comments about contingencies.

1. General Comments

(Comments) One comment suggests that FDA should have CBP collect and review all prior notices with one prior notice submission timeframe for all agencies.

(Response) FDA disagrees. The Bioterrorism Act, while providing for the ability to commission other agencies to help implement the provisions of the Bioterrorism Act, specifies that the Secretary is to receive prior notice for all food imported or offered for import into the United States. FDA personnel are trained and knowledgeable about the risks and hazards involving food products under its jurisdiction and have the expertise to review the prior notice submissions. The integration of prior notice submission timeframes is discussed earlier in this document under the discussion for § 1.279.

(Comments) Several comments suggest allowing the option of submitting prior notice by fax or mail because not everyone has Internet capability, access to a computer, or proficiency in English. One comment asks that they be allowed to continue sending prior notice by fax (as is allowed during certain contingency situations). Several other comments suggest that international mail shippers are at a disadvantage because many mail customers have no access to the Internet, the pre-notification system is not customer-friendly, entries take a long time, and the data requirements are too complex and difficult for customers to determine.

(Response) FDA does not agree that a process for manual transmission is needed, except on a contingency basis. FDA believes that persons engaged in international commerce have, or can get, access to the Internet. If the Internet is not accessible by the submitter, he or she can use a customs broker to submit prior notice through ABI/ACS or another person to transmit prior notice through the FDA PNSI. Allowing manual transmission would not give adequate time for FDA personnel to receive, review, and respond, unless the timeframes for prior notice in the final rule were greatly extended. Thus, manual transmission will be used only as a contingency alternative.

FDA also notes that the data quality of manual systems is usually less than satisfactory, because no automated data validation takes place during data entry. The U.S. Government has a strong commitment to reducing paper-based processes and moving toward e-commerce for all business transactions. Accordingly, under the final rule, paper-

based submissions will not be allowed, except on a contingency basis.

In response to the comment that international mail shippers are disadvantaged, FDA also notes that it has compliance policies to address this situation. Its compliance policy under the IFR had been that ''FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for non-commercial purposes with a non-commercial shipper'' without prior notice. This applied to all such food subject to prior notice, including food shipped by international mail. The Prior Notice Final Rule Draft CPG, announced elsewhere in this issue of the **Federal Register**, would continue that enforcement policy.

(Comments) One comment suggests that instead of submitting prior notice via PNSI, mail shippers be allowed to complete an alternate form requiring minimal information that is similar to the Customs Declaration form in the native language to be completed at the post office. This comment argues that the current requirements are too cumbersome for the average consumer. Similarly, another comment suggests that FDA accept Customs Declaration Forms CN22 and CN23 in lieu of submitting prior notice via PNSI for mail shippers. This comment argues that such forms are much easier to complete and are official documents prescribed by the Universal Postal Convention and are used around the world. In the alternative, this comment suggests that FDA accept data submitted by mail shippers via PNSI in a condensed form determined by the foreign government's postal agency.

(Response) FDA disagrees. Section 801(m) of the act requires the prior notice submission to contain certain data elements, such as the identity of the article of food, manufacturer and shipper of the article, grower, country from which the article originates, country from which the article is shipped, and the anticipated port of entry of the article. Customs Declaration Forms are not adequate substitutes for providing this information to FDA since such forms do not typically require this kind of comprehensive information. Likewise, allowing a foreign government's postal agency to determine which information to submit to FDA also does not guarantee that we will receive the information required by section 801(m) of the act. Therefore, FDA has not provided an alternative form of prior notice submission for food arriving by mail for commercial purposes.

FDA again notes that it has compliance policies that address some of the concerns raised by the comments. Its compliance policy under the IFR had been that ''FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for non-commercial purposes with a non-commercial shipper'' without prior notice. This applied to all such food subject to prior notice, including food shipped by international mail. The Prior Notice Final Rule Draft CPG, announced elsewhere in this issue of the **Federal Register**, would continue that enforcement policy. FDA believes that this proposed compliance policy should not be extended to food that is imported or offered for import for commercial purposes or with a noncommercial shipper without prior notice. Mail shipments associated with a commercial purpose pose a higher risk with respect to ability to reach a greater number of people, and most commercial entities already are familiar with submitting information to FDA and CBP.

(Comments) One comment proposes a two-step process for filing prior notice, whereby FDA would accept the same data submitted for CBP ABI to satisfy the prior notice requirements at the first port of arrival. Then, after accepting ABI data at the port of arrival, complete prior notice data would be filed at the port of entry as step two of the process. The comment contends that utilizing ABI data for prior notice at the port of arrival would allow faster processing, which is a significant issue considering FDA's concern about timely processing of prior notice under a shorter time schedule. This more complete data would be filed concurrent with the CBP clearance entry, and therefore provide FDA with the level of data desired, while removing the issue of time constraints under a reduced schedule measured against the port of arrival.

(Response) FDA disagrees. The purpose of section 801(m) of the Bioterrorism Act is to ensure that FDA has sufficient information before arrival so it can determine what foods to inspect at the border. Therefore, all information required for prior notice must be submitted prior to arrival, not just a portion of the information.

Additional information may be required after arrival and for entry admissibility decisions. That process is completed after arrival for those foods offered for consumption in the United States. (See 68 FR 58974 at 58976 in the preamble to the IFR for additional discussion about the relationship and differences between the prior notice determination and the admissibility determination.)

(Comments) One comment suggests the agencies should synchronize the different filing systems so as to ensure that all notices can be made via Automated Manifest System (AMS). Other comments request FDA to coordinate prior notice with CBP's AMS to eliminate duplication of data submissions.

(Response) FDA disagrees. No interface currently exists between AMS and the existing interface with FDA's OASIS through the ABI/ACS entry processes, which means FDA does not have access to AMS data. FDA and CBP have discussed interfacing with AMS for manifest data and determined that the general cargo data in AMS are not suitable to accommodate the detailed information requirements of section 801(m) of the act. For example, AMS does not collect the country of origin. In addition, its collection of the identities of the article of food and its manufacturer differs from the way those are collected under the prior notice interim final and final rules in such a way that the data would not meet our needs in carrying out the purpose of section 801(m) of the act.

(Comments) One comment urges FDA to upgrade its systems to coincide with normal commercial flow times and recommends that FDA consider the approach used by the Census Bureau, i.e., providing a range of automated filing options for meeting electronic filing requirements by offering an Internet application, a direct link for certified filers, and a personal computer (PC)-based application.

(Response) FDA provides two methods for submitting prior notice: One via ABI/ACS (a PC-based link for certified filers) and another via PNSI (an Internet-based application). Prior notice is not required to be filed at a specific time or during specific hours of the day, but may be submitted 24 hours/day, 365 days of the year. The rule requires FDA to receive the prior notice before the food arrives in the United States, and the time frame is based on the mode of transportation (see § 1.279).

(Comments) One comment suggests that FDA participate in the International Trade Data System (ITDS), which provides for one-window filing of trade-related information by motor carriers and other parties through CBP's ACE system, to more effectively execute its Bioterrorism Act mission.

(Response) FDA is actively participating in the development of CBP's ACE system and has long been a participant in the ITDS. However, ACE is not yet a complete reality and prior

notice requirements have been in effect since December 12, 2003. FDA is working with CBP and others in the international trade community to ensure that the prior notice requirements are reflected in ACE once ACE is fully operational.

(Comments) One comment notes that exporters use different kinds of transmission formats to send prior notice-related information to importers or brokers in the United States. The comment further states that since none of its member companies have received any notice from FDA requesting changes in content or formatting of the transmitted information, they assume that FDA is satisfied with their industry's approach to regulatory compliance. In the event that FDA requires a change to format or content of the reporting now conducted, the comment requests that FDA notify companies well in advance of any such requested change.

(Response) FDA receives prior notice information via ABI/ACS or PNSI. FDA expects that the transmitted information discussed in the comment is submitted to FDA via one of these two methods in the proper format. If the information is inaccurate, the food is subject to refusal. Customs brokers are notified using typical procedures regarding any changes relating to the rule that require an IT change to ABI/ACS, including a 90-day lead time before implementation of the IT change. FDA also provides tutorials on its Web site that explain changes to PNSI (see *http://www.cfsan.fda.gov/~pnts/pnsitut.html*).

2. English Language

(Comments) Many comments suggest that FDA program PNSI in other languages, such as Japanese, Korean, German, and Spanish. These comments state that ''mail users'' must rely on PNSI to submit prior notice, and in many cases, English may not be the native language for many of these users and puts them at a disadvantage, e.g., foreign filers experience higher burdens and are frequently being timed out of PNSI because it takes them longer to complete a prior notice. One comment argues that a reason for noncompliance of prior notice requirements is the inability to understand English well enough to submit prior notice via PNSI.

(Response) FDA agrees that a system available in multiple languages would be advantageous for some users. However, the agency has assessed the feasibility of providing and maintaining PNSI in multiple languages, and has determined that the cost of developing translations into one or more additional languages cannot be accommodated at this time. The cost of updating the translations as new versions of the system are developed would also be substantial. In addition, FDA notes that other import documents required by FDA and by CBP must be filed in English. Therefore, FDA does not plan to program PNSI in other languages and the final rule will continue to require submission of prior notice in the English language.

FDA and CBP nonetheless have taken into account many of the concerns referenced in the comments. For example, the final rule does not apply to homemade foods shipped from an individual to an individual in the United States (see § 1.277, *Scope*, discussed supra). In addition, the agencies' compliance policy under the IFR had been that ''FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for non-commercial purposes with a non-commercial shipper'' without prior notice. This applied to all such food subject to prior notice, including food shipped by international mail. The Prior Notice Final Rule Draft CPG, announced elsewhere in this issue of the **Federal Register**, would continue that enforcement policy.

(Comments) One comment requests that other pieces of the prior notice system also be available in other languages, such as the tutorials for determining the FDA product code. Another comment suggests that FDA provide foreign governments and trade organizations with a detailed outline of the ''prior notice form'' with explanations of the individual requirements so that they could be translated into a foreign language and provided to affected companies.

(Response) While many of the documents regarding prior notice requirements have been translated into other languages, the PNSI tutorials (available at *http://www.cfsan.fda.gov/~pnts/pnsitut.html*) and the FDA Harmonized Tariff Schedule Codes guidance (available at *http://www.cfsan.fda.gov/~dms/htsguid3.html*) have not been translated. FDA intends to continue translating these and other prior notice documents as resources permit. Documents that are available in other languages are posted at *http://www.cfsan.fda.gov/~mow/internat.html*. Foreign governments and trade organizations are welcome to translate these documents and provide them to affected companies.

3. Technical Issues Concerning Both Systems

(Comments) One comment suggests that both systems provide a link to HTS codes.

(Response) FDA agrees. Both PNSI and ABI/ACS provide a link to HTS codes. FDA also has provided guidance regarding HTS codes and a companion list of HTS codes flagged with prior notice indicators. The guidance is posted at *http://www.cfsan.fda.gov/~dms/htsguid3.html* and the updated list is posted at *http://www.cfsan.fda.gov/~pn/htscodes.html*.

(Comments) One comment states that railroads will not load cargo until a prior notice confirmation number is provided, and a prior notice confirmation number cannot be provided without complete planned shipment information, including a railcar number.

(Response) FDA notes that, while this situation seemed to be an issue early in the implementation of the prior notice IFR, it is our understanding and experience that the rail industry has now changed business practices to address this concern. FDA received only one comment on this issue and has not received any other feedback to suggest this matter is still of concern. A check with a large rail shipping company revealed that the restrictions for loading cargo are not at issue; i.e. rail cars can be physically loaded with shipments containing food prior to obtaining prior notice (Ref. 1). Therefore, the prior notice filer does have the ability to obtain the rail car number in order to file prior notice. The rail company did however indicate that rail cars are not connected/added/attached to the U.S. in-bound train until the rail company receives documentation that prior notice has been filed.

(Comments) One comment states that the FDA Help Desk, and other methods now established for resolution of operational issues, simply are not yielding a workable ''fix'' to the ''kinks'' in the new PNSI/ABI system. Another comment recommends the establishment of a system for swift resolution of technical and operational problems for both systems.

(Response) FDA agrees and has established an FDA Help Desk to deal with technical issues involving PNSI. Questions and concerns about operational, rather than technical, problems involving prior notice should be directed to FDA's PNC. While the FDA PNC is available 24 hours a day, 7 days a week to respond to operational issues, it is not equipped to resolve technical issues involving PNSI or ABI.

However, the PNC has a process in place to handle calls involving technical issues and will forward those calls to the Help Desk. CBP also has a well-established system of client representatives to deal with technical problems involving ABI/ACS. CBP client representatives are available to assist users with ABI issues. ABI operational issues are the sole responsibility of CBP.

(Comments) One comment states that the systems go down from time to time, and all the time-consuming entry-work has to be repeated.

(Response) PNSI has been enhanced to allow copying and saving of prior notices within a Web entry and copying of a Web entry, with or without the associated prior notices. Copying allows you to avoid repetitive data entry for similar Web Entries and associated Prior Notices. You also may cancel a Web Entry and then copy it, to correct errors in a Web Entry you have already completed. Instructions for copying a Web entry prior notice are available on FDA's Web site at *http://www.cfsan.fda.gov/~pn/pnstep2.html#copywe.* ABI users are responsible for their own software and its capability to save and/or copy information that has not been transmitted.

(Comments) One comment urges FDA to harmonize their efforts with CBP with respect to the prior notification of food articles and to work with CBP to integrate its joint administration and enforcement of prior notice for both CBP and FDA. One comment recommends that both the FDA and CBP systems be simplified to allow for both a decrease in data entry time and a more efficient method for multiple data entries.

(Response) FDA agrees and is continuously working with CBP to make the administration and enforcement of prior notice as integrated and efficient as possible. Both agencies recognize that ACE, when initiated, will allow for a more harmonized process.

With respect to multiple data entries, PNSI does offer several features that make prior notice data entry faster and reduce the amount of redundant data entry, such as the Copy Web Entry feature, Copy Prior Notice feature, and other shortcuts. Please refer to Time Saving Tips from the FDA PNC for PNSI (*http://www.cfsan.fda.gov/~pn/pntips.html*) for a description of these features. Many private ABI software programs also have features that provide a means for multiple data entries.

(Comments) Several comments express concern about the timeliness of receipt of the prior notice confirmation number. One comment states that it can take an hour or more to receive the prior notice confirmation number that is needed to move the cargo. Another comment states that there have been several instances when the confirmation response has been delayed and asks FDA to improve the timeliness of this response.

(Response) Generally, for prior notice submission via PNSI, the user should receive their confirmation number immediately upon submission of the correctly completed form. For those prior notices submitted via ABI on the anticipated date of arrival, users can expect to receive a response message (confirmation number or rejection) within 15 minutes of submission. For ABI submissions submitted prior to the anticipated date of arrival, users can expect to receive their response message no later than midnight (Eastern Time) on the anticipated date of arrival.

(Comments) One comment states that there are glitches in the software that has been released. The comment notes that perfume is a nonfood product that is subject to FDA's 801(a) jurisdiction, but it does not require prior notice. However, in a procedures memorandum from CBP, it appears that if you disclaim FDA in FD3, it is disclaimed for all purposes. Similarly, if you acknowledge FDA jurisdiction in FD3, then prior notice must be submitted whether or not the importation involves food.

(Response) We have provided instructions describing how to disclaim an article for prior notice, while still sending information required for FDA 801(a) admissibility. The instructions were included in at least four separate ABI Administrative Messages issued by CBP beginning in March 2004 (e.g., Administrative Message 04–0586, dated March 24, 2004). If merchandise marked FD3 in the Tariff Record is subject to prior notice and 801(a) reporting requirements, the required prior notice and 801(a) information should be transmitted. In cases where 801(a) information is required, and prior notice information is not required, filers should transmit the ''PN disclaimer'' (PND) and the information required for 801(a). In this case, the PND Affirmation of Compliance (AofC) code must be the first AofC code recorded (FD01 Record-Positions 20–22) in the ABI transmission. The PND affirmation does not require a qualifier. If the merchandise marked FD3 represents an article exempt from all FDA reporting requirements, the line should be disclaimed using the FD0 marker in the OA Record,[5] as has always been done for FDA disclaims.

(Comments) One comment believes there is a problem with the in-bond system. The comment states that if it is assumed that a shipment arrives in Los Angeles, but is destined for in-bond travel to New York, the shipment is subject to prior notice upon arrival. In order to properly comply with CBP requirements, the arrival date is entered based upon the expected arrival date in New York. The data exchange between CBP and FDA is then triggered by the New York arrival date rather than the Los Angeles arrival date. The comment is concerned that prior notice could be transmitted in a timely manner to CBP, but be held up due to computer programming, making the prior notice untimely. The brokers have fixed this problem in the short term by inputting the Los Angeles arrival date in both places for prior notice purposes and then changing it after prior notice has concluded.

(Response) The anticipated arrival date is a requirement of prior notice and is independent of CBP entry requirements. The Bioterrorism Act requires submission of prior notice before the food arrives in the United States, and not upon arrival as stated in the comment. Therefore, in the example provided, prior notice is required before the article of food arrives in Los Angeles notwithstanding any other CBP entry requirements.

For ABI entries requiring prior notice, the filer must enter separate dates for purposes of entry and prior notice. The filer enters an anticipated arrival date at the entry header level for CBP. For purposes of prior notice, the filer also enters the anticipated arrival date as an affirmation of compliance code ''ADA.'' Therefore, there should not be a problem with choosing which date to submit as raised by the comment.

(Comments) One comment suggests that the systems provide a drop down list of reasons that provide an explanation for the absence of the registration number.

(Response) FDA agrees. In the November 2004 revision of the CPG that explained how FDA intended to enforce the prior notice IFR, a list of reasons was provided as Appendix 1, Reason Codes for Registration Number of Manufacturer Not Provided. This list of reasons is available in both PNSI and ABI/ACS, and the reasons are available as a drop down menu in PNSI. ACS is

[5] This is a ''Conditional Other Government Agency Declaration'' input record that provides a code indicating that there are/are not other government agency review requirements.

programmed in ''batch mode'' which does not lend itself to drop down menus. CBP also has issued Administrative Messages to ABI filers in December 2004 and March 2005 concerning these reason codes. The Prior Notice Final Rule Draft CPG that is announced elsewhere in this issue of the **Federal Register** provides an updated list of reasons to be used in certain limited situations when the manufacturer's facility registration number is not provided in a prior notice submission.

(Comments) One comment recommends that the required data elements be identified so that shippers will know which elements are mandatory and which are not.

(Response) In the preamble to the IFR, FDA provided a table of the data elements for reference describing in which situations the information is mandatory (68 FR 58974 at 58980). The preamble of this final rule also contains table 2 which describes the information requirements. FDA also notes that PNSI is programmed such that if a data element does not apply, the data element is not requested during the prior notice submission process.

(Comments) One comment states that when a prior notice confirmation number is submitted to CBP and FDA, it is sometimes returned with a different prior notice confirmation number. The comment asks why this is and what happens to the original prior notice confirmation number.

(Response) FDA acknowledges that this problem occurred in the early stages of prior notice; however, we have rectified the situation. When we received a report concerning this prior notice confirmation number problem, we immediately modified our software to prevent the reported problem from reoccurring.

4. ABI/ACS Interface

(Comments) One comment states that the ABI system has been proven to be the most efficient means for meeting the prior notice time requirements.

(Response) FDA agrees that for many submitters, the ABI interface is the most efficient means for providing prior notice, as it allows the data to be saved and used for entry purposes. FDA also acknowledges that not all submitters have a custom broker, nor does ABI accommodate all transactions subject to prior notice (e.g., food imported by international mail or inside personal baggage not for personal use). Accordingly, the final rule continues to provide for electronic submission of prior notice via either ABI/ACS or PNSI.

(Comments) One comment points out that some problems with electronic submission of prior notice are being encountered by virtue of the fact that not all brokers interact with FDA in a completely electronic environment. ABI allows for the fully electronic transmission of CBP and FDA data, but ''dual mode'' brokers must also submit information to FDA in paper form. The comment recommends that FDA encourage all brokers to participate in paperless electronic processing.

(Response) ''Dual mode'' filers are those who must submit paper entries when transmitting entry information for FDA admissibility consideration. However, for prior notice, any customs broker or self-filer, including ''dual mode'' filers, may transmit using ABI/ACS or PNSI.

(Comments) One comment urges that for rail intermodal shipments between points in Canada where the transportation transits the United States, FDA should agree that data submitted to the CBP via AMS constitutes advance notice under the FDA regulations.

(Response) FDA disagrees. Under section 801(m) of the act, FDA, not CBP, must receive prior notice. Furthermore, no interface currently exists between AMS and the existing interface with FDA's OASIS through the ABI/ACS entry processes, which means FDA does not have access to AMS data. FDA and CBP have discussed interfacing with AMS for manifest data and determined that the general cargo data in AMS are not suitable to accommodate the detailed information requirements of the prior notice rule. For example, AMS does not collect the country of origin. In addition, its collection of the identities of the article of food and its manufacturer differs from the way those data points are collected under the prior notice final rule in such a way that the data would not meet our needs in carrying out the purpose of section 801(m) of the act.

(Comments) One comment reports that foreign exporters are obliged to use FDA's PNSI as they cannot register as users of CBP's ABI. The comment contends that these exporters, not being able to combine prior notice and a customs declaration for import in one operation, will be in a disadvantaged position compared to U.S. importers because the foreign exporter, after having completed his prior notice, will receive a prior notice confirmation number, which he then has to transmit to his U.S. importer or customs broker.

(Response) FDA disagrees. Prior notice may be submitted electronically through either ABI/ACS or PNSI. Typically, ABI/ACS is used by a person who contracts with a filer who is licensed and approved by CBP to use ABI/ACS. The submitter provides the filer with the information necessary to transmit a complete prior notice through ABI/ACS to FDA. This process is often used to combine the prior notice and entry processes and many importers and foreign exporters find this to be the most advantageous process. FDA and CBP provided the ability to use ABI/ACS in response to comments to the proposed rule. As expected, the ABI/ACS process is used in around 83 percent of prior notice transmissions. PNSI was developed for those submissions that cannot be accommodated by ABI/ACS, and for those who choose not to use a customs broker for prior notice submissions, and these transmissions represent about 17 percent of the total prior notice submissions.

(Comments) One comment asks that the customs broker be allowed access to all pertinent information by electronic means in order to reduce the amount of paperwork required by the prior notice process.

(Response) The means by which the submitter provides the transmitter with the required information is a matter of communication between the submitter and transmitter. The final rule neither requires nor precludes processes the parties select to handle these communications.

(Comments) Several comments request that the agencies change the process for resubmission of prior notice after the original prior notice or entry has been cancelled and when prior notice is submitted after the food is already in the United States. One comment asks that the system interface be modified so that the resubmission automatically cancels the original. Another comment suggests that in the case where the foods are already in the United States and the CBP entry has had to be cancelled and resubmitted, it should not be necessary to repeat the prior notice filing; filing entry should be sufficient. Another suggests that when the second entry is made, CBP allow for submission of the previous prior notice confirmation number rather than the creation of a new prior notice with an accompanying new prior notice confirmation number. Other comments suggest that ABI submission of prior notice be allowed for food in the United States. An additional comment states that CBP entry can be made for articles of food that are already in the United States without adequate prior notice. Another comment recommends that FDA consider allowing the submission of prior notice through the ABI interface even when that prior notice will not be

timely. Finally, one comment suggests that a new prior notice should not be required when errors are made and that an easier way should be created to provide for corrections.

(Response) In the case of a prior notice submitted after the food has arrived, the prior notice is inadequate because of no prior notice and the food may be refused. The post-refusal prior notice (i.e., the prior notice submitted after arrival) may only be submitted via PNSI until such time as ACS or its successor system can accommodate such transactions. The changes to the system requested by the comments cannot be accommodated since such revisions would require programming changes to ACS, which CBP is currently only maintaining, and not enhancing since its replacement system (ACE) is being developed.

(Comments) One comment suggests that because errors in the ABI system need to be corrected in a timely manner to facilitate transmission of prior notice, CBP should be required to be available 24 hours a day, 7 days a week to allow for correction of these clerical errors.

(Response) Inasmuch as the filer has submitted a certified summary that the filer wishes to change, the cancellation of the entry is more than just a simple correction to an ABI transmission. This change requires review because it affects the integrity of cargo release. Accordingly, any corrections to certified entry information must be done during normal business hours.

(Comments) Several comments suggest that PNSI, in its validation processes, should include a check to see if other notices are already on file for the same article and that a warning message should be established to indicate a duplicate prior notice is being filed.

(Response) FDA disagrees. The prior notice submission process allows for transmission through either ABI/ACS or PNSI. The prior notice confirmation number is unique to a transmission through either system but cannot be matched against other transmissions at this time. Programming PNSI to locate duplicate prior notices would require a considerable amount of resources, which would yield minimal benefit since the submitter would know about the duplicate submission after transmitting the prior notice.

(Comments) Several comments request resolution of a PN/ABI system interface obstacle that requires that CBP entry and prior notice be made at the same time. The comment contends that prior notice must be submitted before entry can be made (e.g., for quota class merchandise subject to CBP ''live entry'' requirements) and current system configurations can make it impossible to comply with both CBP and prior notice requirements. The comment recommends that CBP and FDA create a procedure in ABI/ACS that allows the CBP entry to be generated, but not filed, at the time a prior notice is submitted.

Another comment states that filers are insisting on submitting the entry information to CBP via ABI at the same time that they are submitting the prior notice information to the FDA. This apparently creates situations where the food is loaded and ready for shipment before there is a form of electronic release and this situation negates CBP's Customs-Trade Partnership Against Terrorism (C–TPAT) and the Free and Secure Trade (FAST) program requirements. The proximity of certain border points means that although the timeframe has been met with CBP for electronic release via CBP's PAPS, it is difficult to meet the present timeframes of the prior notice as the filer takes a longer time to submit both entries via ABI.

(Response) We disagree. Prior notice and entry need not be made at the same time. Prior notice is a precondition of entry and must be made first but may be done independently of the entry by use of FDA's PNSI or CBP's ''WP'' transaction in ABI. These systems allow for an independent submission of prior notice even if no entry has been filed. The entry filer may then provide the prior notice confirmation number to CBP as part of the entry. The entry will be validated in the CBP/FDA interface and will be allowed if the prior notice has been completed. The importer and filer may make a business decision to file the prior notice with the entry, and FDA and CBP's systems can accommodate this practice.

Because the entry and prior notice submissions may be completed independently, the timeframes are dependent on how the parties at interest choose to file entry and prior notice: The one-step (prior notice with entry) or two-step (independent prior notice followed by entry) process. This allows them to meet both timeframes, which represent two agencies, two processes, and two different sets of requirements.

(Comments) One comment contends that the lack of uniformity between the PNSI and CBP requirements for transmission of carrier information causes confusion to filers and FDA/CBP staff. The comment contends that providing the Standard Carrier Abbreviated Code (SCAC) code for the carrier in lieu of the carrier's name and country is only available when transmitting via PNSI because the CBP system, which is how the majority of prior notices are being transmitted, requires the name and country and does not provide the SCAC option.

(Response) FDA disagrees. The SCAC or International Air Transportation Association (IATA) codes can be transmitted via ABI/ACS via an Affirmation of Compliance. The CBP requirement to provide the name and country of the carrier is for purposes other than prior notice.

(Comments) Several comments recommend an interface between the CBP manufacturer identity (MID) codes and the FDA food facility registration numbers. Specific recommendations include that: (1) CBP allow the MID system to be updated via prior notice submissions; (2) FDA develop an interface with CBP that allows for validation and coordination of data between these two systems; (3) ABI provide a notification to the filer if the information from the MID does not match the facility registration information on file with FDA; and (4) the agencies permit incorrect and duplicate MID information to be corrected though a secure CBP system. Another comment recommends the establishment of a system that validates data and resolves any conflict between CBP and FDA data.

(Response) With respect to correcting and updating MIDs, CBP does not believe it is possible to eliminate all differences between MIDs and related FDA manufacturing facility registration numbers. The same manufacturer may have numerous MIDs, and conversely, a MID may identify more than one manufacturer due to the nature of the algorithm that is employed.

With respect to the comment that asks that FDA develop an interface with CBP to allow for validation and coordination of data, FDA and CBP currently exchange facility data electronically as part of the prior notice and 801(a) processes. CBP sends FDA the MID and facility information (including registration number, when applicable). FDA performs edits to ensure that the MID matches the firm represented by the registration number. In certain cases, FDA will reject a prior notice submission that does not match a MID submission. Filers will receive an ABI rejection communication identifying the mismatch when this occurs. Once the facility and all other required information has been received and validated, FDA will confirm the prior notice submission.

(Comments) Several comments suggest that when a prior notice is transmitted via ABI/ACS and confirmed for review by FDA, the data should be

moved from ACS to OASIS regardless of the estimated time of arrival (ETA) date.

(Response) The ABI/ACS system is not configured to certify information nor transfer information to FDA in real-time as PNSI does. ACS is programmed to collect data in batch mode and does not transmit the data to FDA instantaneously. Therefore, prior notices submitted via PNSI will continue to receive a real-time system response when the prior notice is confirmed for review by FDA. However, prior notices submitted via ABI/ACS will continue to be transmitted in a batch mode and to receive systematic confirmation responses in the pre-arranged timeframes developed by CBP. For those prior notices submitted via ABI on the anticipated date of arrival, users can expect to receive a response message (confirmation number or rejection) within 15 minutes of submission. For ABI submissions submitted prior to the anticipated date of arrival, users can expect to receive a response message no later than midnight (Eastern Time) on the anticipated date of arrival, i.e., the message generally is sent before 11:59 p.m. on the day before the anticipated date of arrival.

(Comments) Several comments state that although PNSI is designed to not require changes in the location of the anticipated port of arrival (thus allowing a shipment to be diverted to a port other than the intended port of arrival transmitted in the prior notice), the CBP ABI system precludes the CBP entry from being accepted at other than the reported port of entry. When this occurs, the CBP entry and original prior notice must be deleted and a new entry must be submitted with a new prior notice creating a new timeframe. The comments recommend that the requirement be consistently applied and that the ABI/ACS system be revised to allow for changes to the port of entry without causing cancellation of the CBP entry.

(Response) FDA disagrees. The prior notice rule does not require a new prior notice when the anticipated port of arrival changes after the prior notice has been confirmed for review by FDA. CBP does require cancellation of entry documentation for entry purposes when the port of entry changes. The cancellation of an electronic ABI entry for CBP results in the cancellation of any associated prior notices filed with the entry in ABI. Amending ABI/ACS to allow amendments, such as when the port of entry changes, would entail substantial and costly revisions to the system; such technical changes are not cost-effective or a good use of limited resources given the development of the Automated Commercial Environment, which will replace ACS.

(Comments) One comment recommends that for a short trial period, the full prior notice edits, with warning messages, should be turned on without rejection of CBP entry processing. The comment reasons that this would be a method of alerting ABI/ACS transmitters to errors without jeopardizing the movement of the food. Another comment suggests that a significant reason for a high rate of noncompliance on data submissions is the lack of the automated systems' capability to advise filers of data inadequacies.

(Response) The systems provide for error messages to be transmitted to filers that identify the reasons for errors in prior notice submissions that can be determined during the data entry process (e.g., certain required data elements are missing or product code submitted is invalid). Over time, the agencies have seen the prior notice rejection rate go down. Both agencies have been providing industry with information regarding error messages.

(Comments) One comment points out that the PNSI Web portal has changed to allow multiple containers to be reported against a single prior notice line but that CBP has not changed their specifications to allow more than a single container to be reported on a prior notice line in ABI. The comment recommends that this change to the FDA Web portal be communicated to CBP so they may change their ABI specifications.

(Response) ABI currently allows filers to submit multiple container numbers per FDA line by sending multiple FD05 records containing affirmation of compliance code ''CNO.'' The first affirmation goes in the FD01 record, with subsequent affirmations in the FD05 record which can be repeated as often as necessary. Filers are able to submit multiple records using the affirmation of compliance code ''CNO'' and provide a different container number in each record.

5. PNSI

(Comments) One comment suggests that to more effectively screen shipments entering the United States, FDA must work to integrate OASIS with the prior notice system.

(Response) FDA's OASIS has always been an integral part of the prior notice process as OASIS provides for internal systematic screening of prior notice submissions in order to assist the agency in making a determination regarding inspection of the food at the border. OASIS also provides for systematic screening to assist FDA in making admissibility decisions.

(Comments) Several comments request extension of the time one is permitted to be logged into a session using PNSI. Comments state that it is difficult to complete entering data before the system times out. Several comments suggest that completing the process in time was difficult for many persons whose native language is not English.

(Response) For security reasons, PNSI is currently configured with a 30-minute time-out. FDA notes that Internet commerce systems are typically configured with a similar, or more stringent, time-out setting. FDA also notes that the time-out setting applies only to a period of user inactivity; no limit is set on the total amount of time the user may be logged into a particular session, nor is there a limit to the amount of time taken to prepare and save or submit a specific Web entry or prior notice. Users are ''timed-out'' only if their session remains inactive for longer than the time-out setting.

Users may also save their entry while it is partially completed. The data are retained and will be available when the user logs back into the system.

(Comments) Several comments express concern about the capacity of the FDA computer systems to process the volume of submissions. These comments suggest that the system needs additional capacity to meet the loads expected when full enforcement is instituted. Several comments also believe that performance issues (e.g., slow response) are hampering their usage of the system.

(Response) FDA recognizes these concerns and is committed to providing systems that will meet user needs. FDA designed the prior notice systems to process a volume of users far in excess of the projected usage. Prior to implementation, FDA thoroughly tested the performance of its system against loads in excess of that anticipated. These tests have shown the system capable of maintaining acceptable response even at these loads. Currently, FDA handles approximately 167,000 prior notices each week and could handle a much higher volume without a capacity problem.

Many factors influence the responsiveness of an Internet based system, including factors beyond the FDA's control, such as the user's computer system (hardware, software, and Internet connection) and traffic on the Internet as a whole. Since prior notice was implemented in December 2003, FDA has carefully monitored both PNSI and OASIS system usage and

performance. During this period, no issues related to load on these systems have been identified. FDA has worked to resolve specific issues, such as hardware failures, which have hampered system performance and availability for short periods.

FDA and CBP also have increased the capacity of the communications link between their systems to ensure that additional bandwidth is available for future increases in load. FDA continues to monitor its system and to test for performance as the system is upgraded and enhanced. Users may obtain current system status information for PNSI at the FDA Industry Systems home page (*http://www.access.fda.gov*) and are requested to contact the Help Desk if they encounter any performance issues currently not identified on the system status page.

(Comments) Several comments recommend that FDA develop an alternate system that supports batch submission of prior notices. The comments suggest that a batch system would save submitters a vast amount of input time and allow the agency faster processing capability. The comments also assert that a batch system would reduce the costs incurred due to double entry between the user's existing systems, e.g., for order entry and filing with FDA. One comment proposes that they be given a defined quantity of registration numbers at their disposal for printing onto their dispatch labels (presumably by registration number they are referring to the prior notice confirmation number). The comment says they would like a fully automated process, where all data relevant for prior notice would be created and then transmitted electronically to CBP and FDA, instead of the current procedure of manual input of all details.

(Response) FDA agrees that a mechanism to facilitate batch/fully automated filing would provide some advantage to certain filers. However, FDA believes that the existing systems (PNSI and ABI) currently provide substantial capabilities in this area. PNSI offers several features that make prior notice data entry faster and reduces the amount of redundant data entry such as the Copy Web Entry feature, Copy Prior Notice feature and other shortcuts. Please refer to Time Saving Tips from FDA's PNC for PNSI (*http://www.cfsan.fda.gov/~pn/pntips.html*) for a description of these features. ABI software can often provide similar copying features, depending on the ABI software package used by the transmitter.

FDA also recognizes that the resources to develop and maintain an additional system would be significant. Therefore, FDA is not prepared to undertake the development of a batch system at this time; following completion of any system upgrades that will be released in conjunction with implementation of the final rule, FDA will reassess the need for and feasibility of developing a batch submission system. FDA notes that some submitters have created their own internal programs that are designed to organize data in ''batch'' mode, which in turn submits their prior notices to PNSI in rapid succession.

(Comments) One comment states that they frequently ship the same article of food in multiple containers. The comment believes that since there is only one article of food, only one prior notice should be required. The comment notes that the FDA Web Portal only allows the input of one container per prior notice; therefore, they have to submit multiple prior notices instead of only one. The comment requests that the FDA Web Portal be changed to allow for the input of multiple containers per article of food.

(Response) FDA agrees. The FDA Web Portal has been changed to allow multiple containers to be reported against a single prior notice line in the above situation.

(Comments) One comment states that most of their orders contain multiple food items in one box and the process of filing prior notice in PNSI for each item is very time consuming because one can only enter one item at a time. The comment suggests updating PNSI to allow users to enter multiple items on one screen (i.e., the user creates a Web entry for each shipment and the system then allows them to specify all items in that shipment on one screen).

(Response) A prior notice contains information on not just the article of food being imported, but also the facilities related to that article such as the manufacturer, shipper, owner and ultimate consignee. Since this information can be unique for each article, it must be provided for each article individually. PNSI does offer several features that make prior notice data entry faster and reduce the amount of redundant data entry such as the Copy Web Entry feature, Copy Prior Notice feature and other shortcuts. Please refer to Time Saving Tips from FDA's PNC for PNSI (*http://www.cfsan.fda.gov/~pn/pntips.html*) for a description of these features.

(Comments) One comment states that FDA's Web Portal does not accept the input of CBP entry numbers. The comment further states that there are times when an entry number is not required for an article of food that requires prior notice. The comment questions why the FDA Web Portal does not accept an entry number when a CBP entry is required and known at the time of filing prior notice. Another comment recommends that the Web Portal software be redesigned in order for filers to receive the relevant entry identifier information with the prior notice confirmation number.

(Response) FDA disagrees. PNSI does accept the CBP entry number. If there is no entry number or other entry identifier, PNSI will provide a system-generated entry identifier to the prior notice submission. We also posted guidance on FDA's Web site at *http://www.cfsan.fda.gov/~pn/pnentgui.html* that describes the entry types and the entry identifiers. (See also discussion infra on the CBP entry identifier in section III.H.5 of this document.)

(Comments) Several comments express concern about system outages for PNSI and/or ABI. These comments suggest that one or both systems had not been available for extended periods in the past or were frequently unavailable. Comments also recommend that FDA provide an alternate method, such as facsimile, for submission during periods when the systems are not available. One comment notes that PNSI has not been functioning properly. The comment states that the System Status update pages indicates that the system is operating as ''normal,'' but the system is really down.

(Response) FDA recognizes that system outages could have the potential to disrupt trade. To minimize outages, FDA has built redundancy into these computer systems (e.g., multiple servers and backup systems) and, to the extent possible, combined planned maintenance activities to be accomplished during a single outage. Planned outages are scheduled for a timeframe with the minimum possible impact to users and notice is provided as far in advance as possible, allowing users to plan their access to the system. System status information, including planned outages, is posted at *http://www.access.fda.gov* and at *http://www.cfsan.fda.gov/~furls/fisstat.html*. Users are requested to contact the Help Desk if any performance issues not identified on the system status page are encountered.

FDA also provides alternate options for users to file prior notice during system outages. Filers who use CBP's ABI/ACS system can utilize PNSI when ABI, ACS, and/or OASIS are unavailable. In addition, FDA has provided a method for filing via facsimile or e-mail when PNSI is

unavailable for an extended period (see the Contingency Plan for System Outages at *http://www.cfsan.fda.gov/~pn/pndguid.html*). These contingency plans are designed to ensure that the flow of trade is not interrupted when system outages cannot be avoided (see also the discussion on contingency plans below).

(Comments) One comment notes that companies continue to report technical difficulties when using PNSI, including the inability to access reliable technical advice through the hot-line. Another comment indicates that the waiting time for the helpline is very long, with a minimum wait time of 15 minutes.

(Response) FDA has made a number of enhancements and has fixed several issues with earlier releases of PNSI. FDA also continues to work to provide the best possible service addressing technical issues through the Help Desk. Users are encouraged to continue to contact the Help Desk for technical assistance. The Help Desk is available Monday through Friday from 7:30 a.m. to 11 p.m. Eastern Time. Users may leave a message or send e-mail at other times, which will be addressed on the next business day.

(Comments) Several comments address the complexity of PNSI. The comments state that the system requires the complete re-creation of all data for each prior notice even when shipments are repetitive with minimal variables in information; that the full address should not be necessary for registered facilities; and that PNSI should allow submitters to save and store data for replication or provide for self-populating fields. One comment, however, notes that their users have had relatively little problem using PNSI.

(Response) FDA continues to provide, to the extent possible, a ''user-friendly'' PNSI application. Several features have been added since the initial release (PNSI 1.0) to assist users, including a feature that allows users to copy individual prior notices and Web Entries, with or without the associated prior notices. Where possible, lists of standard values (e.g., entry types, SCAC & IATA Codes, firm types, quantity and packaging descriptions) are provided to facilitate entry of these values. These enhancements minimize the need for users to enter repetitive information. Similar to the IFR, the prior notice final rule does not require the full address in all cases. When a registration number is provided, name, city and country can usually be provided instead of the name and full address (e.g., § 1.281(a)(6)). FDA continues to work to enhance the system, in response to user comments, as well as to changing business requirements.

(Comments) One comment asks if PNSI will provide guidance on formatting of the information for identification of the submitter, transmitter, and manufacturer. The comment is concerned that PNSI may only accept certain formatting, without providing guidance to the submitter, thereby, causing problems with PNSI accepting and processing prior notice.

(Response) PNSI is supported by several tutorials and help screens which lead the user through correct inputting of data.

(Comments) Several comments address specific issues with the PNSI software (potential ''bugs'') or suggestions for enhanced capabilities. Examples include questions about the completeness of the lists of values (drop-down lists), issues with browser settings and compatibility, and suggestions for additional bar code printouts.

(Response) FDA welcomes user suggestions for improvements to the PNSI system. Discrepancy reports are investigated thoroughly to ensure the system meets both FDA's requirements and user needs to the extent possible. Suggested improvements are also prioritized and reviewed by a Change Control Board who continue to determine appropriate and feasible improvements to the system. FDA encourages users to continue to contact the Help Desk with any technical questions, issues, or suggestions.

(Comments) One comment suggests that PNSI should be revised to create a view screen similar to the printed confirmation with all the information in one place before submission. The comment also suggests that when creating a prior notice for different commodities, the system should not have all commodities default onto prior notice, but should allow the user to use a check box to choose a commodity, rather than to cancel the commodity.

(Response) FDA agrees. The PNSI software has been enhanced to provide a screen that includes all of the information about the prior notice prior to a transmitter completing the submission step. PNSI also has been enhanced to allow copying of prior notices within a Web Entry and copying of a Web Entry, with or without the associated prior notices. A user thus can copy a Web Entry with all associated prior notices, then use the cancel function to remove any prior notices not required for the new entry.

FDA welcomes any additional comments or suggestions on how to improve PNSI; these can be submitted to the Help Desk using the telephone number or e-mail provided at *http://www.cfsan.fda.gov/~furls/helpf.html*.

6. Security of the Systems

(Comments) One comment suggests that FDA create a mechanism whereby interested parties may assert protection from public disclosure under FOIA for information contained in prior notices that they believe is confidential business information.

(Response) We believe that there is no need to create such a mechanism because the agencies would review the prior notice information to determine if it is protected by a FOIA exemption before disclosure to the public.

(Comments) One comment states that in order to complete the PNSI submission, several security settings on their respective computers had to be disabled.

(Response) PNSI is designed to work with the browsers listed at *http://www.access.fda.gov/*, using standard settings. PNSI requires that the browser be set to accept cookies. FDA does not believe that these settings present a security risk to users. Users are encouraged to contact the Help Desk for assistance with specific issues regarding access and system settings.

7. Contingency Plans

In § 1.280(b), (c), (d), and (e) of the IFR, FDA requires that if a custom broker's or self-filer's system is not working or if the ABI/ACS interface is not working, prior notice must be submitted through PNSI. It further states that if the PNSI is not working and/or OASIS is not working, FDA will issue an Internet notification, and submission of prior notice must be by e-mail or by facsimile to FDA. FDA posts the e-mail or facsimile information on its Web site. The prior notice information will only be accepted at the posted e-mail or facsimile locations if FDA determines that PNSI or OASIS is not working.

On August 12, 2004, FDA and CBP published guidance covering a Contingency Plan for System Outages (see *http://www.cfsan.fda.gov/~pn/pndguid.html/*). FDA and CBP identified seven potential system downtime scenarios that could impact transmission, confirmation, and processing of prior notice submissions and developed alternative submission options for each of the identified scenarios.

(Comments) One comment states that FDA and CBP need to formulate and communicate a realistic contingency plan for commercial importations that takes into account CBP ABI downtime, FDA OASIS downtime, and broker

downtime. Two comments express concern that contingency plans include a dependency on PNSI and their experience has shown that PNSI was intended for the casual importer and never intended for commercial operations. The comment states that significant delays will be experienced if 80 percent of the transactions are suddenly routed from the ABI/ACS system to the PNSI system.

(Response) FDA is committed to providing systems that will meet user needs. FDA designed PNSI to process a volume of users far in excess of the projected usage, and tested performance at these volumes. As noted previously, FDA and CBP published guidance covering a Contingency Plan for System Outages (see *http://www.cfsan.fda.gov/~pn/pndguid.html/*) and anyone may submit comment on it.

(Comments) One comment suggests that FDA and CBP provide guidance that defines an appropriate timeframe to wait for prior notice confirmation before assuming the system is down and/or that resubmission is required.

(Response) Generally, for prior notice submissions via PNSI, the user should receive a confirmation number immediately upon submission of the correctly completed form. For those prior notices submitted via ABI on the anticipated date of arrival, users can expect to receive a response message (confirmation number or rejection) within 15 minutes of submission. For ABI submissions submitted prior to the anticipated date of arrival, users can expect to receive a response message no later than midnight (Eastern Time) on the anticipated date of arrival, i.e., the message generally is sent before 11:59 p.m. on the day before the anticipated date of arrival.

The FDA/CBP Contingency Plan states that ''notice advising of any available downtime specifics will be posted at *http://www.access.fda.gov*, *http://www.fda.gov*, *http://www.cfsan.fda.gov/~furls/fisstat.html*, and *http://www.cfsan.fda.gov/~pn/pnoview.html*, and through messages in ABI/ACS (see 21 CFR 1.280(d))'' Section 1.280(c), (d), and (e) of the IFR also lists three of these four Web sites to advise of system downtimes, and specifies in what form prior notice should be submitted during certain system outages (i.e., e-mail or fax). In order to simplify the Web addresses for these notifications and the instructions for submitting prior notice when PNSI or OASIS is not working, the final rule has been revised by providing the outage notification at one Web address (*http://www.fda.gov*). In order to provide more flexibility to respond to various contingencies, the final rule has also been revised by stating that FDA will accept prior notice submissions in the format it deems appropriate during the system(s) outage.

FDA has posted information on the Systems Status Web site located at *http://www.cfsan.fda.gov/~furls/fisstat.html* regarding system downtime that states ''Most problems will be temporary. Try accessing the system again in 15 minutes.'' This site also provides information about scheduled maintenance, which states that ''Periodically FDA Industry Systems will need to undergo maintenance and upgrades. All scheduled maintenance will take place on Saturdays 3 a.m. to 8 a.m. Eastern Time (Saturday 8 a.m. to 1 p.m. GMT). If you are having trouble accessing FDA Industry Systems during that time, please try again after 8 a.m. Eastern Time on Saturday (1 p.m. GMT).'' This site also provides a status history of the system.

(Comments) One comment suggests that FDA should develop and publish a form that could be used if it were ever necessary to file prior notice by fax. The comment asserts that a form also would assist importers in gathering the information necessary to file a prior notice and also would clear up the confusion that currently exists in foreign countries. The comment believes that it was obvious that FDA contemplated issuing a form when it first proposed the prior notice regulations and complains that no explanation has been given by FDA for not producing the form.

(Response) FDA disagrees. A form to be used during contingencies is posted on FDA's Web site only when an applicable system outage is encountered. During a system outage when fax submissions are being accepted, FDA will publish the fax telephone number for the PNC at *http://www.access.fda.gov*, *http://www.fda.gov*, *http://www.cfsan.fda.gov/~furls/fisstat.html*, and *http://www.cfsan.fda.gov/~pn/pnoview.html*, as well as through messages in ABI/ACS. Fax transmission is not allowed except when posted and submitted during PNSI downtimes or specified emergencies. FDA believes that if the form was available and posted even as a reference, there is the potential for misuse or confusion. Our experience with use of the fax form is that submitters will continue to fax the form even after they have been instructed that the form will not be accepted.

(Comments) Some comments express concern that submission of all prior notices relies on electronic systems (even the fax). The comments suggest that the usual flow of goods should be allowed to continue unhindered, with the paperwork sorted out afterwards. One comment further suggests that rather than providing for PNSI as a contingency system when ABI is down, prior notice submissions should function according to all other submissions processed through ABI when CBP declares either a ''national snow day'' or ''power outage.'' The comment recommends that if ABI is not working, the shipment should be allowed to proceed, pending later issuance of a prior notice confirmation via ABI.

(Response) FDA does not agree that if ABI is not working the shipment should be allowed to proceed. In that instance, prior notice can, and therefore should, be submitted via PNSI.

In all contingency situations, except for power failure, some electronic means of prior notice submission is required, either by PNSI, e-mail, or fax. However, in the case of a localized or regional power failure, the Contingency Plan guidance recommends that filers should submit the required prior notice information to FDA at the port of arrival, or if there is no FDA officer at a given port, to CBP via a paper copy of the prior notice e-mail contingency form (FDA 3540) at the time of cargo release.

(Comments) One comment explains that various companies are organizing contingency plans whereby the prior notice confirmation number will be included in the delivery order, which then will be faxed to the office of the steamship line at the port of entry so that the requisite paperwork is in hand when the product is offloaded from the carrier. The comment further explains that this contingency plan takes into account the unique circumstances posed by transporting goods by steamship line insofar as the customs broker or purchaser may not always be able to send the prior notice confirmation number to the carrier prior to the carrier's arrival. The comment asserts that the procedure satisfies FDA's requirements that the prior notice confirmation number must accompany the food when it ''arrives in the United States'' and be provided to CBP or FDA ''upon arrival.'' The comment further urges FDA to include this course of action in its guidance documents.

(Response) FDA agrees that the described scenario satisfies the requirement under § 1.279(g) that the prior notice confirmation number must accompany any article of food for which the prior notice was submitted through PNSI when the article arrives in the United States and must be provided to

CBP or FDA upon arrival. FDA does not believe, however, that it is necessary to include this specific business practice in its guidance documents, as there are various means that private entities may choose to use to comply with the regulation.

As described in the contingency plan guidance, if prior notice already has been submitted via ABI/ACS prior to an interface outage, and confirmation from FDA already has been received, then the submitter may proceed with prior notice using the standard process under the following scenarios:

- ACS, OASIS, and PNSI are all operational, but the link between ACS and OASIS is down on FDA's or CBP's side of the system interface;
- ACS, PNSI, and the link between ACS and OASIS are operational, but OASIS is non-operational;
- ACS and the link between ACS and OASIS are operational, but OASIS is non-operational and PNSI is non-operational or unavailable due to Internet service interruptions;
- OASIS, PNSI and the link between ACS and OASIS are operational but ACS is non-operational; or
- ACS is non-operational, PNSI is non-operational or unavailable due to Internet service interruptions, and OASIS and the link between ACS and OASIS are either operational or non-operational.

The standard process does not include presentation of the prior notice confirmation number to FDA or CBP upon arrival if the prior notice was submitted by ABI/ACS.

If prior notice already has been submitted via ABI/ACS and confirmation from FDA has not been received prior to the interface outage, FDA and CBP recommend that rather than resubmitting via PNSI, submitters should provide to CBP officers, at the time of cargo release, an endorsed (signed) copy of the ABI transmission or some other evidence adequate to show that prior notice has been submitted via ABI/ACS.

If prior notice has been submitted via PNSI prior to the system outage and a confirmation number already has been received, the confirmation number must accompany the article of food (§ 1.279(g)). In addition, FDA and CBP recommend that the submitter also provide the PNSI confirmation page, including the prior notice confirmation number and time stamp, to CBP officers for cargo release. If the prior notice confirmation page is not provided, this may delay cargo release while the CBP officer contacts FDA for verification of the prior notice confirmation number(s) and time of submission.

(Final rule) The final rule in § 1.280(a) requires that prior notice must be submitted electronically to FDA in the English language, except that an individual's name, the name of a company, and the name of a street may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet.

Section 1.280(a)(1) and (a)(2) of the final rule provides for two methods of electronic submission of prior notice: (1) The CBP Automated Broker Interface of the Automated Commercial System (ABI/ACS); or (2) The FDA PN System Interface (PNSI) at *http://www.access.fda.gov*. We corrected a reference in paragraph (a) to state that unless § 1.280(c) applies, prior notice must be submitted through either ABI/ACS or PNSI.

The final rule requires submission of prior notice via PNSI for articles of food imported or offered for import by international mail, and other transaction types that cannot be made through ABI/ACS. Prior notice for articles of food that have been refused under section 801(m)(1) of the act must be submitted through PNSI until such time as ACS or its successor system can accommodate such transactions.

The final rule also provides for contingencies if involved systems were not working, e.g., a custom broker's or self-filer's system, ABI/ACS, PNSI, or OASIS. The final rule requires that prior notice must be submitted through PNSI if a customhouse broker's or self-filer's system or if the ABI/ACS interface is not working. The final rule states that if PNSI or OASIS is not working, FDA will post prominent notification and instructions at *http://www.fda.gov*. FDA will accept prior notice submissions in the format it deems appropriate during the system(s) outage. The final rule does not exempt any specific categories of food articles from prior notice if systems are not performing.

H. What Information Must Be in a Prior Notice? (§ 1.281)

The Bioterrorism Act requires the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; and the anticipated port of entry for the article.

The IFR requires in § 1.281(a), (b), and (c) that specific information be submitted in prior notice: Section 1.281(a) covers general information requirements which apply to all shipments except those arriving by international mail; section 1.281(b) covers limited information requirements for food arriving by international mail; and section § 1.281(c) covers information requirements for food refused under section 801(m) of the act (e.g., food that has already arrived in the United States).

The preamble to the IFR discusses the term, ''an article of food,'' and states that ''the description of an 'article' of food is not the same as the definition of 'food' in § 1.276(b)(5). An 'article' refers to a single food that is associated with the same complete FDA Product Code, the same package size, and the same manufacturer or grower. These requirements are found in the information required in the IFR in § 1.281(a)(5), (a)(6), or (a)(7) and again in § 1.281(b) and (c)'' (68 FR 58974 at 59003).

The comments are discussed in order of the information requirement in the IFR, beginning with comments generally addressing the information requirements.

1. General Comments

(Comments) Several comments express concern that the IFR requires significantly more information than the Bioterrorism Act requires and ask that FDA reduce the number of data elements. One comment notes that the Bioterrorism Act names only six or seven specific items that must be provided. One comment indicates that the information required for prior notice is far in excess of that required in the Codex Committee on Food Import and Export Inspection and Certification Systems Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates (CAC/GL 38–2001). One comment adds that the required information far exceeds what is necessary to enable FDA to identify articles of food that need to be inspected. Another comment suggests that some of the information required for a prior notice is already ''covered'' by the registration requirement of section 305 of the Bioterrorism Act (see the Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 interim final rule, 21 CFR part 1, subpart H, confirmed 70 FR 57505, October 3, 2005), so FDA will already have this information. Another comment suggests that the prior notice could be simplified, thus reducing the possibility of errors and potential trade disruptions, by quoting the registration number and only adding information

specific to a particular shipment. One comment notes that CBP's data fulfill FDA's needs; therefore, the IFR's duplicate system is a waste of resources, and FDA should use CBP's system.

(Response) FDA disagrees with the comments that ask for a reduction in the number of required data elements. FDA has selected those data elements that will allow FDA to meet its statutory obligation to receive, review, and respond to prior notices efficiently and effectively. In addition to the Bioterrorism Act's requirements of the identities of the article of food, the manufacturer and shipper, the grower, if known, the country from which the article originates, the country from which the article is shipped, and the anticipated port of entry for the article, FDA determined that certain additional information is required for efficient enforcement of the Bioterrorism Act, primarily for the means of identifying the article of food and effective enforcement of refusals. For example, the identification of the individual and the firm, if applicable, submitting the prior notice is needed so that FDA knows who is responsible for the information in the prior notice and can communicate with them when necessary via mail, phone, or e-mail. The information also is necessary to follow up when audits, inspections, or enforcement are necessary. Therefore, FDA does not agree with one of the comment's assertions that the prior notice rule should only require the registration number and other information specific to a particular shipment.

The goals of the Bioterrorism Act and the Codex Committee differ, and thus, the requirements of the prior notice rule will differ from that of the Codex Committee on Food Import and Export Inspection and Certification Systems. The purpose of prior notice is to enable FDA to conduct inspections of imported foods at U.S. ports upon arrival and target foods that may pose a significant risk to public health, based on the information submitted. The Codex Committee on Food Import and Export Certification and Inspection Systems is charged with developing principles and guidelines for food import and export certification and inspection systems.

We also do not agree with the comment's assertion that FDA should use CBP's data to fulfill FDA's needs under the Bioterrorism Act. Information that is submitted at the time of CBP entry processing is not useful for prior notice as this information can be submitted or changed after the food has already arrived in the United States and thus does not fulfill the express intent of the Bioterrorism Act that FDA receive information about a shipment before it arrives in the United States.

FDA also does not agree that some of the prior notice information is already ''covered'' by the food facility registration requirement. For example, facilities typically provide general product categories as part of the registration process. This generalized information would not provide the identity of the article being imported or offered for import and, therefore, would not meet the prior notice requirements as defined in section 801(m) of the act. Therefore, we do not agree that some of the registration information could be used to meet the prior notice information needs. Moreover, a facility's registration contains all of the general food product categories the facility manufactures, processes, packs or holds; and would not allow FDA to know specifically which article of food is the subject of the prior notice, which precludes an effective assessment of risk.

(Comments) Several comments recommend that the limited information requirements associated with food arriving by international mail in § 1.281(b) be applied to all importations. One comment suggests that by eliminating such data as the entry type and identifier, the port of entry, the FDA Product code, and the HTS code, all prior notices could be submitted via FDA's PNSI at an earlier time. The comment further asserts that the requirement for these types of data is the primary reason that 80 to 90 percent of prior notices are submitted via ABI/ACS rather than PNSI. Another comment reasons that as the manufacturer and facility identification numbers are not provided for homemade food or postal shipments, the necessity of providing this information for other types and modes should be examined. Another comment recommends that the notification procedure should be simplified, and that the data elements should be limited to the minimum, such as the shipper's name and its contact point, the food facility registration number, and food product codes.

(Response) FDA disagrees. The type of information required for prior notice submissions of food arriving by international mail are limited because of the process by which international mail enters the United States. For international mail shipments, the IFR and the final rule requires the identification of the U.S. recipient rather than the importer, owner, or ultimate consignee because mail is sent only to a U.S. recipient rather than the multiple entities that may be involved in a traditional commercial importation. The final rule does not require an entry identifier because international mail will always receive a system-generated identifier, as international mail shipments cannot be submitted via ABI/ACS. Because the port of entry and time and date of entry are completely subject to the international mail process, the IFR requires only that the submitter identify the date of shipment, i.e., the date the food is shipped, which provides the most information possible to satisfy the anticipated port of entry. Moreover, since international mail is always in the custody of CBP until it is released for delivery to the recipient, no additional shipment information is necessary for communication between FDA and CBP.

FDA also disagrees that information, such as the entry type and identifier, the port of entry, and the FDA Product Code should be eliminated from the prior notice requirements. The anticipated port of entry is specifically required by the statute and FDA has determined that the best possible method of determining product identity is the FDA Product Code. We have eliminated the HTS code in the final rule because it has not been a necessary factor for enhancing communication between FDA and CBP for the purpose of inspection at the port of arrival. However, the entry type and identifier are critical elements in communications between FDA and CBP so that the appropriate food is either held at the port of arrival as appropriate, or allowed to proceed.

FDA also disagrees with the suggestion that the manufacturer and facility registration numbers are not provided for homemade food or postal shipments and, therefore, should not be required for other types of shipments. The IFR excludes homemade food from prior notice requirements entirely, and this exclusion also is in the final rule. Both the IFR and the final rule require submission of the identity of the manufacturer and the manufacturer's registration number in the prior notice for food arriving by international mail.

FDA agrees with the comments that prior notice requirements should be limited to the minimum, and has selected those data elements that will allow FDA to expeditiously meet its statutory obligation to receive, review, and respond to prior notices. FDA, however, does not agree with the comments that the shipper's name and its contact point, the registration number of food facility, and food product codes are the only data elements FDA needs to fulfill this mandate. In addition to the Bioterrorism

Act requirements of the identities of the article of food, the manufacturer and shipper, the grower, if known, the country from which the article originates, the country from which the article is shipped, and the anticipated port of entry for the article, FDA determined that certain additional information is required for efficient enforcement of the Bioterrorism Act, primarily for the means of identifying the article of food and effective enforcement of refusals.

FDA also notes that it is not surprising that 80 to 90 percent of prior notices are submitted via ABI/ACS. Numerous comments on the proposed rule urged FDA to use the existing ACS–OASIS interface between CBP and FDA to accept prior notice information. As stated in the IFR, FDA and CBP agreed with the recommendation that the agencies provide a single point of data entry for CBP and FDA for as many kinds of entries as possible, and modified our systems to allow prior notice to be filed by either CBP's ABI/ACS or FDA's PNSI beginning with the December 12, 2003, effective date of the IFR. FDA also noted at that time that it expected approximately 90 percent of prior notice submissions for all importations of foods to be transmitted by a customs broker or self-filer through the ABI/ACS interface to FDA. (See 68 FR 58974 at 58976, October 10, 2003.) Since implementation, this estimate has proven true, as approximately 83 percent of all prior notices are filed through the ABI/ACS interface.

(Comments) Several comments suggest that all prior notice information requirements that are duplicative of information requirements for CBP via AMS for Advanced Electronic Information or in ABI/ACS for Entry should be eliminated. One comment recommends that prior notice be aligned with CBP ''ACI'' rules, for both timing and data elements. The comment believes that this could lead to a possible reduction in data elements.

(Response) FDA disagrees. Information that is submitted for CBP entry processing is not useful for prior notice as this information can be submitted or changed after the food already has arrived in the United States and prior notice is required before the food arrives.

Moreover, no interface currently exists between AMS and the existing interface with FDA's OASIS through the ABI/ACS entry processes, which means FDA does not have access to AMS data. FDA and CBP have discussed interfacing with AMS for manifest data and determined that the general cargo data in AMS are not suitable to accommodate the detailed information requirements of section 801(m) of the act. For example, its collection of the identities of the article of food and its manufacturer differs from the way those are collected under the prior notice interim final and final rules in such a way that the data would not meet our needs in carrying out the purpose of section 801(m) of the act.

(Comments) Many comments suggest that submitters consolidate similar prior notices into one prior notice based on a variety of reasons, e.g., one prior notice per consignee with all food products consolidated; one prior notice per shipment with all information consolidated; one prior notice per commodity regardless of the quantity, size, color or species; one prior notice per bill of lading; one prior notice per truck or conveyance and one prior notice for the same food type regardless of brand.

(Response) The Bioterrorism Act requires notice for each article of food and requires in that notice, for each article of food, certain information. As stated in the IFR, an ''article'' refers to a single food that is associated with the same complete FDA Product Code, the same package size, and the same manufacturer or grower (68 FR 58974 at 59003). This is consistent with how entry is filed with CBP. An article of food is a unique item related to a specific manufacturer or grower and a specific process or size. All of these pieces of information are critical for a risk-based assessment of the food. The ABI/ACS system provides the capability to submit information for multiple food items as lines in a single entry, when entry level information is consistent for a number of articles in a shipment. For example, shipment level information, such as estimated time of arrival, can be captured once for all articles within a shipment. The ability to minimize data entry by copying specific information from one article, or line, to another depends upon the sophistication of the software being used by the submitter to create the submission to CBP. The FDA PNSI allows for simplified submission of similar articles of food by allowing the submitter to easily repeat common information (e.g., FDA product code, manufacturer, etc.) while entering different quantities (e.g., amount and package size). Both systems thus significantly reduce the amount of repetitive entry. The prior notice requirements in the IFR or the final rule do not require the submission of the brand for the article of food.

(Comments) One comment suggests that different programs should not require different information requirements. The comment particularly focuses on FAST and C–TPAT and recommends that prior notice submissions for those participating in these programs should be subject to fewer information requirements.

(Response) FDA disagrees. All of the information required in a prior notice is necessary for determining what articles to inspect upon arrival and otherwise carrying out section 801(m) of the act. The information is initially screened electronically in order to expedite the PNC's review. If less information is provided, regardless of whether the food is covered by some other program, then the result of that screening would be less reliable. This issue is discussed further in section III.D.6.a of this document (''Additional Exclusions Requested—Special Programs (C–TPAT/FAST) and Flexible Alternatives—General Comments'')

(Comments) Two comments refer to submission of ''blanket'' prior notices; one referencing repetitive shipments of analytical samples and the other suggesting a summary of daily shipments.

(Response) FDA disagrees that it should change its approach from the IFR. As stated in the preamble to the IFR (see 68 FR at 59003), an article of food is a unique item related to a specific manufacturer or grower and a specific process or size. All of these pieces of information are critical for a risk-based assessment of the food. FDA currently receives most of this information from customs brokers or self-filers via ABI/ACS. The ABI/ACS system also provides the capability to submit information for multiple food items as lines in a single entry, when entry level information is consistent for a number of articles in a shipment. For example, shipment level information, such as estimated time of arrival, can be captured once for all articles within a shipment. The ability to minimize data entry by copying specific information from one article, or line, to another depends upon the sophistication of the software being used to create the submission to CBP. The FDA PNSI is designed to allow for simplified submission of similar articles of food by allowing the submitter to easily repeat common information (e.g., FDA product code, manufacturer, etc.) while entering different quantities (e.g., amount and package size). Both systems will thus significantly reduce the amount of repetitive entry of information while preserving the identity of each article of food. Moreover, the purpose of prior notice is for FDA to receive, prior to arrival, information about each article of food being imported or offered for

import for the purpose of enabling such article to be inspected at ports of entry into the United States. Receiving blanket prior notices would not provide the necessary information nor would a daily summary, which by definition would be after-the-fact, not prior to arrival.

2. The Submitter

In § 1.281(a)(1), (b)(1), and (c)(1), the IFR requires submission of the name of the individual submitting the prior notice and his/her business address, telephone number, fax number, e-mail address, and the name and address of the submitting firm, if applicable. If a registration number is provided, city and country may be provided instead of the full address.

(Comments) Several comments assert that it is duplicative and unnecessary to require not only the corporate name and address of the submitter but an individual's name, telephone number, fax number and e-mail address as well. The comments contend that this information already should exist in the FDA registration database and that the name of the submitting firm should be sufficient. The comments assert that in today's job market, individuals change jobs more frequently, thereby making the maintenance of this level of specificity in a database time consuming with minimal benefit.

However, another comment states that the regulatory provisions in the prior notice IFR are silent regarding which person(s) will be contacted by FDA and/or CBP when an issue or problem arises regarding a prior notice and urge FDA to clarify that in refusal circumstances, the agency will contact the person who submitted the prior notice (i.e., the submitter or the transmitter.) The comment further states that by reason of his or her knowledge and/or access to the necessary information, as well as having the implicit authority and responsibility to properly file the prior notice, the submitter or transmitter typically will be in the best position to take corrective action as expeditiously as possible.

(Response) FDA has determined that a fax number is not necessary for communication with the submitter. However, the identification of the individual and the firm, if applicable, submitting the prior notice is needed so that FDA knows who is responsible for the information in the prior notice and can communicate with them when necessary via mail, phone, or e-mail. The information submitted must provide sufficient information to enable FDA to communicate questions, concerns, or enforcement information with the submitter. See section III.J.1 of this document regarding inadequate prior notice (§ 1.283(a)(1)) for a discussion of communication of refusals.

(Comments) One comment suggests that there should be an option to identify whether or not the submitter is C–TPAT certified.

(Response) As we previously explained in the discussion under our assessment of timeframes (see section III.F of this document), C–TPAT participation will not affect timeframes, the amount of information required to be submitted under prior notice, or decisions made during the prior notice review process. Thus, the costs to submitters and the government of submitting such information would not provide benefits. FDA will continue to coordinate with CBP for administration of C–TPAT as it applies to FDA-regulated products, particularly as it relates to admissibility decisions under section 801(a) of the act. However, the prior notice final rule will not require that the submitter self-declare as C–TPAT certified or not C–TPAT certified.

(Comments) One comment asks if it is possible for a submitter to have his/her legal residence in the country of origin.

(Response) Neither the IFR nor the final rule limits the residence or location of the submitter. Section 1.278 of the final rule states that any person with the knowledge of the required information may submit a prior notice.

(Final rule) The final rule requires in § 1.281(a)(1), (b)(1), and (c)(1) the submission of the name of the individual submitting the prior notice and his/her business address, telephone number, and e-mail address, and the name and address of the submitting firm, if applicable. We reworded the last sentence of these paragraphs for clarity to state that if the business address of the individual submitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address.

3. The Transmitter

Section 1.281(a)(2), (b)(2), and (c)(2) of the IFR requires the submission of the identity of the transmitter, if different from the submitter. The IFR requires the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, and phone number, fax number, and e-mail address. If a registration number is provided, city and country may be provided instead of the full address.

(Comments) A comment states that the regulatory provisions in the prior notice IFR are silent regarding which person(s) will be contacted by FDA and/or CBP when an issue or problem arises regarding a prior notice and urges FDA to clarify that in refusal circumstances, the agency will contact the person who submitted the prior notice (i.e., the submitter or the transmitter.) The comment further states that due to his or her knowledge and/or access to the necessary information, as well as the implicit authority and responsibility for properly filing the prior notice, the submitter or transmitter typically will be in the best position to take corrective action as expeditiously as possible.

(Response) FDA agrees. The identification of the individual or the firm, if applicable, transmitting the prior notice is needed so that FDA knows who is responsible for transmitting the information in the prior notice and can communicate with them when necessary via mail, phone, fax, or e-mail. Moreover, the information submitted must provide sufficient information to enable FDA to communicate questions, concerns, or enforcement information with the transmitter. See section III.J.1 of this document regarding inadequate prior notice (§ 1.283(a)(1)) for a discussion of communication of refusals.

(Comments) Some comments ask if FDA would clarify what distinguishes the submitter from a transmitter and if it is possible for an authorized transmitter to have his/her legal residence in the USA.

(Response) The submitter is any person with knowledge of the required information. The transmitter is the person who transmits the required information on behalf of the submitter. The submitter and transmitter may be the same person. (See § 1.278) The final rule does not limit the residence or location of the transmitter.

(Final rule) If the prior notice is transmitted by a person other than the submitter, the final rule in § 1.281(a)(2), (b)(2), and (c)(2) requires the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, telephone number, fax number, and e-mail address. We reworded the last sentence of these paragraphs for clarity to state that if the business address of the individual transmitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address.

4. The CBP Entry Type

Section 1.281(a)(3), (b)(3), and (c)(3) of the IFR require submission of the

entry type, which for § 1.281(b)(3) will be a mail entry.

(Comments) Two comments ask for clarification of the CBP entry type data element and request a list of all of the options for entry type.

(Response) FDA needs this information both for screening to identify the appropriate articles for inspection and for communication between the FDA and CBP staff at the port. Also, the entry type determines which entry identifiers should be used (entry number, in-bond number) to identify the shipment. In addition, the CBP entry type tells us if the article of food is for consumption in the United States or is for export or other uses.

Some examples of CBP entry types are: consumption entries, warehouse entries, and temporary importation bond entries. Each of these types has a designated CBP code. For prior notice submissions made through ABI/ACS, the entry type will consist of the CBP entry code specific for that type of entry; e.g., ''01'' for a consumption entry, ''21'' for a warehouse entry, ''23'' for a temporary importation bond entry, etc. These codes are ones customs brokers and self-filers provide to CBP at entry.

For prior notice submissions made through the FDA PNSI, applicable entry types will be provided for selection in a drop-down menu; e.g., consumption, IT, T&E, mail, FTZ, etc. Explanations of the different entry types are available on PNSI to help the transmitter choose the right one. There also is guidance posted on FDA's Web site located at *http://www.cfsan.fda.gov/~pn/pnentgui.html* that describes the entry types and the entry identifiers (§ 1.281(a)(4) and (c)(3)) associated with those entry types.

(Final Rule) The final rule in § 1.281(a)(3), (b)(3), and (c)(3) requires submission of the entry type. For articles arriving by international mail (§ 1.281(b)(3)), the entry type will always be a mail entry.

5. The CBP Entry Identifier (e.g., the Customs ACS Entry Number or In-Bond Number)

Sections 1.281(a)(4) and (c)(4) of the IFR require the submission of the CBP entry identifier (e.g., CBP entry number or in-bond number), if available. This requirement does not apply to articles arriving by international mail, nor to those carried by or accompanying an individual, unless entry is otherwise required by CBP and an associated CBP entry identifier has been assigned. In these cases, the FDA PNSI will apply a system-generated entry identifier.

(Comments) One comment suggests that PNSI should be modified to allow for use of the house air waybill as a CBP identifier.

(Response) FDA disagrees. The CBP entry identifier information is necessary for proper identification of the information in a prior notice with the appropriate articles for inspection. The submission of the entry identifier also is critical for matching the prior notice to the corresponding CBP entry, which is necessary to assess the adequacy of the prior notice when shipments arrive and are presented for review.

For in-bond entries and FTZ admissions, and for prior notices submitted through the FDA PNSI, an entry identifier is critical for matching the prior notice to the corresponding CBP entry if a consumption entry is submitted so FDA and CBP can ensure that prior notice requirements were satisfied. FDA does not agree that the waybill/Bill of Lading can be used as a CBP identifier, nor do we believe that there is a problem with obtaining a CBP identifier. If the submitter does not have a CBP identifier, a system-generated entry identifier can be provided upon request. The Airway Bill number and Bill of Lading number is a separate data element found in the planned shipment information (§ 1.281(a)(17)(i)). A Bill of Lading number is not always assigned to a shipment at the time of prior notice submission. For certain shipments, such as those sent by international mail, no Bill of Lading may exist. Thus, FDA has determined that we cannot allow for the use of the house air waybill number as a CBP identifier.

(Comments) Two comments request clarification of the CBP entry identifier data element and where it can be located.

(Response) For transmitters submitting prior notice with CBP entry information through the ABI/ACS interface, the CBP entry number assigned by CBP is also the entry identifier. For customs brokers or self-filers submitting prior notice for a food entering the United States as an IT entry, a T&E entry, or FTZ admission, the CBP in-bond number or FTZ admission number assigned by CBP also is the entry identifier. If prior notice is being submitted through PNSI, the entry identifier will depend on the entry type and the reason for the Web submission. If available to the transmitter (e.g., the prior notice is for a CBP entry but the ABI/ACS interface is not available), the CBP entry number must be used. When appropriate, the in-bond number must be used as the entry identifier. If one of the entry identifiers described above does not exist, the transmitter can request a system-generated entry identifier.

There is guidance posted on FDA's Web site at *http://www.cfsan.fda.gov/~pn/pnentgui.html* that describes the entry types and the entry identifiers (§ 1.281(a)(4) and (c)(4)) associated with those entry types.

(Final rule) The final rule requires in § 1.281(a)(4) and (c)(4) the CBP entry identifier (e.g., CBP entry number or in-bond number), if available.

6. The Product Identity

Section 801(m)(1) of the Bioterrorism Act requires that a prior notice must contain the identity of the article of food being imported or offered for import. Section 1.281 (a)(5), (b)(4), and (c)(5) of the IFR requires the identity of the article of food being imported or offered for import, as follows: the complete FDA product code; the common or usual name or market name; the estimated quantity of food that will be shipped, described from largest container to smallest package size; and the lot or code numbers or other identifier of the food if required by the act or FDA regulations; e.g., low-acid canned foods, at § 113.60(c) (21 CFR 113.60(c)); acidified foods, at § 114.80(b) (21 CFR 114.80(b)); and infant formula, at § 106.90 (21 CFR 106.90).

(Comments) One comment suggests that the definition of ''article of food'' should be amended to eliminate quantity and product code as distinguishing factors that require a separate prior notice and that separate prior notices should be based on the uniformity of entry level food data. The comment further asserts that the integrity, or lack thereof, of the food product will not be compromised based on the product type, size and/or quantity.

(Response) FDA disagrees. FDA continues to believe that estimated quantity, including base units and total quantity, is a necessary component of product identity. This information is important for communications with FDA and CBP staff at the border and for examinations to determine whether the amount ordered matches the amount received. For example, as discussed in the preamble to the IFR, if more was received than was ordered, FDA guidance recommends an investigation to determine the cause of the discrepancy as additional and unwanted articles may have been added to intentionally contaminate the shipment (68 FR 58974 at 59005). If less product is received than ordered or than shipped, some of the product may have been intentionally diverted. Moreover, the agency's risk-based decisions are based upon the food type and size of that product as many foods are

processed differently and the health-based problems result from these differences. For example, a manufacturer may have two different low acid canned food (LACF) production lines that are used for filling and sealing different size cans. A problem with pulling a vacuum on one LACF line may cause the food in those size cans to become adulterated; this would not apply to the cans sealed on the other LACF line. FDA would be able to target shipments from this manufacturer for the size cans that may similarly be adulterated. As stated previously, the PNSI system also allows for automatic repeating of like information (e.g., identity of the manufacturer), which decreases repetitive entry of information that is the same for multiple articles of food within a shipment. This also can be accomplished with submission via ABI/ACS, dependent on the filer's own software.

(Comments) One comment requests clarification of the interpretation pertaining to gift packs. The comment asserts that CBP currently processes gift packs according to the description of the entire gift pack as an entity. The comment asks if prior notice is required on the individual items within the gift pack. Another comment recommends that FDA show flexibility and further develop policies that do not create excessive costs for exporters who are shipping multiple food products in the same package.

(Response) A gift pack may contain various articles of food subject to prior notice requirements. In addition, a gift pack may also contain various nonfood articles that are not subject to prior notice requirements. A package with multiple food products, though not a gift pack, is another example of various articles of food. A prior notice is required for each article of food, even when multiple articles of food are designated as a gift pack or are otherwise packaged together.

There is no CBP rule or regulation nor is there a General Rule of Interpretation (GRI) under which gift packs are classified for tariff purposes. In the case of ''gift packs'' that contain multiple products, for entry purposes, CBP will try to classify the gift pack using the concept of a set. That is, if the products included in a gift pack are part of a common activity, the gift pack may be classified under the HTS code that is most applicable. However, CBP does not consider eating to be a common activity even when all items in a gift pack are to be consumed. Therefore, unless there has been an applicable CBP ruling, entries of gift packs should be declared to CBP using the HTS code for each item included with the gift pack. This would apply even when there are food and nonfood items in the pack; e.g. a soup mug and a can of soup, as well as for make-your-own gift packs; e.g., if you created a gift pack by selecting individual items from a list of available products.

The final rule requires a prior notice submission for each article of food. As we explained in the preamble to the IFR, an ''article'' refers to a single food that is associated with the same complete FDA Product Code, the same package size, and the same manufacturer or grower (68 FR 58974 at 59003). Moreover, the ''packer'' of a gift pack is not the facility that manufactured/processed the food pack. Therefore, each article of food in a gift pack must be covered by a separate prior notice. However, the Prior Notice Final Rule Draft CPG, published elsewhere in this issue of the **Federal Register**, describes our proposed enforcement policy for gift packs purchased or otherwise acquired by an individual and imported or offered for import for nonbusiness purposes. This draft guidance states that for these types of gift packs FDA and CBP staff should typically consider not taking regulatory action if there is a prior notice violation because a single prior notice is submitted for a gift pack and the identity of the facility that packed the gift pack is submitted in lieu of the identity of the manufacturer(s) and/or grower(s) for each article of food within the gift pack.

(Comments) One comment states that the regulations should require a separate prior notice for each HTS number in the container and that a detailed description of the product is not necessary.

(Response) FDA disagrees. For prior notice to accomplish its intended purpose and help FDA protect American consumers, a more precise description of the product is necessary than that provided by the HTS number. As we explained in the preamble to the IFR, although the HTS codes are currently utilized by CBP and FDA to identify generally which imports are subject to an FDA admissibility review, these codes are often not sufficient to specifically identify a product for FDA decisionmaking. For example, in many cases, the tariff code does not describe how the product was processed (e.g., commercially sterile or shelf-stable) or how the product is packaged. Thus, several products that FDA considers different from each other (because these differences affect the potential safety of the food) may be combined under one HTS code. (See 68 FR 58974 at 59004.) Moreover, the HTS code has never been sufficient for FDA admissibility decisions; at entry, the FDA product code has been required on FDA-regulated products. Therefore, the FDA product code should be familiar to most submitters of prior notice. Prior notice requires that we now get this information before arrival of the article of food into the United States.

(Comments) One comment asserts that FDA has issued an interim final regulation that requires prior notice needlessly. The comment provides an example of a container containing red wine, under 14 percent alcohol and in multiple varietals and sizes from the same manufacturing facility and asserts that multiple prior notice submissions should not be required.

(Response) FDA disagrees. For prior notice to accomplish its intended purpose and help FDA protect American consumers, a prior notice must be submitted for each article of food. If the food is identified by a single FDA product code, size, and manufacturer, then only one prior notice is required. Currently there are only seven FDA product code designations covering wine: White/still, red/still, rose/still, naturally carbonated sparkling, artificially carbonated sparkling, Champagne, and wine coolers. The identity of the size of the article of food is covered under the requirement to submit the estimated quantity of the article of food (see § 1.281(a)(5)(iii), (b)(4)(iii), and (c)(5)(iii)). In the previous example, although the shipment contains only red wine from the same manufacturer, there are different sizes of bottles within the container and each package size requires a separate prior notice. The reason is that a problem in sealing one size bottle of wine, but not the other size bottles, may result in serious adverse health consequences. As we explained in the preamble to the IFR, FDA believes that package size is necessary and part of product identity. Moreover, the base unit of measure is a characteristic of product identity and is thus necessary for effective review of the prior notice information. Base unit is critical to processing safety requirements and is particularly important when evaluating the safety of low-acid canned foods (68 FR 58974 at 59005).

(Comments) One comment requests that a single prior notice should cover one commodity and alternately suggests that a single prior notice be required for each FDA Product Code. As an example, the comment suggests that a separate prior notice is required for each size of apples in a load with 10 sizes of apples representing one FDA Product Code.

Another comment suggests that all products covered by the same FDA product code should require a single prior notice entry.

(Response) A separate prior notice is required for each article of food represented in a shipment or a load. In the example of different sizes of apples, because apples are identified by one FDA Product Code, and assuming that all the apples represent the same grower, if known, and the remainder of the required information is the same for all the apples, then one prior notice would be sufficient. However, if the articles of food represent the same FDA product code but contain different package sizes, then these are different articles of food and a separate prior notice is required for each.

(Comments) One comment states that prior notice would need to be submitted for each brand, and then each bottle size and format.

(Response) In response to comments to the proposed rule, FDA determined that the brand is not critical for risk-based screening and the IFR did not require identification of the brand of the article of food. This determination has been retained in the final rule. Identification of the size of the article of food is covered under the requirement to submit the estimated quantity of the article of food (see § 1.281(a)(5)(iii), (b)(4)(iii), and (c)(5)(iii)).

a. *The complete FDA product code*. FDA's product code is a unique numeric code currently used by FDA and customs brokers and self-filers to describe food products, as well as other products regulated by FDA. The IFR requires in § 1.281(a)(5)(i), (b)(4)(i), and (c)(5)(i), the complete FDA Product Code be submitted.

(Comments) Several comments ask for clarification about the appropriate FDA product code to use for specific products and for guidance concerning specific types of products. Several comments request that the FDA Product Code Builder be translated into various foreign languages. Two comments request clarification regarding the appropriate product code for gift packs. One comment requests that submitters be advised of the correct product code for foods subject to prior notice requirements.

(Response) The final rule does not attempt to clarify appropriate coding for specific products. The FDA product codes are frequently updated, revised and changed. The active codes are available in the FDA Product Code Builder at *http://www.accessdata.fda.gov/SCRIPTS/ORA/PCB/PCB.HTM*. The FDA Product Code Builder also contains many synonyms for foods covered by the same product code designations; e.g., Rice Flour (FDA Product Code 02C–01) has the synonyms of Bot Gao (Vietnamese rice flour), Harina De Arroz (Latin American rice flour), and Joshinko (Japanese fine, white rice flour, used to make taffy-like sweets). At this time due to resource constraints, FDA does not plan to translate the FDA Product Code Builder into foreign languages. A product code builder tutorial is available at *http://www.cfsan.fda.gov/~pn/pcb-tut.html*.

As stated previously (see the discussion on the identity of the article of food being imported or offered for import), a gift pack is not a single article of food, but multiple articles of food packed together. Each article of food in a gift pack must be covered by a separate prior notice with an FDA product code for each article. However, FDA is proposing an enforcement policy whereby FDA should typically not take regulatory action if a single prior notice is submitted for a gift pack. More details about this proposed enforcement policy are described in the Prior Notice Final Rule Draft CPG, published elsewhere in this issue of the **Federal Register**.

b. *The common or usual or market name*. The IFR in § 1.281(a)(5)(ii), (b)(4)(ii), and (c)(5)(ii) requires the submission of the common or usual name or market name of the article of food as an element of the identity of the article of food. (See 21 CFR 102.5 for additional information about common or usual names.)

(Comments) Several comments ask for clarification about the appropriate common, usual, or market name to use for specific products and for guidance concerning specific types of products. One comment asks if a sufficient common, usual, or market name would be the name or names of products listed in the FDA Product Code Builder.

(Response) The final rule does not attempt to clarify appropriate common, usual, or market names for specific products. The FDA Product Code Builder contains many synonyms, which are common, usual, or market names, for foods covered by the same product code designations; e.g., FDA Product Code 16A—4 Ocean Perch is also known as Pacific Perch, Red Perch, Red Rockfish, and Rosefish. Therefore, anyone needing information about the appropriate common, usual or market name to use should consult the FDA Product Code Builder, which is accessible at *http://www.cfsan.fda.gov/~pn/pcb-tut.html*.

c. *The estimated quantity of food*. The IFR in § 1.281(a)(5)(iii) and (b)(4)(iii) requires the estimated quantity of food that will be shipped, described from largest container to smallest package size and for articles of food that have been refused under section 801(m) of the act in § 1.281(c)(5)(iii), the quantity of food that was shipped, described from largest container to smallest package size.

(Comments) Several comments recommend elimination of the submission of quantity for each article of food, and recommend that such situations involving various sizes and quantities of similar articles of food (e.g., same FDA product code and same manufacturer) be covered by one prior notice submission.

(Response) FDA disagrees. FDA continues to believe that quantity is a necessary component of product identity. FDA also believes that package size is a necessary part of product identity. The base unit of measure is a critical characteristic of product identity and is thus necessary for effective review of the prior notice information. Base unit also is critical to processing safety requirements and is particularly important when evaluating the safety of low-acid canned foods. Both base unit and total quantity (which includes knowing the smallest ''package size'') are necessary for response (examination) and communication with FDA and CBP staff at the port. As noted in FDA's ''Food Security Preventive Measures Guidance for Importers'' (''Guidance for Industry, Importers and Filers, Food Security Preventive Measures Guidance,'' March 2003), these elements are also critical for food security examinations to determine if the amount ordered is the amount received. For example, if more was received than was ordered, the guidance recommends an investigation to determine the cause of the discrepancy, as additional and unwanted articles may have been added to intentionally contaminate the shipment. If less is received than ordered or than shipped, some of the food may have been intentionally diverted. Both base unit and total quantity are currently data elements that can be submitted via ABI/ACS to OASIS.

(Comments) One comment asks for clarification as to the requirements in § 1.281(a)(5)(iii) and (b)(4)(iii) for estimated quantity and the requirement in § 1.281(c)(5)(iii) for the actual quantity.

(Response) The requirement for providing estimated quantity in § 1.281(a)(5)(iii) and (b)(4)(iii) apply to those prior notices provided in accordance with the requirements in the final rule; i.e., those submitted before the food arrives at the port of arrival in

the United States as required in § 1.279. The requirement for providing the actual quantity in § 1.281(c)(5)(iii) applies only to those articles of food refused under section 801(m) of the act, i.e., prior notices submitted after the article of food has arrived at the port of arrival without adequate prior notice and has been refused. In this case, since the article of food already has arrived, the quantity is set and the actual quantity can be determined and submitted in the post-refusal prior notice.

(Comments) One comment asserts that a slide entitled ''Article of Food vs. Shipment of Food'' in an FDA presentation about the IFR provides a conflict of interpretation about the requirement to provide the estimated quantity. The comment asserts that the illustration suggests a separate prior notice is required for each and asks that FDA clarify this presentation.

(Response) The illustration in question (see *http://www.cfsan.fda.gov/~dms/fsbtac17/sld014.htm*) provides the following example:

TABLE 1A.—''ARTICLE OF FOOD'' VS. SHIPMENT OF FOOD[1]

Tuna	24/12 oz. cans	2,000 cases	Company 1
Tuna	48/6 oz. cans	1,000 cases	Company 1
Tuna	24/12 oz. cans	300 cases	Company 2
Tuna	6/66 oz. cans	2,400 cases	Company 3

[1] One shipment; 4 different products; 4 prior notices

FDA reiterates that the previously shown chart illustrates a situation with four different articles of food, each requiring a separate prior notice. The example provides three different manufacturers of the canned tuna; thus, canned tuna from each of these manufacturers requires a separate prior notice submission. Further, the 12 ounce (oz) cans and the 6 oz cans manufactured by Company 1 are different sizes and thus are different articles of food. Accordingly, each requires a separate prior notice submission.

The final rule continues to require submission of the estimated quantity of food that will be shipped, described from largest container to smallest package size. A prior notice will not be inadequate if the estimated quantity changes between the confirmation of prior notice and the time of arrival. Similar to the IFR, the final rule does not require that a prior notice be cancelled and resubmitted if the estimated quantity changes after confirmation.

d. *The lot or code numbers or other identifier*. The IFR in § 1.281(a)(5)(iv), (b)(4)(iv), and (c)(5)(iv) requires the submission of the lot or code numbers or other identifier of the food if required by the act or FDA regulations; e.g., low-acid canned foods, at § 113.60(c); acidified foods, at § 114.80(b); and infant formula, at § 106.90.

(Comments) One comment requests clarification concerning when a lot or code number or other identifier is required for an article of food.

(Response) The lot or code numbers are the identification numbers or code of a production lot, which can more specifically identify a product for screening and examination purposes and for communication within FDA and with CBP and the manufacturer, etc. For example, recalls involving serious health risks are often associated with a specific production lot, such as counterfeit infant formula or under-processed canned food. FDA screening can target these food products for examination based on information of public health emergencies or recalls in foreign countries.

FDA regulations require lot/code identifiers for certain foods. Currently, low acid canned foods, acidified foods, and infant formula are required to bear lot codes or other identifiers (see § 113.60(c) (low-acid canned foods); § 114.80(b) (acidified foods); and § 106.90 (infant formula low-acid canned foods)). The interim final and final rules require lot/code or other identifiers only for these kinds of articles of foods. Many other foods may have lot or code identifiers that are not required by FDA regulation; submission of these identifiers is optional under the final rule.

Submission of the required lot/code identifier is accommodated by ABI/ACS as an affirmation of compliance or through PNSI as a production identifier. ACS currently allows for submission of more than one affirmation of compliance per article of food. PNSI also accepts more than one lot identifier per article of food.

(Final rule) The final rule requires in § 1.281(a)(5)(i), (b)(4)(i), and (c)(5)(i) the complete FDA product code. The final rule in § 1.281(a)(5)(ii), (b)(4)(ii), and (c)(5)(ii) requires the submission of the common or usual name or market name of the article of food as an element of the identity of the article of food. The final rule in § 1.281(a)(5)(iii) and (b)(4)(iii) requires the estimated quantity described from the largest container to the smallest package size. For articles of food that have been refused under section 801(m) of the act, the final rule in § 1.281(c)(5)(iii) requires submission of the quantity of food that was shipped, described from largest container to smallest package size. The final rule in § 1.281(a)(5)(iv), (b)(4)(iv), and (c)(5)(iv) requires the submission of lot or code numbers or other identifiers for articles of food if required to bear such numbers by the act or by FDA regulations.

7. Identity of the Manufacturer

Section 801(m)(1) of the act states that a prior notice must contain the identity of the manufacturer of the article of food being imported or offered for import. Section 1.281(a)(6), (b)(5), and (c)(6) of the IFR requires that prior notice for an article of food that is no longer in its natural state include the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food. The IFR further states that a registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage, and export, or further manipulation and export. The IFR also provides that if the article of food is sent by an individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States, he or she may provide the name and address of the firm that appears on the label under 21 CFR 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and country may be provided instead of the full address.

FDA received many comments on the requirement to provide the name, address and registration number, when applicable, as the identity of the manufacturer. For ease in discussing these comments, we are presenting the issues they raise into the following general categories:

- Does ''the manufacturer'' in section 801(m) of the act mean the place where the food was actually manufactured or can it include other entities? What if more than one entity was involved in the manufacture of the article of food?
- Does FDA have the authority to require the registration number of the manufacturer of the article of food being imported or offered for import as a data element in prior notice?
- Assuming FDA can require the manufacturer's registration number in a prior notice submission, should FDA continue to do so in the final rule and/or should FDA provide an alternative means for submitters to provide the identity of the manufacturer? and

• Questions Seeking Clarification.

a. *Does ''the manufacturer'' in section 801(m) of the act mean the place where the food was actually manufactured or can it include other entities? What if more than one entity was involved in the manufacture of the article of food?* (Comments) Section 1.281(a)(6) of the IFR requires the submission of the identity of the manufacturer of each article of food no longer in its natural state. Several comments recommend that the final rule define ''the manufacturer.'' Some comments note that for ''gray market'' or ''parallel market'' importations (food purchased outside the manufacturer's distribution chain and imported to the United States), the only identifiable product information is that which is on the product itself. The comments suggest that in lieu of the name, address, and registration number of the manufacturer of the food, the prior notice submission should include the name and address of the entity that appears on the label on the food. A comment notes that while this information is not as detailed as that required for other imports, it relieves importers of ''gray market'' foods from having to provide information that in most instances would never be available to them. Other comments suggest that shipments of gifts to individuals but with a commercial purpose, such as business gifts to generate goodwill among colleagues, should be permitted to reference the manufacturer's name and address as shown on the label in lieu of the registration number of the manufacturer.

Several comments request that FDA provide guidance regarding how to complete prior notice for imported food from multiple manufacturing facilities. One comment suggests that the final rule should define the manufacturer as the last entity to conduct a processing operation; e.g., including bottling, but excluding labeling. Another comment provides an example of wine that is produced and bottled at winery ''X'' and sent to winery ''B'' for labeling, which sends the wine to another facility for storage, which then transfers the wine to the freight forwarder ''F'' who stores and consolidates the wine with other wines for shipment to the United States. Another comment provides an example of fresh fruit that is processed in one facility in a foreign country and then is transported to one or several other facilities that re-palletize the fruit, resulting in a finished pallet containing boxes that have been packaged at several packing facilities.

(Response) These comments address, directly or indirectly, the meaning of ''the manufacturer'' in section 801(m) of the act. In construing the prior notice provision of the Bioterrorism Act, FDA is confronted with the question of whether Congress has directly spoken to the precise question presented (''Chevron step one''). *Chevron, U.S.A., Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 842 (1984). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue. *Young* v. *Community Nutrition Institute*, 476 U.S. 974, 980 (1986). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent. *Chevron*, 467 U.S. at 842–843. If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of ''the manufacturer,'' FDA may define this term in a reasonable fashion (''Chevron step two''). *Chevron*, 467 U.S. at 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000).

We have determined that in enacting section 801(m) of the act, Congress did not clearly manifest its intention with respect to the meaning of ''the manufacturer.'' When an article of food is made from one or more raw ingredients, there could be several entities involved in its manufacture. For example, boxed macaroni and cheese might involve preparing the dried macaroni, preparing the dried cheese, combining these materials, and packaging and labeling the finished product. Where multiple steps are carried out by multiple entities, the act does not directly and plainly set forth which entity or entities Congress intended as the manufacturer to be submitted as part of the prior notice. Another question regarding ''the manufacturer'' whose answer is not clearly manifested in the act is whether the manufacturer means the specific facility where the article is manufactured or the entity that owns, or contracts with, the manufacturing facility. Additionally, Congress did not plainly address whether the entity listed on a product's label could be considered the manufacturer. The entity listed on a product's label can be, as provided by 21 CFR 101.5, the packer or distributor. Additionally, under that regulation, the label may state the principal place of business of the manufacturer, packer, or distributor in lieu of the actual place where the food was manufactured or packed or is to be distributed, unless the statement would be misleading.

For the reasons given in the following paragraphs, we have determined that, for purposes of section 801(m) of the act, the phrase, ''the identity of the manufacturer,'' should be interpreted to mean the place where the food was actually manufactured/processed (i.e., the site-specific manufacturing facility). We believe that this interpretation is reasonable and consistent with the goals of the Bioterrorism Act.

In considering whether it is reasonable to interpret the manufacturer as being the actual place where the food was manufactured, we considered the language and purpose of the prior notice provision, as well as the other provisions of the Bioterrorism Act. The purpose of the Bioterrorism Act is ''to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies'' (Public Law 107–188). The prior notice provision contributes to this goal by providing the agency with the information it needs to determine whether, due to significant concerns about an article of imported food, it should inspect the food upon arrival in the United States. Having the identity of the actual place where the food was manufactured (i.e., the site-specific manufacturing facility) will inform these risk-based decisions much better than having the identity of the packer or distributor or even the name and address of the manufacturer's principal place of business.

Information about the manufacturer contributes to FDA's inspection decisions under prior notice in two principal ways. One way is that when FDA receives intelligence regarding potential areas of concern about food shipments, this intelligence is often linked to a site-specific manufacturing facility. For example, FDA received intelligence regarding alleged contamination with a harmful chemical substance of certain imported food products from a certain specific foreign manufacturing facility. FDA flagged shipments from this facility for further PNC review, and subsequently recommended the examination and sampling of several shipments from the site specific facility due to the significant public health threat posed by the articles of food. Because the identity of the site-specific manufacturing facility was included in the prior notices, FDA was able to match the intelligence with the relevant food shipments, without affecting the importation of similar products from other manufacturers. If prior notice only included the name and address listed on the label, FDA could not have confidence that it could flag shipments of the food manufactured at the specific facility, either for further PNC review or for inspection. Matching a third-party distributor or packer with the actual manufacturer that FDA wants to flag

based on intelligence would be very difficult and time consuming, and may even be impossible to do with the information available to the agency. If prior notice included the principal place of business of the manufacturer (e.g., the corporate headquarters location) instead of the site-specific manufacturing facility, FDA's ability to correctly target shipments would not be much better. More often than not, when FDA receives intelligence regarding a manufacturer, it is specific to the site-specific manufacturing facility and not just the manufacturer's corporate identity. In these situations, if the prior notice that has been submitted contains only corporate-level information, FDA would have to target every relevant shipment from every plant the firm owns or contracts with, which could be dozens, or even hundreds. As a result, much time would be spent unnecessarily reviewing many shipments that may not be of interest but whose risk could not be discounted based on the supplied manufacturer information.

The other way information about the manufacturer contributes to FDA's inspection decisions under prior notice is the agency's use of this information during its manual review of a prior notice. Regardless of the reason a shipment is flagged for manual review by the PNC, the identity of the manufacturer is one of the key elements FDA relies on in further assessing the potential risk a shipment poses to the United States. FDA does this by using the identity of manufacturer, as provided in prior notice, to gather additional information from a variety of sources, such as FDA's and other government agencies' databases and research using publicly available information. For example, FDA will often try to determine whether the article of food being imported is consistent with the type or types of food the facility usually makes and ships to the United States, whether the facility's owners, agents, or workers have potential ties to security concerns, and whether FDA has found problems with prior shipments from the facility. The more closely that this information is tied with the site-specific manufacturing facility, the more reliable the risk assessment will be. If prior notice could include the name and address of the firm on the label (in lieu of the site specific manufacturer), and this firm is the product's distributor, then FDA would be able to gather additional information about the distributor but not the manufacturer. A risk assessment based on information concerning the distributor would be much less meaningful than one based on the actual manufacturer because the actual manufacturer has much more control over the product's quality and security than the product's distributor.

For example, when researching the site-specific manufacturer listed in a prior notice to investigate potential security concerns, FDA found information in a government database suggesting the facility had ties to terrorism. Based on this and other information, FDA decided to examine the product covered by the prior notice. If the name and address of a different firm, such as the distributor, had been provided in the prior notice instead, it is unlikely that FDA's research would have turned up this association and unlikely that this shipment would have been flagged for inspection. In its experience under the IFR, when prior notice has not included the identity of the actual manufacturer, FDA has had to attempt to determine the site-specific manufacturer by using alternative means such as inspection, contacting the submitter, and/or contacting the firm listed on the label, a process that in some cases has taken days and even weeks. The only other way to be sure that the subject article of food is not a threat is to have the food stopped and examined at the port of arrival to determine if it is a threat. Stopping shipments while FDA conducts additional research or an inspection would require significant agency resources and could create inefficiencies for the agency, CBP, industry, and consumers as food shipments back-up at the border.

Similarly, if the prior notice included the principal place of business of the manufacturer rather than the specific manufacturing facility, this information is likely to be too broad to be helpful, particularly if it is a large company. Each manufacturing facility is different, in terms of its employees, the food it manufactures for the United States, its manufacturing processes, and its security standards and procedures. One location of a company may have a higher standard for the security of its employees and manufacturing processes than another location. In those cases where the parent company owns or contracts with multiple manufacturing facilities, FDA would have to determine the risk associated with each of these facilities to ensure our review is adequate. Because FDA is under strict timeframes to review, assess risk, and respond to the prior notices, conducting such wide-ranging research is not practical. Not only would this be prohibitively time-consuming (which would have a detrimental impact on trade), in many situations FDA may not be able to ascertain the identity of each of the firm's manufacturing facilities. Alternatively, FDA could attach a risk to the headquarters location, but doing so would result in a less meaningful prior notice risk assessment and may result in articles of food being assigned a lower or higher risk than they should have based on the specific manufacturing facility.

Our interpretation of ''the manufacturer'' to mean the actual place where the food was manufactured also furthers the purposes of the Bioterrorism Act by helping to ensure that imported food is from registered facilities. Under section 801(l) of the act, food that is imported or offered for import is subject to being held if it ''is from a foreign facility for which a registration has not been submitted to [FDA] under section 415'' of the act. FDA checks the information about the site-specific manufacturing facility provided in prior notice to verify that facility's registration status. If the prior notice provided only the name and address listed on the label of the food rather than the actual manufacturing facility, FDA would have no practicable means to readily determine whether the manufacturing facility is registered. As explained previously, the name and address on the label could be, for example, the distributor or the parent company of the facility.

Collecting information regarding the manufacturing facility of an imported product and its registration status goes back to well before prior notice. As part of the admissibility review process for the various types of imported goods it regulates, FDA collects, among other information, the ''FDA Manufacturer'' and applicable registration numbers. (See, for example, 70 FR 69576, November 16, 2005.)

The Bioterrorism Act expanded the registration requirement with respect to food facilities. New section 415 of the act requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to be registered with FDA, unless the facility is exempted. Under new section 801(1) of the act, food from a foreign facility that has not registered under section 415 of the act is subject to being held until the foreign facility has registered. It could be argued that FDA should make its determination about the food manufacturing facility's registration status as part of the entry and admissions process. The reason it is necessary to make this determination at the time FDA is reviewing prior notice

is that if the article of food is held under section 801(l) of the act, it may not be delivered to the importer, owner, or consignee and cannot be moved under bond under section 801(b) of the act. Operationally, the only way to implement these movement restrictions is to conduct the registration status review before entry is filed, which is when the prior notice review is conducted.

The comments recommending that the prior notice rule be expanded to allow the identity of the entity shown on the product label in lieu of the identity of the manufacturer are generally based on the argument that information about the manufacturer, especially its registration number, is not always available to the submitter, such as when food is purchased outside the manufacturer's distribution chain. The statute indicates that Congress considered the issue of whether it would be difficult or impossible to provide the identity of the manufacturer but chose to require it nonetheless. Among the data required by prior notice are the identity of the manufacturer and, for food in its natural state, the identity of the grower, if known. Section 801(m) of the act expressly provides that the identity of the grower does not need to be submitted if it is not known within the prior notice timeframes; however, the act does not include this exemption for the identity of the manufacturer. This indicates that this information about the manufacturer must be submitted regardless of any potential difficulties in obtaining it. With respect to the comments that were concerned about situations where the person submitting prior notice does not know the registration number of the manufacturer, as discussed elsewhere in this preamble, FDA and CBP are modifying the final rule such that the identity of the manufacturer can be submitted as the name of the manufacturer and either the registration number, city, and country of the manufacturer, or both the full address of the manufacturer and the reason the registration number is not provided.

Regarding situations where multiple steps are carried out by multiple entities, we have determined that ''the manufacturer'' can reasonably be interpreted to mean the last facility that manufactured/processed the article. A facility is the last facility that manufactured/processed the food if the food does not undergo further manufacturing/processing, other than the addition of labeling or any similar activity of a *de minimis* nature. This interpretation is based on the definition of a foreign manufacturer under the food facility registration provision, section 415(b)(3) of the act, and our implementing rule, 21 CFR part 1, subpart H (see specifically §§ 1.227(b)(2) and 1.226(a)). It also is consistent with the definition of FDA manufacturer collected as part of the entry and admissibility process, which states that if more than one party processed the article, then the manufacturer is the last party who substantially transformed the product. (See, for example, 70 FR 69576, November 16, 2005.)

Applying this definition to the example pertaining to wine in the comments, the manufacturer for purposes of prior notice would be winery ''X'' since this is the facility that produced and bottled the wine. The other facilities involved in this example perform either manufacturing activities of a *de minimis* nature, such as labeling, or other activities not related to manufacturing, such as storing and consolidating the wine. Thus, although some of these facilities might have to register with FDA as required by 21 CFR part 1, subpart H as holders or packers of food intended for consumption in the United States, the facilities in the example other than winery ''X'' are not considered the last facility under the prior notice final rule's definition of ''manufacturer.'' Regarding the comment on fresh fruit, FDA assumes that the comment is using the term ''processed'' to mean an activity (such as treatment against pests or polishing) that leaves the food still in its natural state, as explained in the definition of ''no longer in its natural state'' under § 1.276(b)(10). Although subsequent facilities palletize the fruit, these would not be manufacturers because they only pack the food and packing is not considered manufacturing/processing. Under this scenario, no information for any manufacturers would be required for the prior notice. Instead, under § 1.281(a)(7) of the final rule, the prior notice would require the name and address of the grower, if known.

Consistent with the interpretation that the identity of the manufacturer requires site-specific information, we are removing the provision in the IFR stating that if the article of food is sent by an individual as a personal gift to an individual in the United States, then the name and address of the firm that appears on the label could be submitted instead of the identity of the facility that manufactured the food. We note, however, that under the enforcement policy contemplated in the Prior Notice Final Rule Draft CPG, FDA and CBP would typically consider not taking regulatory action when no prior notice is submitted with respect to gifts that are shipped by an individual to an individual.

Given the importance of having the site-specific manufacturer, we are also proposing a change to the CPG regarding the identity of the manufacturer. The Prior Notice Interim Final Rule CPG had a policy that covered situations where, after a good faith effort, the person submitting prior notice did not know the name and address of the facility that manufactured the food. It stated that if the submitter provided certain alternative information, such as the identity of the facility's headquarters, FDA and CBP should typically consider not taking any regulatory action despite this noncompliance with the prior notice requirements. The Prior Notice Final Rule Draft CPG does not continue this policy because, as described above, FDA and CBP believe that knowing the identity of the facility involved in the food's production is critical to ensuring that FDA can effectively target food for inspection at the border upon arrival and can effectively determine whether food should be held because it is from an unregistered manufacturing facility.

Accordingly, section 1.276(b)(9) of the final rule defines manufacturer for the purpose of prior notice submission as the last facility, as that word is defined in § 1.227(b)(2), that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a *de minimis* nature. If the food undergoes further manufacturing/processing that exceeds an activity of a *de minimis* nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer. We have removed in the final rule the option that was in the IFR to provide the label information in § 101.5 instead of the name, address, and registration number of the manufacturer for food sent by an individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States. Unless excepted elsewhere in the regulation, the identity of the manufacturer must be submitted for an article of food that is no longer in its natural state.

b. *Does FDA have the authority to require the registration number of the manufacturer of the article of food being imported or offered for import as a data element in prior notice?* (Comments) Many comments state that the Bioterrorism Act does not require registration numbers to be submitted in prior notice. Some comments further assert that the statute clearly states that the ''identity of the manufacturer'' must

be included for prior notice but it does not allude to nor require the registration number. Another comment explains that if Congress intended FDA to require the registration number, it would have specifically articulated this requirement as it did in section 321 of the Bioterrorism Act for drug and device imports. The comment concludes that the failure of the Congress to include registration numbers in the enumerated statutory elements of prior notice is powerful evidence that Congress did not intend for FDA to require it. Another comment states that the act does not prescribe how the identity of the manufacturer must be provided, and therefore Congress has not spoken to this issue. Accordingly, FDA is entitled to deference in crafting a permissible construction of the statutory requirements.

One comment notes that all wineries producing wine for consumption in the United States are required under section 415 of the Bioterrorism Act to provide to FDA their name, the street addresses of their facilities and the trade names under which they do business. It further states that as long as the importer provides the name and address of the manufacturer of the wine, this will be sufficient for FDA to identify whether the manufacturer is registered with the FDA, and that additionally requiring the importer to furnish a registration number is unnecessary to implement the Bioterrorism Act.

Another comment asserts that the obligation to verify that the manufacturer of a food article imported or offered for import into the United States is registered, or is required to do so, is an obligation imposed upon the FDA by Congress under the Bioterrorism Act, not upon the importer. The comment further asserts that for FDA to shift its burden to importers who are not related to the facilities required to be registered is, at the very least, unjust and certainly was not the intent of Congress. The comment further states that FDA has the ability and access to the information necessary to verify registration status of manufacturers; unaffiliated importers do not. Another comment asserts that FDA's overly broad interpretation of the prior notice provision of the Bioterrorism Act results in an anticompetitive business environment that is contrary to the spirit of the Bioterrorism Act. Another comment emphasizes that to enforce the registration requirement through the means of prior notice requirements, which affect persons that are completely unrelated to the party responsible for registering the facility, is inappropriate.

Another comment states that the U.S. Congress placed the burden upon the FDA to ensure that a facility's owner, operator or agent in charge complies with the registration requirements established under the Bioterrorism Act and while it is reasonable for the FDA to request that importers assist them in this task by asking for facility registration numbers on prior notice submissions, the agency must not condition lawful entry on the provision of this number that may, for a variety of reasons, be unavailable to the importer.

Another comment claims that FDA has no jurisdiction to enforce the registration requirements upon the affected foreign facilities. Another comment asserts that domestic food manufacturers are not faced with this dilemma because they are already within the United States, and there are no equivalent requirements to verify that domestic foods are produced at facilities that are properly registered with FDA.

(Response) FDA's position remains that it has the authority to require the registration of the manufacturer as a data element in prior notice. Under section 801(m) of the act, prior notice must include the identity of the manufacturer. The manufacturer's registration number is an identifier, just as, for example, Employer Identification numbers, Social Security numbers, and driver's license numbers are regularly used to help identify establishments and individuals. Such numerical identifiers are much better for matching than name and address information alone. For example, names and addresses often do not have standardize formats, there can be alternative spellings and abbreviations, and misspellings are not uncommon. In addition, many facilities have similar names, even facilities in the same country or city. Unique identifiers are all the more important given the high volume of prior notices that FDA needs to process, FDA's goal of processing them expeditiously, and the need to ensure that FDA can accurately flag shipments of potential concern.

As contemplated by the Registration of Food Facilities rule, § 1.241(c), FDA also uses the identity of the manufacturer collected as part of prior notice to ensure that imported food is from registered facilities. Section 801(l) of the act, which was enacted as part of the Bioterrorism Act, states that if an article of food is being imported or offered for import into the United States, and such article is from a foreign facility for which a registration has not been submitted under section 415 of the act, such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so registered. In the preamble to the IFR, we described how we would use registration in concert with prior notice to carry out our responsibilities under section 801(l) of the act ''Registration is designed to work in concert with prior notice at the border, as reflected in new section 801(l) of the FD&C Act, which provides that food from facilities that must register may not be admitted into distribution for consumption in the United States unless the relevant facilities have been registered. To enforce section 801(l) of the FD&C Act as intended by Congress, FDA has determined that it must review registration status of manufacturers and shippers as part of prior notice. The information provided by registration will allow FDA to check prior notice submissions against registration data to confirm the identity. Moreover, the information provided by prior notice submissions can serve as a crosscheck as to whether these facilities are registered as required and have provided the necessary updates * * *. FDA does not agree that it should confirm registration without requiring that the number be submitted. Each registered facility will be assigned a unique registration number by FDA. Thus, the registration number will help identify the manufacturer. Without a registration number, it may be difficult to determine exactly which registered facility to associate with the article: Different firms may have the same or similar names and more than one firm may operate from a particular location.'' (68 FR 58974 at 59001). FDA continues to believe that it should use the information in prior notice to verify the manufacturer's registration status, and that the registration number is the simplest and fastest way for us to do this. FDA further notes that it verifies the registration status of both domestic and foreign facilities. FDA's procedures for enforcing the registration requirements for domestic facilities are explained in FDA's ''Compliance Policy Guide—Guidance for FDA Staff, Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' See *http://www.cfsan.fda.gov/~furls/cpgreg2.html*.

c. *Assuming FDA can require the manufacturer's registration number in a prior notice submission, should FDA continue to do so in the final rule and/or should FDA provide an alternative means for submitters to provide the identity of the manufacturer other than*

the registration number? (Comments) Several comments recommend elimination of the registration number as a requirement for identifying the manufacturer of a food no longer in its natural state. One comment suggests that inclusion of a food facility registration number does not ensure the legitimacy of the shipment and that a black market for certain foods could result if registration numbers continue to be required for prior notice. Many others comments recommend elimination of the requirement for the manufacturer's registration number in various situations:

- The food facility is not required to register because ingredients or finished goods manufactured by it are not consumed in the United States, and thus it has no registration number;
- The manufacturer that has gone out of business and does not have a facility registration number;
- Samples for:
  - Any reason/any type of sample;
  - Any product samples not intended for public consumption or for retail sale;
  - Quality control;
  - Research;
  - Analytical samples that are not intended for human or animal consumption;
  - Quality assurance samples that will be used for taste testing or quality control that includes human consumption;
- Fine wines;
- Registration numbers of the parties in possession of the wine over the past 2 years;
- All wines and distilled spirits, when a registration number is not available;
- Wine produced more than 5 years prior to the date of its import (the year of production is typically indicated on the bottle's label, and label approvals are required under U.S. Tax and Trade Bureau regulations);
- All food produced prior to December 12, 2003;
- All food sent into the country for the personal consumption of the recipient and not for business use or redistribution;
- Gifts arriving in the United States from one individual to another in a business setting; and
- Consumer-to-consumer shipments.

Some comments state that the requirement to provide the manufacturer's registration number in the prior notice is overly burdensome and unreasonable for some segments of the food industry. The comments suggest that there are numerous legitimate reasons that food companies may seek to import food products from manufacturers whose registration number is unknown or which are not required to register with FDA.

Other comments recommend alternatives to the requirement to submit the manufacturer's registration number. The most commonly recommended alternative to submission of the manufacturer's registration number is to allow submitters to identify the manufacturer by providing the name and address of the facility with an accompanying reason as to why the registration number was not submitted. One comment specifically recommends a drop-down menu that allows the submitter to explain the reason for the lack of a registration number, such as ''product was not obtained from the manufacturer.'' The comment reasons that this optional approach allows FDA to continue to require registration numbers, but does not per se invalidate a prior notice based on the absence of this single piece of information. Another comment suggests that the submitter affirm that it believes, to the best of its knowledge, that the manufacturer is registered with FDA. One comment recommends that only the manufacturer's name for a ''gray market'' food should be sufficient for the prior notice when the submitter does not know the manufacturer's registration number.

Another comment asserts that FDA must consider alternative means for ensuring that all facilities subject to the Registration of Food Facilities Rule (21 CFR part 1, subpart H) have an updated registration on file with FDA that has been verified. The comment further suggests that taking such action will allow the FDA to ensure that the regulations are not implemented in a manner that prevents the lawful import of safe and healthy food products based solely upon the unavailability of the confidential facility registration number. Several comments assert that confirmation that a facility is registered can be made without obtaining the registration number of the facility.

One comment states that, though FDA has indicated that it wants the new facility registration requirement to be enforced through the prior notice regime, enforcement can be accomplished without requiring that the facility registration numbers be included in the prior notice. With the name and address of the manufacturer included, FDA can look up the manufacturer in its database of registered manufacturers. If the manufacturer has not registered, then the FDA could deny entry to the articles of food in question. The manufacturers therefore already have a strong incentive to register with the FDA, since that is the only way their products can gain entry into the United States.

Other comments suggest inspection of a food shipment to ensure its safety when the prior notice submission lacks the required registration number, rather than refusal of that food as an acceptable alternative. The comments state that this approach will avoid situations where shipments are rejected while still preserving FDA's regulatory discretion. Another comment states that importers who obtain food from parties other than the original food manufacturers are willing to bear the burden of increased inspections when they do not provide a manufacturer's registration number in the prior notice. Other comments agree that the manufacturer's registration number should be required in prior notice submissions, but that the prior notice should not be deemed inadequate (i.e., the food should not be refused under 801(m) of the act) if the manufacturer is identified by name and address of the facility and a reason for lack of submission of the manufacturer's registration number is provided.

Another comment suggests that the final rule should be amended to provide that the prior notice only need to include such information about the manufacturers of older vintage wines that is readily available to the importer, together with registration numbers for all persons who have owned the wine and all facilities that have stored the wine over the preceding 2 years.

One comment suggests that FDA permit the importation of quality assurance samples that will be used for taste testing or quality control that includes human consumption without the facility registration number of the foreign manufacturer or processor. The comment further suggests that in lieu of the registration number, the prior notice should include the manufacturer's name and location along with the identification of the person sending the samples.

While most comments state that the name and address of the manufacturer could be submitted in prior notice, one comment states that re-sellers will not normally supply the name of their supplier or the name of the manufacturer of a particular product to their customers. The comment asserts that supplying the name of the manufacturer would allow that customer to circumvent the re-seller and attempt to make direct contact with the supplier or manufacturer, thus taking business away from the re-seller. Another comment states that if only the

name of the manufacturer is submitted in a prior notice, the prior notice should not be considered inadequate.

Other comments support requiring the registration number of the original processor on prior notice submissions, particularly when a third-party is exporting the product to the United States. One comment further recommends that FDA should revise its rules regarding the use of registration numbers in general, and in the prior notice rule in particular, to protect legitimate buyers and distributors from unauthorized ''gray market'' imports. Several comments suggest that the manufacturer's registration number should be required and that only the registration number be submitted, not the name and country. Additionally, some comments suggest that if manufacturer and facility registration numbers are provided and the numbers provided are specific to a particular facility location, the requirement to complete the address information should be removed to avoid duplication of information.

(Response) To effectively implement the prior notice and registration provisions in the Bioterrorism Act, the final rule requires the registration number of the manufacturer or, if the registration number is not provided, the facility's full address and reason the registration is not provided. Reasons for not providing a registration number include, for example, the manufacturing facility is out of business; the manufacturing facility is a private residence and thus is not a ''facility'' for the purposes of the registration requirements; and the submitter is unable to determine the registration number of the manufacturing facility.

Matching of facilities is vital for making an initial assessment on the accuracy of the prior notice; assessing the risk of the associated article of food based on the associated manufacturing facility, its operations, and history of importations; and verifying registration status. Without the registration number, PNC reviewers have to conduct this matching using the name and address submitted in a prior notice. Due to the potential for human error during data input or deviations in the spelling or format of a facility's name, address or city, FDA may incorrectly think it has found a match between the facility described in the prior notice and a facility in the registration database. Similarly, the facility described in the prior notice may be close, but not exact, to several facilities listed in the registration database, causing uncertainty as to which, if any, is the correct match. This is complicated by the fact that the manufacturing facility submitted as part of prior notice might not be registered. At best this matching process may take significantly longer (depending on the number of manufacturers, products, and other factors involved), impeding FDA's ability to complete its review within the prior notice timeframes. At worst, a facility mismatch will result in FDA conducting its risk assessment based on incorrect information.

The information provided in a registration thus enables FDA to better assess risk of the product itself, as it gives the PNC more information upon which to base its assessment. PNC reviewers use the registration information to verify whether the articles of food in the shipment match the food product categories that the owner, operator, or agent-in-charge of the facility listed in the site-specific facility's registration with FDA. The registration information also provides alternate names for a facility, lists the parent company and subsidiaries of the facility, verifies addresses, and provides the identity of the officers of the facility and/or their U.S. Agents. This additional information may identify potential terrorist threats (e.g., a facility and/or facility official has ties with a terrorist organization). Not providing the registration number in a prior notice leads to prolonged or incomplete searches, which in turn could lead to additional cargo delays or examinations at the port of arrival as the PNC completes its intensive review (see earlier discussion under timeframes). We also note that registered facilities generally do not make their registration numbers public, so they generally have to be obtained directly from the manufacturer or its designee during the importation process as part of completing a prior notice. Thus it is harder to falsify registration information than the facility's name and address, deterring the submission of false manufacturer identification information.

In some cases, the registration number of the manufacturer is not available to the submitter, and therefore, we have revised the rule to provide an alternate means for satisfying the requirement to provide the identity of the site-specific manufacturer in prior notices. For purposes of the prior notice final rule, the identity of the manufacturer is the name of the manufacturer and either: (1) The registration number, city, and country of the manufacturer or (2) both the full address of the manufacturer and the reason the registration number is not provided (see § 1.281(a)(6), (b)(5), (c)(6)). One of the following reasons may be submitted when no manufacturer registration number is provided:

- Situations where the facility is out of business, as stated in § 1.235(a);
- Private residence, as stated in § 1.227(b)(2);
- The facility is a restaurant, as defined in § 1.227(b)(10), and qualifies for the restaurant exemption in § 1.226(d);
- The facility is a retail food establishment, as defined in § 1.227(b)(11), and qualifies for the retail food establishment exemption in § 1.226(c);
- The facility is a nonprocessing fishing vessel, as stated in § 1.226(f);
- Nonbottled drinking water collection and distribution establishment, as stated in § 1.227(b)(2);
- The manufacturer satisfies the definition of ''farm'' in § 1.227(b)(3), and qualifies for the farm exemption in § 1.226(b); or
- The submitter is unable to determine the registration number of the manufacturer. The full address of the manufacturer has been provided by the submitter.

The Prior Notice Final Rule Draft CPG that is announced elsewhere in this issue of the **Federal Register** lists these reasons to use when the registration number is not provided and describes our proposed enforcement policies.

As discussed previously, without the registration number, it will be more difficult and/or may take more time for us to verify the identity of the manufacturing facility and its registration status and to determine whether the article of food is subject to being held under section 801(l) of the act. Thus, it is in the interest of the parties involved in the import to provide the manufacturer's name and registration number, and not simply the manufacturer's name and full address, because the registration number will help us process the shipment more expeditiously. The submitter should exercise a reasonable amount of effort to obtain and provide the registration number before using the reason ''the submitter is unable to determine the registration number of the manufacturer.''

FDA does not agree with the comments asserting that the registration number is sufficient by itself to ''identify'' a facility in a prior notice submission. The additional information is needed to verify that the registration number, which is comprised of eleven digits, is accurate. Without additional information, there is a significant possibility of typographical errors, leading to misidentification of facilities, which could lead to foods being stopped

at the port for inadequate prior notice and registration. There also is the possibility of someone entering data in an attempt to ''guess'' at a registration number. Having identifying information in addition to the registration number helps prevent such guessing. Having this confirmatory information also allows us to notify submitters of a mismatch before the prior notice is accepted and confirmed for review, which allows them to correct any inadvertent errors before the food arrives at the port, where it otherwise may be subject to refusal for an inadequate (inaccurate) prior notice.

If the prior notice does not contain either the manufacturer's registration number or the reason and name and full address, the food is subject to refusal of admission under section 801(m)(1) of the act for failure to provide adequate prior notice, as the identity of the manufacturer is incomplete. The food also may be subject to a hold under section 801(l) of the act if the food is from a foreign manufacturer that is not registered under section 415 of the act.

In response to comments from those who are importing food from a facility that is not registered because food manufactured by it is not intended to be consumed in the United States, FDA notes that these shipments are subject to hold under 801(l) of the act. Under section 801(l) of the act, food is subject to being held if it is imported or offered for import into the United States and it is from a foreign facility that has not registered. This provision applies regardless of whether the food was intended for consumption in the United States at the time it was manufactured, for example where an article of food is made in Country X for consumption in Country X, but is purchased by a third party who re-labels the product for import and resale in the United States.

(Comments) One comment recommends that inter-company gifts be exempt from the requirement to provide the manufacturer's registration number on the prior notice because these items have no commercial value and are sent as business gifts. The comment suggests that FDA use the same approach for business and nonbusiness gifts, by allowing a listing of the manufacturer's name and address as it appears on the product's label.

(Response) The provisions in the final rule regarding the registration number are being revised, and these revised provisions apply to both business and nonbusiness shipments. The final rule no longer allows for submission of the name and address as it appears on the label in any situation. However, the rule also is being changed such that the submitter may submit either the manufacturer's registration number, city, and country or both the manufacturer's full address and the reason why the registration number is not provided.

d. *Questions seeking clarification.*

i. *Designation of grower.* (Comments) Two comments state that they are exempt from the registration requirements because they are farms; however, they want guidance regarding the steps these farms should follow to ensure that their products move through the prior notice system without delays at the port.

(Response) If the article of food is no longer in its natural state, such that the identity of the manufacturer is required, the submitter can submit a reason for why the registration number was not provided; i.e., facility is a grower, meets farm exemption. These reasons also are listed in the Prior Notice Final Rule Draft CPG announced elsewhere in this issue of the **Federal Register**. If the article of food is in its natural state, the identity of the manufacturer is not required and the systems will know that they do not need to verify the manufacturing facility's registration status.

ii. *Manufacturer cancels registration.* (Comments) A comment asks what designation is appropriate for the scenario where at the time of production the manufacturing/processing facility was legitimately registered with the FDA, but cancelled its registration prior to the importer submitting prior notice.

(Response) If the manufacturing facility still is operational, but chooses to cancel its registration with FDA, then the food from this facility is subject to refusal under 801(l) of the act. As stated therein, ''If an article of food is being imported or offered for import into the United States, and such article is from a foreign facility for which a registration has not been submitted to [FDA], such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so registered.'' If the facility has canceled its registration because it has gone out of business, then this reason may be entered on the prior notice.

iii. *Identity of manufacturer for samples.* (Comments) One comment states that there are some circumstances involving market survey and consumer complaint samples where the manufacturing facility is unknown to the submitter of prior notice and the manufacturing facility may not have a registration number because it does not do business in the United States. One comment provides the example of when shoppers are hired to collect company trademark products, package these according to company-established protocol, enclose purchase information and ship these to designated laboratories in the United States. and the shoppers often have no way of knowing the identity of the specific manufacturing facility. One comment states that it is not likely that a manufacturer's registration number would be available for competitive product samples and for finished product samples used for evaluation purposes, as well as for articles used for research and development purposes. The comment states that the registration number does not fall under the Freedom of Information Act and in some cases, the manufacturer's facility may not be required to register since the article of food was not intended for consumption in the United States. Another comment provides the example of when a consumer expresses a concern about either the quality or safety of a purchased food, and the consumer is instructed to ship that product to the U.S.-based franchise company laboratory for a timely analytical assessment.

(Response) We have revised the final rule such that the identity of the manufacturer must include the name of the manufacturer and either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided. Relevant to these comments, one of the reasons for not providing the registration number is that the submitter is unable to determine it. However, as described above, if the article of food is from an unregistered facility, it is subject to being held under section 801(l) of the act. Moreover, without the registration number, it will be more difficult and/or may take more time for FDA to verify the identity of the manufacturing facility and its registration status. As a result, the food may be delayed until the verification is completed.

While the final rule requires prior notice, including the identity of the manufacturer, for shipments of samples, under the enforcement policy proposed in the Prior Notice Final Rule Draft CPG, FDA and CBP should typically consider not taking any regulatory action with respect to prior notice violations when an article of food is imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption without prior notice.

iv. *U.S. manufacturer of product being imported.* (Comments) Two

comments express concern that FDA would reject a prior notice for imported food that contains a U.S. manufacturing facility and that facility's registration number.

(Response) Both ABI/ACS and PNSI accept the identity of a manufacturing facility from any internationally recognized country designation, including the United States. FDA recognizes that some food imported into the U.S. is manufactured in the U.S., exported, and then re-imported. Prior notice applies to these articles of food and identification of the U.S. facility as the manufacturer is correct.

v. *Require manufacturer to reveal or conceal the registration number.* (Comments) Two comments recommend that FDA compel manufacturers to divulge their food facility registration numbers upon inquiry. Another comment requests that FDA issue guidance stating that: FDA does not require the registration number on commercial documents; the inclusion of a registration number on commercial documents will not facilitate clearance by CBP or FDA of the shipment; and FDA recommends that companies reveal this confidential information once only in a formal letter and ensure by all possible means that their customer (e.g., distributor, importer, or customs broker) also respect the confidentiality of this information. One comment cautions about reported abusive and misleading declaration of a registration number in a prior notice for shipments that are unconnected with the food facility that actually owns that registration number. Another comment suggests that FDA should revise both the prior notice and registration rules to clarify that those doing business with the owner of a facility should not and have no reason to demand the facility registration number.

Several comments suggest that FDA provide a means for importers and others to verify a facility's registration, even if such verification does not disclose any information beyond affirmation or denial. One comment suggests that FDA compare Manufacturer Identity (MID) data submitted through ABI/ACS to the FDA Food Facility Registration database and notify the transmitter of a MID mismatch while keeping actual registration information secure. The comment reasons that this process would give the submitter and transmitter of a prior notice a noncompliance alert and also would alert the agency of possible additional intensive review requirements even before the prior notice submission has been completed. Another comment encourages the agency to allow American importers to query a database that would do nothing more than confirm whether the details provided are accurate. Another comment suggests that FDA make the registration database available to authorized customs brokers only.

(Response) FDA does not intend to direct registered food facilities to divulge their registration numbers on documents or upon request. However, FDA does agree that guidance regarding divulging registration numbers and prior notice submissions may help to clarify the process, and provided this guidance in our ''Guidance for Industry, Questions and Answers Regarding Registration of Food Facilities Final Guidance'' available at *http://www.cfsan.fda.gov/~dms/ffregui4.html*.

vi. *Exporting facility.* (Comments) One comment requests that FDA accommodate the importation of previously manufactured food products that were purchased at retail outlets outside the United States and recommends that FDA require only the registration number of the exporting facility and information identifying the company responsible for the product. The comment reasons that this information, along with other identity information required by prior notice, should be sufficient for FDA and CBP to make risk decisions about a particular import.

(Response) FDA disagrees. The Bioterrorism Act requires the identity of the manufacturer as well as the shipper. The identity of the shipper or the exporting facility alone is not sufficient to satisfy the requirements of the statute. The facility that manufactured the food must be identified.

vii. *Food imported or offered for import for transshipment, storage, and export, or further manipulation and export.* In the IFR, a registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage, and export, or further manipulation and export. We have removed this exception in the final rule because we have determined that section 801(m) of the act requires the identity of the manufacturer for food imported or offered for import into the United States, regardless of whether that food will be consumed in the United States. Likewise, under section 801(l) of the act, food is subject to being held if it is imported or offered for import into the United States and it is from a foreign facility that has not registered. This provision applies even if the food is not for consumption in the United States. As noted previously, if the submitter is unable to determine the registration number of the manufacturer, the submitter may provide a reason along with the name and full address of the manufacturer.

(Final rule) Section 1.281(a)(6), (b)(5), and (c)(6) of the final rule requires for an article of food that is no longer in its natural state, the identity of the manufacturer, as follows: the name of the manufacturer; and either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided.

8. The Grower, if Known

The Bioterrorism Act requires the submission of the identity of the grower of the article, if that identity is known within the specified period of time that notice is required to be provided. Section 1.281(a)(7), (b)(6), and (c)(7) of the IFR requires for an article of food that is in its natural state, submission of the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated, and the submitter does not know the identity of any of the growers, the submitter may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations.

(Comments) One comment asks that the requirement to identify the grower not be mandatory in the final rule and suggests exempting the growers and providing the information of growers on a voluntary basis. Another comment asserts that it is virtually impossible to identify each grower once grain is commingled at the country elevator.

(Response) The Bioterrorism Act requires the identity of the grower, if known, in the submission of prior notice. Therefore, we cannot eliminate the requirement to provide the identity of the grower in all cases, as suggested by the comment. If the identity of the grower is not known at the time of submission of the prior notice, and the food has been consolidated, then the submitter may, but is not required to, provide the name and address of the consolidator (§ 1.281(a)(7), (b)(6), and (c)(7)).

(Comments) Another comment states that a single shipment of fresh fruit may represent hundreds of growers, all of whom are known by the submitter of the prior notice. The comment asserts that requiring submission of an individual prior notice for each article represented by a single grower seems unnecessarily burdensome. The comment suggests that in lieu of requiring identification of all

known growers in the prior notice, the rule should require the submitter of the prior notice to retain a complete list of growers and to make this list available to FDA for inspection and copying upon request.

(Response) We do not agree. Periodic access, inspection, and copying of a complete listing of all growers of an article of food does not satisfy the requirement to identify the grower of the article of food, if known, within the specified period of time that notice is required to be provided. FDA responded to a similar comment in the prior notice IFR and explained that FDA does not agree that a list would satisfy the statutory requirement, as it would not tell FDA which grower was associated with the particular article of food as envisioned by the statute (68 FR 58974 at 59006). We affirm the view here.

(Comments) One comment requests that FDA reconsider the requirement to submit the names of multiple growers, if known, in the prior notice. The comment notes that submitters of prior notices must provide separate notices for each grower in the case of consolidated shipments (if the growers are known), which it asserts is onerous and costly for exporters of consolidated shipments of horticulture products. The comment believes that the proposed recordkeeping rules will cause the names of the growers to be recorded and available and the prior notice information is a duplication of effort. The comment asks that, for consolidated shipments, FDA permit the submission of one prior notice providing the name of the consolidator or one notice with the names of all the growers.

(Response) FDA disagrees. Adding the capability to accept a list of growers would add considerable complexity to both the data entry software (PNSI and/or ABI) and the screening programs. FDA responded to a similar comment in the prior notice IFR and explained that FDA does not agree that a list would satisfy the statutory requirement, as it would not tell FDA which grower was associated with the particular article of food as envisioned by the statute (68 FR 58974 at 59006). And as we explained in the previous response, periodic access, inspection, and copying of a complete listing of all growers of an article of food does not satisfy the requirement to identify the grower of the article of food, if known, within the specified period of time that notice is required to be provided. FDA notes that users of PNSI can create a prior notice for one grower, copy that prior notice, and edit just the grower information and the quantity and packaging information, assuming the imports for each grower are distinctly packaged.

(Final rule) Section 1.281(a)(7), (b)(6), and (c)(7) of the final rule requires for an article of food that is in its natural state, the submission of the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, the name and address of the firm that has consolidated the articles of food from different growers or different growing locations may be submitted.

9. FDA Country of Production

The Bioterrorism Act requires the submission of the identity of the country from which the article originates. The IFR in § 1.281(a)(8), (b)(7) and (c)(8), requires that a prior notice contain the FDA Country of Production of the article of food being imported or offered for import into the United States. As set out in the IFR definition at § 1.276(b)(4), the FDA Country of Production is, for an article of food in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If, however, an article of food is wild fish, including seafood, that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. For a food that is no longer in its natural state, the FDA Country of Production is the country where the article of food was made. However, if an article of food is made from wild fish, including seafood, that was made aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. The IFR also provides that the FDA Country of Production of food grown and harvested or collected or made in a U.S. Territory is the United States.

(Comments) One comment asks what is required as the country of production in a case where spirits are exported in bulk to a third-country for local bottling and subsequent export from that third-country for consumption in the United States.

(Response) For a food that is no longer in its natural state (e.g. spirits), the FDA Country of Production is the country where the article of food was made (e.g. bottled). For an article of food that undergoes multiple manufacturing steps, as in this comment, the FDA Country of Production would be country where the last facility performs a manufacturing/processing step that exceeds an activity of a *de minimis* nature.

(Final rule) The final rule retains without change the provisions in § 1.281(a)(8), (b)(7), and (c)(8) of the IFR.

10. Shipper

The Bioterrorism Act requires the submission of the identity of the shipper of the article. The IFR at § 1.281(a)(9), (b)(8), and (c)(9) requires that the shipper be included in a prior notice. The IFR defines shipper (§ 1.277(b)(12)) as the owner or exporter who consigns and ships the article of food from a foreign country or the person who sends an article of food in international mail to the United States.

(Comments) One comment states that the FDA has augmented section 307 of the Bioterrorism Act to require not only supply chain party identification but also the registration number of the shipper. The comment further states that the requirement to submit the shipper's registration number is easily met. There were no other comments received on this issue.

(Response) We revised certain sections pertaining to the identity of the shipper. The IFR required the registration number of the shipper, if the shipper is required to be registered. The final rule requires the identity of the shipper only if the shipper is different from the manufacturer. Moreover, the final rule eliminates the requirement to submit the registration number of the shipper, if the shipper is required to be registered, and made the submission of the registration number optional. The identity of the shipper in the final rule is satisfied by submission of the name and full address of the shipper.

(Final rule) The final rule in § 1.281(a)(9), (b)(8), and (c)(9) requires the name and full address of the shipper, if the shipper is different from the manufacturer. If the address of the shipper is a registered facility, the submitter may submit the registration number of the shipper's registered facility.

FDA revised this requirement to require the shipper's information only when the shipper is different from the manufacturer in order to eliminate duplicative requirements. Moreover, we eliminated the requirement to provide the registration number of the shipper, if the shipper is required to be registered, and made the submission of the registration number optional.

In the IFR, the shipper's registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage, and export,

or further manipulation and export. We have removed this exception in the final rule since the shipper's registration number is now optional.

11. The Country From Which the Article is Shipped

The Bioterrorism Act requires the submission of the identity of the country from which the article is shipped. The IFR requires in § 1.281(a)(10) and (c)(10) submission of the identity of the country from which the article is shipped. In § 1.281(b)(9), the IFR requires submission of the identity of the country from which the article is shipped (i.e., mailed).

(Comments) There were no comments received on this issue.

(Final Rule) The final rule retains without change the provisions in § 1.281(a)(10), (b)(9), and (c)(10) of the IFR.

12. Anticipated Arrival Information

Section 1.281(a)(11) of the IFR requires the submission of anticipated arrival information to include the anticipated port of arrival and anticipated border crossing; the anticipated date on which the article of food will arrive at the anticipated port of arrival; and the anticipated time of that arrival. In § 1.281(c)(11), the IFR requires the submission of the actual port of arrival. Anticipated arrival information is not required for food arriving by international mail.

A prior notice will not be inadequate if the anticipated port of arrival, the anticipated date of arrival, or the anticipated time of arrival changes between the time of confirmation of prior notice and the time of arrival, as provided by § 1.282(a) of the IFR.

The anticipated arrival information must specify the anticipated port of arrival and, if there is more than one border crossing location within that port, the specific anticipated border crossing where the food will be brought into the United States.

(Comments) One comment suggests the elimination of the anticipated arrival information as a data element. Another comment suggests that in light of the MOU between FDA and CBP, arrival data are no longer important, as CBP can provide the personnel to conduct the necessary inspections.

(Response) Section 801(m) of the act requires the submission of the identity of the anticipated port of entry for the article of food, therefore, this data element cannot be eliminated. The anticipated time and date of arrival are needed for planning resources because it relates to when the food will first become available for examination at the border. The coordination procedures between FDA and CBP should not be construed to mean that arrival information is no longer important nor that we will not, whenever possible, conduct necessary inspections at the port. Moreover, FDA's working with CBP personnel does not negate our need for anticipated time and date of arrival since headquarters and field staff still need to know when articles of food plan to arrive.

(Comments) One comment states that the arrival information should be linked to the ABI entry filing at the port of entry because the FDA prior notice requirement is inconsistent with the existing entry clearance processes of CBP. The comment contends that requiring prior notice at the port of arrival will result in severe disruption to flight schedules, with the possible consequence of aircraft offload for any affected food shipment for which prior notice was not submitted.

(Response) FDA disagrees. The Bioterrorism Act requires notification about articles of food prior to arrival in the United States. Although prior notice and entry information can be submitted together through ABI/ACS, prior notice cannot be substituted by the entry process, which legally can occur well after the food has arrived in the United States. Since implementation of the IFR, FDA and CBP have noted no severe disruptions, including to flight schedules due to lack of prior notice of some articles of food within an aircraft, truck, or vessel load. FDA points out that in December 2003, CBP issued and began implementation of the Advance Electronic Cargo Information rule, which also requires information about cargo before it arrives in the United States and allows for prohibition of landing authorization if such information is not provided in advance of arrival. (See 19 CFR 122.12(c) (international airports), 19 CFR 122.14(d)(4) (landing rights airports); and 19 CFR 122.15(a) (user fee airports).)

(Comments) One comment recommends that FDA ask CBP to change their ABI system to provide for port diversion functionality. The comment acknowledges that, although the FDA prior notice system is designed to allow a shipment to be diverted to a port other than the intended port of entry reported in the prior notice, CBP's ABI system precludes the CBP entry from being accepted at other than the reported port of entry. Another comment requests that when a prior notice is transmitted via either the Cargo or Border Cargo Selectivity application, the data should be moved from ACS to OASIS regardless of the estimated time of arrival date.

(Response) Such changes to the ABI system are not feasible at this time given resource constraints, and the development of CBP's new Automated Commercial Environment. Moreover, CBP transfers information to FDA at 8 p.m. on the day before arrival for truck shipments and 9 p.m. on the day before arrival for air shipment. Information is transferred to FDA on the same day if that information is submitted the same day as anticipated arrival of the shipment. CBP and FDA believe that this is sufficient for meeting the timeframes for receipt, review, and response to prior notice submission.

(Comments) Two comments address the difficulty of obtaining exact arrival information, including a specific time of arrival for air shipments, because many airlines are often closed at night. The comment also states that including a specific date and time for arrivals by ocean vessel is difficult.

(Response) FDA disagrees. From FDA's standpoint, ''time of arrival'' relates to when the food will first become available for examination at the port. For vessels, this would be when the vessel docks in the port. For planes, this would be when the plane lands. For land vehicles, such as trucks, buses, and trains, this would be when they cross the border. FDA believes that someone involved in importing or offering for import an article of food has an indication of anticipated arrival into the United States of that food and can inform the submitter and/or transmitter of the prior notice. FDA also emphasizes that the information being requested is ''anticipated'' information, not ''exact'' or ''specific'' information as the comment incorrectly describes.

(Final rule) FDA and CBP have determined that for the purposes of communication, the identity of the border crossing within the port of arrival is no longer necessary. Therefore, that information is not required in the final rule. The final rule requires in § 1.281(a)(11) the anticipated arrival information, including the anticipated port of arrival, the anticipated date on which the article of food will arrive at the anticipated port of arrival, and the anticipated time of that arrival. If the article of food is arriving by express consignment operator or carrier, and neither the submitter nor transmitter is the express consignment operator or carrier, and the prior notice is submitted via PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the anticipated arrival information. This revision is being made because anticipated arrival

information is often not available to people who ship food using an express consignment operator or courier (see also the discussion in section III.E of this document describing the shipper as it relates to who is authorized to submit prior notice). For food that has been refused under section 801(m) of the act, § 1.281(c)(11) of the final rule requires the port of arrival. We revised this provision in the final rule to require the actual date on which the article of food arrived at the port of arrival. This information is important for shipments where no previous prior notice was filed so that FDA knows how long it has been since the refused food shipment arrived in the United States. For shipments where a previously refused prior notice was filed, the actual arrival date will help FDA to connect the refused prior notice to the post-refusal prior notice submission. Anticipated arrival information is not required for food arriving by international mail.

13. The Importer, Owner, Ultimate Consignee, and U.S. Recipient

In § 1.281(a)(12) and (c)(12), the IFR requires the name and address of the importer. In § 1.281(a)(13) and (c)(13), the IFR requires the name and address of the owner if different from the importer or ultimate consignee. In § 1.281(a)(14) and (c)(14), the IFR requires the name and address of the ultimate consignee. However, the identity of the importer, owner, and ultimate consignee are not required for an article of food that is imported or offered for import for transshipment through the United States under a T&E entry.

The identity of the importer, owner, or ultimate consignee is not required for an article of food that is imported or offered for import via international mail. Instead, § 1.281(b)(11) of the IFR requires the name and address of the U.S. recipient.

a. *Importer*. (Comments) There were no comments received on this issue.

(Final rule) The final rule in § 1.281(a)(12) and (c)(12) requires the name and full address of the importer. FDA continues to require the identity of the importer so that FDA can take steps to ensure that food refused admission under section 801(m) of the act is not delivered to the importer illegally. FDA is inserting the word ''full'' in front of ''address'' in the final rule to make clear that the complete address is required. Consequently, FDA also is revising the subsequent sentence of this paragraph to state that if the business address of the importer is a registered facility, then the facility's registration number also may be provided in addition to the facility's full address. Providing the registration number will facilitate FDA's review. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a T&E entry.

b. *Owner*. (Comments) One comment asks that FDA clarify what it means by owner and provide examples.

(Response) In the preamble to the IFR, in response to a comment, we explained that the ''owner'' is the entity who owns the article of food at the time of arrival (68 FR 58974 at 59011). However, if a prior notice is given after the article is refused under section 801(m)(1) of the act, then the owner is the entity who owns the article of food at the time the prior notice is submitted (Id.).

(Final rule) The final rule in § 1.281(a)(13) and (c)(13) requires the name and full address of the owner if different from the importer or ultimate consignee. FDA is continuing to require the identity of the owner so that FDA can take steps to ensure that food refused admission under section 801(m) of the act is not delivered to the owner illegally. FDA is inserting the word ''full'' in front of ''address'' in the final rule to make clear that the complete address is required. Consequently, FDA is revising the subsequent sentence to state that if the business address of the owner is a registered facility, then the facility's registration number may be provided in addition to the owner's full address. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a T&E entry.

c. *Ultimate consignee*. (Comments) One comment states that the ultimate consignee, as defined by CBP (Customs Directive No. 3550–079A), is not necessarily the party to whom the merchandise is delivered and asks who is the ultimate consignee for purposes of this rule. Another comment notes that there are a number of manufacturers in Canada who ship their product to public warehouses in the United States to have product available on a just-in-time basis for their customers. The comment states that at the time the product crosses the border, it is still the property of the manufacturer and it does not have a specific customer (consignee) in the United States other than the manufacturer because the consignee is still to be determined. The comment asks for guidance as to how to comply and fill out the prior notice for these types of shipments.

(Response) FDA intends to interpret the ''ultimate consignee'' consistent with CBP's use of that term in regards to the entry of merchandise. In a case where a customer or consignee has not been identified, as described in the previous comment, the public storage warehouse where the merchandise will be delivered and stored should be identified as the ultimate consignee in the prior notice submission.

(Final rule) Section 1.281(a)(14) and (c)(14) of the final rule requires the name and full address of the ultimate consignee. FDA is continuing to require the identity of the ultimate consignee so that FDA can take steps to ensure that food refused admission under section 801(m) of the act is not delivered to the ultimate consignee illegally. FDA is inserting the word ''full'' in front of ''address'' in the final rule to make clear that the complete address is required. Consequently, FDA is revising the subsequent sentence to state that if the business address of the ultimate consignee is a registered facility, then the facility's registration number also may be provided in addition to the facility's full address. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a T&E entry.

d. *U.S. recipient*. (Comments) There were no comments received on this issue.

(Final rule) The identity of the importer, owner, or ultimate consignee is not required for an article of food that is imported or offered for import via international mail. Instead, the final rule requires in § 1.281(b)(11) the name and address of the U.S. recipient. FDA is continuing to require the identity of the U.S. recipient so that FDA can take steps to ensure that food refused admission under section 801(m) of the act is not delivered to the U.S. recipient illegally.

14. Mode of Transportation

Section 1.281(a)(15) and (c)(15) of the IFR requires submission of the identity of the mode of transportation.

(Comments) There were no comments received on this issue.

(Final rule) The final rule retains without change the provisions in § 1.281(a)(15) and (c)(15) of the IFR. The mode of transportation data element is necessary to calculate whether prior notice is timely, as well as for identification of the article of food at the time of arrival for the purposes of planning examinations and communicating with CBP for enforcement and examination.

15. Carrier

Section 1.281(a)(16) and (c)(16) of the IFR requires the SCAC or IATA code of the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States, or if codes are not applicable, then the name and country of the carrier.

(Comments) Several comments ask for clarification of identification of the carrier and provide examples of when the article of food is transferred from one carrier to another both prior to arrival in the United States and after arrival in the United States.

(Response) In the prior notice proposed rule, we had proposed to require the identity of each carrier or transporter firm that transports the article of food from the country from which the article was shipped into the United States. We agree with the comments we received to the proposed rule that asked FDA to eliminate the requirement to identify multiple carriers, and revised the proposed provisions to require in the IFR the submission of the identity of the carrier that is or will be carrying the article of food from the country from which the article is shipped to the United States. In doing so, FDA acknowledged the suggestion that the only pertinent carrier is the one arriving at the U.S. port. The final rule clarifies that the carrier is the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States to the port of arrival.

(Final rule) FDA and CBP have determined that identity of the country of the carrier is not necessary when the SCAC or IATA codes are not provided; the name alone of the carrier is sufficient for communication between the two agencies. However, FDA and CBP have determined that the license plate number of a privately owned vehicle as well as the State or Province that issued the license plate number is necessary for such communication.

While identity of the license plate number and State or Province that issued the license is needed to identify the carrier of the food at the port of arrival, it is more properly categorized as part of the identity of the carrier than as part of the identity of the planned shipment information. Therefore, the requirement for the submission of the license plate number (and State or Province that issued the license) for food arriving by privately owned vehicle has been moved to § 1.281(a)(16) and (c)(16). FDA has found that the identification of the privately owned vehicle as the carrier, when applicable, is such a critical factor in the identification of the article of food for examination and communication, that we have included this information in § 1.281(a)(16) and (c)(16) of the final rule.

Section 1.281(a)(16) and (c)(16) of the final rule requires the identity of the carrier by submission of the SCAC or IATA code of the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States to the port of arrival, or if these codes are not applicable, then the name of the carrier. If the carrier is a privately owned vehicle, the final rule requires the submission of the license plate number of the vehicle and the State or Province that issued the license plate number. Identification of the carrier is not required for an article of food that is imported or offered for import via international mail.

Identification of the carrier is necessary to enable FDA and CBP to identify the appropriate article of food for inspection or holding when the food arrives in the United States. FDA notes that a carrier typically is a different firm than the shipper. The broker or self-filer currently submits carrier information to ABI/ACS when entry is made, and it later is transmitted to OASIS.

16. Planned Shipment Information

In § 1.281(a)(17) and (c)(17), the IFR requires submission of planned shipment information as it exists when the prior notice is submitted. FDA recognized that some of this information may change after the prior notice has been submitted and addressed this in the IFR in § 1.282(a), which specifies when changes require resubmission to FDA.

Many comments addressed the planned shipment information. These comments are discussed in order of appearance of the specific data elements in the IFR and preceded by a discussion of general comments.

a. *General comments.* (Comments) One comment suggests that a complete list of ABI mandatory and optional data elements be immediately published via the CBP Administrative Message system. The comment asserted that some planned shipment information, such as the vessel carrier flag, is not necessary when the carrier code is submitted.

(Response) The ''vessel carrier flag'' is not part of the planned shipment information. For food arriving by ocean vessel, the vessel name and voyage number are part of the planned shipment information. The preamble to the final rule contains a table of information required at the end of this section (table 2 of this document). Each information requirement listed in the table 2 of this document is annotated to indicate when that information is required.

(Comments) One comment suggests an additional requirement for planned shipment information. The comment suggests that a number assigned through CBP's PAPS be required and that the PAPS number could be added after the prior notice is submitted, but before the truck arrives at the border. The comment asserts that this amendment of a confirmed prior notice, would greatly decrease a truck's waiting time at the border and aid in quickly clearing trucks through CBP.

(Response) PAPS is a CBP border cargo release mechanism that utilizes barcode technology to expedite the release of commercial shipments. FDA at this time has no plans to utilize PAPS in reviewing prior notices or otherwise administering the prior notice program, and therefore, FDA is not adding the PAPS number as an additional data element.

(Comments) One comment requests clarification as to whether the additional requirement for planned shipment information, as applicable (carrier, vessel name, voyage flight numbers and bill of lading number), will require a resubmission of prior notice when those details change due to transportation arrangements outside of the control of the supplier.

(Response) When we issued the IFR, we recognized that some of this information may change after the prior notice has been submitted, and addressed this in § 1.282(a) of the IFR, which specifies when changes require resubmission to FDA. If planned shipment information required in § 1.281(a)(17) changes after you receive notice that FDA has confirmed your prior notice submission for review, you are not required by the IFR to resubmit prior notice. The final rule retains this provision.

b. *Airway bill number(s) and bill of lading number(s)—§ 1.281(a)(17)(i) and (c)(17)(i).* (Comments) One comment stated that FDA should simplify the data requirements and make the requirements more manageable. The comment states that one data element should link all information secured by prior notice, which would be beneficial for locating shipments in the event of a possible crisis. The comment suggests that the waybill/bill of lading number be utilized as a single reference point because all shipments that are moved are repeatedly covered by this number.

(Response) FDA does not agree that the waybill/Bill of Lading can be used as a single reference point for all shipments instead of the prior notice confirmation number. A Bill of Lading number is not always assigned to a shipment at the time of prior notice submission. For certain shipments, such as those sent by international mail, no Bill of Lading may exist. Thus, FDA has determined that it is better to use a unique confirmation number provided by the FDA system to transmitters.

(Final rule) The Airway Bill number(s) or Bill of Lading number(s) have been valuable information for identification, examination and communication; however, this information is generally not available to an individual submitter of an article of food that is arriving via express consignment operator or carrier. The express consignment operator or carrier tracking number is available to those individuals who send an article of food via express courier. Therefore, we have amended the final rule to allow the submission of the express consignment operator or carrier tracking number in lieu of the Airway Bill or Bill of Lading numbers when the article of food is arriving by express consignment operator or carrier and the submitter is not the express consignment operator or carrier.

Section 1.281(a)(17)(i) and (c)(17)(i) of the final rule requires submission of the Bill of Lading number(s) or the Airway Bill number(s), as applicable to the mode of transportation and when it exists. This information is not required for an article of food that is imported or offered for import via international mail or when carried by or otherwise accompanying an individual when entering the United States. For food arriving by express consignment operator or carrier when the submitter is not the express consignment operator or carrier, the tracking number may be submitted in lieu of the Bill of Lading or Airway Bill number.

c. *Vessel name and voyage number—§ 1.281(a)(17)(ii) and (c)(17)(ii).* (Comments) One comment asks the purpose of this requirement because the vessel name and voyage number are provided to other U.S. agencies, such as CBP and U.S. Coast Guard, at an even earlier stage than required for the prior notice.

(Response) The planned shipment information is necessary to ensure the effective enforcement of section 801(m) of the act. Submission of the vessel name and voyage number in prior notice associates that information with the article of food and enables FDA to effectively communicate with CBP regarding examination of that article of food prior to arrival of that food. It is one of the means that FDA and CBP use to match the prior notice review to the food when it arrives at the port; e.g., what conveyance is carrying the article of food. The final rule will continue to require the vessel name and voyage number for food arriving by ocean vessel. As we discussed in the preamble to the IFR, while we are dedicated to increasing information sharing capabilities with other agencies, it is generally difficult to have the required information readily accessible if we need to coordinate with other agencies or governments to obtain from them the information necessary to respond to bioterrorism incidents or other food-related emergencies (68 FR 58974 at 58992).

(Final rule) Section 1.281(a)(17)(ii) and (c)(17)(ii) of the final rule requires submission of the vessel name and voyage number for food arriving by ocean vessel, when they exist.

d. Flight number—§ 1.281(a)(17)(iii) and (c)(17)(iii). (Comments) There were no comments received on this issue.

(Final rule) The final rule requires the flight number for food arriving by air carrier. The flight number has been valuable information for identification, examination and communication; however, this information is generally not available to an individual submitter of an article of food that is arriving via express consignment operator or carrier. The express consignment operator or carrier tracking number is available to those individuals who send an article of food via express consignment operator or carrier. Therefore, § 1.281(a)(17)(iii) and (c)(17)(iii) of the IFR have been amended to allow the submission of the express consignment operator or carrier tracking number in lieu of the flight number when the article of food is arriving by express consignment operator or carrier and the submitter is not the express consignment operator or carrier.

e. *Trip number—§ 1.281(a)(17)(iv) and (c)(17)(iv).* (Comments) Several comments request clarification of the definition of trip numbers. One comment reasons that the load tender numbers or manifest numbers should be used as trip numbers for food arriving by truck because loads are tendered to carriers with these numbers, and the carrier uses the numbers for billing reference. Another comment reasons that trip number appears to refer to a number that relates to the particular trip or journey rather than the vehicle. Another comment asserts that the trip number should identify the conveyance, everything onboard a trailer or container entering the United States. One comment recommends elimination of the mandatory requirement for trip number.

(Response) FDA disagrees. Land carriers use the ''Trip'' number to signify a train number, bus route number, and/or a truck route number. This number normally designates a repetitive route between two locations (e.g., Washington, DC to New York, NY) and may signify the specific truck, bus, or train route (e.g., Train # 138 or Bus # 4411). This information is necessary for communication between FDA and CBP, and thus, the final rule continues to require a trip number for food arriving by truck, bus, or rail.

(Final rule) Section 1.281(a)(17)(iv) and (c)(17)(iv) of the final rule requires submission of the trip number for food arriving by truck, bus, or rail, as applicable to the mode of transportation and when it exists. This information is not required for an article of food that is imported or offered for import via international mail.

f. *Container number(s)—§ 1.281(a)(17)(v) and (c)(17)(v).* (Comments) One comment suggests that FDA should allow for multiple container submissions on one prior notice.

(Response) Multiple container numbers can be submitted for one prior notice on screen via PNSI submission or through use of multiple qualifiers for the Affirmation of Compliance code for container number via ABI/ACS submission.

(Final rule) Section 1.281(a)(17)(v) and (c)(17)(v) of the final rule requires the identification of container numbers for food arriving as containerized cargo by water, air, or land, as applicable to the mode of transportation and when it exists. This information is not required for an article of food that is imported or offered for import via international mail or when carried by or otherwise accompanying an individual when entering the United States.

g. *Car number—§ 1.281(a)(17)(vi) and (c)(17)(vi).* (Comments) No comments were received on this issue.

(Final rule) The final rule retains the provisions of the IFR and requires submission of the identity of the car number for food arriving by rail, when it exists. This information is not required for an article of food that is imported or offered for import via international mail or when carried by or otherwise accompanying an individual when entering the United States.

h. *License plate number and State or Province—§ 1.281(a)(17)(vii) and (c)(17)(vii).* (Comments) No comments were received on this issue.

(Final rule) FDA has determined that while identity of the license plate number and State or Province that issued the license is needed to identify the carrier of the food at the port of arrival, it is more properly categorized as part of the identity of the carrier than as part of the identity of the planned shipment information. Therefore, the requirement for the submission of the license plate number (and State or Province that issued the license) for food arriving by privately owned vehicle has been moved to § 1.281(a)(16) and (c)(16). The final rule requires the submission of the license plate number of the vehicle and the State or Province that issued the license plate number, if the carrier is a privately owned vehicle. By including the identification of the privately owned vehicle as a carrier information requirement, when applicable, you must resubmit the prior notice in accordance with this subpart (see § 1.282) if the privately owned vehicle information changes after the prior notice has been confirmed by FDA for review. Identification of the license plate number and State or Province that issued the license is not required for an article of food that is imported or offered for import via international mail.

i. *Harmonized tariff schedule (HTS) codes—§ 1.281(a)(17)(viii) and (c)(17)(viii).* (Comments) One comment suggests the use of the HTS codes in lieu of FDA product codes and asserts that the HTS codes provide all the information that the FDA would need for prior notice.

(Response) The HTS codes often are not sufficient to specifically identify a product for FDA decisionmaking. For example, in many cases, the tariff code does not describe how the product was processed (e.g., commercially sterile or shelf-stable) or how the product is packaged, which is indicated in the Process Indicator Code (PIC) element of FDA's product code. Several products that FDA considers different from each other (because these differences affect the potential safety of the food) may be combined under one HTS code. Therefore, the HTS codes do not provide all the information that is required to identify the food.

Additionally, at the time that FDA and CBP issued the IFR, we believed that the HTS code was needed for communication between FDA and CBP and that the identification of the HTS would assist CBP in the efficient processing of prior notice through ACS. We also thought that, for prior notices submitted through the FDA's PNSI, the HTS numbers were needed to ensure that the data collected from the CBP entry when it is transmitted through ABI/ACS could be matched to prior notice. We have found that the HTS code is neither critical for communication with CBP nor for identification of the food for examination purposes. Accordingly, we have removed the requirement to submit the HTS code as a part of prior notice planned shipment information.

(Comments) One comment suggests that FDA and CBP upgrade the flags associated with HTS numbers. The comment also states that prior notice cannot be submitted through ABI/ACS if the HTS code does not have a FDA flag. One comment states that FDA should not rely solely upon HTS flags to implement the prior notice requirements.

(Response) FDA agrees and monitors and updates the HTS flags. Guidance about the HTS flags is posted at *http://www.cfsan.fda.gov/~dms/htsguid3.html*. Prior notice can be submitted on any product because of intended use, regardless of the HTS flag. Not having a FDA flag associated with the HTS code does not prevent submission of prior notice via ABI/ACS or PNSI.

(Final rule) Section 1.281(a)(17) and (c)(17) of the final rule requires submission of the following planned shipment information, as applicable, based on the mode of transportation:

- Bill of lading number(s), Airway bill number(s), or express consignment operator or carrier tracking number when the article of food is arriving by express consignment operator or carrier and the submitter is not the express consignment operator or carrier (not applicable to food carried by or otherwise accompanying an individual);
- For food arriving by ocean vessel, vessel name and voyage number;
- For food arriving by air carrier, flight number or the express consignment operator or carrier tracking number when the article of food is arriving by express consignment operator or carrier and the submitter is not the express operator or carrier;
- For food arriving by truck, bus, or rail, the trip number;
- For food arriving as containerized cargo by water, air, or land, the container number(s) (not applicable to food carried by or otherwise accompanying an individual); and
- For food arriving by rail, car number (not applicable to food carried by or otherwise accompanying an individual).

We also added the phrase ''to the mode of transportation and when it exists'' after ''as applicable'' in the opening sentence of § 1.281(a)(17) and (c)(17) to clarify that the data elements under planned shipment information are applicable by mode of transportation and when the data element exists. For example, rail car number, container number, and train trip number may be applicable for rail shipments, and vessel name, voyage number, and container number may be applicable for food arriving by ocean vessel.

The final rule does not require that prior notice be cancelled and resubmitted if this planned shipment information changes after FDA has confirmed the prior notice for review. A prior notice will not be inadequate if any of the planned shipment information changes between the confirmation of prior notice and the time of arrival.

j. *Refused articles.* (Comments) One comment requests clarification of the process for resubmission if a prior notice is refused for reasons other than failure to satisfy prior notice requirements. The comment asks once the failure is rectified, should companies use the PNSI or ABI/ACS to resubmit the load for clearance?

(Response) A food may be refused under 801(m) of the act only if it is imported or offered for import with inadequate prior notice; i.e., no prior notice, untimely prior notice, or inaccurate prior notice. To resolve a refusal, prior notice or a revised prior notice must be submitted via PNSI until such time as ACS or its successor system can accommodate such transactions.

The following table 2 summarizes the information required under § 1.281(a), (b), and (c):

TABLE 2.—PRIOR NOTICE INFORMATION REQUIRED BY CATEGORY

Information	Transshipment	Carried By or Accompanying an Individual	Food Not in Natural State	Food in Natural State	Mail	After Section 801(m) of the Act Refusal
§ 1.281 paragraph(s)	(a) and (c)	(a)	(a)	(a)	(b)	(c)
Submitter	Y	Y	Y	Y	Y	Y
Transmitter	Y	Y	Y	Y	Y	Y
Entry type	Y	Y	Y	Y	Y	Y
Entry identifier	Y	Y	Y	Y	N	Y
FDA product code	Y	Y	Y	Y	Y	Y
Common, usual, or market name	Y	Y	Y	Y	Y	Y
Estimated quantity	Y	Y	Y	Y	Y	Actual
Lot/Code #	Y	Y	Y	N	Y	Y
Manufacturer	Y	Y	Y	N	Y	Y
Grower, if known	Y	Y	N	Y	Y	Y
Country of production	Y	Y	Y	Y	Y	Y
Shipper	Y	Y	Y	Y	Y	Y
Country from which article is shipped	Y	Y	Y	Y	Y	Y
Port of arrival	Anticipated[1]	Anticipated[1]	Anticipated[1]	Anticipated[1]	N	Actual[1]
Date of arrival	Anticipated[1]	Anticipated[1]	Anticipated[1]	Anticipated[1]	N	Actual
Time of arrival	Anticipated[1]	Anticipated[1]	Anticipated[1]	Anticipated[1]	N	N
Date of mailing	N	N	N	N	Anticipated	N
Importer	N	Y	Y	Y	N	Y
Owner	N	Y	Y	Y	N	Y
Ultimate consignee	N	Y	Y	Y	N	Y
U.S. recipient	N	N	N	N	Y	N
Mode of transport	Y	Y	Y	Y	N	Y
Carrier	Y	Y	Y	Y	N	Y
Bill of lading/airbill	Planned[1]	N	Planned[1]	Planned[1]	N	Actual[1]
Vessel/Voyage	Planned	Planned	Planned	Planned	N	Actual
Flight #	Planned[1]	Planned[1]	Planned[1]	Planned[1]	N	Actual[1]
Trip #	Planned	Planned	Planned	Planned	N	Actual
Container #	Planned	N	Planned	Planned	N	Actual
Car #	Planned	N	Planned	Planned	N	Actual
Hold information	N	N	N	N	N	Y

[1] If the article of food is arriving by express consignment carrier or operator, and the submitter and/or transmitter is not the express consignment operator or carrier, and the prior notice is submitted via the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of this information.

I. What Must You Do If Information Changes After You Have Received Confirmation of a Prior Notice From FDA? (§ 1.282)

In § 1.282 (a)(1) of the IFR, if any of the information required in § 1.281(a) except the quantity information, the anticipated arrival information, or the planned shipment information, changes after FDA has confirmed the prior notice submission for review, you must resubmit prior notice. For food arriving by international mail, if any of the information required in § 1.281(b), except the anticipated date of mailing, changes after FDA has confirmed the prior notice submission for review, you must resubmit prior notice.

The IFR also states that the original prior notice should be cancelled in PNSI or if originally submitted via ABI/ACS, the entry should be deleted.

(Comments) Some comments request that FDA revisit the concepts outlined in §§ 1.289 through 1.294 of the proposed rule, which allowed amendments to be made to product identity, estimated quantity, and arrival information, without having to cancel the entry and resubmit the prior notice under a new entry. The comments contend that such amendments were acceptable and would not taint the adequacy of a prior notice or compromise food security, if the amendments are made within the applicable 2-, 4-, or 8–hour timeframes per mode of transportation at issue. The comments suggest that amendments allow for a degree of flexibility in the prior notice system and acknowledge a well-known fact in the industry that this type of information may change after prior notice has been submitted. Some comments suggest that allowing the submitter or filer to update or correct information provided in a prior notice will facilitate the steady flow of prior notice submissions, without jeopardizing the security and safety of the food supply.

(Response) Unlike the proposed rule, the IFR does not allow for amendments relating to the product identity. After considering the comments on whether the final rule should allow amendments, and based on our experience with the IFR, we believe the approach in the IFR is sound. The reduced timeframes in the IFR, which are continued in the final rule, provide very little leeway in the time FDA has to receive, review, and respond to the prior notice submissions. Moreover, the timeframes are based, in part, on not receiving amendments because allowing amendments would increase the review time. In addition, ACS cannot accommodate changes in prior notice submissions that have been confirmed by FDA for review because CBP also needs finality so it can complete its own screening of the entry. Therefore, to keep the timeframes as short as possible, we are not permitting changes to prior notice without restarting the clock.

Moreover, we believe that the prior notice information required by the final rule should be sufficiently fixed to be submitted within the timeframes. The final rule allows for estimates for some information—estimated quantity, anticipated arrival information, and planned shipment information—and changes to any of these data elements does not require that the prior notice be resubmitted.

(Comments) Some comments request that FDA create a mechanism to allow correction of errors in a manner that does not restart the prior notice clock. One comment requests the final rule provide for correction of errors within the timeframe of the 2-, 4-, or 8–hour deadline. The comments suggest that a streamlined process, possibly through electronic means, of making clerical corrections or correcting errors in timely filed prior notice should be a permanent feature of the integrated FDA-CBP process. Some comments contend that without the opportunity to correct the error post-submission, shippers may find their shipments frozen in an extended period of delay, which would frustrate the purpose of the FDA-CBP Integration Plan that is aimed at reducing such timeframes. Comments also suggest this would create an unintended legislative loop between the two regulatory frameworks meant by the Integration Plan to be seamlessly and efficiently integrated.

Some comments object to the IFR's requirements because after the CBP entry or entry summary has been certified, there currently is no mechanism for making corrections, including corrections of simple clerical errors, without canceling the entry and submitting a new entry. Comments state that the requirement to cancel and resubmit a prior notice when submitted information changes or to correct a clerical error creates additional work in an already overburdened environment. According to the comments, in the air and truck environment where cargo is processed on weekends and at off-hour operations, CBP is unavailable to process these entry cancellations. The comments state that in such circumstances, cargo could be forced into refused status due to CBP's inability to act in a timely manner.

Similarly, other comments state that many imported articles of food are time sensitive and must be shipped in a temperature controlled environment. The comments note that clerical errors in the prior notice may not be corrected, and if an error is discovered after a CBP entry is certified, the entry must be cancelled. According to the comments, if CBP is not available to cancel the entry (e.g., the shipment arrives over the weekend), the delay may cause the shipment to be destroyed. The comments request that FDA and CBP find a way to address this problem, either by allowing clerical revisions after the entry has been certified, permitting entry deletions under certain circumstances, or ensuring CBP availability on a 24 hours/7 days a week/365 days a year schedule.

(Response) Because we reduced the timeframes for submitting prior notice in the IFR to the least amount of time that we need to meet our statutory responsibility to receive, review, and respond to prior notice submissions, the IFR did not provide for amendments or updates. The timeframes in the final rule also provide the least amount of time we need to receive, review and respond to prior notice submissions and therefore, the final rule also does not provide for amendments or updates. The use of ABI/ACS precludes amendments and updates without substantial and costly revisions to the system; such technical changes are not cost-effective or a good use of limited resources given the development of the Automated Commercial Environment, which will replace ACS. Changes to ABI/ACS submissions that have been electronically transmitted to FDA's OASIS and confirmed by FDA for review are not feasible because CBP also needs finality so it can complete its own screening of the entry.

Changes to confirmed prior notice submissions, other than those relating to estimated quantity, anticipated arrival information, and planned shipment information, must be processed by resubmission of prior notice unless the article of food will not be offered for import or imported into the United States. The responsibility is on submitters to provide accurate prior notice to FDA, and we encourage affected parties to take appropriate measures to verify entries for accuracy before sending. FDA notes that both ABI and PNSI systems allow for correction of errors that are revealed by the systems' validation process. In PNSI, a PN confirmation number will not be provided if it detects errors in the submitted data.

Moreover, FDA notes that if CBP is unavailable to cancel a prior notice, submitters can create and submit new

replacement entries and prior notices using either ABI or a combination of ABI and PNSI even when the original entry has not yet been cancelled. However, the submitter should cancel the previously submitted inaccurate ABI entry (via request to CBP) at the first chance possible to avoid subsequent administrative and operational problems with entry release. This is a revision to the IFR in that § 1.282(c) of the final rule uses the correct term ''cancel'' versus ''delete'' when describing what CBP should be requested to do in this case. When an entry is ''deleted'' versus ''cancelled'' in ABI, the filer is able to re-use the original entry number. However, PNSI will reject a prior notice submission that attempts to re-use a previous entry number. Therefore, we revised the final rule to provide for cancellation of the entry, rather than deletion of an entry.

(Comments) Some comments request that FDA and CBP develop a process for reviewing amendments that do not affect the security of the cargo in less than the full eight hours, so that the shipments' release from the port is not delayed unduly.

(Response) The requirements for amendments set forth in the proposed rule were eliminated from the IFR. This final rule provides that if required information (except estimated quantity, anticipated arrival information, including the anticipated date of mailing, and planned shipment information) changes after FDA has confirmed prior notice for review, the prior notice should be cancelled and a prior notice with the correct information must be submitted. The reduced timeframes in the IFR, which are continued in the final rule, provide very little leeway in the time FDA has to receive, review, and respond to the prior notice submissions. Moreover, the timeframes are based, in part, on not receiving amendments because allowing amendments would increase the review time. In addition, ACS cannot accommodate changes in prior notice submissions that have been confirmed by FDA for review because CBP also needs finality so it can complete its own screening of the entry. Because we are maintaining the IFR timeframes in the final rule, it is difficult to accommodate amendments.

(Comments) Some comments state that changes to prior notice should be required for material changes only. Materiality would need to be determined.

(Response) We agree. The final rule requires that, if certain required information changes after FDA has confirmed prior notice for review, the prior notice should be cancelled and a prior notice with the correct information must be submitted. Changes to other information (i.e., estimated quantity, anticipated arrival information, and planned shipment information) do not require the submitter to re-submit a revised prior notice.

(Comments) Some comments suggest that entry deletions, rather than cancellations, should be permitted for legitimate reasons.

(Response) FDA believes the comment misunderstands § 1.282(c) of the IFR because that provision states, ''If you submitted the prior notice via ABI/ACS, you should cancel the prior notice via ACS by requesting that CBP *delete* the entry'' (emphasis added). However, the final rule now recommends that if you cancelled a prior notice submitted via ABI/ACS, you should cancel the prior notice via ACS by requesting that CBP cancel, rather than delete, the entry (§ 1.282(c)). When an entry is ''deleted'' versus ''cancelled'' in ABI, the filer is able to re-use the original entry number. However, PNSI will reject a prior notice submission that attempts to re-use a previous entry number. Therefore, we revised the final rule to provide for cancellation of the entry, rather than deletion of an entry.

(Comments) One comment requested clarification regarding whether the additional requirement for planned shipment information as applicable (carrier, vessel name, voyage flight numbers, and bill of lading number) will necessitate a resubmission when those details change due to transportation arrangements outside the control of the supplier.

(Response) No. The final rule does not require resubmission of prior notice if the planned shipment information changes after prior notice has been submitted and confirmed for review by FDA.

(Comments) One comment notes that part of the process of completing a prior notice is to obtain a CBP entry number, which many firms use a customs broker to do. The comment states that this works well in most cases, but can create problems for products arriving by boat. The comment further states that of all the modes of transportation, boats are the most unpredictable and can arrive earlier or later than expected. Early arrivals pose a problem because of the 8 hour notice period and the relatively short timeframe in which a company learns of an impending early arrival. Given the fact that customs brokers may not work a 24–hour, 7-day per week schedule, prior notice shipments that arrive on the weekend, holiday, or after normal business hours will be filed late and could be subject to civil penalties. The comment recommends that the prior notice system allow custom entry numbers to be updated after the customs entry has been filed by the customs brokers and that any penalty considerations be deferred under these circumstances.

(Response) The type of updates recommended by this comment is not necessary because prior notice can be submitted without a customs entry number. In the situation described, where prior notice must be submitted before entry can be filed, prior notice may be submitted using PNSI without a CBP entry identifier (e.g., a CBP entry number). PNSI will provide a system-generated entry identifier. Once a customs broker is secured during normal business hours to file the entry, the prior notice confirmation number(s) can be given to the broker who can affiliate the prior notice(s) to the customs entry via the ABI submission.

(Comments) Some comments request clarification on what happens to the food if the information relating to product identity, estimated quantity, or anticipated arrival changes after prior notice is submitted.

(Response) The final rule requires that if required information (except estimated quantity, anticipated arrival information, including the anticipated date of mailing, and planned shipment information) changes after FDA has confirmed prior notice for review, the prior notice must be resubmitted. As we explained in the preamble to the IFR, ''FDA proposed to allow changes to certain information in the prior notice after a prior notice was submitted. * * *. Some comments stated that if the timeframe for submitting prior notice was changed, i.e., shortened to 4 hours for land and air and 8 hours for water, then amendments and updates would not be necessary. * * * FDA agrees with the comments that state that if the deadline for submission of prior notice were reduced, amendments and updates would not be necessary. FDA has chosen timeframes that provide it with very little leeway in the time it has to 'receive, review and respond' to the prior notice submissions. Thus, we concluded that we could no longer permit changes to prior notice without restarting the clock. In addition, the use of ABI/ACS precludes amendments and updates: changes to ABI/ACS submissions that have been electronically transmitted to FDA's OASIS and confirmed by FDA for review are not feasible because CBP also needs finality so it can complete its own screening of the entry. Therefore, the interim final rule does not allow for

changes to a prior notice after the transmitter has been notified that FDA has confirmed the prior notice for review.'' (68 FR 58974 at 59013 and 59014)

We retain this view and therefore, changes in product identity require resubmission of a prior notice with the correct information. We do not require resubmission of a prior notice if the estimated quantity, anticipated arrival information, including the anticipated date of mailing, and planned shipment information changes, because these data elements are not firm in the first place. Moreover, such changes would not alter FDA's ability to review the prior notice or to examine the food.

(Comments) Some comments request that FDA maintain the flexibility, as provided by the IFR, to provide anticipated port arrival information for date and time of arrival and point of crossing. The comments state that this flexibility is critical for minimizing trade disruption and note that times of arrival and entry locations often change and importers need the flexibility to accommodate these unanticipated changes without refiling entry information.

(Response) Section 1.281(a)(11), which requires anticipated arrival information, has been revised in the final rule. The requirement to provide the identity of the border crossing within the anticipated port of arrival has been eliminated in the final rule. As with the IFR, in the final rule, changes in anticipated port of arrival, anticipated date of arrival, and anticipated time of arrival do not require cancellation and resubmission of the prior notice.

(Comments) Some comments suggest that the requirement that all prior notice data be transmitted via the PNSI portal after the prior notice time limitations or refusal will increase the load on this limited system. The comments state that the PNSI system capacity must be dramatically increased before the August 2004 full enforcement deadline in order to ensure that legitimate trade is not impacted due to a failure of the system.

(Response) FDA does not agree that post-refusal prior notice submissions have or will impact or overload PNSI. PNSI has operated effectively since the IFR took effect and has sufficient capacity for any increase in submissions after the effective date of this final rule. FDA has carefully monitored both PNSI and OASIS system usage and performance. No issues related to load on PNSI have been identified since the IFR took effect. Until such time as ACS or its successor system can accommodate such transactions, post-refusal prior notice must be submitted via PNSI (see § 1.280(a)(2)).

(Final Rule) Section 1.282 of the final rule requires that if required information (except estimated quantity, anticipated arrival information, including the anticipated date of mailing, and planned shipment information) changes after FDA has confirmed prior notice for review, the prior notice should be cancelled and a prior notice with the updated information must be submitted.

J. What Happens to Food That Is Imported or Offered for Import Without Adequate Prior Notice? (§ 1.283)

The IFR in § 1.283 identifies consequences and procedures for failure to provide adequate prior notice and describes the requirements and procedures for various situations.

The comments received will be discussed below in the order each issue appears in § 1.283 of the IFR, proceeded by comments generally addressing consequences.

1. General Comments

(Comments) Some comments suggest that enforcement actions should be based on levels of culpability (e.g., negligent, grossly negligent, and fraudulent), number of infractions, and seriousness of infractions.

(Response) FDA and CBP take various considerations, such as the seriousness of the violation, into account when deciding whether to take an enforcement action in response to violations of the prior notice rule and, if so, what actions to take. For areas in which we have established enforcement policies for prior notice, these are contained in, and communicated to the public through a Compliance Policy Guide (CPG). Elsewhere in this issue of the **Federal Register**, we are announcing the availability of the Prior Notice Final Rule Draft CPG, which describes our proposed enforcement policies for the final rule.

(Comments) Some comments request clarification on the penalties for inadvertent errors, such as clerical errors, in the prior notice submission.

(Response) As described in the previous response, FDA and CBP take into account the nature of the violation in determining how to respond to prior notice violations. The validation process built into ABI and PNSI should assist in catching inadvertent errors, such as clerical errors, because the systems will not accept data with certain errors. This validation process then allows the submitter to correct errors before final submission of prior notice data.

(Comments) Some comments ask if there are any measures that importers should undertake to avoid delays at the port of entry.

(Response) FDA advises that most delays based on inaccurate and untimely submission of prior notice are avoidable and recommends that importers focus on measures to increase accurate and timely submissions of prior notice.

(Comments) Some comments state that the ''Category 3'' refusal and fine provision is excessive for a shipment showing up at the border in advance of the 2-hour timeframe elapsing and FDA should consider lowering the penalty for this type of offense. Other comments request clarification about what will happen to trucks that arrive too early, i.e., will they be turned away or will they be allowed to wait in the compound?

(Response) Section 1.283(a)(1)(iii) of the final rule provides that if an article of food arrives early (i.e., before the prior notice time has elapsed), its arrival will not be considered untimely if FDA already has reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response. However, if FDA has not reviewed the prior notice submission and responded to CBP before the food arrives, the food is subject to refusal. As noted previously, in determining whether to refuse the food, assess a CBP civil monetary penalty, or take other regulatory action, we will take into account the seriousness of the violation and other considerations. Trucks arriving before FDA has processed the prior notice will be handled as appropriate under the individual circumstances.

(Comments) Some comments state that the implementation plan for the prior notice rule must include a contingency plan to ensure that border traffic can still be cleared and does not come to a standstill as new systems are put in place and problems are resolved. Comments point out that it is essential for FDA and CBP to have appropriate mechanisms and procedures in place (such as referral to a secondary inspection, where appropriate) so that border congestion is not increased by the application of the rules.

Some comments request clarification on arrangements between FDA and CBP, the Canada Border Services Agency, and the bridge authorities to address issues surrounding refusal of entry due to missing or incomplete prior notice information. The comments indicate that the relevant agencies on both sides of the border should have a plan in place to deal with the inevitable

problems posed by larger volumes of returning trucks to ensure that busy border crossings do not become a ''no man's'' land. Some comments indicate that local staff at busy border crossings, such as the Peace Bridge and Ambassador Bridge, have indicated that trucks will be turned back for missing/incomplete prior notice if secure storage cannot be arranged. Comments suggest that CBP could stamp a shipping document (such as the bill of lading) ''Refused—BTA'' or implement procedures that CBP had in place for refused trucks prior to the Bioterrorism Act.

Some comments suggest that carriers should be permitted a variety of options when and if they are advised that one or more products within a shipment have been refused due to a failure to have an adequate prior notice. According to the comments, these options may include, permission to hold the cargo at the border while the proper information is submitted to the FDA and before mandatory notice of intended destination for delivery; returning the cargo to the exporting facility directly; holding the cargo at a designated carrier's closest facility; and/or holding the cargo at a designated FDA holding facility, not necessarily a general order bonded warehouse, near the port of entry.

(Response) FDA and CBP have not experienced any major disruptions in border traffic as a result of the implementation of the IFR in December 2003. The agencies also have not made any significant revisions to the IFR in this final rule that cause us to believe there will be major disruptions in trade once the provisions in this final rule take effect, particularly since we are providing a 180-day period between publication of this rule and the effective date of its provisions. This period of time should allow for full understanding by affected parties of the requirements of the final rule.

We also note that the automated validation process in ABI and PNSI will catch most missing and incomplete submissions before refusal because the systems will not accept submissions with certain errors or omissions. If refusal does occur, the carrier will have the option to segregate refused food from the rest of the shipment (§ 1.283(a)(3)), the option to export after refusal with CBP concurrence (§ 1.283(a)(5)), and the option to have refused food held at the port of entry, unless directed otherwise by CBP or FDA (see § 1.283(a)(1)).

(Comments) Some comments recommend establishing an electronic means to resolve the refused admission status.

(Response) Both the IFR and the final rule provide for a response to an 801(m) refusal to be provided to FDA by mail, e-mail, fax, or courier. FDA will respond in kind, as we have not experienced any problems as a result of this flexibility.

2. Inadequate Prior Notice (§ 1.283(a)(1))

(Comments) Several comments request that FDA notify the submitter, filer, importer, or ultimate consignee, either in lieu of or in addition to the carrier, about inadequacies in a prior notice submission that result in refusal of the food. The comments state that the carrier is not in a position to resolve the problem when the article of food is refused. The comments note that the carrier has temporary possession of the product, has minimal vested interest in the shipment, particularly if is offloaded, and has little, if any, resources or incentive to resolve the refusal. However, according to the comments, the exporter, importer, or ultimate consignee has an ownership interest in the refused food and a strong economic incentive to resolve the refusal swiftly, or to export or destroy the refused food if the prior notice defects cannot be corrected. The comments state that delaying notification to the submitter, importer, and ultimate consignee, unduly hinders the resolution of the problem.

One comment specifies that the filer of the prior notice, who is in most cases the importer, supplier, owner of the merchandise, or a representative of one of these entities, should be notified directly, without any intermediate communication, so that the filer may promptly take corrective action and mitigate any possible adverse regulatory and commercial consequences. Some comments request that FDA or CBP notify the General Order Manager (GOM) when a shipment has been rejected or denied entry and also provide the rationale for that decision.

(Response) FDA disagrees. The IFR does not require FDA or CBP to provide notice about a refusal, and we continue to believe this is appropriate. As an operational matter, the carrier would have to be notified of the refusal. The carrier can then notify others, such as the entity that hired the carrier to transport the article of food, that there is a problem with the prior notice. It would be resource-intensive for FDA or CBP to assume responsibility for notifying various other entities of the refusal. FDA notes that, although we collect the contact information for the submitter and transmitter, which we could use to contact parties about certain actions, including refusals, routinely notifying these and other parties about a refusal would take limited staff resources away from other functions, such as reviewing prior notices. FDA will try to notify other parties (e.g., submitter), in addition to the carrier, if feasible, and we often do contact these other parties as resources allow. FDA notes that for the future migration of ABI/ACS to the ITDS/ACE environment, FDA has requested the ability to provide electronic prior notice ''refusal'' messaging. This capability does not currently exist. If electronic prior notice refusal messaging is in place, it would significantly reduce the resources required to notify ITDS participants of these refusals.

(Comments) Some comments express concern that trucking companies that pick up FDA-regulated freight in Canada or Mexico bound for the United States cannot ascertain that the importer, shipper, or customs broker has filed the appropriate prior notice. The comments ask what form of proof FDA (or other border regulatory agencies) will consider acceptable in order to release the motor carrier from responsibility if the prior notice was not filed appropriately. The comments state that it is not clear whether FDA will supply an official document that the importer, shipper, or customs broker would issue to the motor carrier to assure the carrier that prior notice has been filed.

(Response) Under § 1.279(d) of the final rule, FDA notifies the submitter when the prior notice has been confirmed for review, with a message containing a prior notice confirmation number. Section 1.279(g) of the final rule requires that the prior notice confirmation number must accompany any article of food for which the prior notice was submitted through PNSI when the article arrives in the United States and must be provided to CBP or FDA upon arrival. To address the concern in the comments, carriers may consider, as a matter of business practice, requesting from their customers proof of confirmation of prior notice submission prior to transporting the food to the United States, even when there is no requirement to provide the confirmation number to CBP or FDA upon arrival.

(Comments) Some comments request clarification on whether information for FDA clearance will be allowed to be transmitted via ABI, PNSI or either, for a shipment of food that will be entered after the arrival of a vessel or an aircraft. Comments ask what error message will be sent back to the transmitter for entry that is untimely filed, e.g., will the transmitter receive a refused admission

status or some other error message? In addition, comments ask what the mechanism is for communicating with the carrier on the disposition of the prior notice. The comment states that carriers cannot view the FDA ''may proceed'' messages in CBP's AMS, and the ABI participant (usually the customs broker) is responsible for communicating freight holds to the various parties involved, including importers, container freight stations (CFS), and truckers.

(Response) FDA clarifies that if an article of food subject to prior notice requirements arrives in the United States and prior notice has not been received for review by FDA in the timeframes prescribed in the final rule, the food is subject to refusal under section 801(m) of the act, unless FDA already reviewed the prior notice, determined its response, and advised CBP of that response. See also the discussion above regarding communication of refusal status.

(Comments) One comment requests clarification as to how transmitters may confirm the validity and existence of registration numbers provided by the shippers, importers, and carriers. The comment states that the transmitter might bring in goods based on erroneous, but good faith information.

(Response) FDA will identify anomalies in the initial submission of registration numbers based on review of the information prior to confirmation of receipt of the prior notice, and will respond accordingly. If our subsequent review, after the prior notice is confirmed for review, reveals problems with a submitted registration number that causes the prior notice submission to be deemed inaccurate, the food is subject to refusal under section 801(m) of the act. Subsequent corrections to the submitted information can be provided by resubmitting corrected information in a post-refusal prior notice (see § 1.283(c)).

If our subsequent review reveals problems with the submitted registration number such that an article of food is from a foreign facility that is not registered under section 415 of the act and 21 CFR, part 1, subpart H, and is imported or offered for import into the United States, the food is subject to hold under section 801(l) of the act. To resolve a hold, the facility must register and obtain a registration number, and that number must be provided to FDA. This is covered under § 1.285(i) of the final rule.

As discussed in response to comments 157 and 158 in the preamble to the Registration of Food Facilities Interim Final Rule (68 FR 58894 at 58931, October 10, 2003), section 305 of the Bioterrorism Act states that FDA's list of registered facilities and registration documents FDA receives under the rule are not subject to disclosure under FOIA. Furthermore, section 305 of the Bioterrorism Act provides that any information derived from the list of facilities or registration documents that would disclose the identity or location of a specific registered person is not subject to disclosure under FOIA. This does not preclude the registered facility from disclosing its registration number, such as to the submitter or others with whom it has a business relationship.

(Comments) Some comments request that FDA clarify the penalties for inadequate prior notice. One comment asks about the consequences when foods are accidentally shipped without meeting the prior notice requirements, i.e. can they be transshipped?

(Response) Prior notice is required for food imported or offered for import into the United States, including shipments intended for transshipment. If adequate prior notice is not provided, the food is subject to refusal. Refused food must be held, in accordance with the provisions of § 1.283(a), unless CBP concurrence is obtained for export and the food is immediately exported from the port of arrival under CBP supervision. An article of food that has been refused is considered general order merchandise and can only be moved under appropriate custodial bond unless immediately exported under CBP supervision. If the food is held at a secure facility outside of the port, FDA must be notified of the location of the secure facility before the food is moved there. Post-refusal prior notice can be submitted as provided by § 1.283(c).

We also note that CBP may seize goods imported contrary to law, assess civil monetary penalties, including those under 19 U.S.C. 1595a(b) against every person who directs, assists, financially or otherwise, or is in any way concerned in the importation of any merchandise contrary to law, and refer violations for criminal investigation and prosecution. Section 1.284 of the final rule lists other consequences for failure to submit adequate prior notice. For example, under 21 U.S.C. 335a, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States or any person who has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

(Comments) Some comments ask whether an entry of food would be subject to detention if the product code does not precisely reflect the nature of the product.

(Response) The final rule requires the submission of accurate information that is submitted in the prior notice, including the product code, which is required in § 1.281 (a)(5)(i), (b)(4)(i), and (c)(5)(i) of the final rule. If the product code does not accurately identify the food, the food is subject to refusal. Section 1.283(a)(1)(ii) of the final rule states that if prior notice has been submitted and confirmed by FDA for review, but upon review of the notice or examination of the article of food, the notice is determined to be inaccurate, the food is subject to refusal of admission under section 801(m)(1) of the act.

3. Status and Movement of Refused Food (§ 1.283(a)(2))

(Comments) Some comments request that FDA clarify the process for food that is refused and later deemed to be admissible.

(Response) Section 1.283 of the final rule identifies the consequences and procedures for food that is refused because of inadequate prior notice. If the refused food is not immediately exported with CBP concurrence, it is considered general order merchandise and must be held until adequate prior notice is submitted and FDA has notified CBP and the transmitter that the food is no longer refused because of inadequate prior notice. If in response to a request for FDA review, FDA determines that the article is not subject to the prior notice requirements or that the prior notice submission is complete and accurate, it will notify the requester, the transmitter, and CBP that the food is no longer subject to refusal under section 801(m)(1) of the act. A determination that an article of food is no longer refused under section 801(m)(1) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. Moreover, a determination that an article of food is no longer refused under section 801(m)(1) does not mean that it will be granted admission under other provisions of the act or other U.S. laws (§ 1.283(g)). Further information regarding the process may be found in the preamble to the IFR (68 FR 58974 at 59016 through 59022).

(Comments) Some comments state that the holding period for prior notice should be no longer than the original required prior notice timeframe. The comments contend that exceeding this

time period does not increase the safety to the public and may cause a bottleneck for all freight movements if thousands of shipments are held at their port of arrival. Comments suggest that, before the holding period is fully implemented, FDA should determine the percentage of shipments that are still not in conformity with the prior notice rule and determine the potential for harming the movement of all freight into and out of the United States when prior notice is fully implemented.

(Response) Section 1.283(a)(2) of the final rule states that refused food will be considered general order merchandise. In the first instance, it is not within our control how long it will take the parties associated with the article of food being held to satisfy the prior notice requirements. Moreover, CBP regulations address the length of time an imported product will be held in General Order (G.O.) Status (19 CFR part 127). Section 1.283(a)(1) of the final rule states that refused food that is not immediately exported must be held at the port of entry unless directed by CBP or FDA. Accordingly, the final rule does not require refused food to be held at the port of arrival unless so directed by CBP or FDA. In § 1.283(c)(3), we state that FDA will try to review and respond to post-refusal prior notice submissions within the prior notice timeframes.

(Comments) Some comments request that FDA establish procedures for handling refused merchandise. The comments contend that secure storage facilities and cargo movement procedures have not been established for refused merchandise. According to the comments, there is no mechanism to handle refused refrigerated or frozen shipments. The comments state that perishable food that is held or is not properly stored may no longer be commercially viable when it is released or sold at auction. Comments also state that highly perishable shipments that are held past their commercially viable time period and small shipments that have little commercial value will quickly fill any warehouse, including any G.O. warehouse, with no one to claim them. Other comments request that FDA and CBP develop a joint operational plan for handling refused merchandise with input from the importing and shipping industries. Another comment states that directions on executing CBP 6043 Permit to Transfer or CBP 7512 ''Restricted in-bond'' is needed to avoid major congestion.

(Response) Section 1.283(a)(2)(i) of the final rule provides that food refused under section 801(m)(1) of the act has ''General Order'' status. Under CBP laws and regulations, general order merchandise must generally be held in a general order warehouse (19 CFR 127.1). CBP regulations also empower the port director, if merchandise requires specialized storage facilities that are unavailable in a bonded facility, to direct the storage of the merchandise by the carrier or by any other appropriate means (see 19 CFR 4.37(f), 122.50(f), or 123.10(f)). Additionally, fruit and other perishables may be held by the port director in a bonded cold-storage warehouse for a reasonable period, if it is probable that entry will be made at an early date (19 CFR 127.28(c)).

FDA and CBP believe that general order storage qualifies as secure facilities for purposes of the Bioterrorism Act, as it is subject to the requirements set forth at 19 CFR part 19. In particular, 19 CFR 19.9 contains controls that will ensure that refused food will be adequately controlled while in storage and will not be released from general order storage without CBP authorization.

FDA also emphasizes that refusal under section 801(m) of the act occurs when no prior notice or inadequate or untimely prior notice is submitted, as required under the Bioterrorism Act for articles of food imported or offered for import into the United States. Costs and other consequences described by the comments due to refusal for inadequate prior notice should be avoided when adequate prior notice is submitted to FDA. The final rule also outlines procedures for satisfying the prior notice requirements after food has been refused and procedures for requesting an FDA review of the refusal.

(Comments) One comment requests that FDA establish a clear definition of ''perishable'' shipments. The comment states that destroying or selling frozen, refrigerated, and fresh merchandise held at a secure facility after 3 days, for inadequate prior notice, is unreasonable and an excessive financial burden on international trade.

(Response) FDA does not agree that it is necessary or pertinent to establish a definition of ''perishable'' for purposes of implementing the prior notice requirements of the Bioterrorism Act, which requires FDA to receive prior notice of food imported or offered for import into the United States. Financial burdens associated with merchandise directed to a secure facility because of inadequate, untimely or no prior notice generally can be avoided by ensuring FDA receives adequate prior notice in accordance with this final rule.

(Comments) Some comments request that FDA consider the ''port of entry'' to be the port where legal entry is accomplished. The comments state that these ports have facilities for proper food storage, as well as the CBP and FDA processes and personnel to deal with any irregularities. The comments point out that international shipments are not legally ''entered'' with CBP at the port of arrival, but instead are moved under bond to a subsequent port where CBP entry is made. Further, shipments are not released at the port of entry until clearance is obtained from CBP, and carriers are under a strict obligation to retain control of shipments from the port of arrival to the legal entry port. The comments note that under the IFR, shipments of food will not be permitted to be moved from the port of first arrival to the port of legal entry if prior notice is not provided or is inadequate. According to the comments, express carriers may be required to unload and reload entire planes in order to find one or two shipments. The comments state that this is especially problematic because proper facilities for the storage of food may not be available at the ports of arrival. Comments further note that express consignment operators have invested millions of dollars to construct and operate dedicated sorting facilities that use state of the art automation and scanning equipment. These facilities are far better suited to identifying and detaining food shipments of concern to FDA than the ramps or conventional air freight handling facilities commonly found at the ports of arrival. Other comments state that there are no cold storage facilities currently available in San Diego/Otay Mesa. The comments contend that the Mexican authorities will not permit such shipments to be returned to Mexico.

(Response) The IFR and the final rule at § 1.283(a)(1) require that food refused due to inadequate prior notice food must be held within the port of arrival only if directed by CBP or FDA, and that otherwise refused food must be held within the port of entry.

As we discussed in the preamble to the IFR, we defined ''port of arrival'' and ''port of entry'' to provide flexibility to ensure that ''food that has been refused may move to the port of destination where, for example the consumption or warehouse entry will be filed, unless directed by CBP or FDA. Generally, we do not intend to hold shipments at the border unless our assessment of the situation leads us to believe it is warranted; e.g., the food may present a serious risk to public health or that the prior notice violation is egregious.'' (See 68 FR 58974 at 58988.)

(Comments) One comment requests that FDA notify public food storage warehouses when a shipment is being held, is not accepted for entry, or when such shipments are released. The comment points out that the warehouses receive shipments via multiple transport methods, store them for multiple customers, and should be officially informed of the status of the shipments, rather than relying on information from the owners of the articles of food.

(Response) Under § 1.283(a)(2), refused food shall not be entered and shall not be delivered to the importer, owner, or consignee. As discussed previously, FDA does not believe it should modify the rule to require notice of the refusal to any specific entity or entities. The entity moving the food to a warehouse can notify the warehouse of the food's status, and the warehouse can likewise ask or require that it be provided this information before accepting the food for storage.

(Comments) Some comments state that the requirement in § 1.283(a)(2)(ii) for carriers to notify FDA regarding delivery of refused shipments within 24 hours of arrival and then to make delivery immediately imposes an unreasonable burden on carriers.

(Response) We have changed the requirement to notify FDA of the location where the food has been or will be moved from within 24 hours of refusal to before the food is moved to that location. FDA needs this information before the food is moved to verify that the facility where the food is to be held is a secure facility. Moreover, because refused food shall not be delivered to the importer, owner, or ultimate consignee, before the food is moved, FDA needs to verify that the secure facility is not owned by any of these parties.

For clarity and consistency, we also are changing the phrase ''designated location'' to ''secure facility'' in § 1.283(a)(2)(ii) and throughout the final rule. In addition, § 1.283(a)(2)(ii) of the IFR states that refused food must be moved under appropriate custodial bond. We have revised this paragraph in the final rule to state that the refused food must be moved under appropriate custodial bond, unless immediately exported under CBP supervision. The final rule also clarifies that the refused food may be held at the port of entry or at a secure facility.

(Comments) Some comments request clarification on whether ''refused goods'' will have to be exported or destroyed.

(Response) Articles of food that have been refused under section 801(m) of the act because of inadequate prior notice must be held until prior notice requirements have been satisfied, unless the food is immediately exported with CBP concurrence from the port of arrival. The decision to export the refused food is not the responsibility of FDA or CBP. If no prior notice submission or request for FDA review is submitted in a timely fashion after a food is refused, the food will be dealt with as set forth in CBP regulations relating to general order merchandise. It may only be sold for export or destroyed as agreed to by CBP and FDA.

(Comments) One comment requests clarification on the process for designating a ''secure facility'' after a shipment of food is refused admission status. The comment points out that the CF3461 entry document currently designates a CBP exam site in box 29 and requests clarification on whether refused goods will be sent automatically to the designated CBP exam site or if arrangements can be made to designate another facility.

(Response) FDA clarifies that a refusal under section 801(a) of the act, relating to admissibility, differs from a refusal under section 801(m) of the act, relating to prior notice. A food refused under section 801(m) of the act must be held within the port of entry for the article of food unless directed to another location by CBP or FDA. If CBP or FDA directs the food to be delivered to a secure facility, this will not necessarily be the CBP exam site designated in box 29 of the CF3461 entry document.

(Comments) Some comments ask if FDA will publish a list of approved ''secure facilities'' by port so that transmitters can designate these facilities.

(Response) Early in our prior notice experience, FDA had indicated that we would publish a list of secure facilities. However, our experience has shown us that it is not practicable to maintain such a list since the secure status of facilities changes very rapidly. While we will not maintain such a list, FDA will verify whether a facility is secure on a case-by-case basis.

(Comments) Some comments request that FDA and CBP jointly issue a guidance document explaining in greater detail how they intend to hold and store articles of food, particularly perishable food, refused admission into the United States. One comment requests that FDA clarify the process for food that is held and later deemed to be admissible.

(Response) FDA agrees and, as resources permit, will publish a guidance document that will set out procedures for food refused for failure to meet prior notice requirements.

(Comments) Some comments state that there are an insufficient number of general order warehouses to store the food articles that have been refused for noncompliance with these regulations.

(Response) FDA disagrees. Under CBP laws and regulations, general order merchandise must generally be held in a general order warehouse (19 CFR 127.1). However, in ports where there is no bonded warehouse authorized to accept general order merchandise, CBP regulations also empower the port director to direct the storage of the merchandise by the carrier or by any other appropriate means (see 19 CFR 4.37(f), 122.50(f), or 123.10(f)). In addition, our experience has not shown that there are an insufficient number of general order warehouses to store food that has been refused under prior notice.

(Comments) Some comments state that FDA must delay full enforcement of the prior notice regulations until it has done all that is necessary to equip the U.S. ports to handle refused perishable goods.

(Response) FDA believes that the ports are equipped to handle refused perishable goods. Since the IFR took effect, we have not been aware of problems relating to perishable goods not being properly maintained while being held at the ports.

(Comments) Some comments ask whether public storage warehouses will be stuck with unsaleable food items or whether they will be compelled to re-export at their own expense if the owner abandons a shipment that is refused entry because of inadequate prior notice. Comments indicate that a warehouse loses its lien abilities if a refused shipment is not allowed in interstate/intrastate trade and is re-exported. Thus, according to the comments, if the owner of the food does not pay storage and handling for the product, the warehouse has no collateral to compel payment. Comments also state that even if it does remain at the warehouse and the owner declines payment, the product has been refused entry so it cannot be sold to allow the warehouse to recoup its charges.

(Response) Under the final rule, food refused under section 801(m) of the act is considered to be general order merchandise and generally must be held at a general order warehouse. If the refused food is not immediately exported and if no prior notice is submitted or resubmitted and no request for FDA review of the refusal is submitted, then the food will be dealt with as set forth in CBP regulations relating to general order merchandise (19 CFR part 127), except that, unless otherwise agreed to by CBP and FDA,

the article may only be sold for export or destroyed (§ 1.283(a)(6)).

We made a minor change to the final rule by changing the last phrase of § 1.283(a)(6) from ''* * * except that the article may only be sold for export or destroyed as agreed to by CBP and FDA'' to ''* * * except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.'' This change was needed because concurrence from FDA is not needed whenever a refused article of food is sold for export or destroyed, and no prior notice is submitted or resubmitted and no request for FDA review is submitted. We are adding the phrase ''unless otherwise agreed to by CBP and FDA'' to allow for the improbable (but not impossible) scenario when a refused prior notice shipment would need to be transferred to another agency for examination or investigation; in these cases, we would want concurrence from both FDA and CBP.

(Comments) Some comments request that FDA revise the requirement to store refused merchandise at local port facilities. One comment indicates that this provision of the IFR does not make sense and does not provide any measure of security or safety to the food supply. The comment points out that, before the IFR, shipments were allowed to be held at the importer's premises and suggested that this practice should be allowed to continue. According to the comment, ports and land borders do not have sufficient storage capacity to handle the possibly overwhelming demand for space that will be needed when the prior notice regulations are implemented.

(Response) FDA disagrees. Section 801(m)(2)(B) of the act specifically requires that food refused under section 801(m) be held and not delivered to the importer, owner, or consignee. The IFR and the final rule require that refused food must be held within the port of entry for the article unless directed to another location by CBP or FDA. Therefore, an importer's premises, as suggested by the comment, would not be appropriate since the Bioterrorism Act specifically requires that the refused food not be delivered to the importer, owner, or consignee. Nor would such a location be adequate because it also may not be secure.

(Comments) Some comments object because shipments of food for which prior notice has not been provided will not be permitted to be moved to the port of entry. According to the comments, the operator will be required to off-load these shipments and detain them at the port of arrival until the prior notice is provided.

(Response) FDA disagrees. The IFR and the final rule require that refused food must be held within the port of entry for the article unless directed to another location by CBP or FDA. Thus, refused food may be permitted to move to the port of entry; such food is not required to be held at the port of arrival.

(Comments) Some comments express concern about the time it takes for FDA to release food offered for import into the United States, and request that FDA examine its inspection procedures and reduce the time to clear and release the food. The comments indicate that some shipments of food have been held at the port of entry for periods ranging from 2 weeks to 2 months, which has a serious economic impact on importers of perishable foods. The comments point out that there are already additional costs associated with the IFR, such as fees charged by custom brokers to file the prior notice. The comments further state that the delays are adding more costs that importers must bear, including the cost to store the food during this period, additional freight charges, and costs incurred due to spoilage of perishable products.

(Response) We know of no instance where a food has been held at any port facility or secure location for an extended period of time as described in the comment (2 weeks to 2 months) due to FDA's review of a prior notice submission or due to FDA's refusal of food for failure to provide adequate prior notice. Perhaps the comment actually is referring to delays caused by FDA's admissibility review under section 801(a) of the act. Nevertheless, FDA will make every effort to minimize the time necessary to perform prior notice assessments to minimize delays in releasing shipments.

4. Segregation of Refused Foods (§ 1.283(a)(3))

(Comments) Some comments state that in an ''LTL'' (less-than-truckload) environment, where an average trailer contains about 40 shipments, there is a potentially serious impact on several parties when prior notice is not filed in a timely fashion for one of the articles of food. The comments point out that the motor carrier's potential loss of productivity from having equipment tied up when an article of food has been denied entry or is being held has a serious negative impact on the profitability of cross-border trucking operators. According to the comments, this kind of down time has a serious negative impact on truck drivers' compensation, when they are paid based on miles driven, and greatly reduces the number of allowable hours a driver is allowed to operate under Federal Motor Carrier Safety regulations. The comments also indicate that holding a trailer at a port of entry affects not only the motor carrier's operations, but also all of the shippers, importers, and consignees whose goods are on board. Some comments request that FDA require importers to provide motor carriers with proof that prior notice was transmitted to FDA. The comments state that currently FDA and CBP only suggest that motor carriers require proof of prior notice filing from customers, but this type of arrangement is not required by law or regulation. According to the comments, because FDA system's acknowledgement of receipt of a prior notice does not mean that the information received is correct or complete, carriers are still left vulnerable to carrying goods that could be turned back at the border. The comments indicate that this type of action by FDA would tie up a carrier's equipment, negatively affect driver wages, and have a serious effect on carrier productivity.

(Response) Financial burdens associated with refused food because of inadequate or no prior notice generally can be avoided by ensuring FDA receives adequate prior notice in accordance with this final rule. For example, while the final rule requires only that the prior notice confirmation number accompany any food for which the prior notice was submitted through PNSI when the article arrives in the United States, it does not preclude the carrier from requiring proof of confirmation of prior notice submission prior to transporting the food to the United States when prior notice is submitted through ABI/ACS. Moreover, according to § 1.283(a)(3) of the final rule, segregation may take place to separate food that has not been placed under hold from food refused for inadequate prior notice.

(Comments) Some comments request clarification on who is responsible for the physical segregation of the refused food from the rest of the shipment: The carrier, FDA or CBP, customs broker, or importer. Comments also ask whether FDA or CBP officials will always supervise the segregation.

(Response) The IFR at § 1.283(a)(3) states that segregation may take place to separate food that has not been placed under hold from food refused for inadequate prior notice. The final rule clarifies this paragraph by adding that other merchandise not subject to prior notice requirements may be segregated from refused food.

The segregation may be done by any person as long as the refused food is held as required and not delivered to the importer, owner, or consignee. Neither FDA nor CBP is responsible for segregation. However, the IFR and final rule state that FDA or CBP may supervise the segregation. If FDA or CBP determine that supervision is necessary, segregation must not take place without supervision.

(Comments) Some comments indicate that carriers should have the option of unloading refused articles of food so they can deliver the rest of their load without being detained any longer than necessary. The comments point out that carriers do not have title or financial interest in the goods they transport and they cannot provide information to provide or correct an inadequate prior notice.

(Response) Carriers already have the option to segregate food so that they can deliver the rest of their load. As discussed previously, the IFR and the final rule at § 1.283(a)(3) state that segregation may take place to separate food that has not been placed under hold from food refused for inadequate prior notice.

5. Costs (§ 1.283(a)(4))

(Comments) Some comments ask who is responsible for costs associated with FDA verification of a shipment that is initially refused and then it is later determined that the shipment's documentation fulfills all requirements and complies with regulations; i.e., the shipment was improperly refused.

(Response) Section 1.283(a)(4) of the final rule provides that neither FDA nor CBP will be responsible for transportation, storage, or other expenses resulting from refusal.

6. Export After Refusal (§ 1.283(a)(5))

(Comments) Some comments request clarification on procedures for exporting fresh vegetables after refusal. The comments indicate that some ports of arrival do not have cold storage facilities.

(Response) The procedures for exporting fresh vegetables after a refusal under section 801(m) of the act are no different than other exports, with the following qualifications: Food refused under section 801(m) must be immediately exported from the port of arrival with CBP concurrence and under CBP supervision.

7. Post-Refusal Prior Notice Submissions (§ 1.283(c))

In § 1.283(c)(2) of the final rule, FDA revised the text to read ''the prior notice should be canceled'' instead of ''you should cancel'' to indicate that the cancellation of the prior notice can be done by CBP, upon request by the filer, if originally submitted in ABI/ACS or by the transmitter if originally submitted in PNSI.

(Comments) Some comments object because the current ABI system cannot accept prior notice after the articles of food arrive in the United States. Instead, filers must use the PNSI system. The comments suggest there is no valid reason for this limitation and request modifications to allow filers to use the ABI system for submitting prior notice, even after cargo has arrived in the United States. Other comments request removal of edits for date sensitive prior notice in ABI and PNSI. Some comments point out that if prior notice is transmitted after the articles of food arrive, the filer must enter an incorrect anticipated date of arrival, which is on or after the actual date of arrival. According to the comments, this skews FDA information, prevents FDA from determining whether prior notice was filed timely, and gets the filer in the habit of submitting false information. The comments also ask that if prior notice is submitted in this manner, how FDA can determine if the date was filed timely or not? The comments also state that because ABI will not accept prior notice on articles of food that have already arrived, this leads to the more time consuming filing of prior notice in PNSI and also leads to a corruption of the correct data.

(Response) Prior notice submitted after the food has arrived in the United States is a post-refusal submission. Under § 1.280(a)(2) of the IFR, post-refusal submission of prior notice must be completed via PNSI. The final rule retains this provision, but re-worded the text to state that post-refusal submissions must be submitted in PNSI until such time as ACS or its successor system can accommodate such a transaction. Post-refusal information requirements are found at § 1.281(c). Among other data elements, a post-refusal submission requires the location and address where the article of refused food will be or is being held, the date the article has arrived or will arrive at that location, and identification of a contact at that location (§ 1.281(c)(18)). The final rule now also requires the date the article of food arrived at the port of arrival.

Post-refusal submissions cannot be submitted via ABI/ACS because CBP's system cannot be modified at this time to accept information about the location where the article of refused food will be or is being held and the actual date of arrival of the article of refused food. Amending ABI/ACS would entail substantial and costly revisions to the system; such technical changes are not cost-effective or a good use of limited resources given the development of the Automated Commercial Environment, which will replace ACS.

PNSI programming changes should address the concern raised in the comment about ''submitting false information.'' These same concerns should not arise under the final rule since the final rule requires the actual date of arrival for post-refusal submissions.

FDA made a minor change in the text of § 1.283(a)(6) by replacing the phrase, ''in a timely fashion,'' with the phrase, ''in accordance with paragraph (d) of this section,'' to clarify that the timeliness of a request for FDA review is found at paragraph (d). We made a similar change in § 1.285(g).

8. FDA Review After Refusal (§ 1.283(d))

(Comments) One comment requests that the final regulations make it clear that the request for the review and/or the participation in the review can be conducted by any of the parties named in § 1.283(d) of the IFR or by a designated representative, such as a customs broker, freight forwarder, or attorney.

(Response) Section 1.283(d)(2) of the final rule provides that the carrier, submitter, importer, owner, or ultimate consignee may submit a written request asking FDA to review whether the article of food is subject to the requirements of this subpart under § 1.277. FDA has added carrier in the final rule since the carrier is often the entity notified of the refusal. Although not explicitly stated in the rule, a designated representative of any of the parties listed (carrier, submitter, importer, owner, and ultimate consignee) may act on behalf of that party.

Furthermore, FDA revised § 1.283(d)(1) to state that the request for FDA review may include whether the information submitted in a prior notice is complete, in addition to accurate. (In the IFR, we also cited § 1.276(b)(5), but we deleted it in the final rule because it is redundant.) FDA revised § 1.283(d)(5) to be consistent with the changes made to § 1.283(d)(1). In § 1.283(d)(3), FDA revised the final rule to delete acceptance of requests for review by mail and express courier. We are limiting delivery to fax and e-mail to ensure that requests are expeditiously received and directed to the appropriate staff.

9. International Mail (§ 1.283(e))

(Comments) Some comments request clarification on the disposition of mail for which prior notice is required, but is not provided. Comments also ask about the U.S. Postal Service's responsibilities for mail lacking prior notice.

(Response) In the case of food arriving by international mail, if prior notice is inadequate or if the prior notice confirmation number is not affixed, the article will be held by CBP for 72 hours for FDA inspection and disposition. If the article is refused and there is a return address, the parcel may be returned to the sender. If there is no return address or the food in the shipment appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel back to the sender or, if there is no return address, destroy the parcel, at FDA expense. Under the prior notice final rule, only FDA and CBP have responsibilities for the destruction or return of refused foods that arrive via international mail.

FDA revised § 1.283(e) and § 1.285(k) in the final rule to change the word ''stamped 'No Prior Notice—FDA Refused'" to ''marked 'No Prior Notice—FDA Refused'" to more accurately describe the marking that is placed on international mail packages arriving with inadequate prior notice or without the prior notice confirmation number affixed as required. In certain cases, the package cannot be stamped and a label/sticker is placed on the package.

We also note that the Prior Notice Final Rule Draft CPG proposes an enforcement policy for foreign-to-foreign mail. Under the proposed policy, if there is no prior notice FDA and CBP should typically consider not taking any regulatory action in the case of international mail where the recipient is not in the United States since the sender does not have control over the transportation route that the foreign-to-foreign mail will transit.

10. Prohibitions on Delivery and Transfer (§ 1.283(f))

(Comments) Some comments ask whether CBP will put a manifest ''hold'' on food cargo until the prior notice confirmation is received. The comments state that, at the present time, cargo can be moved inland on an IT or T&E entry without FDA review. The comments ask if FDA will remind the transmitters that products should remain intact until a ''may proceed'' message is received. The comments further ask if ocean carriers will be advised of the FDA status of the articles of food when the shipment involves ''doors moves'' beyond 50 miles from the port of entry.

(Response) Food arriving as an IT or T&E entry is subject to FDA review of prior notice before it arrives in the United States. Food that arrives with no prior notice is subject to refusal and must be held within the port of entry for the article unless directed to another location by CBP or FDA. Food that is refused under section 801(m) of the act is considered G.O. merchandise and cannot be entered or delivered to the importer, owner, or consignee.

For clarity, FDA revised § 1.283(f)(2) of the final rule to state that an article of food refused under section 801(m)(1) of the act may not be transferred by any person from the port or other designated secure facility.

11. Relationship to Other Admissibility Decisions (§ 1.283(g))

(Comments) Some comments request that FDA integrate the section 801(m) and the section 801(a) clearance processes and develop mechanisms to expedite the release of imported food for sale and use in domestic commerce. One comment states that currently numerous shipments that are offered for import are cleared for section 801(m), but are held pending section 801(a) review. The comments indicate that little is gained if shipments with adequate prior notice under section 801(m) are permitted to move promptly across the borders of the United States, only to encounter delays arising from the release process under section 801(a). The comments further note that in many cases, the shipments held for section 801(a) review are eventually released without another further examination or sampling. The comments suggest that a concurrent section 801(a) and section 801(m) review would eliminate rework, decrease unnecessary holds on shipments, and decrease the burden on both the importing community and FDA.

Another comment also suggests that FDA integrate the prior notice information collection system with the existing OASIS (section 801(a) of the act) information management system as fully as possible. The comment states that these systems currently function separately, essentially creating two sequential FDA reviews. The comment believes that by merging these systems and resources, food security would be enhanced and productivity for FDA and the industry will be improved. In addition, the comment states that such a merger would be a natural extension of the ongoing integration efforts with CBP.

(Response) FDA does not agree that doing the OASIS review under section 801(a) of the act concurrently with the prior notice review under section 801(m) of act would reduce the burden on the industry or FDA. Under section 801(m), prior notice for imported food shipments must be provided to FDA before the arrival, and an article of food is subject to refusal of admission if adequate prior notice has not been provided. Section 801(m) also provides that refused food must be held until adequate notice is given and may not be delivered to the importer, owner, or consignee. Thus, the refusal standard under section 801(m) is based on whether the requisite information has been provided in a timely fashion.

The refusal standard in section 801(a) of the act is based on, among other things, whether the article appears to be adulterated or misbranded. Admissibility decisions under section 801(a) may be made after entry has been made. Thus, if prior notice is adequate, requests for further information, examination, or sampling of the food that is necessary to determine admissibility under section 801(a) may occur. The article of food need not be held at the port for FDA to accomplish its section 801(a) review.

Because the section 801(m) review must occur prior to arrival, concurrent section 801(a) and section 801(m) reviews also would have to occur prior to arrival. FDA also notes that section 801(a) reviews typically take longer to complete than section 801(m) reviews. FDA believes such a concurrent process would be inefficient and impractical and would likely increase congestion at the ports of arrival. Thus, FDA generally intends to continue with its current practice of reviewing prior notice prior to arrival to decide whether to inspect the food at the time of arrival, based on information that suggests that the food is a potential significant risk to public health, and to allow shipments to proceed beyond the point of arrival to conduct section 801(a) reviews.

(Comments) One comment asks FDA to clarify expectations at the port regarding ''may proceed'' decisions. The comment notes that the IFR indicates that ''the system will transmit a message back through OASIS to ABI/ACS interface for CBP that the article of food may be conditionally released.'' The comments continue to state that the IFR indicates that staff operating ''24 hours a day, seven days a week'' will review at the port of arrival or closest examination site. The comment notes that this implies decisions were to be

made at the port of entry. However, companies have reported that since December 12, 2003, conditional release messages have not consistently been received at entry. The comment asks that FDA clarify when this message should be received and the implications for companies that enter the United States within the ''release.''

(Response) The IFR states, ''If the FDA system does not indicate that further evaluation of or action on the notice or article of food is necessary for prior notice purposes, the system will transmit a message back through the OASIS to ABI/ACS interface for CBP that the article of food 'may be conditionally released under section 801(b) of the act.' However, if additional evaluation of the prior notice information is necessary, FDA headquarters staff, operating 24 hours a day, 7 days a week, will review and assess the information and may initiate an examination or other action by FDA or CBP of the article of food at the port of arrival or elsewhere, or in the case of rail shipments, within the confines of the closest appropriate examination site.'' (68 FR 58974 at 58976) The IFR clearly states that the conditional release message is sent from FDA to CBP, not to any other person. This is to ensure that CBP staff will know when the food arrives if prior notice has been satisfied and that no further examination by FDA is necessary. This conditional release does not provide information about FDA's section 801(a) admissibility decision. Further, the IFR clearly states that FDA headquarters staff operates 24 hours a day, 7 days a week and will review the prior notice and make the decision regarding further action on the prior notice submission. FDA and CBP do not intend to change these procedures for implementation of the final rule.

(Comments) One comment encourages FDA to consider low risk status to expedite its section 801(a) deliberations.

(Response) FDA does use a risk based approach when making prior notice and admissibility decisions. FDA screening under section 801(a) is separate from the subject of the final rule, FDA's screening under section 801(m) of the act. Therefore, this comment is outside the scope of the final rule.

(Final rule) Section 1.283 of the final rule describes the consequences for an article of food that is imported or offered for import with inadequate prior notice. The final rule sets out procedures for resolving the inadequacy as well as for the movement and status of the refused food.

K. What Are the Other Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart? (§ 1.284)

Section 1.284 of the IFR provides that failure of a person who imports or offers for import an article of food to submit prior notice is a prohibited act under section 301(ee) of the act (21 U.S.C. 331(ee)) and sets out the civil, criminal, and debarment actions that the United States may bring against persons who are responsible for the commission of a prohibited act.

(Comments) One comment states that many of the mistakes made during the initial implementation of the prior notice IFR can be attributed to difficulties with both government and industry computer systems. The comment indicates that such mistakes should not be part of an importer's record.

(Response) FDA acknowledges that some mistakes in prior notice submissions may have occurred because changes were needed in PNSI and CBP's ABI/ACS or because industry needed to develop appropriate software to facilitate the submission of prior notice. During the initial implementation of the IFR that extended for more than 8 months after the IFR took effect, FDA and CBP exercised enforcement discretion to accommodate that situation. During this period, the two agencies focused their resources on education to achieve compliance with the prior notice requirements, escalating imposition of civil monetary penalties, and ultimately refusal of shipments. This final rule will take effect 180 days after today's publication date to allow affected parties time to understand the requirements that differ from those in the IFR, and make appropriate changes, including changes that may be needed to filers' software. In enforcing prior notice, we will continue to take into account the circumstances, such as whether a violation is due to mistakes that can be attributed to difficulties in government and industry computer systems during initial implementation.

(Comments) Some comments request clarification on the penalties that apply for food that arrives without proper prior notice. Some specifically request clarification of civil monetary penalties and an explanation of the mechanism and criteria for application of these penalties. One comment notes that, in the absence of clearly defined procedures for assessing penalties, the current policy of liquidated damages would apply, which has always been unacceptable with the community and sureties.

(Response) CBP, in consultation with FDA, may assess civil monetary penalties under 19 U.S.C. 1595a(b) against any person who directs, assists, financially or otherwise, or is in any way concerned in the importation of any merchandise contrary to law. During the early implementation phase, FDA recommended to CBP that civil monetary penalties (CMPs) be assessed only to those parties who failed to submit prior notice. The parties were notified via e-mail regarding their failure to submit prior notice before FDA recommended CMPs. As of May 2008, CBP has pursued CMPs on a total of 29 PNC related cases. Any CMPs that CBP brings are subject to the administrative proceedings described in 19 U.S.C. 1618 and 19 CFR part 171. Furthermore, liquidated damages would not apply in the case of prior notice violations because no bond obligations would vest under the basic importation bond.

(Comments) Some comments note that there are few options available in the current penalty structure to assist FDA in enforcing compliance other then civil and criminal charges. Comments suggest that some form of monetary consequences, in lieu of civil and criminal charges, should be available to allow FDA more flexibility in application.

(Response) Section 1.284 of the final rule provides consequences of failing to comply with the requirements for submitting prior notice. These are the primary enforcement options, aside from refusal of the food, available to FDA under the Federal Food, Drug, and Cosmetic Act. In addition, CBP can seize goods imported contrary to law, assess civil monetary penalties or take other enforcement action, including referral to U.S. Immigration and Customs Enforcement (ICE), as provided for under its laws in lieu of or in addition to refusal of the food or other civil and criminal penalties.

(Comments) Some comments suggest that failure to provide prior notice in a timely fashion should result in refused entry and the movement of the food to a secure facility where the prior notice can be secured. The comments state that failure to enter U.S. commerce should be considered a sufficient deterrent and that monetary penalties would be counterproductive. The comments suggest that this arrangement would avoid instances where businesses find themselves unable to trade or constantly in situations of being in violation, and consequently subject to criminal action.

(Response) FDA does not agree that refusal and movement of the food to a secure facility will provide a sufficient

deterrent in all cases. CBP may assess civil monetary penalties under 19 U.S.C. 1595a(b) and will, in consultation with FDA, continue to assess those penalties when warranted. FDA may further use the civil, criminal, and debarment provisions provided by the Bioterrorism Act. These statutory penalties are used only when warranted, and to date have been used relatively infrequently.

(Comments) One comment notes that importers receive conflicting information as to the enforcement guidelines at individual crossing points and/or from individual FDA and CBP enforcement officers. The comment recommends extension of the full enforcement date, which would allow FDA and CBP to upgrade their current training efforts with the officers at all ports of entry to ensure uniform and consistent enforcement of the IFR.

(Response) FDA and CBP will continue to coordinate staff training and industry outreach activities to ensure consistent enforcement of the final rule. FDA believes that the effective date of 180 days after publication of the final rule provides sufficient time to communicate and implement changes to the final rule. As we establish enforcement policies, these will be made publicly available through our compliance policy guides. These policies and other information about the final rule may be found through links on FDA's Web site at *http://www.fda.gov*. FDA notes that the communication issues experienced when the prior notice IFR initially took effect have been addressed and we generally have found the prior notice process to be proceeding smoothly.

(Comments) Some comments state that serious inconsistencies in interpretation or application of the prior notice requirements at multiple ports have caused confusion, delayed shipments, and increased shipment costs. Examples provided by the comments include: the shifting percentage of shipments that are physically held at the port due to incomplete or inaccurate prior notice submissions during the initial phases of enforcement, varying information regarding whether the carrier must be in possession of the actual prior notice confirmation number at the time of arrival regardless of whether the submission was made via an ABI transmission, conflicting information as to whether submissions of bonded freight will be allowed through the ABI system, and failure to notify importers of specific errors pertaining to their submissions. Some comments request that FDA establish a national office with authority to resolve various field and port interpretations and actions. Comments note the importance of a timely resolution to disputes because of the potential financial impact to commerce if food shipments are detained needlessly.

(Response) The initial source for resolving all perceived conflicts is the final rule, and related information, including the responses to comments in this preamble, the Prior Notice Final Rule CPG, and the Prior Notice of Imported Food Questions and Answers, which may be found through links on FDA's Web site at *http://www.fda.gov*. FDA's PNC, which directs all prior notice activities, has been operating since the prior notice IFR took effect on December 12, 2003. The PNC is available 24 hours a day, 7 days a week, and 365 days a year to answer questions and resolve, as appropriate, operational concerns. The PNC can be reached at 866–521–2297 for calls originating in the United States and 703–621–7728 for calls originating from outside the United States. In addition, FDA notes that based on the current PNC call/inquiry volume levels as compared to those experienced during the initial 18 months of implementation, repetitive prior notice submitters have now been experiencing fewer difficulties in submitting prior notice.

(Comments) One comment requests that FDA outline what actions will be taken against a company that is not complying with prior notice requirements, but has committed the error only by acting on incorrect advice from an FDA representative. The comment wants to know what recourse is available to industry when a company faces large fines due to inaccurate FDA guidance.

(Response) The PNC is responsible for resolution of these actions, on a case-by-case basis. The advice that a submitter may have received from an agency representative is considered when determining whether an enforcement action is warranted. FDA notes that under the proposed enforcement policy in the Prior Notice Final Rule Draft CPG, we intend to take into consideration the circumstances surrounding a violation, including the seriousness of the violation and flagrant and repeat violations.

(Comments) One foreign government agency requests access to the quantity and identity of the industries that are not complying with the prior notice IFR so that they could help bring these industries into compliance. The comment suggests creating a mechanism to notify foreign governments of any noncompliance related to the Bioterrorism Act to enable them to provide a faster and more efficient response.

(Response) FDA has established mechanisms for working cooperatively with foreign government regulatory authorities on issues of mutual concern, including matters relating to compliance with the prior notice regulations. When requested and as resources allow, FDA/PNC personnel have continued to participate in briefings for foreign governments and organizations and at industry trade meetings. These have included presentations to European Community visitors to the United States, joint FDA-Canadian Food Inspection Agency import meetings, and other foreign government and industry outreach events widely attended by both industry and other government agencies, e.g., WESCCON (Western Cargo Conference). FDA continues to work with foreign governments to develop more efficient and effective communications. In addition, information about compliance with prior notice requirements is posted at *http://www.cfsan.fda.gov/~pn/pnsum.html*.

(Comments) Some comments request that FDA provide a sufficient period of time for implementation of the final rule so that affected parties can prepare for any changes in the rule.

(Response) FDA agrees and is providing 180 days after publication of the final rule, which should be sufficient time for implementing changes necessary to comply with the final rule.

(Comments) One comment states that FDA and CBP categorize some articles of food differently; i.e., some articles that are ''drugs'' for FDA purposes are classified by CBP as ''foods.'' The comment indicates that such products should not be denied entry or assessed monetary penalties and suggests that the final rule provide for immediate release and cancellation of monetary penalties for such articles that are not ''food,'' as defined by the FDA.

(Response) FDA does not agree that a change in the final rule would alleviate the concern expressed by the comment. The scope of the final rule is stated explicitly in § 1.277. Situations involving discrepancies between FDA and CBP classification of an imported article as a food or drug are best resolved on a case-by-case basis as they arise. However, because FDA and CBP have worked closely to identify and resolve such issues, the agencies believe that such situations will be rare. In cases of doubt, the submitter should contact the PNC to determine whether a product is an article of food subject to prior notice requirements.

FDA uses a list of HTS codes to indicate which products FDA believes prior notice is or may be required under the prior notice regulations. FDA has provided this list to CBP so that CBP can ''flag'' the HTS codes in its entry systems to screen for foods for which prior notice to FDA is required and to ensure that, as appropriate, prior notice has been provided. FDA publishes this list to inform the food industry which HTS codes have been ''flagged'' in CBP entry systems with prior notice indicators. Guidance about the HTS flags is posted at *http://www.cfsan.fda.gov/~dms/htsguid3.html*.

(Comments) One comment suggests that FDA consider the importer's circumstances when denying entry or assessing penalties. The comment states that, although it is reasonable to expect a company whose principal business is importing food to abide by regulations applicable to food imports, companies that rarely import food products will likely have greater difficulty in complying with the requirements. The comment further states that although these companies should be required to comply before their entries are released, blanket denials of entry or assessments of monetary penalties are not appropriate.

(Response) Elsewhere in this issue of the **Federal Register**, we are announcing our Prior Notice Final Rule Draft CPG which describes our policies for enforcing prior notice. Under the CPG, we are proposing to take into consideration the circumstances surrounding a violation, including the seriousness of the violation and flagrant and repeat violations.

(Final rule) Section 1.284 of the final rule states that the importing or offering for import into the United States of an article of food in violation of the requirements of section 801(m) of the act, including the requirements of this subpart, is a prohibited act under section 301(ee) of the act and sets out the civil, criminal, and debarment actions that the United States may bring against persons who are responsible for the commission of a prohibited act.

L. What Happens to Food That is Imported or Offered for Import From Unregistered Facilities That Are Required to Register Under Subpart H of This Part? (§ 1.285)

Section 1.285 of the IFR outlines the consequences for food arriving at the port of arrival from facilities that are not registered as required under section 415 of the act and 21 CFR part 1, subpart H. These are similar to provisions in the IFR for handling food that is refused for inadequate prior notice. The IFR states that if an article of food from a foreign manufacturer that is not registered as required under section 415 of the act and subpart H is imported or offered for import into the United States, the food is subject to being held at the port under section 801(l) of the act and refusal under section 801(m) of the act and § 1.283 for failure to provide adequate prior notice. Under the IFR, the failure to provide the correct registration number of the foreign manufacturer, if registration is required under section 415 of the act and 21 CFR part 1, subpart H, renders the identity of that facility incomplete for purposes of prior notice.

(Comments) Several comments state that FDA should increase inspections of imported food when they arrive at the port, rather than denying admission based on lack of the manufacturer's registration number.

(Response) If the prior notice does not include a registration number, it can instead include the full address of the manufacturer and the reason why the registration number is not provided. In this situation, the article of food will not be refused admission solely because of the lack of the manufacturer's registration number. We agree with the comments it is appropriate to consider the fact that the registration number is not provided in determining whether FDA should inspect the food, either upon arrival or as part of the admissions process.

While an article of food will not be refused admission solely because of the lack of the manufacturer's registration number, the food is nonetheless subject to being held under section 801(l) of the act if the manufacturer has not registered under section 415 of the act. It may take FDA more time to determine the registration status of the manufacturer if the name and full address, but not the registration number, is provided as part of prior notice. Thus, if the registration number is not provided, this may delay the food at the border until this verification is completed.

(Comments) Some comments state that, although the prior notice regulations clearly indicate that the manufacturer's registration number is required on the prior notice, even for U.S. Goods Returned, they do not expressly indicate that refusal will result when the registration number is not provided. Rather, according to the comments, § 1.285(a) of the regulations only indicates that articles of food arriving from an unregistered foreign facility will be subject to refusal, as will articles of food arriving with an inaccurate registration number in the prior notice. In more general terms, under § 1.283(a)(1)(ii), articles of food arriving with an ''inaccurate'' prior notice are subject to the same possibility of refusal upon arrival. The comments state that the language of the regulations does not guarantee refusal, but provides for flexibility and discretionary enforcement. Comments suggest that FDA should not refuse entries for which the importer does not know and cannot determine the registration number.

(Response) As discussed in the previous response, if the prior notice does not include a registration number, it can instead include the full address of the manufacturer and the reason why the registration number is not provided. In this situation, the article of food will not be refused admission solely because of the lack of the manufacturer's registration number, although the food is nonetheless subject to being held under section 801(l) of the act if the manufacturer has not registered under section 415 of the act.

Because this is a change from the IFR, in the final rule we have deleted the text in ' 1.285(a) that states that failure to provide the manufacturer's registration number renders the identity of the facility incomplete for purposes of prior notice. We have also clarified the text in ' 1.285(b) by removing the phrase ''imported or offered for import from a foreign facility that is not registered as required under section 415 of the act'' because it is redundant.

As part of our effort to develop policies for enforcing prior notice and section 801(l) of the act, we are publishing the Prior Notice Final Rule Draft CPG, announced elsewhere in this issue of the **Federal Register**.

(Final rule) Section 1.285 of the final rule describes the consequences and processes for food imported or offered for import in the United States that is from a facility that is not registered under section 415 of the act and 21 CFR part 1, subpart H. The food is subject to being held and cannot be delivered to any importer, owner, or consignee.

FDA also made other minor changes in this section.

- We revised the requirement in § 1.285(c)(2) to notify FDA of the location where the food has been or will be moved from within 24 hours of refusal to before the food is moved to the hold location. FDA needs this information before the food is moved to verify that the facility where the food is to be held is a secure facility. Moreover, because refused food shall not be delivered to the importer, owner, or ultimate consignee, before the food is moved, FDA needs to verify that the

hold location is not owned by any of these parties. In addition, § 1.285(c)(2) of the IFR states that food under hold must be moved under appropriate custodial bond. We have revised this paragraph in the final rule to state that the refused food must be moved under appropriate custodial bond, unless immediately exported under CBP supervision. The final rule also clarifies that the refused food may be held at the port of entry or at a secure facility.

• We revised § 1.285(g) for clarity by adding the word, ''number,'' after the word, ''registration.'' We also changed the last phrase of § 1.285(g) from ''* * * except that the article may only be sold for export or destroyed as agreed to by CBP and FDA'' to ''* * * except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.'' Similar to § 1.283(a)(6), this change was needed because concurrence from CBP and FDA is not needed whenever an article of food placed under hold under section 801(l) of the act is sold for export or destroyed, and no registration number or request for FDA review is submitted. We are adding the phrase ''unless otherwise agreed to by CBP and FDA'' to allow for the improbable (but not impossible) scenario when such a shipment would need to be transferred to another agency for examination or investigation; in these cases, we would want concurrence from both FDA and CBP.

• In § 1.285(h), we added the phrase, ''is not for personal use,'' after the phrase, ''food carried by or otherwise accompanying an individual arriving in the United States,'' because if it is for personal use, then it is not subject to prior notice as provided by § 1.277(b)(1).

• We deleted references and provisions in § 1.285(i) and (l) relating to refusals, because the process for resolving a prior notice submission for an article of food from a facility that is not registered as required is based on holds under section 801(l) of the act and not refusals under section 801(m) (see discussion above for § 1.285(a)). Under § 1.285(i)(2), we are allowing submission of the notification resolving the hold by fax and e-mail only, and deleting the option to submit the notification by mail and express courier. We also made other minor revisions to this § 1.285 to simplify the text.

• We revised § 1.285(j)(2) of the final rule to allow the carrier to submit a request for review after hold. Under § 1.285(j)(3), we revised the final rule to allow submission of the request for review after hold by fax and e-mail only, and deleted the option to submit the notification by mail and express courier.

M. Outreach and Enforcement

As discussed in the IFR, FDA directed outreach to both domestic and international stakeholders after publication of the IFR (68 FR 58974). Our outreach activities included many methods of communication:

• Dissemination of materials to guide affected domestic and international food facilities through the new processes established to implement prior notice requirements;

• Numerous domestic and international outreach meetings to the food industry, trade organizations, and State and foreign government regulators;

• A series of videoconferences and a satellite downlink video broadcast to more than 1,000 sites around the world;

• Materials provided for and events targeted to the media;

• Presentations by FDA officials and exhibits at professional and trade conferences and meetings to inform industry and State and local government representatives of the new requirements;

• Presentations by USDA's Foreign Agricultural Service (FAS) and U.S. embassy officials who disseminated materials and answered questions in various countries;

• Cooperative arrangements with CBP and other Federal agencies to ensure that information on the interim final regulations and their requirements is disseminated to affected companies and individuals; and

• Issuance of several guidance documents (all available on the Internet) that explain the prior notice requirements, including, ''Prior Notice of Imported Food: Questions and Answers,'' ''What You Need to Know About Prior Notice of Imported Food Shipments,'' and numerous Web-based tutorials for PNSI. Many of these guidance documents are available in foreign languages; e.g., Arabic, French, Hindi, Japanese, Malay, Portuguese, and Spanish.

Specifics regarding each of these activities are included on FDA's Web site. In addition, FDA also provided training in new or revised procedures for its field personnel, as well as CBP field personnel. FDA included an initial transition period in the December 2003 prior notice CPG for more than 8 months, during which the agencies emphasized education to achieve compliance, rather than refusal of articles of food with inadequate prior notice.

Shortly after publication of the IFR, FDA began disseminating at U.S. ports flyers and posters summarizing the new requirements and informing representatives of affected entities how to provide prior notice to FDA. We also provided (and continue to provide) online assistance and the FDA Help Desk to deal with technical issues involving PNSI after the IFR became effective.

When FDA reopened the comment period on the IFR in the **Federal Register** of April 14, 2004, under discussion of Flexible Alternatives in question 7, we asked: ''Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?'' Many comments address various issues concerning outreach and enforcement. Discussion of these issues by subject follows, proceeded by a discussion of general issues.

1. General Outreach and Enforcement Issues

(Comments) Several comments acknowledge that the outreach activities conducted by FDA and CBP were of tremendous assistance to affected persons with the implementation of the PNSI and encourage continued communication between the trade community and FDA and CBP. Several other comments state that FDA and CBP's outreach efforts were ineffective and encourage continued efforts toward education and outreach.

(Response) FDA received praise from the Small Business Administration for our efforts to address regulatory flexibility and the impact on small business of the interim final rule. FDA and CBP will continue outreach efforts to affected industry and other governments, as resources allow. These efforts will focus on changes to and implementation of the final rule. The PNC also will continue to answer questions and provide technical assistance upon request, and FDA and CBP will issue and update guidance as policies change or need clarification.

2. Prior Notice Submission Training Program From Flexible Alternative Question 7

(Comments) Many comments believe that a training program will improve the accuracy of the data being submitted under the regulations and that a training program would resolve many of the other problems being encountered with the present rules. One comment suggests that, following a detailed analysis of compliance issues, FDA should target its training to specific problems and their solutions, and to entities new to the process. One comment suggests that FDA offer a training program for brokers and other transmitters and submitters. Other

comments recommend that specific outreach and training should be conducted for each mode of transportation. Another comment cautions that the FDA and CBP should have resources to implement an educational campaign before initiating another training and outreach program.

(Response) FDA and CBP will conduct training focused on changes between the final rule and the IFR. Depending on resources, the education and outreach may take the form of public meetings, Web-based interactive training, or posting on our Web sites of guidance and other outreach materials. As resources permit, we also may translate our guidance and other outreach materials into other languages.

3. Requests for Additional Outreach

(Comments) There were many comments that request additional outreach and training, as well as some comments that suggest specific outreach programs, such as:

- Providing an expanded program that would educate and train all stakeholders, including substantially more and varied educational programs before the full enforcement of the IFR, and escalating training efforts in the area of shipper and carrier education and compliance;
- Establishing an effective mechanism for disseminating answers to specific questions to affected persons;
- Providing enforcement guidance that addresses specific enforcement issues, such as enforcement of the food facility registration requirements at the time of prior notice submission and describing enforcement procedures in detail;
- Providing guidelines on the procedures to submit prior notice either via FDA's PNSI or CBP's ABI, such as instructions on cancellation or change of a prior notice and descriptions on what is meant by identifying goods by the common, usual or market name;
- Explaining procedures of the rule in foreign languages and establishing point of contacts in foreign countries;
- Publicizing the rule to individual Americans who will travel abroad, and making compliance with it a simple, practicable, and straight forward process;
- Providing a Web-based tutorial;
- Using CBP's ABI Administrative Messages to announce changes in PNSI;
- Establishing an FDA and CBP agency-industry working group and/or a more formal advisory committee with representatives of various industry groups;
- Improving staffing on the ''hotline'' and/or creation of an exclusive Help Line staffed with individuals with the requisite technical expertise and the ability to resolve operational problems as they arise;
- Creating dedicated e-mail addresses within FDA to which specific questions can be addressed and/or specific e-mail addresses for different technical and operations areas;
- Providing prompt information to submitters regarding inadequacies or inaccuracies in prior notice, including shipment level feedback to the filer; and
- Holding public meetings before the final rule takes effect to ensure that all affected parties understand the rule and can be heard.

(Response) We will provide outreach and training on the final rule as resources permit. At a minimum, we will provide guidance and instructions on the process for filing prior notice on our Web site. This guidance, along with detailed instructions on the use of PNSI, including step-by-step help, is available at *http://www.cfsan.fda.gov/~furls/helpf.html*.

We agree with the recommendation to establish an effective mechanism for disseminating answers to specific questions to industry, and have issued guidance documents for each of the rules we have issued to implement the authorities in the Bioterrorism Act that provide our response to the frequently asked questions (FAQs), including the prior notice IFR. We anticipate doing the same for this final rule. These guidance documents are designed to help affected parties comply with the legal requirements established by the various rules. We intend to issue additional guidance as new questions arise and as resources permit.

In terms of providing enforcement guidance, in December 2003, FDA and CBP issued a CPG that stated that, until August 12, 2004, the two agencies generally would utilize communication and education strategies with escalating imposition of civil monetary penalties rather than refusal of shipments. The two agencies revised the CPG in June 2004, August 2004 (August 16, 2004, 69 FR 50389), November 2004, March 2005, and November 2005 (November 14, 2005, 70 FR 69160), as our enforcement policies changed and evolved. Published elsewhere in this issue of the **Federal Register** is a notice of availability for the Prior Notice Final Rule Draft CPG, which describes FDA's and CBP's proposed policies for enforcing this final rule. A copy of the CPG may be found at *http://www.fda.gov/ora* under ''Compliance References.''

Generally, FDA enforcement procedures regarding imports are provided in FDA's Regulatory Procedures Manual, Chapter 9. This guidance is posted at *http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9/default.htm*.

FDA agrees, in part, with the recommendation about providing user guidelines and has provided guidance and instructions on the process for filing prior notice. This guidance, along with detailed instructions on the use of the PNSI, including step-by-step help, is available at *http://www.cfsan.fda.gov/~furls/helpf.html*. Instructions for contacting FDA with questions about prior notice are also available at that Web site.

FDA cannot provide specific instructions on the use of ABI software to file prior notice, as that software is developed and made available through private vendors. Users should contact their vendor for specific instructions on the use of their ABI software. CBP does regularly issue to filers ABI Administrative Messages which provide instruction and guidance regarding submission of prior notice through ABI/ACS.

As part of our outreach efforts for the prior notice IFR, we issued a number of documents explaining the requirements of the IFR and/or PNSI and provided them on our Web site in English and one or more other languages, including:

- FDA Industry Systems, Index of Help Pages at *http://www.cfsan.fda.gov/~furls/helpol.html*) (also available in Spanish);
- HELP: Getting Started: Create New Account Quick Start Guide) (also available in Spanish);
- OUTREACH: Overview of Prior Notice Interim Final Rule (Slide Presentation) (also available in Arabic, French, Malay and Spanish);
- Booklet: What You Need to Know About Prior Notice of Imported Food Shipments (also available in French and Spanish); and
- Fact Sheet on the Interim Final Rule—Prior Notice of Imported Food Shipments (also available in French, Malay, Polish, Portuguese, Spanish, Arabic, Chinese, Hindi, and Japanese).

We also have an ''FDA Food and Cosmetic International/Foreign Language Documents and Videos,'' which is a list of all food (and cosmetic) documents that have been translated and the languages in which they are available on our Web site at *http://www.cfsan.fda.gov/~mow/internat.html*. Many of the documents describing prior notice requirements and guidance have been translated into foreign languages.

FDA does not currently maintain staff in foreign countries. However, FDA has

developed the Beyond our Borders initiative, which includes plans to build an on-the-ground presence for FDA in Asia, Europe, Latin America, and the Middle East. In March of 2008, we received approval from the U.S. Department of State to establish eight full time permanent FDA positions at U.S. diplomatic posts in the People's Republic of China, pending authorization from the Chinese government. Furthermore, CBP, U.S. Department of State, and USDA Food Agricultural Service staff are located at U.S. Embassies in many foreign countries. These U.S. government entities frequently provided assistance to foreign stakeholders, including foreign government officials and private companies, in understanding the requirements of various U.S. regulations, including those provided in our Bioterrorism Act regulations. We will routinely update these U.S. officials abroad about changes to and implementation of this prior notice final rule.

As resources permit, we also will continue to translate guidance documents and system instructions into other languages.

FDA agrees with the comment requesting publicizing the rule to individual Americans who will travel abroad, and making compliance with it a simple, practicable, and straight forward process. CBP Publication # 0000–0512, revised January 13, 2005, Know Before You Go—Regulations for U.S. Residents, is posted at *http://www.cbp.gov/xp/cgov/travel/vacation/kbyg/*. This publication is the primary CBP guidance document concerning import regulations targeted to travelers and contains information about the prior notice final rule's requirements for importation of food. In addition to providing information about prior notice requirements, the publication also provides a link to FDA's Web site at *http://www.fda.gov/oc/bioterrorism/bioact.html*.

FDA also agrees with the comment that requests us to provide a Web-based tutorial. Since October 2003, FDA has provided a PNSI tutorial in the form of step-by-step help on its Web site (*http://www.cfsan.fda.gov/~furls/helpf.html*). FDA welcomes any additional comments or suggestions on how to improve the help information; these can be submitted to the PNC using the phone number or e-mail provided on that Web page.

FDA and CBP agree that operational issues impacting ABI filers should be announced using Administrative Messages, and intend to continue to use that system, as we have routinely done since December 2003. When appropriate, information about the PNSI system will also be announced both on the FDA Web site and through CBP's Administrative Messages.

CBP also has established avenues of communication with trade working groups and ensures FDA's participation when the subject for discussion is prior notice. FDA does not plan to establish a formal advisory committee to address prior notice.

FDA agrees with the comment to improve help desk staffing, as resources permit. Our Web site contains a tutorial on how to submit a registration for a facility subject to the requirements at 21 CFR part 1, subpart H. In addition, the PNC staff can answer questions about how to submit prior notice. Questions regarding clarification of the rule that are not addressed in this preamble or existing publications should be submitted to FDA at *industry@fda.hhs.gov*. We will generally not provide an individual response to these questions, but will answer them in Question and Answer Guidance Documents so the information will be broadly available.

FDA has included features in PNSI to inform submitters of many types of inadequacies in the information provided, such as missing required fields. FDA also has coordinated with CBP to provide prompt messaging back to users when Prior Notice is filed through ACS. FDA notes that certain inaccuracies cannot be identified electronically, but could be detected in an intensive prior notice review (e.g., the packaging of an actual shipment (12 oz cans of tuna fish) does not match the prior notice data submitted for that shipment (e.g., 6 oz cans of tuna fish)).

With respect to holding public meetings to provide an opportunity for parties to voice their opinions on the IFR, FDA and CBP published the IFR on October 10, 2003, and opened the comment period through December 24, 2003. We reopened the comment period from April 14, 2004, through July 13, 2004. We reviewed 320 timely comments that raised multiple issues, and have considered those comments as we developed this final rule. We also held numerous outreach meetings both domestically and abroad—in person and by video conferencing—to explain the requirements of the IFR to affected parties and answer questions of clarification to ensure all were able to provide meaningful comment to FDA and CBP. The comment period was the time for all parties to be heard on the provisions of the IFR. While the agencies welcome discussion and wanted to ensure that all stakeholders understand their obligations under the statute and the IFR, the comment period ended July 13, 2004, and the agencies did not consider comments submitted outside of the open comment periods.

(Comments) Several comments recommend that FDA provide feedback to the industry detailing areas of noncompliance and compliance. One foreign government stated its willingness to work with FDA to increase the level of industry compliance within their country through outreach and education activities. It requests that FDA provide it on a timely basis detailed information concerning noncompliance by their industry. Another comment suggests that FDA could post on its Web site a description of the types of errors most commonly observed in filed prior notices.

(Response) We agree, and have been posting on our Web site summary information about submission of prior notice, including data on the types of errors. See *http://www.cfsan.fda.gov/~pn/pnsum.html*. We stated that this information will also be analyzed to help FDA take appropriate enforcement action when necessary. FDA presented the Summary Information in two categories: (1) *General interest*—Information about the number and types of prior notices that are being submitted, and which systems are being used to submit them; and (2) *Specific requirements*—Information about submission of the required information. We provided an initial posting of the summary information and two subsequent updates. The August 2004 update included some summary information from December 2003 through April 2004 and some snapshots of activity in July 2004, along with information on specific information requirements such as registration number and carrier information.

We also posted information summarizing the number of facilities registered pursuant to 21 CFR part 1, subpart H at: *http://www.cfsan.fda.gov/~furls/ffregsum.html*. This summary includes a breakdown of the number of registered facilities by country and U.S. State.

4. Enforcement Timeframe

(Comments) Many comments state that because FDA and CBP have not informed prior notice submitters of specific deficiencies in their submissions, FDA must extend the enforcement date of the rule to allow more time to communicate errors and allow adequate time to fix them. One comment suggests that the agencies should develop and implement a notice-

specific informational system that provides detailed feedback to submitters when a prior notice is deemed to be noncompliant. Another comment states that exporters should be advised of noncompliant shipments in order to take corrective action prior to the shift to full enforcement. One comment believes that part of the phase-in period should include a feedback program to let brokers know which importers and corresponding transactions are handled with inadequate or no prior notice. The comment states that this program should be developed in conjunction with the industry to define measurements (history profile and/or transactional), and determine what the notification process should be. One comment encourages FDA to expeditiously publish a notice that it intends to continue outreach and delay enforcement of the regulation so that the business community may have a greater opportunity for education, training, and continued dialogue with the agencies. Other comments recommend a delay in the final phase of enforcement until all systems are fully operational.

(Response) FDA disagrees. The obligation to comply with applicable regulations is on the parties subject to a regulation as specified therein; FDA does not have an obligation to inform all prior notice submitters of specific deficiencies in their submissions before beginning enforcement of a rule. FDA and CBP, however, were cognizant of the potential effect the prior notice IFR could have on trade and thus, after publication of the IFR, FDA published guidance that included a transition period during which we emphasized education to achieve compliance, rather than general refusal of noncompliant shipments (the December 2003 Prior Notice Interim Final Rule CPG) (68 FR 69708). In addition, during the prior notice transition periods from April 2004 through April 2005, we provided compliance summaries that informed submitters, and those who transmit on their behalf, of the major areas of deficiencies with respect to missing data elements. These represented the general deficiencies we were seeing in prior notice submissions during the educational transition period (see *http://www.cfsan.fda.gov/~pn/pnsum.html*). The compliance summaries also generally described the deficiencies in prior notices that are not confirmed for review (e.g., failure to provide a valid registration number). However, we do not plan to communicate submission deficiencies to other than the submitter and transmitter. FDA believes that the effective date of 180 days after publication of the final rule provides sufficient time for the business community to become familiar with all the provisions of the final rule. Moreover, we plan to conduct outreach after publication of the final rule to affected industry and other governments, as resources allow. These efforts will focus on changes to the final rule. Given the delayed effective date, the fact that the changes in the final rule are not very extensive, and the public's experience in complying with the IFR, FDA believes there is no need for a phased-in enforcement approach similar to what was done for the IFR.

(Comments) One comment states that if FDA discovers that a large number of problems are experienced during the grace period between publication of this final rule and the effective date, FDA should consider extending the effective date, especially for first time offenders.

(Response) FDA believes that the 180 day delay in effective date is adequate for affected parties to become familiar with all the provisions in the Prior Notice Final Rule. While we do not anticipate extending the effective date past 180 days, we intend to take into account the circumstances of the violation in enforcing the final rule.

5. Enforcement Penalties

(Comments) One comment requests that the agencies publish procedures that clearly define what types of penalties will be issued for failure to comply under § 1.284 and to whom they will be issued.

(Response) Sections 1.283 and 1.284 of the final rule describe the consequences for failing to submit adequate prior notice or otherwise failing to comply with the final rule. We believe these adequately describe the types of penalties. The Prior Notice Final Rule Draft CPG describes our proposed enforcement policies, and states, for example, that we intend to focus our resources on more serious violations and repeat or flagrant violations.

Civil monetary penalties, which are issued by CBP, may also be assessed in response to a prior notice violation. CBP has posted a variety of publications that explain both the administrative process for fines, penalties, forfeitures, and liquidated damages, such as: ''What Every Member of the Trade Community Should Know About: Customs Administrative Enforcement Process: Fines, Penalties, Forfeitures and Liquidated Damages,'' which is posted at: *http://www.cbp.gov/linkhandler/cgov/trade/legal/informed_compliance_pubs/icp052.ctt/icp052.pdf*, and ''What Every Member of the Trade Community Should Know About: Mitigation Guidelines: Fines, Penalties, Forfeitures and Liquidated Damages,'' which is posted at *http://www.cbp.gov/linkhandler/cgov/trade/legal/informed_compliance_pubs/icp069.ctt/icp069.pdf*. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

N. The Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes

We stated in the preamble to the IFR (68 FR 58974 at 58995) that FDA and CBP would publish a plan, including an implementation schedule, to achieve the goal of a uniform, integrated system and to coordinate prior notice timeframes for air and truck modes of transportation with timeframes finalized by CBP when they finalize their rule entitled ''Required Advance Electronic Presentation of Cargo Information,'' all while fulfilling the Bioterrorism Act mandates. For this reason, as well as to obtain comments on other aspects of the rule, we issued an IFR, with an opportunity for public comment for 75 days. Moreover, to ensure that those who comment on this IFR would have had the benefit of actual experience with the systems, timeframes, and data elements, FDA also stated it intended to reopen the comment period for an additional 30 days to coincide with the issuance of the plan by FDA and CBP relating to timeframes. We extended this comment period twice on April 14, 2004, and May 18, 2004, thereby providing an opportunity for affected persons to comment for 165 days.

In April 2004, FDA and CBP announced the Joint Food and Drug Administration-Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes (the Plan).

The comments addressing the Plan are discussed in the following paragraphs. Comments addressing our assessment of reducing the prior notice timeframes are found earlier in section III.F (''When must prior notice be submitted to FDA?'' (§ 1.279)) of this document. We respond to the other questions (e.g., special programs and flexible alternatives) raised in our April 14th reopening of the comment period in sections III.D (''What is the Scope of this subpart?'' (§ 1.277)) and III.M (Outreach and Enforcement) of this document.

1. Increased Integration

FDA and CBP have increased their integration and are continuing to do so in the following ways:

- Co-location of all FDA Prior Notice staff with CBP's targeting staff;
- Further refinement to FDA's targeting rule sets in CBP's targeting system, coupled with additional training in targeting techniques;
- Continued targeting support from CBP and other Federal law enforcement analysts; and
- Enhancement of communications and cooperation with CBP to facilitate information exchange and to ensure expeditious access and examination of food shipments FDA has decided to inspect upon arrival.

(Comments) One comment suggests that FDA should consider performing the OASIS review concurrently with the ''FDA BTA review'' to eliminate duplicative work and burdens on both the importing community and FDA. Another comment suggests that FDA coordinate the prior notice procedure with FDA's ''Hold Intact Notice'' so that FDA can avail itself of the opportunity to identify in advance shipments for inspection, sampling or detention, or permit the shipment to pass and be delivered without delay.

(Response) FDA disagrees. As we previously explained in an earlier response in section III.J.11 of this document, FDA does not agree that doing the OASIS review under section 801(a) of the act concurrently with the prior notice review under section 801(m) of act would be beneficial to industry or FDA. Because the section 801(m) review must occur prior to arrival, concurrent section 801(a) and section 801(m) reviews also would have to occur prior to arrival. FDA believes such a concurrent process would be inefficient and impractical and would likely increase congestion at the ports of arrival.

(Comments) Comments state that co-locating FDA PNC staff with CBP's targeting staff is a positive step because the two agencies' personnel are both accountable for the risk analysis process, and thus, both agencies' personnel can easily interact and share information, leading to increased efficiencies and integration of the risk analysis process.

(Response) FDA agrees and has co-located the PNC with CBP's targeting staff.

(Comments) Comments strongly support further refinement of FDA's targeting rule sets in order to maintain and improve the risk analysis system to flag specific shipments for security concerns. Comments further support the continuing plan to target shipments for which little is known, while maintaining expedited processing for those shipments and importers that are well known and have provided FDA and CBP with the means by which they can assure general compliance. These comments also argue that products subject to FDA's prior notice requirements should be eligible for full expedited processing and information transmission benefits allowed with C–TPAT, FAST, and any other similar programs established in the future. One comment specifically encourages FDA and CBP to incorporate the current information contained within these programs and allow for the removal of the maximum number of flags within the risk analysis system for those companies that demonstrate their compliance by participation in these additional security programs.

(Response) FDA agrees that refining our targeting rule sets helps to improve both agencies' risk analysis systems. As we discussed previously, FDA has decided not to consider any special programs, such as C–TPAT and FAST, in implementing the prior notice rule.

(Comments) All the comments favor initiatives to provide additional training of FDA staff in targeting techniques that will increase the efficiency and effectiveness of the border crossing systems. One comment particularly notes that additional training should be targeted towards those individuals and issues that will provide measurable additional value to the prompt and efficient release of compliant cargo.

(Response) Any effective targeting technique allows for the identification of food likely to be at risk for adulteration based on a scientific risk assessment. Targeted training will be provided, as resources permit.

(Comments) Comments support enhanced communications and cooperation with CBP to facilitate information exchange and ensure fast access to foods that are subject to prior notice holds. Comments state that this will be critical to the food industry, as any delays will translate into added costs and inefficiencies to their current supply chain. One comment encourages FDA and CBP to integrate technologies used for implementing the Bioterrorism Act with NEXUS, US VISIT, FAST, C–TPAT, and other programs at the border.

(Response) FDA agrees that exchanging information between the agencies is important to evaluation of and response to food safety and security challenges.

(Comments) One comment encourages FDA and CBP to work with their Canadian counterparts to ensure that information is shared and technologies are working in parallel to make crossing the border seamless, efficient, and safe.

(Response) FDA agrees that exchange of information between its international counterparts, when feasible, is critical to evaluation and response to food safety and security challenges.

(Comments) One comment notes that FDA recently announced the signing of an MOU with CBP to commission CBP officers in ports and other locations to conduct investigations and examinations of imported foods on behalf of FDA. The comment questions whether this would have any consequences on the selections for controls by CBP officials stationed in EU ports.

(Response) Investigation and examination of food as a result of prior notice is conducted upon or after arrival of the food in the United States. Therefore, the MOU should not have any consequences on CBP operations at EU ports.

2. General Comments on the Plan

The Plan as announced in April 2004 and revised in November 2004 outlines the following:

- From November 1, 2004, to January 3, 2005, we plan to assess existing procedures and staffing needed to receive, review, and respond to the prior notices submitted in accordance with the Prior Notice IFR (i.e., 2 hours before arrival by land by road; 4 hours before arrival by air or by land by rail; and 8 hours before arrival by water).
- From January 4, 2005, to February 3, 2005, we intend to identify what changes to work practices and staffing would be necessary to determine if FDA could continue to receive, review, and respond to all prior notice submissions with reduced timeframes (e.g., 1 hour/30 minutes before arrival by land by road; 2 hours before arrival by land by rail; and by ''wheels up'' for flights originating in North and Central America, South America (north of the Equator only), the Caribbean, and Bermuda; otherwise 4 hours before arrival by air).
- From February 4, 2005, to May 3, 2005, we plan to implement necessary changes and make appropriate adjustments to ensure we could receive, review, and respond to all prior notice submissions with reduced timeframes.

Under the Bioterrorism Act, any timeframe must be sufficient to receive, review, and respond to prior notice submissions, as set out in section 801(m)(2)(A) of the act (21 U.S.C. 801(m)(2)(A)). The agencies emphasized that the evaluation of whether to reduce

the timeframes for prior notice review will depend on the level of compliance industry achieves during the assessment.

(Comments) Numerous comments concur with the proposed joint FDA-CBP plan for increasing integration of both agencies' activities, as this would eliminate the requirement for importers to maintain two different timeframes for submission of data. One comment concurs with the joint plan and states that it would minimize procedures and costs for firms. One comment states that it was confident that, with proper planning and development, additional integration of the security processes and the differing timeframes can be coordinated through the actions outlined in the published joint plan.

(Response) FDA agrees that increased integration of activities, including timeframes when appropriate and feasible, would be advantageous, provided FDA still is able to meet its statutory obligation to receive, review, and respond to prior notice. As discussed previously (see section III.F, When must prior notice be submitted to FDA? (§ 1.279)), FDA conducted an assessment of FDA response times with reduced timeframes and determined that if it changed the prior notice timeframes to be consistent with those of CBP's advance electronic information rule, the agency would not have adequate time to receive, review, and respond to the prior notices. Moreover, commerce actually would be adversely impacted by shorter prior notice timeframes for submission, because this would significantly increase the number of shipments where FDA would not be able to decide whether it should examine the food at the port of arrival by the end of the timeframe. Such shipments would be delayed at the port of arrival until FDA has either completed its review or decided to examine or not examine the food at the port or arrival without the benefit of a complete review. Accordingly, FDA has retained the timeframes in the IFR.

(Comments) One comment requests that FDA explain why the maritime transportation timeframe was not considered in the joint plan.

(Response) FDA did not include the maritime transportation timeframe because the CBP advance electronic information timeframe for cargo arriving by water is 24 hours, which is significantly greater than the time established by the prior notice IFR for this mode of transportation (8 hours before arrival).

(Comments) One comment suggests that assessment of the resources encompass all potential resources available at the port, including those of the Department of Homeland Security (DHS) in order to make better use of DHS resources at the border. Another comment states that any assessment taken up during this timeframe must take into account the problems inherent in the current systems, as well as the fact that not all submissions will be properly prepared or followed up on, as this could potentially translate into current practices or staffing appearing to be inadequate when, in fact, they may not be.

Another comment asserts that some border crossings were not designed for today's traffic volumes or the post 9-11 environment and recommends that these physical resources be included in the assessment of existing procedures. This comment also encourages CBP to audit staffing levels at border crossings to determine if additional staff is needed.

(Response) FDA agrees that any assessment must take into account the availability of all resources, including those resources of agencies with which we maintain MOU or other agreements covering inspection and sample collection, which can, or should, be devoted to the receipt, review, and response of prior notice. Accordingly, DHS resources are used in implementing this rule, as described elsewhere in this preamble.

(Comments) Two comments noted that they are experiencing significant delays on shipments that cross the border on Fridays due to FDA's limited hours on that day. The comments are concerned about uncertainty regarding transit times and that customers' date-sensitive orders will not be received on time. Another comment noted that waiting times due to traffic volume has increased at the bridge at Detroit because of the inability to move prior notice shipments through the tunnel. The comment states that these delays have made it very difficult to deliver to U.S. facilities that do not operate 24 hours and that these delays will continue to cost exporters and importers and may cause U.S. processing facilities to have unplanned downtime due to a lack of raw material. Another comment notes that different FDA locations ask for more information than the Bioterrorism regulations or systems can process, thereby holding up shipments that move freely at other border crossing locations.

(Response) Prior notice is submitted electronically through ABI/ACS or PNSI. There is no ability for individual ports to require different information as part of the prior notice submission process. The PNC directs all prior notice activities for FDA and ensures consistent review of submitted prior notices. If industry is having difficulties with a specific port, they should contact the PNC to have the issues resolved. FDA believes it is likely that the concerns raised in the comments relate to admissibility decisions being made under section 801(a) of the act, which is a separate review than the one made under section 801(m) of the act, as described previously.

(Comments) One comment states that FDA personnel should be assigned to all arrival ports, particularly those where high risk shipments may arrive.

(Response) FDA does not have the personnel to cover all possible ports of arrival. Accordingly, under the authority of section 314 of the Bioterrorism Act, FDA and CBP signed an MOU in December 2003 that allowed FDA to commission thousands of CBP officers in ports and other locations to conduct, on FDA's behalf, investigations and examinations of imported foods. This FDA-CBP collaboration significantly strengthens the implementation of the Bioterrorism Act to assure the security of imported foods. The MOU enables FDA to work more efficiently with CBP and builds upon FDA's and CBP's long history of close cooperation. Additionally, the MOU enhances the two agencies' teamwork in training, day-to-day operations, and information sharing. As part of the MOU, FDA and CBP provide specialized training for the commissioned CBP employees who will carry out this work, and both agencies have expanded their existing cooperative arrangements to directly share information affecting the safety and security of imported foods. (See *http://www.fda.gov/oc/bioterrorism/moucustoms.html*.)

(Comments) One comment states that there were connection problems with FDA's computer system, perhaps as a result of submission overloads to the system, with session ''timeouts'' occurring. The comment notes that it is crucial that an infrastructure with the capacity to deal with the information being required by FDA be in place in order for stakeholders to meet the requirements of prior notice.

(Response) As discussed in section III.G, *How must you submit the prior notice? (§ 1.280)*, FDA has carefully monitored both PNSI and OASIS system usage and performance since prior notice was implemented in December 2003. During this period, no issues related to load on these systems have been identified. Both systems have experienced occasional outages (including planned down times for maintenance and upgrades). During

these outages, messages between the CBP and FDA systems are held in a queue, resulting in a backlog. Initially, we did experience some difficulties when trying to clear the queue after returning to normal operations, but these issues have been resolved. FDA and CBP also have increased the capacity of the communications link between their systems to ensure that additional bandwidth is available for future increases in load. FDA continues to monitor the production system and to test for performance as the system is upgraded and enhanced.

(Comments) One comment suggests that FDA and CBP take the integrated timeframes further and require only one notification that should meet both FDA and CBP requirements and prevent confusion and delays in the case of a bioterrorism event.

(Response) FDA disagrees. The Bioterrorism Act and the Trade Act have different statutory requirements. In implementing these laws, the agencies require different information and use different targeting and screening tools. FDA and CBP have discussed interfacing with AMS (the module of ACS through which carriers, port authorities, or service bureaus transmit electronically the cargo declaration portion of the inward foreign manifest to CBP) for manifest data and determined that the general cargo data in AMS are not suitable to accommodate the detailed information requirements of section 801(m) of the act. For example, AMS does not collect the country of origin. In addition, its collection of the identities of the article of food and its manufacturer differs from the way those are collected under the prior notice interim final and final rules in such a way that the data would not meet our needs in carrying out the purpose of section 801(m) of the act.

(Comments) One comment asserts that it is redundant for FDA to repeat a feasibility analysis of submission timeframes because CBP has clearly addressed those issues. Another comment proposes that FDA accelerate the schedule for implementing the joint plan, and make this evaluation with CBP as quickly as possible. One comment supports the plan and suggested that any short term assessment take into account the problems involved with the current systems. Another comment expresses concern that full enforcement of the IFR will be in effect during the proposed review period and that consequently, industry will be placed in the difficult position of trying to comply with timeframe requirements that are not synchronized. Another comment suggests that other reasons for noncompliance, such as the need for additional discretion on data and education, be included in the evaluation.

In response to the agencies' statement that the evaluation of timeframes will depend on the level of compliance industry achieves during the assessment, one comment asserts that it is not appropriate for the agencies to place the burden of compliance entirely on the trade. The comment further states that the trade's ability to provide the information required also depends on the systems working properly, the efficiencies of the government personnel involved, the educational outreach levels and the feedback individual importers receive in relation to their current processes. These are areas that are controlled and managed by the agencies, so they also must be considered when assessing the probability of reducing timeframes. One comment expresses concern that the implementation schedule of the Plan may be delayed due to industry noncompliance with the IFR. Another comment asserts that this lack of communication from the agencies to submitters regarding errors could negatively impact the assessment of compliance of the trade and subsequently, the agencies' decisions regarding the trade's future ability to provide a high level of compliance.

(Response) FDA disagrees. The obligation to comply with applicable regulations is on the parties subject to a regulation as specified therein; FDA does not have an obligation to inform all prior notice submitters of specific deficiencies in their submissions before beginning enforcement of a rule. Nonetheless, after publication of the IFR, FDA published guidance that included a transition period during which we emphasized education to achieve compliance, rather than general refusal of noncompliant shipments (the December 2003 Prior Notice Interim Final Rule CPG) (68 FR 69708). In addition, we have provided compliance summaries that inform submitters, and those who transmit on their behalf, of the major areas of deficiencies, in general, that we were seeing in prior notice submissions during this educational transition period (see *http://www.cfsan.fda.gov/~pn/pnsum.html*), and generally advise the submitter of deficiencies in prior notices that are not confirmed for review (e.g., failure to provide a valid registration number). Moreover, FDA and CBP believe that the level of compliance was sufficiently high during the assessment period. The assessment period began almost a year after the IFR went into effect. During that time, we resolved initial problems with the government's prior notice systems and processes. Our extensive outreach and focus on education instead of refusals and other enforcement actions helped ensure that industry submission rates were at or near 100 percent for most prior notice information by November 2004. In certain circumstances, such as with the manufacturer's registration number, FDA and CBP continued to provide flexible enforcement. With these measures, prior notice was operating smoothly during the assessment period.

(Comments) One comment fully supports this process and encourages FDA to provide for any changes that may be needed to allow the timing reductions that are critical to economic prosperity. The comment suggests that once the program has been operational for a time, and the systems glitches worked out from past experience, the assessment would translate into a faster processing time.

(Response) As stated previously, the prior notice timeframes must ensure that we have sufficient time to receive, review, and respond to the prior notice.

(Comments) Several comments encourage both agencies to ensure that they allow for the proper communications with the trade prior to planning for or implementing any changes as a result of the previously mentioned assessments, so that the interests of all parties involved can be assessed and the best changes can be implemented. One comment requests that sufficient resources be allocated by FDA and CBP to implement the Plan.

(Response) The IFR included an extended public comment period, and comments were received and reviewed during the development of this final rule. We also held numerous outreach meetings both domestically and abroad—in person and by video conferencing—to explain the requirements of the IFR to affected parties and answer questions of clarification to ensure all were able to provide meaningful comment to FDA and CBP. The final rule will not take effect until 180 days following publication. The agencies plan additional outreach and guidance during that 180-day period.

(Comments) Some comments request that FDA issue a final prior notice rule only after there has been a period of full enforcement followed by an additional comment period. These comments argue that both FDA and industry need the benefit of experience with active and full enforcement before fine-tuning the prior notice regulation into a final rule.

Comments suggest that FDA reopen the comment period for 60 days after full enforcement has been in place for 90 to180 days or for at least 6 months. In the interim, the comments recommend that the rule should be maintained as an IFR for a longer period of time with phased implementation, as one comment suggests, while developing the final rule.

(Response) FDA reopened the comment period for a total period of almost 6 months to allow parties an opportunity to provide meaningful comment based on their experiences in complying with the IFR. FDA also extended the initial eight-month transition period from August 2004 to November 2004 for several of the data elements that our review indicated had higher error submission rates while continuing educational outreach activities. The implementation date for this final rule is 180 days after publication. The IFR remains in effect until the time the final rule takes effect. No comment period is associated with the publication of the final rule.

(Comments) One comment urges the FDA to build into the final rule the capability to administratively amend the prior notice provisions quickly, if needed. The comment notes that this would be particularly important for imports from any country with which the FDA has reached a bilateral arrangement. This arrangement would serve as the basis for having different (e.g., more efficient, effective, or risk based) prior notice requirements. The comment further notes that this ability to administratively amend the rule would be important so that FDA could adjust procedures quickly and efficiently to reflect actual reductions in risks through such arrangements.

(Response) FDA disagrees. The Bioterrorism Act requires that FDA receive prior notice for every article of food imported or offered for import into the United States. There are no exceptions based on the country of production or the country from which the article of food is shipped.

To the extent that FDA and CBP believe that changes in our policies related to enforcing this final rule are needed, we will announce those as revisions to the Prior Notice Final Rule Compliance Policy Guide, a draft of which we are announcing elsewhere in this issue of the **Federal Register**.

IV. Analysis of Economic Impacts

A. Final Regulatory Impact Analysis

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The requirements of this final rule have not changed significantly from the IFR, although there are changes, such as those relating to the identity of the manufacturer. Because of these changes, FDA has determined that this final rule may have a significant economic impact on a substantial number of small entities. Under the requirements of the RFA, and as explained in section IV.B of this document, FDA has analyzed the economic impacts of this rule on small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount as compared to the IFR.

In this regulatory impact analysis for the prior notice final rule we: (1) Respond to comments on the economic analysis of the IFR, (2) revise the economic analysis of the IFR using new data, (3) present an economic analysis of the leading alternative to the IFR using new data, and (4) explain the marginal benefits and costs of the final rule itself, relative to the IFR.

1. Need for Regulation

Section 307 of the Bioterrorism Act of 2002 requires prior notice of all food imported or offered for import into the United States. Before the prior notice requirement was instituted in 2003, there were no security assessments made specifically on imported food products, and all such shipments were allowed to move into the United States prior to FDA being notified of their existence, which legally could have occurred up to 15 days after the food had arrived in the United States and been moved to its final destination. Requiring prior notice of imported foods allows FDA to target food that may pose a significant risk to public health and inspect it upon arrival. The prior notice submission requirement protects the Nation's food supply against actual or threatened terrorist acts and other food-related emergencies. It helps ensure that imported food shipments that appear to pose a significant threat to public health are stopped at the border upon arrival before they are allowed to move into the United States. This final rule replaces the IFR that is already in effect.

2. Final Rule Coverage

This final rule applies to all food for humans and other animals that is imported or offered for import into the United States for use, storage, or distribution in the United States, including food for gifts and trade and quality assurance or quality control samples, food for transshipment through the United States to another country, food for future export, and food for use in a U.S. Foreign Trade Zone.

This final rule does not apply to food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States; food that was made by an individual in his or her personal residence and sent by that individual as a personal gift to an individual in the United States; or food that is imported then exported without leaving the port of arrival until export.

This final rule also does not apply to meat food products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*); poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); or egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

Finally, prior notice is not required for articles of food subject to Art. 27(3) of The Vienna Convention on Diplomatic Relations (1961), i.e., shipped as baggage or cargo constituting the diplomatic bag.

As required by the Bioterrorism Act, prior notice submissions must provide

the identity of the article, manufacturer, shipper, and grower (if known), the FDA Country of Production, the country from which the article is shipped, and the anticipated port of arrival. In addition, the notification must provide the identity of the person who submits and transmits the prior notice, the importer, the owner, the consignee, the carrier, the CBP entry identifier, the anticipated time and date of arrival, anticipated shipment information, and, if the food has been refused admission and required to be held, the location where it is held. For food shipments arriving in the United States through international mail, notification of the import must be sent before the article is mailed. Only the prior notice information that is relevant to that type of shipment must be submitted for articles of food arriving by international mail.

3. Comments on the Interim Final Regulatory Impact Analysis

(Comment) The extra work of completing prior notices because each separate food line in an entry needs a prior notice has forced brokers to raise their fees to clients and forced manufacturers to raise their prices to U.S. consumers.

(Response) FDA agrees this is a possible impact of the rulemaking, and noted in the IFR regulatory impact analysis that the costs of prior notice would likely be partially passed on to consumers in the form of higher retail prices for some foods (68 FR 58974 at 59024).

(Comment) One comment states that smaller U.S. importers cannot afford the additional costs charged by a broker to submit the FDA information via the ABI system. As a result, they are having their foreign suppliers submit prior notice. Some small companies estimate that, including Web site disruptions, 80 packages would take 40 to 80 hours for prior notice. The comment believes that this is totally unmanageable.

(Response) We account for increase in broker costs due to prior notice in our analysis; the comment estimate of the time it takes to complete prior notice is accurately reflected in the IFR and final rule analysis. FDA expects importers to modify their business practices to find the most cost effective way to deal with prior notice requirements. In this case, the small importer can avoid higher broker fees by having the foreign supplier submit the prior notice. Another alternative would be for the small importer to submit prior notice themselves through PNSI. We would expect small firms would comply in whichever manner is most cost effective. It is also possible some of the costs of prior notice could be passed on to consumers in the form of higher retail prices for some foods; in this case the small importer would not feel the complete impact of the higher broker submission costs.

(Comment) The costs of the IFR were underestimated because some types of imported fruits and vegetables were not included in the ''loss of freshness, loss in value'' calculation.

(Response) Some fruits and vegetables are regulated by USDA's APHIS regulations (certain types of citrus, tomatoes, avocados, and other products) and already have to be inspected or checked at the port of entry regardless of the prior notice regulation. For importers of these fruits and vegetables, the requirement to have certain documentation available at the port of entry and coordinating times to be at the port of entry is not new. Thus, persons importing fruits and vegetables subject to APHIS' requirements are not included in the ''loss of freshness'' calculation as these costs of doing business are already taken into account when scheduling importation of the produce. FDA believes we have accounted for every other type of possible instance where a fruit or vegetable regulated under this rulemaking could experience a loss in freshness or value.

Several fresh produce importers commented on the IFR that they considered prior notice redundant as their produce shipments already have to be inspected at the port of entry by USDA. These comments further support the exclusion of some fruits and vegetables from the ''loss of freshness'' cost calculations presented here and in the IFR's regulatory impact analysis.

(Comment) The cost to complete a prior notice to send food by mail, for companies that ship low volumes of inexpensive food products, is higher than the value of the product being shipped and therefore shipping to the United States may be discontinued.

(Response) FDA stated in the analysis of the IFR that the costs of completing prior notice submissions may be partially passed along to the consumer in the form of higher retail prices for some foods (68 FR 58974 at 59024). FDA's IFR analysis also acknowledged the possibility that companies in the business of sending small shipments of food to private individuals in the United States may stop shipping to U.S. addresses (68 FR 58974 at 59067).

(Comment) A number of postal services take issue with the requiring of filing prior notice for personal food items. The comments state that the labor-intensive process of mailing personal food items will cause a decrease in the items being shipped, thus decreasing the business of the mail system.

(Response) When the cost of shipping increases, the number of items shipped is indeed likely to decrease. Although some of the reduction in postal revenues would represent a dead-weight loss, it is primarily a transfer, not a social cost and therefore is not included in the cost estimates for this analysis.

(Comment) Several comments express concern about their continued ability to import fine wine because although they can obtain the name and address of the site-specific manufacturer of the wine, obtaining the manufacturers' (i.e., the wineries') registration numbers for these products often is difficult to those not in the winery's direct distribution chain. The comments state that smaller importers, wholesalers, retailers, restaurants, clubs or hotels will be negatively affected by not having the registration number for the manufacturer of the fine wine. The comments further state that the prior notice rule will negatively impact small producers by reducing the number of potential representatives and sales venues as secondary fine wine market importers disappear.

(Response) FDA does not believe that the fine wine industry will be negatively affected by the prior notice final rule. The final rule at § 1.281(a)(6) requires the identity of the manufacturer as follows: The name of the manufacturer and either: (1) The registration number, city, and country of the manufacturer or (2) both the full address of the manufacturer and the reason the registration number is not provided (hereafter ''the identity of the manufacturer''). Even if a wine importer, retailer, or wholesaler cannot obtain the registration number (e.g., the winery refuses to disclose its registration number because the importer, retailer, or wholesaler is outside the winery's distribution chain), the prior notice can include the name and full address of the winery, which comments stated is obtainable. We do not include additional costs to fine wine manufacturers or importers in this final rule analysis; however, we do refine the estimate of the difference between the IFR requirements and this final rule modification.

(Comment) Smaller importers that buy from brokers and wholesalers because they are too small to buy directly from larger food manufacturers will be put out of business. These smaller importers allege that they will not be able to provide the

manufacturers' registration numbers on their prior notices as required by the final rule. The comments argue that the registration number requirement interferes with small businesses' rights to free trade because now only larger businesses that deal with the manufacturers directly, rather than buying through brokers and wholesalers, will be able to obtain the manufacturer's information that is required for prior notice.

(Response) The final rule provides an alternative for submitters to provide the identity of the manufacturer when the manufacturer's registration number is not obtainable. Under the final rule, submitters may provide the name and full address of the site-specific manufacturing facility along with a reason as to why the registration number was not used in the prior notice.

(Comment) While most comments state that the name and address of the manufacturer could be submitted in prior notice, one comment states that re-sellers will not normally supply the name of their supplier or the name of the manufacturer of a particular product to their customers. The comment asserts that supplying the name of the manufacturer would allow that customer to circumvent the re-seller and attempt to make direct contact with the supplier or manufacturer, thus taking business away from the re-seller. Another comment states, however, that smaller importers buy from brokers and wholesalers specifically because they are too small to buy directly from larger manufacturers and other corporations, as large entities typically would not find it cost-effective to deal with smaller importers.

(Response) Depending on the business atmosphere, FDA believes that it is likely that many resellers will be willing to supply the name and the address of the manufacturers of the products they sell. Unlike the manufacturer's registration number, which many may view as confidential business information that is to be disclosed only on a ''need to know'' basis, the name and full address of a facility is public information that not only is typically in phone books and on the Internet, but it also often is provided on documents typically exchanged between buyers and sellers (e.g., receipts, purchase orders, and bills of lading). The issues discussed in these comments are addressed further in Options 1 and 3.

4. Regulatory Options Considered

In the analysis of the IFR, FDA analyzed 12 options. The 12 options focused on varying timeframes for prior notice submission and prior notice submission by transport type. The options regarding shorter submission timeframes by transport type are similar to the options presented in this analysis; we do not analyze those options with longer minimum submission timeframes (e.g. 8 hours, 12 hours) or options that do not vary prior notice submission timeframe by transport type again here, although this final rule analysis updates the analysis of the chosen IFR option. The costs and benefits of all twelve options analyzed for the prior notice IFR can be found in the **Federal Register** of October 10, 2003 (68 FR 58974 at 59025).

This final regulatory impact analysis emphasizes the differences between the IFR and final rule, and compares new options against the IFR. Each option covers all food subject to the final rule that is imported or offered for import into the United States; the mode of transportation for the food is specifically addressed in options where minimum prior notice time constrains importation.

Option 1 (IFR). The minimum prior notice time will be 2 hours for articles of food arriving by land by road, 4 hours for articles of food arriving by land by rail and by air, and 8 hours for articles of food arriving by water, with electronic submission of information. Most changes in prior notice information require resubmission of corrected or new information.[6]

Option 2. This option includes all components of Option 1, but would reduce the minimum prior notice time for food arriving by land by road to 1 hour for general entries and 30 minutes for FAST[7] participants, reduce minimum prior notice time for food arriving by land by rail to 2 hours, and reduce the minimum prior notice time for food arriving by air on flights originating in North and Central America, South America (north of the equator only), the Caribbean, and Bermuda to ''wheels-up''. This option would integrate FDA's prior notice timeframes with the timeframes required by CBP's Advance Manifest Rule.

Option 3 (Final Rule). This option includes all components of Option 1, except the final rule now allows, when the submitter is unable to determine the registration number of the manufacturer, the site-specific facility name and full address instead of the facility's, name, partial address, and registration number.

Option 1: Minimum prior notice time is 2 hours for articles of food arriving by land by road, 4 hours for articles of food arriving by land by rail and by air, and 8 hours for articles of food arriving by water; information is submitted electronically, most changes in information require resubmission.

This option is already in place as the IFR and will be compared against other options for assessing costs and benefits of the changes between the IFR and final rule.

a. *Option 1—Prior Notice IFR.* In the economic analysis of the IFR we calculated the number of entities that would submit prior notice and the costs to those entities of: Learning prior notice, computer acquisition, information coordination, submitting prior notice, creating the PNSI, not being able to use CBP's BRASS[8] system, and loss of value to fresh produce that waits longer at the port of arrival than before prior notice was required.

i. *Number of entities affected.* Prior Notice for an article of food may be submitted by any person with knowledge of the required information, e.g., a foreign food manufacturer, a food exporter or importer, a consignee. The flexibility of the identity of the prior notice submitter makes it difficult to get a precise count of the number of unique people or firms who submit at least one prior notice annually. In the IFR we estimated, based on FDA OASIS data from 2001, that there were 77,427 unique people or firms who submitted prior notice. To update the number of prior notice submitters in the final rule we use two sources of data: U.S. Census data and data from OASIS.

First we use U.S. Census data by North American Industry Classification System (NAICS) codes. Six-digit NAICS codes for Industry, 42–Food Wholesalers, indicates that there are 68,651 U.S. businesses registered under this code. We use this information because, in general, establishments importing products into the United States are classified in Wholesale Trade

[6] You do not have to resubmit your prior notice if there are changes in: (1) The estimated quantity of product, (2) the anticipated arrival information, (3) the planned shipment information, or (4) the anticipated date of mailing for shipments by mail.

[7] The Free and Secure Trade (FAST) program is a Border Accord Initiative between the United States, Mexico, and Canada designed to ensure security and safety of imported and exported products. Eligibility for the FAST program requires participants (carrier, drivers, importers, and southern port of entry manufacturers) to submit an application, agreement, and security profile depending on their role in the Customs and Trade Partnership Against Terrorism (C–TPAT) and FAST programs. The FAST program allows known low risk participants to receive expedited CBP entry processing. (Ref. 2)

[8] Border Release Advance Screening and Selectivity (BRASS) is a CBP program that allows expedited arrival processing for high-volume, repetitive shipments that have been judged by CBP to be low risk.

(Ref. 3) (*http://www.naics.com*). Thus the number of U.S. businesses engaged in the wholesale food industry could likely be the number of persons who submit prior notice for the goods they receive. Table 3 of this document shows a breakdown of business by six-digit NAICS code for food wholesalers.

TABLE 3.—UPDATED ESTIMATE FOR NUMBER OF PRIOR NOTICE SUBMITTERS

NAICS Codes for Wholesale Trade Related to Food From the NAICS Association[1]

6 digit NAICS Code		Numbers of U.S. Businesses
424210	Drugs and Druggists' Sundries Merchant Wholesalers[2]	8,288
424410	General Line Grocery Merchant Wholesalers	8,061
424420	Packaged Frozen Food Merchant Wholesalers	1,250
424430	Dairy Product (except Dried or Canned) Merchant Wholesalers	2,195
424440	Poultry and Poultry Product Merchant Wholesalers	899
424450	Confectionery Merchant Wholesalers	3,202
424460	Fish and Seafood Merchant Wholesalers	4,157
424470	Meat and Meat Product Merchant Wholesalers	3,299
424480	Fresh Fruit and Vegetable Merchant Wholesalers	5,494
424490	Other Grocery and Related Products Merchant Wholesalers	14,763
424510	Grain and Field Bean Merchant Wholesalers	5,217
424520	Livestock Merchant Wholesalers	5,106
424590	Other Farm Product Raw Material Merchant Wholesalers	2,158
424810	Beer and Ale Merchant Wholesalers	2,181
424820	Wine and Distilled Alcoholic Beverage Merchant Wholesalers	2,381
Total Number of Businesses		68,651

[1] Source of original data: NAICS Association, September 29, 2008, available online at *http://www.naics.com/naics42.htm*.
[2] This category is included to capture wholesale merchants of botanicals, herbs, and vitamins.

Next, using OASIS data, we are able to estimate that there were 123,063 unique manufacturers and 25,929 unique importers of food in FY 2007. Combining the OASIS data with the Census data we estimate that the number of prior notice submitters annually ranges from 68,000 to 149,000. We use the average of this range, 108,500, as the number of entities likely affected by having to submit prior notice.

ii. *Costs to entities*. We update the cost calculations to the new number of entities affected for learning prior notice, buying computers, and information coordination. We do not update the costs of FDA information technology here. Table 4 of this document shows these cost calculations; for a complete discussion of how these costs were calculated refer to the preamble in the prior notice IFR (68 FR 58974 at 59025).

TABLE 4.—COST CALCULATIONS FOR LEARNING PN, INFORMATION TECHNOLOGY, INFORMATION COORDINATION, AND FDA SYSTEM COSTS

Cost to Learn About the Prior Notice Requirements	Manager cost	Admin. Worker cost (two workers)
Number of firms	108,500	108,500
Wage rate per hour for manager and admin. worker (including overhead)	$56.74	$25.10
1-day learning seminar	8 hours	8 hours
First year one time learning costs	$49,250,320	$21,786,800
Total first year learning costs for learning		$71,037,000
Annual learning costs for new entrants		$7,103,700
Facilities and Responsible Parties Without Initial Internet Access		
Number of facilities		4,340
Computer equipment cost per facility		$2,000
Annual cost of Internet access ($20 per month x 12)		$240
Search costs for equipment and access ($25.10 x 8 hours)		$201
Total first year one time cost of electronic transmitting capacity		$10,593,940
Annual one time cost of electronic transmitting capacity for firms entering industry in subsequent years		$1,059,394
Information Gathering and Coordination Costs		
Number of firms submitting notices		108,500
Administrative worker wage rate (doubled to include overhead)		$25.10
Time to coordinate existing accounts		16 hours

TABLE 4.—COST CALCULATIONS FOR LEARNING PN, INFORMATION TECHNOLOGY, INFORMATION COORDINATION, AND FDA SYSTEM COSTS—Continued

First year cost of coordination of information on current accounts	$43,573,600
Annual cost of coordination of information on new accounts	$4,357,360
FDA Prior Notice System Costs	
Infrastructure design and implementation	$7,400,000
Contractor services	$5,100,000
FDA PN system interface cost	$12,500,000
CBP ABI/ACS system modification costs	$500,000
Total prior notice system cost	$13,000,000

We also have new data on the number of prior notices submitted based on 2007 data collected by FDA's PNC. Therefore, we do update, for the IFR and all other options, the costs of submitting prior notices, the costs of not being able to use CBP's BRASS system, and the lost value of fresh produce and seafood.

Also, due to an oversight in the calculation of the costs for the IFR, FDA did not calculate the costs to importers of providing the imported product's manufacturer registration number and full facility address on prior notice. We correct that oversight here.

b. *Updated annual costs to submit prior notice.* FDA's PNC received 9,804,050 prior notices for FY 2007, which is about 3 million more prior notices than we estimated in the analysis of the IFR. The difference in number of submissions is in part due to an increase in the number of prior notices submitted for each imported food entry. In the IFR analysis, we estimated that there were about 2.6 lines (prior notices) submitted for each food shipment.[9] New OASIS shipment data show that for 2007, the average number of lines per entry for food, food related, infant food, and food additive industry codes is 3.6 lines per entry.

We use these new data on entry lines to estimate that FDA receives 9,804,050 prior notices per year, which translates into approximately 2.7 million imported food entries (based on 3.6 lines per entry[10]) annually. Table 5 of this document shows that the annual costs to complete a prior notice will be $202.5 million instead of the $187.5 million estimated in the IFR.

TABLE 5.—COST TO COMPLETE A PRIOR NOTICE BY IMPORT ENTRY (MUST BE ELECTRONIC)

Broker cost per entry to submit prior notice	$75
Entry total based on 9.8 million lines	2,700,000
Total annual costs of all prior notices, including updates to the information	$202,500,000

c. *Updated costs to BRASS users.* Under the prior notice rule, no food product shipments imported into the United States are eligible to take advantage of CBP's BRASS system. We update the number of entries that used the BRASS system in FY 2002 (242,000) to estimate the number of imported food entries that would have used the BRASS system in FY 2007 (305,000) if it would have been available to them. Table 6 of this document shows that the updated costs to BRASS users are $61 million annually; the previous estimate was about $48 million annually.

TABLE 6.—UPDATED ADDITIONAL COSTS FOR BRASS USERS

Additional Submission Costs	
Total Cost per import entry	$75
FY2002 BRASS line total for FDA-regulated products	1,098,054
BRASS yearly entry total (3.6 lines per entry)	305,015
Additional annual costs of submissions for BRASS users	$22,876,125
Additional Border Wait Time	
Cost per half hour	$125
BRASS yearly entry total	305,015
Additional annual border wait costs for former BRASS users	$38,126,875
Total Annual additional food importing costs for BRASS users	$61,003,000

d. *Updated costs to submit prior notice by mode of transport.*

i. *2-hour minimum prior notice time for food arriving by land by road.* Prior notices for perishable articles of food from Canada and Mexico that arrive in the United States by land by road must be submitted at least 2 hours before the food arrives in the United States. In the analysis of the IFR, we assumed that this minimum submission time should eliminate the probability of having to resubmit prior notice (due to proximity to the U.S. port of entry) for all but 5 percent of those perishable products imported from Canada and Mexico.

Data from the FDA PNC for 2007 indicate that 85 percent of the articles of food arriving from Canada enter the United States by land by road; and approximately 94 percent of the articles of food arriving from Mexico enter the United States by land by road.[11] Using these updated estimates, we calculate the proportion of the total retail value of highly perishable produce and seafood from Canada and Mexico that arrive in the United States by land by road. We then calculate the lost product value for the 5 percent of highly perishable produce and seafood from Canada and Mexico for which importers may have to resubmit the prior notice when the minimum submission time is 2 hours. Table 7 of this document shows the revised estimated loss in value caused by the cancelled and resubmitted prior notice information for the 5 percent of imported Mexican and Canadian perishable seafood and produce affected.

We do not include the lost value for perishable seafood and produce imported from Central America because perishable products from Central America are most likely to arrive by air into the United States. We also do not include the cost of additional truck time

[9] As explained in more detail in the economic analysis of the interim final rule, OASIS data indicate there are typically more than two different articles of food per import entry; e.g., 100 cases of canned tuna and 50 cases of canned peaches in the same shipment. A prior notice must be filed for each of the lines in an entry.

[10] This is likely a slight overestimate of prior notices per entry because food-related items (such as eating utensils) are not subject to prior notice.

[11] The mode of transportation field in prior notice is user defined; thus, the person submitting the prior notice is responsible for informing FDA by what mode of transport the food will enter the United States. As mode of transport is user defined, there is a possibility of error.

with this option because the minimum prior notice time for articles of food arriving by vehicle is only 2 hours.

TABLE 7.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 1 FOR ARTICLES OF FOOD ARRIVING BY LAND BY ROAD (2-HOUR MINIMUM NOTICE REQUIREMENT)

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
94% of total retail value for Mexican produce	$3,251,014,000
1.2% Reduction in value for 5% of Mexican produce	$1,951,000
2001 Imported Canadian produce total retail value	$401,826,000
85% of total retail value for Canadian produce	$341,552,000
1.2% Reduction in value for 5% of Canadian produce	$205,000
Total lost value for produce	$2,156,000
Perishable Seafood	**Dollars**
2001 Imported Mexican seafood total retail value	$112,277,000
94% of total retail value for Mexican seafood	$105,540,000
4.2% Reduction in value for 5% of Mexican seafood	$222,000
2001 Imported Canadian seafood total retail value	$1,863,218,000
85% of total retail value for Canadian seafood	$1,583,735,000
4.2% Reduction in value for 5% of Canadian seafood	$3,326,000
Total lost value for seafood	$3,548,000

ii. *4-hour minimum prior notice time for food arriving by land by rail and by air.* The 4-hour minimum submission time for prior notice applies to articles of food imported or offered for import by land by rail and by air. A 4-hour minimum prior notice time for railroads and airplanes could constrain products arriving from the countries bordering the United States. Data from the PNC for 2007 show that about 4 percent of the articles of food arriving from Canada were imported into the United States by land by rail and only about 2 percent of the articles of food arriving from Mexico were imported into the United States by land by rail. Similarly, about 8 percent of the articles of food arriving from Canada were imported into the United States by air, while only about 3 percent of the articles of food arriving from Mexico were imported into the United States by air.

To estimate potential lost value for produce imported from Canada and Mexico by rail and air, we adjust the total retail value of highly perishable produce and seafood from Canada and Mexico to account for the 12 percent from Canada and the 5 percent from Mexico that are imported by land by rail or by air. Table 5 of this document shows the articles of food arriving by rail and air from Canada and Mexico that may have to resubmit prior notice when the minimum prior notice timeframe is 4 hours before arrival in the United States.

For Central American and Caribbean countries, most, if not all, of their perishable products are imported to the United States by air. Table 8 of this document shows the loss of value for the estimated 20 percent of air shipments from Central America for which prior notice needs to be resubmitted under Option 1.[12]

TABLE 8.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 1 FOR SHIPMENTS ARRIVING BY AIR AND BY LAND BY RAIL (4-HOUR MINIMUM NOTICE REQUIREMENT)

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
5% of total retail value for Mexican produce	$172,926,000
2.4% reduction in value for 20% of Mexican produce	$830,000
2001 Imported Canadian produce total retail value	$401,826,000

[12] The estimated 20 percent cancellation and resubmission rate for prior notices when the minimum submission time is 4 hours is used in the IFR analysis. (See 68 FR 58974 at 59045.)

TABLE 8.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 1 FOR SHIPMENTS ARRIVING BY AIR AND BY LAND BY RAIL (4-HOUR MINIMUM NOTICE REQUIREMENT)—Continued

Perishable Produce	Dollars
12% of total retail value for Canadian produce	$48,219,000
2.4% reduction in value for 20% of Canadian produce	$231,000
2.4% reduction in value for 20% of Central American and Caribbean produce	$1,044,000
Total lost value for produce	$2,105,000
Perishable Seafood	**Dollars**
2001 Imported Mexican seafood total retail value	$112,277,000
5% of total retail value for Mexican seafood	$5,614,000
8.3% reduction in value for 20% of Mexican seafood	$93,000
2001 Imported Canadian seafood total retail value	$1,863,218,000
12% of total retail value for Canadian seafood	$204,954,000
8.3% Reduction in value for 20% of Canadian seafood	$3,712,000
2001 Imported Central American and Caribbean seafood total retail value	$251,796,000
8.3% Reduction in value for 20% of Central American and Caribbean seafood	$4,180,000
Total lost value for seafood	$7,985,000

e. *Updated IFR costs to include the costs of manufacturer name, registration number and partial address on prior notice.* Section 1.281(a)(6), (b)(5), and (c)(6) of the IFR requires that prior notice for an article of food that is no longer in its natural state include the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food.[13] This IFR requirement has not been fully enforced by FDA, as described in CPG Sec. 110.310; however, it is a requirement of the rule and therefore we evaluate it as a cost of the IFR. We correct an oversight in the calculation of the costs of the IFR by including the costs of submitting the food manufacturer registration number and facility address on prior notice here.

f. *How some importers will be affected.* The November 2004 revision of the IFR CPG stated that if the manufacturer's registration number was not given on the prior notice, the submitter should select the appropriate reason identifying why the manufacturer's registration number and/or name and address was not provided. The reason codes provided by PNSI and ABI/ACS were:

- A—facility is out of business
- B—facility is a private residence
- C—facility is a restaurant
- D—facility is a retail food establishment
- E—facility is a nonprocessing fishing vessel
- F—Facility is nonbottled water collection and distribution establishment
- G—Individual gift-label name/address
- H—Grower-satisfies farm exemption
- I—Samples-quality assurance, research or analysis purposes only
- J—U.S. manufacturing facility that is not required to register
- K—Unable to determine the registration number of the manufacturer
- L—Unable to determine identity of manufacturer-providing identity of manufacturer's headquarters
- M—Unable to determine identity of manufacturer or headquarters-providing invoicing firm's identity
- O—Gift pack for nonbusiness purposes-providing single prior notice and identity of packer

Prior notices submitted without manufacturer registration numbers but using reason codes A through F, H, and J would be compliant with IFR requirements because the manufacturer would be exempt from being registered according to the Registration of Food Facilities rule (21 CFR part 1, subpart H). Prior notices submitted without manufacturer registration numbers but using reason code G would be compliant with IFR requirements because the prior notice IFR allows that if an article of food is sent by an individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States, the submitter may provide the name and address of the firm that appears on the label instead of the name, address, and registration number of the manufacturer. A prior notice submitted without the manufacturer name, address, and/or registration number but using reason code I, K through M, or O would not be compliant with IFR requirements. However, FDA's enforcement policy was that it should typically consider not taking any regulatory action for prior notice violations in these cases.

We can use information from the PNC on the CPG code reasons given for FY 2007 to determine how many submitters had trouble providing the manufacturer registration number and facility address as is required by the IFR (submitters who used reason codes I, K through M, and O).

[13] The interim final rule further states that a registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage, and export, or further manipulation and export. The interim final rule also provides that if the article of food is sent by an individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States, he or she may provide the name and address of the firm that appears on the label under § 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and country may be provided instead of the full address.

The PNC was able to determine that about 92.5 percent of prior notices contained the manufacturer's name, address, and registration number as required by the IFR. Table 9 of this document shows that about 2.9 percent of prior notice submissions (2.91 percent) for 2007 used reason codes I, K, L, M, and O.

TABLE 9.—NO MANUFACTURER REGISTRATION NUMBER ON PRIOR NOTICE, REASON CODE LINE COUNT FOR FY 2007

Reason Code	Description	PN Lines Count	% of Total Lines
Total prior notice submissions for fiscal year 2007		9,804,050	
A	Facility is out of business	43,479	0.44%
B	Facility is a private residence	30,801	0.31%
C	Facility is a restaurant	5,146	0.05%
D	Facility is a retail food establishment	47,705	0.49%
E	Facility is a nonprocessing fishing vessel	2,488	0.03%
F	Facility is a nonprocessing drinking water collection and distribution establishment	1,417	0.01%
G	Individual gift label name/address in lieu of registration number	36,808	0.38%
H	Grower satisfies farm exemption	267,369	2.73%
I	Samples—quality assurance, research or analysis purposes only	55,374	0.56%
J	U.S. manufacturing facility that is not required to register	15,142	0.15%
K	Unable to determine the registration number of the manufacturer	166,647	1.70%
L	Unable to determine identity of the manufacturer—providing identity of manufacturer's headquarters	15,674	0.16%
M	Unable to determine identity of manufacturer or headquarters providing invoicing firms identity	15,839	0.16%
O	Gift pack for nonbusiness purposes—providing single prior notice and identity of packer	32,371	0.33%
Total times a reason code was given (includes submission for PNSI and ABI/ACS) for fiscal year 2007		637,153	7.51%

FDA posits that larger entities (e.g., medium to large importers) that deal directly with foreign manufacturers will not be impacted by this IFR requirement (are not part of the 2.91 percent) as they will be able to obtain the manufacturers' registration numbers and facility addresses for the products they are importing. Therefore, it is mostly the small U.S. retailers or individuals that buy from other wholesalers or retailers in foreign countries that may have a problem obtaining the registration number, city, and country of the actual food manufacturing facility.

Using data from the U.S. Census Bureau, FDA was able to determine that for 2006, about $64.8 billion foods, feeds, and beverages were imported into the United States. Some of this value of imported food could be affected by the IFR requirement that the registration number, city, and country of the manufacturer be provided on prior notice; to assess how this imported value may be affected, we present best and worst case scenarios.

In our best case scenario, few imported foods would be affected by manufacturer registration number, name and partial address being required on prior notice. For our best case scenario we subtract the full import value of the potentially ''unaffected'' categories listed in table 10 of this document from $64.8 billion, the total value of food, feeds, and beverages imported into the United States in 2006 (Ref. 4). In essence, we subtract out those food categories that are likely comprised of foods that are still in their natural state such that a manufacturer is not required for the prior notice (e.g., green coffee). This is our ''best case'' scenario because not all foods imported from the categories below will come from facilities that are not required to be registered (i.e., vegetables could be farm commodities or could be processed). The remaining imported foods value, about $29 billion, represents the value of alcoholic beverages, bakery products, non-agricultural, and ''other'' imported foods, which are products from facilities more likely to be subject to the food facility registration requirements.

About 2.91 percent of the prior notice submissions for FY 2007 indicated that the importer could not provide the name, address, and/or registration number of the actual manufacturing facility. While we do not know the value of imported foods for each of the prior notice submissions in the 2.91 percent affected, in the absence of better information, for our best case scenario we reduce the value of imported foods affected to $843 million, or 2.91 percent of $29 billion. For the worst case scenario, we apply the 2.91 percent of import lines for 2007 that could not provide the registration number, city, and country of the actual manufacturer to the entire value of FDA-regulated imported food shipments, $59 billion, giving us a possible $1.7 billion in imported foods value that could be affected by the prior notice IFR requiring the name, registration number, and partial address of the manufacturing facility on most prior notices.

The estimated $843 million to $1.7 billion in imported food affected by the facility name, registration number, and partial address requirement for prior notice is an overestimate of the imported value likely affected for two

reasons. First, the 2.91 percent of prior notice submissions that could not supply the information required by the IFR are most likely goods imported by small or very small U.S. retailers or individuals. These goods are likely purchased for import not through the manufacturer but through middlemen, thus the importers often do not have access to, or knowledge of, the manufacturer registration number and facility address. These small U.S. retailers or individuals would not be importing large quantities of food; therefore, the value of their imported shipments should be small, much smaller in total than the $843 million to $1.7 billion estimate.

Second, we expect that most of those persons importing without knowledge of the manufacturing facility's registration number or address will adjust business practices, and perhaps their supply chain, to other entities in the supply chain that will provide them with this information for prior notice submissions. For the persons who can adjust business practices, the value of the food imported will be affected by prior notice, but not lost, because importation of those products will not cease. However, some of these businesses will find that the costs associated with changing business practices to supply the necessary information on prior notice will cause importing food products into the United States to no longer be profitable. These persons will cease importing and the value of these imported goods that is lost will be a cost of the rule. Thus we must adjust our value of imported food affected by the manufacturer identity requirement to reflect that: (1) Most importers will adjust business practices to continue importing and (2) some importers will cease doing so.

To account for the businesses that cease importing food into the United States, we estimate that 3 percent of the possible $843 million to $1.7 billion of imported food value is lost. We do this because according to the Small Business Administration, about 3 percent of small businesses closed between 2003 and 2007 (Ref 5). We estimate this value to be $25 million to about $52 million.

To account for the businesses that change importing practices, we estimate that 3,157 prior notice submitters (2.91 percent of the estimated 108,500 submitters) will spend 80 hours adjusting their supply chain.[14] As with table 4 of this document, we use the manager wage rate, including overhead, of $56.74 per hour.

Taking the midpoint of the lost value due to cessation of importation ($38.5 million) plus the costs to the 3,157 firms to change business practices, we estimate that the cost of the manufacturer identity requirement in the IFR to be about $52.8 million.

TABLE 10.—IMPORTS OF GOODS BY END USE CATEGORY AND COMMODITY (2006 SEASONALLY ADJUSTED DATA)

	Best Case Scenario (Millions)	Worst Case Scenario (Millions)
Foods, feeds, and beverages (FFB) total[1]	$64,782	$64,782
Categories of imported food products subtracted		
Meat products	$5,611	$5,611
Fish and shellfish	$9,867	
Vegetables	$4,943	
Cane and beet sugar	$1,121	
Cocoa beans	$520	
Tea, spices, etc.	$715	
Food oils, oilseeds	$1,999	
Feedstuff and food grains	$1,577	
Fruits, frozen juices	$5,503	
Nuts	$856	
Green coffee	$2,035	
Dairy products and eggs	$1,070	
Remaining value of imports that may be affected by the IFR identity of the manufacturer requirement	$28,965	$59,171
Imported value reduced further to represent that 2.91% of prior notice submissions could not provide registration number and site-specific information on prior notice for fiscal year 2007	$843	$1,722
3 percent of imported food value lost through cessation of importation into U.S.	$25.3 to $51.7 million	
Costs that reflect change in business practices for 3,157 submitters (80 hours x $56.74 per hour)	$14.3 million	
Total Value Affected	$52.8 million	

[1] Source of original data: U.S. Census Bureau, U.S. Bureau of Economic Analysis, US DOC News, November 9, 2007, pages 12 and 15, available online at *http://www.bea.gov/newsreleases/international/trade/2007/pdf/trad0907.pdf*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the FEDERAL REGISTER.)

[14] These costs are costs incurred beyond the information gathering and coordination costs presented in table 4 of this document.

Table 11 of this document presents a summary of the revised estimated costs associated with Option 1, including the marginal costs to importers who may be affected by the IFR requirement that a facility's name, registration number and partial address be provided on prior notice. Also included in the summary table 11 of this document are the discounted present value of the costs at the OMB-recommended discount rates of 3 and 7 percent.

TABLE 11.—SUMMARY OF UPDATED COSTS FOR OPTION 1—IFR

	(In Thousands of Dollars)
Learning costs	$71,037
Coordination costs	$43,574
Computer acquisition costs	$10,594
FDA prior notice system cost	$13,000
Annual costs to fill out prior notice screens	$202,500
Additional costs for BRASS users	$61,003
Lost value for produce	$4,261
Lost value for seafood	$11,533
Cost for truck time	$0
Costs of manufacturer registration number and full facility address requirement	$52,800
Total first year costs for Option 1	$470,302
Annual costs after first year[1]	$293,118
PV of costs at 7% for 20 years	$3,270,884
PV of costs at 3% for 20 years	$4,532,872

[1] Annual costs include the start-up costs of prior notice to the estimated 10 percent of new businesses that enter the market each year.

g. *Benefits of Option 1.* FDA's prior notice system provides us with enhanced knowledge of what articles of food are being imported or offered for import into the United States. Requiring prior notice of imported food shipments and defining the required data information improves our ability to detect accidental and deliberate contamination of food and to deter deliberate contamination.

Before prior notice was required, FDA received almost no advance notice information about food products entering the United States from foreign sources, or the location of the food's anticipated port of arrival. With the information required by prior notice, FDA does know what articles of food are being imported or offered for import before they arrive at the port. In the event of a credible threat for a specific product or a specific manufacturer or processor, for example, FDA will be able to mobilize and assist in the detention and removal of products that may pose a serious health threat to humans or animals.

FDA's PNC reviews prior notices and assesses the risk related to imported food shipments. Personnel at the PNC decide on a case-by-case basis whether the article of food needs to be held for examination upon arrival at the port. Having notice of an article of food imported or offered for import into the United States before it reaches a U.S. port allows FDA personnel to be ready at any time to respond to shipments that appear to pose a significant health risk to humans or animals.

h. *Cost benefit summary table.* Table 12 presents the costs of Options 1 annualized over 20 years.

TABLE 12.—UPDATED COST BENEFIT SUMMARY TABLE FOR OPTION 1

	Annualized Costs Over 20 Years at 7% Discount Rate (Millions)	Annualized Costs Over 20 Years at 3% Discount Rate (Millions)
Option 1—2 hour prior notice for vehicle, 4 hour for rail and air, 8 hour for vessels (IFR)	$304	$301
Benefits—FDA will know what articles of food are being imported or offered for import, before they arrive at the port. In the event of a threat of significant public health risk to humans or animals, FDA and CBP will be able to mobilize and assist each other in the detention and removal of those products.		

Option 2 (A and B): Minimum prior notice time frame would be 1 hour before arrival for articles of food arriving by land by road or 30 minutes for FAST participants, 2 hours before arrival for articles of food arriving by land by rail, ''wheels-up'' for flights originating in North and Central America, South America (north of the equator only), the Caribbean, and Bermuda; 4 hours for all other flights, and 8 hours before arrival for vessels; information would be submitted electronically, most changes in information would require resubmission

This option coordinates FDA minimum prior notice times with those of CBP for imports arriving by land by road, by land by rail, and by air.[15] For this option's timeframes we present two scenarios: (1) The costs and benefits of Option 2 when FDA's PNC is staffed at its current level and must review and respond to prior notices received within the minimum timeframe required and (2) the costs and benefits of Option 2 when the PNC has increased its staff to review and respond to prior notices received within the minimum timeframe required.

Option 2A: PNC is Staffed at its Current Level and Must Review and Respond to Prior Notices Within the Minimum Timeframe Required

a. *Costs of Option 2A.*

i. *1-hour or 30 minute minimum prior notice time for food arriving by land by road.* A significant portion (approximately 31 percent) of the prior notices reviewed by the PNC on a daily basis is for articles of food that arrive in the United States by land by road. The PNC conducts a more intensive security review on at least 225 to 250 prior

[15] We do not examine or integrate timeframes for products arriving by water. Persons that use vessels to import their products are usually dealing with merchandise that is not highly perishable in nature and thus less time-sensitive. FDA did not receive comments requesting the coordination of FDA and CBP timeframes for food arriving by water. FDA's current minimum prior notice timeframe for notification of food being imported by water is 8 hours before arrival; CBP's current minimum prior notice timeframe for articles being imported by water is 24 hours before arrival.

notices per day. Of these prior notices that are flagged as potentially high-risk and require a more intensive security review, about 77 (31 percent of 250) are for articles of food arriving by land by road. Complicating matters further is that prior notice submissions and expiration times are not evenly distributed over an 8-hour shift or 24-hour day; an overwhelming majority of prior notice submissions arrive during a certain 12-hour time period.

The PNC has estimated using 2007 data that most prior notices submitted for land border entries took between 30 and 110 minutes to review. This range indicates that if the prior notice minimum submission time frames were reduced from 2 hours to 1 hour, approximately 27 percent of those high risk prior notices for articles of food arriving by land by road that are selected for a more intensive review would exceed the minimum prior notice timeframe and would have to be delayed at the port of arrival while the PNC completes its review and risk assessment, as discussed earlier in this document.

If the minimum prior notice submission time for articles of food arriving by land by road is shortened to 30 minutes, the intensive security reviews (described previously) on approximately 69 percent of the high-risk targeted land border prior notices would not be completed within the prior notice timeframe. Again, as a result of the shorter timeframe, it would be necessary for the PNC to delay the movement of these shipments at the port of arrival in order to complete their review and risk assessment.

The synopsis stated in the previous paragraph implies that the PNC likely will not be able to review and respond to all prior notices received for articles of food arriving by land by road within the minimum time if the minimum prior notice submission time for articles of food arriving by land by road is either 1 hour or 30 minutes. The loss of value to fresh produce and seafood calculated in table 8 of this document reflects that some articles of food (about 27 to 69 percent of high risk prior notices) will be held at the port of arrival past the 30 minutes or 1 hour minimum prior notice submission time frame while the PNC completes its review.

In table 13 of this document, we first calculate the lost value to fresh produce and seafood as if FDA had the additional staff necessary to receive, review, and respond to prior notices within the minimum prior notice submission time[16] and then increase those costs (in terms of lost value to perishable produce and seafood arriving in the United States by land by road by 48 percent—the average of 27 and 69 percent) to account for the fact that some of these articles of food will be held up at the port pending prior notice review completion given the current PNC staffing level.

We note that we base this analysis on the typical (average) prior notice review time. Given that most prior notices for land border entries took between 30 and 110 minutes to review, the typical article of food arriving by land by road should not have to wait longer than 2 hours to enter; which is equivalent to the time that articles of food arriving by land by road will have to wait to enter the United States under Option 1. However, no matter what the minimum prior notice submission timeframes are, there will always be some articles of food whose review will take longer than the minimum allotted prior notice review timeframes.

TABLE 13.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 2A FOR SHIPMENTS ARRIVING BY LAND BY ROAD (1-HOUR OR 30-MINUTE MINIMUM NOTICE REQUIREMENT)

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
94% of total retail value for Mexican produce	$3,251,014,000
0.6% Reduction in value for 2.5% of Mexican produce	$488,000
48% Increase in lost value due wait time past minimum submission timeframe	$234,000
Total lost value for Mexican produce	$722,000
2001 Imported Canadian produce total retail value	$401,826,000
85% of total retail value for Canadian produce	$341,552,000
0.6% Reduction in value for 2.5% of Canadian produce	$51,000
48% Increase in lost value due wait time past minimum submission timeframe	$24,000
Total lost value for Canadian produce	$75,000
Total lost value for produce	$797,000
Perishable Seafood	**Dollars**
2001 Imported Mexican seafood total retail value	$112,277,000
94% of total retail value for Mexican seafood	$105,540,000

[16] We use the same probability of resubmission structure established in the analysis of the IFR (68 FR 58974 at 59025). This minimum submission time should eliminate the probability of having to resubmit prior notice for all but 2.5 percent of those perishable products imported from Canada and Mexico by land by road.

TABLE 13.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 2A FOR SHIPMENTS ARRIVING BY LAND BY ROAD (1-HOUR OR 30-MINUTE MINIMUM NOTICE REQUIREMENT)—Continued

Perishable Seafood	Dollars
2.1% Reduction in value for 2.5% of Mexican seafood	$55,000
48% Increase in lost value due wait time past minimum submission timeframe	$26,000
Total lost value for Mexican seafood	$81,000
2001 Imported Canadian seafood total retail value	$1,863,218,000
85% of total retail value for Canadian seafood	$1,583,735,000
2.1% Reduction in value for 2.5% of Canadian seafood	$831,000
48% Increase in lost value due wait time past minimum submission timeframe	$399,000
Total lost value for Canadian seafood	$1,230,000
Total lost value for seafood	$1,311,000

ii. *2-hour minimum prior notice time for food arriving by land by rail and ''wheels-up'' or 4-hour minimum prior notice time by air*. The 2-hour minimum submission time for food imported by land by rail should reduce the probability of having to resubmit prior notice for virtually all articles of food imported from Canada and Mexico by rail. However, with current staffing levels at the PNC, the possibility exists that some articles of food arriving by rail may be held at the minimum prior notice submission timeframe.

Data from the PNC for 2007 show that only about 4 percent of the articles of food imported from Canada and only about 2 percent of the articles of food imported from Mexico are imported by land by rail. Thus, articles of food arriving by land by rail represent only a slight fraction of all prior notices received and are therefore not necessarily the constraining factor when the PNC is staffed at its current level. Although we cannot rule out the possibility that some additional effects may be associated with articles of food imported from by land by rail under Option 2A, we assume those effects would be negligible. We therefore do not estimate additional costs for articles of food arriving by land by rail for Option 2A.

Reducing the prior notice submission timeframe to ''wheels-up'' for food imported by air on flights originating in North and Central America, South America (north of the equator only), the Caribbean, and Bermuda will eliminate the need for any resubmission of prior notice information for those shipments. Because prior notice does not need to be submitted until ''wheels-up,'' the probability of not having the correct prior notice information on the shipment is eliminated.

However, according to 2007 data from the PNC, if the minimum prior notice submission time is reduced from 4 hours to ''wheels up'' for some articles of food arriving by air, approximately 5 percent of the prior notice reviews would not be completed in time if flight time was less than 3 hours given the current PNC staffing level. Perishable produce and seafood imported into the United States from the Bahamas, Belize, the Dominican Republic, El Salvador, Haiti, Honduras, Jamaica, and Nicaragua can all be flown to Miami, Florida in less than 3 hours. Perishable produce and seafood imported by air from Canada and Mexico also can be flown into the United States in less than 3 hours.

Table 14 of this document shows that while there is no value loss from perishable produce and seafood having to resubmit prior notice (because the minimum prior notice submission timeframe is ''wheels-up''), there may be a loss of value for about 5 percent of perishable produce and seafood coming from the locations listed previously if the PNC does not have more than its current level of personnel to review and respond to prior notices when the minimum prior notice time frame is ''wheels-up.'' Even if the PNC cannot respond to all prior notices for articles of food arriving in the United States by air when the flight time is less than 3 hours, we would still not expect the costs (value loss on perishable produce and seafood) to importers of these articles of food to be less than the costs in Option 1 where the minimum prior notice time frame is 4 hours for articles of food arriving by air. Again we note that this analysis is based on the typical review time for prior notice for articles of food arriving by air. No matter what the minimum prior notice submission timeframe, there will always be some articles of food for which the PNC will not be able to respond and complete its risk assessment within the timeframe allotted.

To estimate the potential loss in value for perishable products due to a delay in PNC review, we use the following information in table 14 of this document: (1) The total retail value of the perishable products from Central America, adjusted to encompass perishable products coming from countries whose flight times to the United States are less than 3 hours; (2) the total retail value of perishable products from Canada and Mexico, adjusted to reflect the proportion of these articles of food that arrive into the United States by air (8 percent for Canada and 3 percent for Mexico); and (3) the estimated loss for the delay in review, which we equate to 1 hour[17] of the perishable product's lifespan.

[17] We chose 1 hour as the loss in value because the PNC, staffed at its current level, will not complete its review for articles of food arriving by air when flights are less than 3 hours and prior notice is required at ''wheels-up,'' but generally will complete its review when the minimum prior notice time for articles of food arriving by air is 4 hours.

TABLE 14.—LOSS IN VALUE CAUSED BY DELAYED PRIOR NOTICE REVIEW UNDER OPTION 2A FOR SHIPMENTS ARRIVING BY AIR ("WHEELS-UP MINIMUM NOTICE REQUIREMENT")

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
3% of total retail value for Mexican produce	$103,756,000
5% Experience a 0.6% loss in value due wait time past minimum submission timeframe	
Total lost value for Mexican produce	$31,000
2001 Imported Canadian produce total retail value	$401,826,000
8% of total retail value for Canadian produce	$32,146,000
5% Experience a 0.6% in value due wait time past minimum submission timeframe	
Total lost for Canadian produce	$10,000
2001 Imported Central American produce total retail value (coming from countries that are less than 3 hours by air to U.S.)	$62,510,000
5% Experience a 0.6% loss in value due wait time past minimum submission timeframe	
Total lost value for Central American produce	$19,000
Total lost value for produce	$60,000
Perishable Seafood	**Dollars**
2001 Imported Mexican seafood total retail value	$112,277,000
3% of total retail value for Mexican seafood	$3,368,000
5% Experience a 2.1% loss in value due wait time past minimum submission timeframe	
Total lost value for Mexican seafood	$4,000
2001 Imported Canadian seafood total retail value	$1,863,218,000
8% of total retail value for Canadian seafood	$149,057,000
5% Experience a 2.1% loss in value due wait time past minimum submission timeframe	
Total lost value for Canadian seafood	$157,000
2001 Imported Central American seafood total retail value (coming from countries that are less than 3 hours by air to U.S.)	$73,021,000
5% Experience a 2.1% loss in value due wait time past minimum submission timeframe	
Total lost value for Central American seafood	$77,000
Total lost value for seafood	$238,000

Table 15 of this document presents a summary of the costs associated with Option 2A, including the costs of the option at the OMB-recommended discount rates of 3 and 7 percent.

TABLE 15.—SUMMARY OF COSTS FOR OPTION 2A

	(In Thousands of Dollars)
Learning costs	$71,037
Coordination costs	$43,574

TABLE 15.—SUMMARY OF COSTS FOR OPTION 2A—Continued

	(In Thousands of Dollars)
Computer acquisition costs	$10,594
FDA prior notice system cost	$13,000
Annual costs to fill out prior notice screens	$202,500
Additional costs for BRASS users	$0

TABLE 15.—SUMMARY OF COSTS FOR OPTION 2A—Continued

	(In Thousands of Dollars)
Lost value for produce	$857
Lost value for seafood	$1,549
Cost for truck time	$0
Costs of manufacturer registration number and full facility address requirement	$52,800

TABLE 15.—SUMMARY OF COSTS FOR OPTION 2A—Continued

	(In Thousands of Dollars)
Total first year costs for Option 2	$395,911
Annual costs after first year	$218,727
PV of costs at 7% for 20 years	$2,482,785
PV of costs at 3% for 20 years	$3,426,122

b. *Implications for the benefits of Option 2A*. If FDA cannot appropriately review and respond to submitted prior notices within the reduced submission times frames under Option 2A given current FDA PNC staffing, there are two possible outcomes:

(1) Prior notice screening and risk assessment requirements will have to be relaxed so that fewer prior notices are forwarded to the PNC for intensive review. Taking this action will reduce the social benefits of the rule by increasing the probability that an article of food posing a significant health threat to humans or animals will enter the United States unchecked; or

(2) The PNC will be unable to complete its intensive review process for some or all of the prior notices forwarded to it within the shortened timeframes, and will frequently cause an unpredictable delay in the movement of these articles of food at the port of arrival until the PNC completes its review. This additional time for review will result in higher private costs to individuals importing articles of food into the United States than implied by the prior notice times.

Had the shortened review time frames in Option 2A been in effect in FY 2007, the PNC would have held at least 6,000 to 16,000 articles of food arriving by land by road. For air shipments, if the minimum prior notice submission time frame had been shortened to ''wheels-up'', approximately 728 prior notice reviews in FY 2007 would not have been completed for flights less than 3 hours. As a result, it would have been necessary for the PNC to delay the movement of these shipments at the port of arrival in order to complete their review and risk assessment.

To be able to review prior notices within a 1 hour prior notice submission time for articles of food arriving by land by road (given the current number and dispersion of prior notices by land by road and by other modes of transportation), the PNC estimates that it would need more than twice its current level of resources. The additional resources needed would include increasing the number of permanent employees who review prior notices from 27 to at least 50 FTEs, an increase in the number of first line supervisors, a tripling of computer access to both FDA and CBP systems, and a tripling of the current number of telephone lines.

If the minimum timeframe to submit prior notices for articles of food arriving by land by road was reduced to 30 minutes, the PNC may need 3 times the number of staff to handle the prior notice review volume within this timeframe.

c. *Cost benefit summary table*. Table 16 presents the costs of Options 2A annualized over 20 years.

TABLE 16.—UPDATED COST BENEFIT SUMMARY TABLE FOR OPTION 2A

	Annualized Costs Over 20 Years at 7% Discount Rate (Millions)	Annualized Costs Over 20 Years at 3% Discount Rate (Millions)
Option 2A—1 hour or 30 minute prior notice for food arriving by land by road, 2 hours for rail, ''wheels-up'' or 4 hours for air, 8 hour for vessels; The PNC is staffed at its current level	$230	$227
Benefits—FDA will know what articles of food are being imported or offered for import, before they arrive at the port. In the event of a potential threat of significant health risk to humans or animals, FDA will be able to mobilize and assist in the detention and removal of those products from U.S. commerce.		

Option 2B: PNC has Increased Staff to Review and Respond to Prior Notices within the Minimum Time Frame Required

a. *Costs of Option 2B*. For Option 2B we assume the PNC staff has been at least doubled, if not tripled. As stated earlier in this analysis, the PNC estimates that it would need more than twice, and possibly three times its current number of permanent employees to review prior notices if the minimum submission timeframe was 1 hour or 30 minutes before arrival for articles of food arriving by land by road, ''wheels-up'' for food arriving by air, and 2 hours for food arriving by land by rail. In addition to increasing prior notice permanent review staff from 27 to 50 or even 100 or more FTEs, an increase in the number of first line supervisors would be necessary, as would a corresponding increase in both computer access and telephone lines to FDA and CBP systems.

Assuming that the costs to hire additional FTEs including overhead is $150,000 per FTE, then doubling the number of prior notice reviewers by adding an additional 27 permanent employees to the existing 27 employees would cost at least $4,050,000; tripling the number of prior notice reviewers would cost at least $8,100,000. These costs could be higher if additional overhead is required. We include $6,075,000 in our summary cost table for Option 2B as this represents the midpoint in costs between doubling and tripling the number of permanent employees at the PNC. These costs could be higher if additional overhead is required.

i. *1-hour or 30-minute minimum prior notice time for food arriving by land by road*. Under this option, prior notices for perishable articles of food from Canada and Mexico that arrive in the United States by land by road must be submitted 1 hour or 30 minutes before the food arrives in the United States. Using the same probability of resubmission structure established in the analysis of the IFR (68 FR 58974 at 59025), this minimum submission time should eliminate the probability of having to resubmit prior notice for all but 2.5 percent of those perishable products imported from Canada and Mexico by land by road.

Using the same formula we used in the analysis of Option 1, we calculate the proportion of the total retail value of highly perishable produce and seafood from Canada and Mexico that arrives in the United States by land by road. We then adjust the new retail value, to calculate the lost product value (1 hour out of 168 hours for produce, 1 hour out

of 48 hours for seafood) for the 2.5 percent of highly perishable produce and seafood from Canada and Mexico for which prior notices would have to be resubmitted due to changes in the shipment when the minimum submission time is 1 hour or 30 minutes.[18]

Table 17 of this document shows the loss in value caused by the cancelled and resubmitted prior notice information for the 2.5 percent of imported Mexican and Canadian perishable seafood and produce affected. We do not include the cost of truck time for this option, because the minimum prior notice time for articles of food arriving by vehicle is only 1 hour or 30 minutes.

TABLE 17.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 2B FOR SHIPMENTS ARRIVING BY LAND BY ROAD (1-HOUR OR 30-MINUTE MINIMUM NOTICE REQUIREMENT)

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
94% of total retail value for Mexican produce	$3,251,014,000
0.6% Reduction in value for 2.5% of Mexican produce	$488,000
2001 Imported Canadian produce total retail value	$401,826,000
85% of total retail value for Canadian produce	$341,552,000
0.6% Reduction in value for 2.5% of Canadian produce	$51,000
Total lost value for produce	$539,000
Perishable Seafood	**Dollars**
2001 Imported Mexican seafood total retail value	$112,277,000
94% of total retail value for Mexican seafood	$105,540,000
2.1% Reduction in value for 2.5% of Mexican seafood	$55,000
2001 Imported Canadian seafood total retail value	$1,863,218,000
85% of total retail value for Canadian seafood	$1,583,638,000
2.1% Reduction in value for 2.5% of Canadian seafood	$831,000
Total lost value for seafood	$886,000

ii. *2-hour minimum prior notice time for food arriving by land by rail and ''wheels-up'' or 4-hour minimum prior notice time by air.* The 2-hour minimum submission time for food imported by land by rail should reduce the probability of having to resubmit prior notice for virtually all articles of food imported from Canada and Mexico by that mode of transport. Data from the PNC for 2007 show that only about 4 percent of the articles of food imported from Canada and only about 2 percent of the articles of food imported from Mexico are imported by land by rail. We do not calculate any lost value due to prior notice resubmission for products shipped by rail.

Reducing the prior notice submission time frame to ''wheels-up'' for food imported by air on flights originating in North and Central America, South America (north of the equator only), the Caribbean, and Bermuda will eliminate the need for any resubmission of prior notice information for those shipments. Because prior notice does not need to be submitted until ''wheels-up'', the probability of not having the correct prior notice information on the shipment is eliminated.

A 4-hour minimum prior notice time for flights not originating in North and Central America, South America (north of the equator only), the Caribbean, and Bermuda will not constrain these imports because flights from locations other than those listed will all take longer than 4 hours. Therefore, the probability of having incorrect shipment information is all but eliminated as the shipment information can be verified before the prior notice is sent.

Table 18 of this document presents a summary of the costs associated with Option 2B, including the costs of the option at the OMB-recommended discount rates of 3 and 7 percent.

TABLE 18.—SUMMARY OF COSTS FOR OPTION 2B

	(In Thousands of Dollars)
Learning costs	$71,037
Coordination costs	$43,574
Computer acquisition costs	$10,594
FDA prior notice system cost and cost of additional FTEs	$19,075
Annual costs to fill out prior notice screens	$202,500
Additional costs for BRASS users	$0
Lost value for produce	$539
Lost value for seafood	$886
Cost for truck time	$0

[18] In the IFR, we assumed a 2.5 percent prior notice resubmission rate when the minimum notice submission time for food imported by land by road was 1 hour. In this option, that minimum submission timeframe is 1 hour or 30 minutes for participants of CBP's accelerated entry programs.

TABLE 18.—SUMMARY OF COSTS FOR OPTION 2B—Continued

	(In Thousands of Dollars)
Costs of manufacturer registration number and full facility address requirement	$52,800
Total first year costs for Option 2	$401,005
Annual costs after first year	$218,353

TABLE 18.—SUMMARY OF COSTS FOR OPTION 2B—Continued

	(In Thousands of Dollars)
PV of costs at 7% for 20 years	$2,483,938
PV of costs at 3% for 20 years	$3,425,873

b. *Benefits of Option 2B*. Importers will benefit from the shorter times for submitting prior notice under Option 2B because it is less likely that articles of food will need to ''wait'' longer than the minimum prior notice time frame before entering the United States. Submitting FDA's Prior Notice information at the same time as CBP's entry information may reduce costs for submitters.[19] If FDA's Prior Notice and CBP submissions can be done simultaneously, submitters may be able to coordinate the two entry submissions so as to reduce total submission costs.

c. *Cost benefit summary table*. Table 19 presents the costs of Options 2B annualized over 20 years.

TABLE 19.—UPDATED COST BENEFIT SUMMARY TABLE FOR OPTION 2B

	Annualized Costs Over 20 Years at 7% Discount Rate (Millions)	Annualized Costs Over 20 Years at 3% Discount Rate (Millions)
Option 2B—1 hour or 30 minute prior notice for food arriving by land by road, 2 hours for rail, ''wheels-up'' or 4 hours for air, 8 hour for vessels; the PNC has increased staff	$229	$226
Benefits—FDA will know what articles of food are being imported or offered for import, before they arrive at the port. In the event of a potential threat of significant health risk to humans or animals, FDA will be able to mobilize and assist in the detention and removal of those products.		

Option 3: Minimum prior notice time is 2 hours for articles of food arriving by land by road, 4 hours for articles of food arriving by land by rail and by air, and 8 hours for articles of food arriving by water; information is submitted electronically, most changes in information require resubmission; the manufacturer registration number is not required when the submitter is unable to determine it.

Option 3 represents Option 1 but with a change to the requirement for providing the identity of the manufacturer.

As stated in Option 1, smaller importers or individuals that buy food for import into the United States from brokers, wholesalers, or foreign retailers because they are too small to buy directly from food manufacturers may find it difficult to continue importing certain products when manufacturer name, registration number, and partial address is required on prior notice. However, the final rule provides an alternative for submitters in providing the identity of the manufacturer when they are unable to determine the manufacturer's registration number. Under the final rule, submitters may provide the name and full address of the site-specific manufacturing facility along with the reason why the registration number was not provided.

Most of the comments concerned with the identity of the manufacturer were concerned about submitters not being able to provide registration number; a smaller percentage of the comments also raised concerns about being able to provide the name and address of the manufacturer. Unlike the manufacturer's registration number, which many may view as confidential business information that is to be disclosed only on a ''need to know'' basis, the name and full address of a facility is public information that not only is typically in phone books and on the Internet, but it also often is provided on documents typically exchanged between buyers and sellers (e.g., receipts, purchase orders, and bills of lading).

Even with the flexibility of not requiring the manufacturer registration number on prior notice when the submitter is unable to determine it, there will likely be some adjustment costs for small importers and individuals. These adjustments to business practices should be less costly and occur less often than those in Option 1 because importers no longer have to provide the manufacturer registration number but may instead provide only the site-specific facility name and full address and the reason the registration number is not provided.

We adjust the costs of the final rule to now reflect the requirement that if the manufacturer's registration number is not available, then the name and full address of the site-specific manufacturing facility must be provided. For Option 1, using information from table 9 of this document, we estimated that about 2.91 percent of prior notices submitted for FY 2007 did not contain the appropriate manufacturer name, address, and/or registration number as required by the codified of the IFR. With the extra flexibility in manufacturer identity allowed by Option 3, we expect the percentage of prior notices still affected by this requirement to be 1.21 percent (2.91 percent - 1.70 percent). We expect those who submitted prior notice under the IFR using reason code K—Unable to determine the registration number of the manufacturer (1.70 percent), should likely be able to submit the manufacturer site-specific name and full address as required by the prior notice final rule codified. We expect that those who submitted prior notice under the IFR using reason codes I, L, M, and O (0.56 percent, 0.16 percent, 0.16 percent, and 0.33 percent, respectively),

[19] Comments on the IFR stated several reasons for recommending that prior notice timeframes be the same as CBP's advance electronic information timeframes for food arriving by air and by land (both by road and by rail): (1) It would minimize the complexity of the process by presenting a more streamlined flow of information and avoid unnecessary duplication, (2) it would result in fewer errors, (3) it would provide better compliance rates, (4) it would allow for fewer disruptions at the border, (5) it would significantly reduce the burden on the trade community without creating additional security risks, and (6) it would allow operators at close border points to load and verify truck loads and travel routes prior to submitting notice.

could still have problems submitting the identity of the manufacturer as required by the final rule.

We must further adjust the 1.21 percent of prior notices expected to still be affected by the manufacturer identity requirement of prior notice to address the fact that the final rule is more restrictive than the IFR in regards to providing the identity of the manufacturer on prior notice for food sent by an individual as a personal gift.

In cases of food sent by an individual as a personal gift, the IFR allows the name and address on the product label to substitute for the manufacturer's name, address, and registration number on prior notice. The final rule requires that if the manufacturer's registration number is not available, the full name and address of the site-specific facility that manufactured the gift must be included on prior notice.[20] Therefore, we add 0.38 percent (for reason code G—Individual gift label name/address in lieu of registration number from the November 2004 revision of the IFR CPG) to the 1.21 percent we expect may have problems with the manufacturer identity requirement of the final rule. Thus, we expect a total of 1.59 percent of all prior notices annually to be affected by the revised manufacturer identity requirement of the final rule as opposed to the 2.91 percent affected by the manufacturer identity requirement of the IFR.

We can again use the data from table 10 of this document, adjusted now by 1.59 percent instead of 2.91 percent, to determine the potential imported food value affected by the final rule requirement that either the registration number or the name and address of the site-specific facility be included in prior notice. We repeat the data from table 10 here in table 20 of this document. As with Option 1, we present the best and worst case scenarios to represent the possible range of imported foods value that may be affected by the final rule requirement and then adjust that value to reflect changes in business practices and businesses ceasing importing food into the United States. Taking the midpoint of the lost value due to cessation of importation ($21 million) plus the costs to the 1,725 firms to change business practices, we estimate that the cost of the manufacturer identity requirement in the final rule to be about $28.8 million.

TABLE 20.—IMPORTS OF GOODS BY END USE CATEGORY AND COMMODITY (2006 SEASONALLY ADJUSTED DATA)

	Best Case Scenario (Millions)	Worst Case Scenario (Millions)
Foods, feeds, and beverages (FFB) total[1]	$64,782	$64,782
Categories of imported food products subtracted		
Meat products	$5,611	$5,611
Fish and shellfish	$9,867	
Vegetables	$4,943	
Cane and beet sugar	$1,121	
Cocoa beans	$520	
Tea, spices, etc.	$715	
Food oils, oilseeds	$1,999	
Feedstuff and food grains	$1,577	
Fruits, frozen juices	$5,503	
Nuts	$856	
Green coffee	$2,035	
Dairy products and eggs	$1,070	
Remaining value of imports that may be affected by identity of the manufacturer requirement	$28,965	$59,171
Imported value reduced further to represent that only 1.59% of prior notice submissions could not provide manufacturing facility site-specific information on prior notice for CY 2007	$461	$941
3 percent of imported food value lost through cessation of importation into U.S.	$13.8 to $28.2 million	
Costs that reflect change in business practices for 1,725 submitters (80 hours x $56.74 per hour)	$7.8 million	
Total Value Affected	$28.8 million	

[1] Source of original data: U.S. Census Bureau, U.S. Bureau of Economic Analysis, US DOC News, November 9, 2007, pages 12 and 15, available online at *http://www.bea.gov/newsreleases/international/trade/2007/pdf/trad0907.pdf*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the FEDERAL REGISTER.)

a. *Changes in to the final rule that are not quantified*. The final rule is more restrictive than the IFR in regards to providing the identity of the manufacturer on prior notice for the importation of transshipments. For transshipments, the IFR allows the name and full address of the manufacturer to substitute for the manufacturer's name and partial address, and registration number on prior notice. The final rule requires that if the manufacturer's registration number is not available, the site-specific full name and address of the facility that manufactured the article of food must be included on prior notice. We do not expect this requirement of the final rule to affect transshipments significantly as the final rule does allow the importer to provide the site-specific name and full address of the manufacturing facility instead of the registration number.

Also, for the final rule, FDA removed a few of the prior notice data elements that are required in the IFR. Specifically, submitters no longer need to include the fax number of the submitter and transmitter, the anticipated border crossing, the country

[20] FDA plans to continue its enforcement policy that it should typically consider not taking any regulatory action for prior notice violations relating to individual gifts; however, the final rule does require at least the name and full address of the site-specific facility where the gift was manufactured.

of the carrier, or the 6–digit HTS code on their prior notices. Other changes include making the shipper's registration number optional but always requiring its full addresses; and the option of submitting the tracking number for articles of food arriving by express consignment instead of anticipated arrival information when the prior notice is submitted through PNSI. However, these and other changes in filing requirements, on net, are not large enough to affect the time needed to file prior notice or the costs charged by brokers to file prior notice; therefore, we do not update the estimated time needed or the estimated costs charged to file prior notice.

Table 21 of this document presents a summary of the revised estimated costs associated with Option 3, the final rule, including the marginal costs to importers who may be affected by the identity of the manufacturer requirement. Also included in table 21 of this document are the discounted present value of the costs at the OMB-recommended discount rates of 3 and 7 percent.

TABLE 21.—SUMMARY OF COSTS FOR OPTION 3—THE FINAL RULE

	(In Thousands of Dollars)
Learning costs	$71,037
Coordination costs	$43,574
Computer acquisition costs	$10,594
FDA prior notice system cost	$13,000
Annual costs to fill out prior notice screens	$202,500
Additional costs for BRASS users	$61,003
Lost value for produce	$4,261
Lost value for seafood	$11,533
Cost for truck time	$0
Costs of change in manufacturer identity requirement	$28,800
Total first year costs for Option 3	$446,302
Annual costs after first year1	$293,118
Present value (PV) of costs at 7% for 20 years	$3,248,454
PV of costs at 3% for 20 years	$4,509,571

[1] Annual costs include the startup costs of prior notice to the estimated 10 percent of new businesses that enter the market each year.

b. *Benefits of Option 3 (final rule).* Option 3 allows for the submission of alternative manufacturer information that could be used to verify the registration status of the manufacturer. This is more flexible to importers than the requirements of Option 1, the IFR. Once the facility has been identified in the database and a valid registration has been verified, the manufacturer information required on prior notice for Option 3 provides the same level of security and assurance as the registration number required by Option 1.

c. *Cost benefit summary table.* Table 22 presents the costs of Option 3 annualized over 20 years.

TABLE 22.—UPDATED COST BENEFIT SUMMARY TABLE FOR OPTION 3

	Annualized Costs Over 20 Years at 7% Discount Rate (Millions)	Annualized Costs Over 20 Years at 3% Discount Rate (Millions)
Option 3—2-hour prior notice for vehicle, 4-hour for rail and air, 8-hour for vessels; change in the identity of the manufacturer requirement (Final rule)	$655	$652
Benefits—FDA will know what articles of food are being imported or offered for import, before they arrive at the port. In the event of a threat of significant public health risk to humans or animals, FDA will be able to mobilize and assist in the detention and removal of those products. The benefits of the final rule are enhanced by the change in the identity of the manufacturer requirement.		

Summary Table of All Options Analyzed

TABLE 23.—COSTS AND BENEFITS OF ALL OPTIONS ANALYZED

Costs	Option 1	Option 2A	Option 2B	Option 3
	In Thousands of Dollars	In Thousands of Dollars	In Thousands of Dollars	In Thousands of Dollars
Learning costs	$71,037	$71,037	$71,037	$71,037
Coordination costs	$43,574	$43,574	$43,574	$43,574
Computer acquisition costs	$10,594	$10,594	$10,594	$10,594
FDA prior notice system cost	$13,000	$13,000	$19,075	$13,000
Annual costs to fill out prior notice screens	$202,500	$202,500	$202,500	$202,500
Additional costs for BRASS users	$61,003	$0	$0	$61,003

TABLE 23.—COSTS AND BENEFITS OF ALL OPTIONS ANALYZED—Continued

Costs	Option 1	Option 2A	Option 2B	Option 3
	In Thousands of Dollars	In Thousands of Dollars	In Thousands of Dollars	In Thousands of Dollars
Lost value for produce	$4,261	$857	$539	$4,261
Lost value for seafood	$11,533	$1,549	$886	$11,533
Cost for truck time	$0	$0	$0	$0
Costs of change in manufacturer identity requirement	$52,800	$52,800	$52,800	$28,800
Total first year costs	$470,302	$395,911	$401,005	$446,302
Annual costs	$293,118	$218,727	$218,353	$293,118
PV of costs at 7% for 20 years	$3,270,884	$2,482,785	$2,483,938	$3,248,454
PV of costs at 3% for 20 years	$4,532,872	$3,426,122	$3,425,873	$4,509,571
Benefits for all options (benefits not quantified)				
FDA will know what articles of food are being imported or offered for import, before they arrive at the port. In the event of a threat of significant public health risk to humans or animals, FDA will be able to mobilize and assist in the detention and removal of those products.				

Sensitivity Analysis

The prior notice rule is unique in that the rule is published with an accompanying Compliance Policy Guide (CPG). The CPG provides guidance regarding enforcement of the prior notice requirements, including describing the circumstances where FDA and CBP should typically consider not taking any regulatory action even though certain requirements are not met. In some of these circumstances, the compliance policy applies when alternative information is submitted. If we estimate the costs of the IFR taking into account information from the IFR CPG and compare those costs to the final rule taking into account information from the final rule draft CPG, the main cost difference, as when comparing Option 1 and Option 3, is the cost of the change regarding providing the manufacturer identity.

For Option 1 (the IFR) we estimated that this cost was about $52.8 million and for Option 3 (the final rule) we estimated this cost was about $28.8 million. If information based on the CPG is included in the estimate of the cost of the IFR and final rule, then the rule costs regarding providing the identity of the manufacturer are $0 and $5.9 million respectively. The costs regarding providing the identity of the manufacturer is $0 under the IFR taking into account information from the IFR CPG based on the assumption that the submitter would use one of the reason codes in table 9 (A through O) when the submitter is not able to satisfy some or all of the requirements regarding providing the identity of the manufacturer of the product. The same cost under the final rule taking into account information from the final rule draft CPG is about $5.9 million[21] based on the assumption that if the submitter would otherwise use reason code L or M in table 9, because it was unable to determine the identity of the site-specific manufacturer, it would now change supply chains, find some other means to continue importing the food, or cease importing the food because it finds it unprofitable to attempt to continue to do so under the circumstances (0.32 percent or 31,513 of the 9.8 million entry lines for which prior notice was submitted in 2007).

As discussed in more detail elsewhere in this document, the benefit of not including reason codes L and M in the final rule draft CPG is that knowing the identity of the facility involved in the food's production, as opposed to the identity of the facility's headquarters or the invoicing firm, is critical to ensuring that FDA can effectively determine whether food should be held because it is from an unregistered manufacturing facility.

B. Small Entity Analysis (or Final Regulatory Flexibility Analysis)

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. FDA finds that this final rule may have a significant economic impact on a substantial number of small entities. While this final rule provides more flexibility to small entities than the IFR because the final rule allows the full address of the site-specific manufacturer to be given instead of the partial address and registration number on prior notice, this information may still be difficult for some businesses to obtain.

Comments on the IFR Related to Small Businesses

(Comment) One comment states that smaller U.S. importers cannot afford the additional costs charged by a broker to submit the FDA information via the ABI system. As a result, they are having their foreign suppliers submit prior notice. Some small companies estimate that, including Web site disruptions, 80 packages would take 40 to 80 hours for prior notice. The comment believes that this is totally unmanageable.

(Response) We account for increase in broker costs due to prior notice in our analysis; the comment estimate of the time it takes to complete prior notice is accurately reflected in the IFR and final rule analysis. FDA expects importers to modify their business practices to find the most cost effective way to deal with prior notice requirements. In this case, the small importer can avoid higher broker fees by having the foreign supplier submit the prior notice. Another alternative would be for the small importer to submit prior notice

[21] We calculated this cost using the same method we used in Option 1 (table 10) and Option 3 (table 20) except we use 0.32 percent for the reduction of imported value and to reduce the number of submitters from 108,500 to reflect changing business practices.

themselves through PNSI. We would expect small firms would comply in whichever manner is most cost effective. It is also possible some of the costs of prior notice could be passed on to consumers in the form of higher retail prices for some foods; in this case the small importer would not feel the complete impact of the higher broker submission costs.

(Comment) The cost to complete a prior notice to send food by mail, for companies that ship low volumes of inexpensive food products, is higher than the value of the product being shipped and therefore shipping to the United States may be discontinued.

(Response) FDA stated in the analysis of the IFR that the costs of completing prior notice submissions may be partially passed along to the consumer in the form of higher retail prices for some foods (68 FR 58974 at 59024). FDA's IFR analysis also acknowledged the possibility that companies in the business of sending small shipments of food to private individuals in the United States may stop shipping to U.S. addresses (68 FR 58974 at 59067).

(Comment) A number of postal services take issue with the requiring of filing prior notice for personal food items. The comments state that the labor-intensive process of mailing personal food items will cause a decrease in the items being shipped, thus decreasing the business of the mail system.

(Response) When the cost of shipping increases, the number of items shipped is indeed likely to decrease. Although some of reduction in postal revenues would represent a dead-weight loss, it is primarily a transfer, not a social cost and therefore is not included in the cost estimates for this analysis.

(Comment) Several comments express concern about their continued ability to import fine wine because although they can obtain the name and address of the site-specific manufacturer of the wine, obtaining the manufacturers' (i.e., the wineries') registration numbers for these products often is difficult to those not in the winery's direct distribution chain. The comments state that smaller importers, wholesalers, retailers, restaurants, clubs, or hotels will be negatively affected by not having the registration number for the manufacturer of the fine wine. The comments further state that the prior notice rule will negatively impact small producers by reducing the number of potential representatives and sales venues as secondary fine wine market importers disappear.

(Response) FDA does not believe that the fine wine industry will be negatively affected by the prior notice final rule. The final rule at § 1.281(a)(6) requires the identity of the manufacturer as follows: The name of the manufacturer and either: (1) The registration number, city, and country of the manufacturer or (2) both the full address of the manufacturer and the reason the registration number is not provided (hereafter ''the identity of the manufacturer''). Even if a wine importer, retailer, or wholesaler cannot obtain the registration number (e.g., the winery refuses to disclose its registration number because the importer, retailer, or wholesaler is outside the winery's distribution chain), the prior notice can include the name and full address of the winery, which comments stated is obtainable. We do not include additional costs to fine wine manufacturers or importers in this final rule analysis; however, we do refine the estimate of the difference between the IFR requirements and this final rule modification.

(Comment) Smaller importers that buy from brokers and wholesalers because they are too small to buy directly from larger food manufacturers will be put out of business. These smaller importers allege that they will not be able to provide the manufacturers' registration numbers on their prior notices as required by the final rule. The comments argue that the registration number requirement interferes with small businesses' rights to free trade because now only larger businesses that deal with the manufacturers directly, rather than buying through brokers and wholesalers, will be able to obtain the manufacturer's information that is required for prior notice.

(Response) The final rule provides an alternative for submitters to provide the identity of the manufacturer when the manufacturer's registration number is not obtainable. Under the final rule, submitters may provide the name and full address of the site-specific manufacturing facility along with a reason as to why the registration number was not used in the prior notice.

(Comment) While most comments state that the name and address of the manufacturer could be submitted in prior notice, one comment states that re-sellers will not normally supply the name of their supplier or the name of the manufacturer of a particular product to their customers. The comment asserts that supplying the name of the manufacturer would allow that customer to circumvent the re-seller and attempt to make direct contact with the supplier or manufacturer, thus taking business away from the re-seller. Another comment states, however, that smaller importers buy from brokers and wholesalers specifically because they are too small to buy directly from larger manufacturers and other corporations, as large entities typically would not find it cost-effective to deal with smaller importers.

(Response) Depending on the business atmosphere, FDA believes that it is likely that many resellers will be willing to supply the name and the address of the manufacturers of the products they sell. Unlike the manufacturer's registration number, which many may view as confidential business information that is to be disclosed only on a ''need to know'' basis, the name and full address of a facility is public information that not only is typically in phone books and on the Internet, but it also often is provided on documents typically exchanged between buyers and sellers (e.g., receipts, purchase orders, and bills of lading). The issues discussed in these comments are addressed further in Options 1 and 3.

Costs per Small Entity

FDA does not have detailed information on the approximately 108,500 persons (e.g. exporters, U.S. importers or U.S. purchasers or their agents) that will be primarily responsible for submitting the prior notice information; table 3 gives a description of some of these entities. Many of these submitters may have fewer than 100 employees[22], thus making them small businesses as defined by the Small Business Administration. Because many of the prior notice submitters are likely to be small businesses, all options considered in the Final Regulatory Impact Analysis in section IV.A of this document are regulatory relief options.

FDA does not have enough information about the 108,500 prior notice submitters to perform a detailed analysis of the costs per small business by industry sector. We do, however, update some of the costs per submitter that were presented in the IFR Regulatory Flexibility Analysis (68 FR 59066). Table 24 of this document shows the average costs per submitter to learn the rule, coordinate information, and submit prior notice. Table 24 also shows the average costs to the submitter to absorb the costs of not being able to use BRASS, to absorb costs of lost value of perishable products, and the cost regarding providing the identity of the manufacturer.

[22] For NAICS industry sector 42-Wholesale Trade, a business is defined as small by SBA if it has fewer than 100 employees.

TABLE 24.—COSTS PER SUBMITTER FOR PN FINAL RULE CHOSEN OPTION

Activity	Total Costs	Cost per importer (n = 108,500)
Learning costs	$71,037,000	$655
Coordination costs	$43,574,000	$402
Annual costs to fill out prior notice screens	$202,500,000	$1,866
Costs for BRASS users	$61,003,000	$562
Lost value for perishables	$15,794,000	$146
Costs of change in manufacturer identity requirement	$28,800,000	$265
Total estimated average costs per submitter		$3,896

C. Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) Major Rule

SBREFA (Public Law 104–121) defines a major rule for the purpose of Congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this final rule is not a major rule for the purpose of Congressional review.

V. Paperwork Reduction Act of 1995

The collection of information provisions of this final rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 1.280, 1.281, 1.282, 1.283, and 1.285 have been approved under OMB Control No. 0910–0520.

From the IFR to the final rule, FDA removed a few of the required prior notice data elements. Specifically, submitters no longer need to include the fax number of the submitter and transmitter, the anticipated border crossing, the country of the carrier, or the 6–digit HTS code in their prior notices. Other changes include the addition of the registration number of the transshipper for articles of food for transshipment, storage and export, or manipulation and export; flexibility in submitting the registration number and the city and country of the manufacturer and shipper instead of full addresses of these entities; and the option of submitting the tracking number for articles of food arriving by express consignment instead of anticipated arrival information when the prior notice is submitted through PNSI. However, these and other changes in filing requirements, on net, are not large enough to affect the time needed to file prior notice or the costs charged by brokers to file prior notice. Therefore we do not re-estimate a Paperwork Reduction Act burden for this final rule.

VI. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Taube, Anthony C., Memorandum to file, November 13, 2006.

2. U.S. Customs and Border Protection, *http://www.cbp.gov/linkhandler/cgov/trade/cargo_security/ctpat/fast/fast_ref_guide.ctt/fast_ref_guide.pdf*.

3. The NAICS Association, September 29, 2008, available online at *http://www.naics.com*.

4. U.S. International Trade in Goods and Services September 2007, U.S. Census Bureau, U.S. Bureau of Economic Analysis, US DOC News, November 9, 2007, pages 12 and 15, available online at *http://www.bea.gov/newsreleases/international/trade/2007/pdf/trad0907.pdf*.

5. The Small Business Administration, Office of Advocacy, Frequently Asked Questions Updated September 2008, available online at *http://www.sba.gov/advo/stats/sbfaq.pdf*.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Subpart I, consisting of §§ 1.276 through 1.285, is revised to read as follows:

Subpart I—PRIOR NOTICE OF IMPORTED FOOD

General Provisions

Sec.
1.276 What definitions apply to this subpart?
1.277 What is the scope of this subpart?

Requirements to Submit Prior Notice of Imported Food

Sec.
1.278 Who is authorized to submit prior notice?
1.279 When must prior notice be submitted to FDA?
1.280 How must you submit prior notice?
1.281 What information must be in a prior notice?
1.282 What must you do if information changes after you have received confirmation of a prior notice from FDA?

Consequences

Sec.
1.283 What happens to food that is imported or offered for import without adequate prior notice?
1.284 What are the other consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?
1.285 What happens to food that is imported or offered for import from unregistered facilities that are required to register under subpart H of this part?

General Provisions

§ 1.276 What definitions apply to this subpart?

(a) *The act* means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart, unless defined in this section.

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article originates* means FDA Country of Production.

(3) *Country from which the article is shipped* means the country in which the article of food is loaded onto the conveyance that brings it to the United States or, in the case of food sent by international mail, the country from which the article is mailed.

(4) *FDA Country of Production* means: (i) For an article of food that is in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish, including seafood that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is in its natural state was grown, including harvested or collected and readied for shipment, in a Territory, the FDA Country of Production is the United States.

(ii) For an article of food that is no longer in its natural state, the country where the article was made; except that, if an article of food is made from wild fish, including seafood, aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in a Territory, the FDA Country of Production is the United States.

(5) *Food* has the meaning given in section 201(f) of the act, except as provided in paragraph (b)(5)(i) of this section.

(i) For purposes of this subpart, food does not include:

(A) Food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)); or

(B) Pesticides as defined in 7 U.S.C. 136(u).

(ii) Examples of food include fruits, vegetables, fish, including seafood, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

(6) *Full address* means the facility's street name and number; suite/unit number, as appropriate; city; Province or State as appropriate; mail code as appropriate; and country.

(7) *Grower* means a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.

(8) *International mail* means foreign national mail services. International mail does not include express consignment operators or carriers or other private delivery services unless such service is operating under contract as an agent or extension of a foreign mail service.

(9) *Manufacturer* means the last facility, as that word is defined in § 1.227(b)(2), that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a *de minimis* nature. If the food undergoes further manufacturing/processing that exceeds an activity of a *de minimis* nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer.

(10) *No longer in its natural state* means that an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Crops that have been cleaned (e.g., dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, or polished are still in their natural state for purposes of this subpart. Whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of this subpart.

(11) *Port of arrival* means the water, air, or land port at which the article of food is imported or offered for import into the United States. For an article of food arriving by water or air, this is the port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the United States. The port of arrival may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the U.S. Customs and Border Protection (CBP).

(12) *Port of entry*, in section 801(m) and (l) of the act (21 U.S.C. 381(m) and (l)), means the port of entry as defined in 19 CFR 101.1.

(13) *Registration number* means the registration number assigned to a facility by FDA under section 415 of the act (21 U.S.C. 350d) and subpart H of this part.

(14) *Shipper* means the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail or express consignment operators or carriers or other private delivery service to the United States.

(15) *United States* means the Customs territory of the United States (i.e., the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico), but not the Territories.

(16) *You* means the person submitting the prior notice, i.e., the submitter or the transmitter, if any.

§ 1.277 What is the scope of this subpart?

(a) This subpart applies to all food for humans and other animals that is imported or offered for import into the

United States for use, storage, or distribution in the United States, including food for gifts and trade and quality assurance/quality control samples, food for transshipment through the United States to another country, food for future export, and food for use in a U.S. Foreign Trade Zone.

(b) Notwithstanding paragraph (a) of this section, this subpart does not apply to:

(1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States;

(2) Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States;

(3) Food that is imported then exported without leaving the port of arrival until export;

(4) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(5) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*);

(6) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*); and

(7) Articles of food subject to Article 27(3) of The Vienna Convention on Diplomatic Relations (1961), i.e., shipped as baggage or cargo constituting the diplomatic bag.

Requirements To Submit Prior Notice of Imported Food

§ 1.278 Who is authorized to submit prior notice?

A prior notice for an article of food may be submitted by any person with knowledge of the required information. This person is the submitter. The submitter also may use another person to transmit the required information on his/her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person.

§ 1.279 When must prior notice be submitted to FDA?

(a) Except as provided in paragraph (c) of this section, you must submit the prior notice to FDA and the prior notice submission must be confirmed by FDA for review as follows:

(1) If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival;

(2) If the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival;

(3) If the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival; or

(4) If the article of food is arriving by water, no less than 8 hours before arriving at the port of arrival.

(b) Except in the case of an article of food imported or offered for import by international mail:

(1) If prior notice is submitted via Automated Broker Interface/Automated Commercial System (ABI/ACS), you may not submit prior notice more than 30-calendar days before the anticipated date of arrival.

(2) If prior notice is submitted via the FDA Prior Notice System Interface (FDA PNSI), you may not submit prior notice more than 15-calendar days before the anticipated date of arrival.

(c) Notwithstanding paragraphs (a) and (b) of this section, if the article of food is arriving by international mail, you must submit the prior notice before the article of food is sent to the United States.

(d) FDA will notify you that your prior notice has been confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(e) The PN Confirmation Number must accompany any article of food arriving by international mail. The PN Confirmation Number must appear on the Customs Declaration (e.g., CN22 or CN23 or U.S. equivalent) that accompanies the package.

(f) A copy of the confirmation, including the PN Confirmation Number, must accompany any article of food that is subject to this subpart when it is carried by or otherwise accompanies an individual when arriving in the United States. The copy of the confirmation must be provided to U.S. Customs and Border Protection (CBP) or FDA upon arrival.

(g) The PN Confirmation Number must accompany any article of food for which the prior notice was submitted through the FDA PNSI when the article arrives in the United States and must be provided to CBP or FDA upon arrival.

§ 1.280 How must you submit prior notice?

(a) You must submit the prior notice electronically to FDA. You must submit all prior notice information in the English language, except that an individual's name, the name of a company, and the name of a street may be submitted in a foreign language. All information, including the items listed in the previous sentence, must be submitted using the Latin (Roman) alphabet. Unless paragraph (c) of this section applies, you must submit prior notice through:

(1) The U.S. Customs and Border Protection (CBP) Automated Broker Interface of the Automated Commercial System (ABI/ACS); or

(2) The FDA PNSI at *http://www.access.fda.gov*. You must submit prior notice through the FDA Prior Notice System Interface (FDA PNSI) for articles of food imported or offered for import by international mail, and other transaction types that cannot be made through ABI/ACS. Prior notice for articles that have been refused under section 801(m)(1) of the act and under this subpart must be submitted through the FDA PNSI until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions.

(b) If a customhouse broker's or self-filer's system is not working or if the ABI/ACS interface is not working, prior notice must be submitted through the FDA PNSI.

(c) If FDA determines that FDA PNSI or the Operational and Administration System for Import Support (OASIS) is not working, FDA will post prominent notification and instructions at *http://www.fda.gov*. FDA will accept prior notice submissions in the format it deems appropriate during the system(s) outage.

§ 1.281 What information must be in a prior notice?

(a) *General*. For each article of food that is imported or offered for import into the United States, except by international mail, you must submit the information for the article that is required in paragraphs (a)(1) through (a)(17) of this section:

(1) The name of the individual submitting the prior notice and his/her business address, phone number, and e-mail address, and the name and address of the submitting firm, if applicable. If the business address of the individual submitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, phone number, and e-

mail address. If the business address of the individual transmitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

(3) The entry type;

(4) The U.S. Customs and Border Protection (CBP) entry identifier (e.g., CBP entry number or in-bond number), if available;

(5) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The estimated quantity of food that will be shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, e.g., low-acid canned foods, by § 113.60(c) of this chapter; acidified foods, by § 114.80(b) of this chapter; and infant formula, by § 106.90 of this chapter;

(6) For an article of food that is no longer in its natural state, the identity of the manufacturer, as follows:

(i) The name of the manufacturer; and

(ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided;

(7) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(8) The FDA Country of Production;

(9) If the shipper is different from the manufacturer, the identity of the shipper, as follows:

(i) The name of the shipper; and

(ii) The full address of the shipper. If the address of the shipper is a registered facility, you also may submit the registration number of the shipper's registered facility;

(10) The country from which the article is shipped;

(11) Anticipated arrival information about the article of food being imported or offered for import, as follows:

(i) The anticipated port of arrival;

(ii) The anticipated date on which the article of food will arrive at the anticipated port of arrival;

(iii) The anticipated time of that arrival; and

(iv) Notwithstanding paragraphs (a)(11)(i) through (a)(11)(iii) of this section, if the article of food is arriving by express consignment operator or carrier, and neither the submitter nor transmitter is the express consignment operator or carrier, and prior notice is submitted via the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the information required in paragraphs (a)(11)(i) through (a)(11)(iii) of this section. Until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions, the tracking number may not be submitted in lieu of information required in paragraphs (a)(11)(i) through (a)(11)(iii) of this section, if the prior notice is submitted via ABI/ACS.

(12) The name and full address of the importer. If the business address of the importer is a registered facility, you also may submit the registration number of the importer's registered facility. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(13) The name and full address of the owner if different from the importer or ultimate consignee. If the business address of the owner is a registered facility, you also may submit the registration number of the owner's registered facility. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and full address of the ultimate consignee. If the business address of the ultimate consignee is a registered facility, you also may submit the registration number of the ultimate consignee's registered facility. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) code of the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States to the port of arrival, or if this code is not applicable, then the name of the carrier. If the carrier is a privately owned vehicle, the license plate number of the vehicle and the State or Province that issued the license plate number;

(17) Planned shipment information, as applicable to the mode of transportation and when it exists:

(i) The Airway Bill number(s) or Bill of Lading number(s), as applicable. This information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States. If the article of food is arriving by express consignment operator or carrier, and neither the submitter nor transmitter is the express consignment operator or carrier, and the prior notice is submitted via the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), as applicable. Until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions, the tracking number may not be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), if the prior notice is submitted via ABI/ACS;

(ii) For food arriving by ocean vessel, the vessel name and voyage number;

(iii) For food arriving by air carrier, the flight number. If the article of food is arriving by express consignment operator or carrier, and neither the submitter nor transmitter is the express consignment operator or carrier, and the prior notice is submitted via the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the flight number. Until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions, the tracking number may not be submitted in lieu of the flight number, if the prior notice is submitted via ABI/ACS;

(iv) For food arriving by truck, bus, or rail, the trip number;

(v) For food arriving as containerized cargo by water, air, or land, the container number(s). This information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States; and

(vi) For food arriving by rail, the car number. This information is not required for an article of food when carried by or otherwise accompanying an individual.

(b) *Articles arriving by international mail.* For each article of food that is imported or offered for import into the United States by international mail, you must submit the information for the article that is required in paragraphs (b)(1) through (b)(11) of this section:

(1) The name of the individual submitting the prior notice and his/her

business address, phone number, and e-mail address, and the name and address of the submitting firm, if applicable. If the business address of the individual submitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, phone number, and e-mail address. If the business address of the individual transmitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

(3) The entry type (which will be a mail entry);

(4) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The estimated quantity of food that will be shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, e.g., low-acid canned foods, by § 113.60(c) of this chapter; acidified foods, by § 114.80(b) of this chapter; and infant formula, § 106.90 of this chapter;

(5) For an article of food that is no longer in its natural state, the identity of the manufacturer, as follows:

(i) The name of the manufacturer; and

(ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided;

(6) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(7) The FDA Country of Production;

(8) If the shipper is different from the manufacturer, the identity of the shipper, as follows:

(i) The name of the shipper; and

(ii) The full address of the shipper. If the address of the shipper is a registered facility, you also may submit the registration number of the shipper's registered facility;

(9) The country from which the article is shipped (i.e., mailed);

(10) The anticipated date of mailing; and

(11) The name and address of the U.S. recipient.

(c) *Refused articles*. If the article of food has been refused under section 801(m)(1) of the act and under this subpart, you must submit the information for the article that is required in paragraphs (c)(1) through (c)(18) of this section. However, if the refusal is based on § 1.283(a)(1)(iii) (Untimely Prior Notice), you do not have to resubmit any information previously submitted unless it has changed or the article has been exported and the original prior notice was submitted through ABI/ACS. If the refusal is based on § 1.283(a)(1)(ii), you should cancel the previous submission per § 1.282(b) and (c).

(1) The name of the individual submitting the prior notice and his/her business address, phone number, and e-mail address, and the name and address of the submitting firm, if applicable. If the business address of the individual submitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, phone number, and e-mail address. If the business address of the individual transmitting the prior notice is a registered facility, then the facility's registration number, city, and country may be provided instead of the facility's full address;

(3) The entry type;

(4) The CBP entry identifier (e.g., CBP entry number or in-bond number), if available;

(5) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The quantity of food that was shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, e.g., low-acid canned foods, by § 113.60(c) of this chapter; acidified foods, by § 114.80(b) of this chapter; and infant formula, by § 106.90 of this chapter;

(6) For an article of food that is no longer in its natural state, the identity of the manufacturer, as follows:

(i) The name of the manufacturer; and

(ii) Either the registration number, city, and country of the manufacturer or both the full address of the manufacturer and the reason the registration number is not provided;

(7) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated and the submitter does not know any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(8) The FDA Country of Production;

(9) If the shipper is different from the manufacturer, the identity of the shipper, as follows:

(i) The name of the shipper; and

(ii) The full address of the shipper. If the address of the shipper is a registered facility, you also may submit the registration number of the shipper's registered facility;

(10) The country from which the article is shipped;

(11) Arrival information about the article of food being imported or offered for import, as follows:

(i) The port of arrival; and

(ii) The date on which the article of food arrived at the port of arrival.

(iii) Notwithstanding paragraph (c)(11) of this section, if the article of food arrived by express consignment operator or carrier, and neither the submitter nor transmitter is the express consignment operator or carrier, and the prior notice is submitted via the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the information required in paragraph (c)(11) of this section. Until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions, the tracking number may not be submitted in lieu of information required in paragraph (c)(11) of this section, if the prior notice is submitted via ABI/ACS;

(12) The name and full address of the importer. If the business address of the importer is a registered facility, you also may submit the registration number of the importer's registered facility. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(13) The name and full address of the owner, if different from the importer or

ultimate consignee. If the business address of the owner is a registered facility, you also may submit the registration number of the importer's registered facility. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and full address of the ultimate consignee. If the business address of the ultimate consignee is a registered facility, you also may submit the registration number of the ultimate consignee's registered facility. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The SCAC or IATA code of the carrier which carried the article of food from the country from which the article is shipped to the United States to the port of arrival, or if this code is not applicable, then the name of the carrier. If the carrier is a privately owned vehicle, the license plate number of the vehicle and the State or Province that issued the license plate number;

(17) Shipment information, as applicable to the mode of transportation and when it exists:

(i) The Airway Bill number(s) or Bill of Lading number(s), as applicable; however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States. If the article of food arrived by express consignment operator or carrier, and neither the submitter nor transmitter is the express consignment operator or carrier, and the prior notice is submitted via the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), as applicable. Until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions, the tracking number may not be submitted in lieu of the Airway Bill number(s) or Bill of Lading number(s), if the prior notice is submitted via ABI/ACS;

(ii) For food that arrived by ocean vessel, the vessel name and voyage number;

(iii) For food that arrived by air carrier, the flight number. If the article of food arrived by express consignment operator or carrier, and neither the submitter nor transmitter is the express consignment operator or carrier, and the prior notice is submitted via the FDA PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of the flight number. Until such time as FDA and CBP issue a determination that ACS or its successor system can accommodate such transactions, the tracking number may not be submitted in lieu of the flight number, if the prior notice is submitted via ABI/ACS;

(iv) For food that arrived by truck, bus, or rail, the trip number;

(v) For food that arrived as containerized cargo by water, air, or land, the container number(s); however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States; and

(vi) For food that arrived by rail, the car number; however, this information is not required for an article of food when carried by or otherwise accompanying an individual;

(18) The location and address where the article of refused food will be or is being held, the date the article has arrived or will arrive at that location, and identification of a contact at that location.

§ 1.282 What must you do if information changes after you have received confirmation of a prior notice from FDA?

(a)(1) If any of the information required in § 1.281(a), except the information required in:

(i) Section 1.281(a)(5)(iii) (quantity),

(ii) Section 1.281(a)(11) (anticipated arrival information), or

(iii) Section 1.281(a)(17) (planned shipment information), changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart unless the article of food will not be offered for import or imported into the United States.

(2) If any of the information required in § 1.281(b), except the information required in § 1.281(b)(10) (the anticipated date of mailing), changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart, unless the article of food will not be offered for import or imported into the United States.

(b) If you submitted the prior notice via the FDA PNSI, you should cancel the prior notice via the FDA PNSI.

(c) If you submitted the prior notice via ABI/ACS, you should cancel the prior notice via ACS by requesting that CBP cancel the entry.

Consequences

§ 1.283 What happens to food that is imported or offered for import without adequate prior notice?

(a) For each article of food that is imported or offered for import into the United States, except for food arriving by international mail or food carried by or otherwise accompanying an individual, the consequences are:

(1) *Inadequate prior notice*—(i) *No prior notice*. If an article of food arrives at the port of arrival and no prior notice has been submitted and confirmed by FDA for review, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)). If an article of food is refused for lack of prior notice, unless U.S. Customs and Border Protection (CBP) concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(ii) *Inaccurate prior notice*. If prior notice has been submitted and confirmed by FDA for review, but upon review of the notice or examination of the article of food, the notice is determined to be inaccurate, the food is subject to refusal of admission under section 801(m)(1) of the act. If the article of food is refused due to inaccurate prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(iii) *Untimely prior notice*. If prior notice has been submitted and confirmed by FDA for review, but the full time that applies under § 1.279 for prior notice has not elapsed when the article of food arrives, the food is subject to refusal of admission under section 801(m)(1) of the act, unless FDA has already reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response. If the article of food is refused due to untimely prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(2) *Status and movement of refused food*. (i) An article of food that has been refused under section 801(m)(1) of the act and paragraph (a) of this section shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended (19 U.S.C. 1490).

(ii) Refused food must be moved under appropriate custodial bond unless immediately exported under CBP supervision. If the food is to be held at the port, FDA must be notified of the location where the food is held at that port before the food is moved there. If the food is to be held at a secure facility outside the port, FDA must be notified of the location of the secure facility before the food is moved there. The refused food shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. If the food is to be held at a secure facility outside a port, the food must be taken directly to that secure facility.

(3) *Segregation of refused foods*. If an article of food that is refused is part of a shipment that contains articles of food that have not been placed under hold or other merchandise not subject to this subpart, the refused article of food may be segregated from the rest of the shipment. This segregation must take place where the article is held. FDA or CBP may supervise segregation. If FDA or CBP determines that supervision is necessary, segregation must not take place without supervision.

(4) *Costs*. Neither FDA nor CBP are liable for transportation, storage, or other expenses resulting from refusal.

(5) *Export after refusal*. An article of food that has been refused under paragraph (a) of this section may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority. If an article of food that has been refused admission under paragraph (a) of this section is exported, the prior notice should be cancelled within 5-business days of exportation.

(6) *No post-refusal submission or request for review*. If an article of food is refused under section 801(m)(1) of the act and no prior notice is submitted or resubmitted, no request for FDA review is submitted in accordance with paragraph (d) of this section, or export has not occurred in accordance with paragraph (a)(5) of this section, the article of food shall be dealt with as set forth in CBP regulations relating to general order merchandise (19 CFR part 127), except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.

(b) *Food carried by or otherwise accompanying an individual*. If food carried by or otherwise accompanying an individual arriving in the United States is not for personal use and does not have adequate prior notice or the individual cannot provide FDA or CBP with a copy of the prior notice (PN) confirmation, the food is subject to refusal of admission under section 801(m)(1) of the act. If before leaving the port, the individual does not arrange to have the food held at the port or exported, FDA or CBP may destroy the article of food.

(c) *Post-Refusal prior notice submissions*. (1) If an article of food is refused under paragraph (a)(1)(i) of this section (no prior notice) and the food is not exported, prior notice must be submitted in accordance with §§ 1.280 and 1.281(c).

(2) If an article of food is refused under paragraph (a)(1)(ii) of this section (inaccurate prior notice) and the food is not exported, the prior notice should be canceled in accordance with § 1.282 and you must resubmit prior notice in accordance with §§ 1.280 and 1.281(c).

(3) Once the prior notice has been submitted or resubmitted and confirmed by FDA for review, FDA will endeavor to review and respond to the prior notice submission within the timeframes set out in § 1.279.

(d) *FDA review after refusal*. (1) If an article of food has been refused admission under section 801(m)(1) of the act, a request may be submitted asking FDA to review whether the article is subject to the requirements of this subpart under § 1.277, or whether the information submitted in a prior notice is complete and accurate. A request for review may not be used to submit prior notice or to resubmit an inaccurate prior notice.

(2) A request may be submitted only by the carrier, submitter, importer, owner, or ultimate consignee. A request must identify which one the requester is.

(3) A request must be submitted in writing to FDA and delivered by fax or e-mail. The location for receipt of a request is listed at *http://www.fda.gov*—see Prior Notice. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each refused article.

(4) The request must be submitted within 5-calendar days of the refusal. FDA will review and respond within 5-calendar days of receiving the request.

(5) If FDA determines that the article is not subject to the requirements of this subpart under § 1.277 or that the prior notice submission is complete and accurate, it will notify the requester, the transmitter, and CBP that the food is no longer subject to refusal under section 801(m)(1) of the act.

(e) *International mail*. If an article of food arrives by international mail with inadequate prior notice or the PN confirmation number is not affixed as required, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If FDA refuses the article under section 801(m)(1) of the act and there is a return address, the parcel may be returned to sender marked ''No Prior Notice—FDA Refused.'' If the article is refused and there is no return address or FDA determines that the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender or, if there is no return address, destroy the parcel, at FDA expense.

(f) *Prohibitions on delivery and transfer*. (1) Notwithstanding section 801(b) of the act, an article of food refused under section 801(m)(1) of the act may not be delivered to the importer, owner, or ultimate consignee until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801(m)(1) of the act.

(2) During the time an article of food that has been refused under section 801(m)(1) of the act is held, the article may not be transferred by any person from the port or other designated secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food no longer is refused admission under section 801(m)(1) of the act. After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

(g) *Relationship to other admissibility decisions*. A determination that an article of food is no longer refused under section 801(m)(1) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer refused under section 801(m)(1) of the act does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

§ 1.284 What are the other consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?

(a) The importing or offering for import into the United States of an article of food in violation of the requirements of section 801(m) of the act, including the requirements of this subpart, is a prohibited act under

section 301(ee) of the act (21 U.S.C. 331(ee)).

(b) Section 301 of the act prohibits the doing of certain acts or causing such acts to be done.

(1) Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin persons who commit a prohibited act.

(2) Under sections 301 and 303 of the act (21 U.S.C. 331 and 333), the United States can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act.

(c) Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States or any person who has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

§ 1.285 What happens to food that is imported or offered for import from unregistered facilities that are required to register under subpart H of this part?

(a) *Consequences*. If an article of food from a foreign facility that is not registered as required under section 415 of the act (21 U.S.C. 350d) and subpart H of this part is imported or offered for import into the United States, the food is subject to being held under section 801(l) of the act (21 U.S.C. 381(l)).

(b) *Hold*. Unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival, if an article of food has been placed under hold under section 801(l) of the act, it must be held within the port of entry for the article unless directed by CBP or FDA.

(c) *Status and movement of held food*. (1) An article of food that has been placed under hold under section 801(l) of the act shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended (19 U.S.C. 1490).

(2) Food under hold under section 801(l) of the act must be moved under appropriate custodial bond unless immediately exported under CBP supervision. If the food is to be held at the port, FDA must be notified of the location where the food is held at the port before the food is moved there. If the food is to be held at a secure facility outside the port, FDA must be notified of the location of the secure facility before the food is moved there. The food subject to hold shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. If the food is to be held at a secure facility outside a port, the food must be taken directly to that secure facility.

(d) *Segregation of held foods*. If an article of food that has been placed under hold under section 801(l) of the act is part of a shipment that contains articles that have not been placed under hold, the food under hold may be segregated from the rest of the shipment. This segregation must take place where the article is held. FDA or CBP may supervise segregation. If FDA or CBP determine that supervision is necessary, segregation must not take place without supervision.

(e) *Costs*. Neither FDA nor CBP will be liable for transportation, storage, or other expenses resulting from any hold.

(f) *Export after hold*. An article of food that has been placed under hold under section 801(l) of the act may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority.

(g) *No registration or request for review*. If an article of food is placed under hold under section 801(l) of the act and no registration number or request for FDA review is submitted in accordance with paragraph (j) of this section or export has not occurred in accordance with paragraph (f) of this section, the food shall be dealt with as set forth in CBP regulations relating to general order merchandise, except that, unless otherwise agreed to by CBP and FDA, the article may only be sold for export or destroyed.

(h) *Food carried by or otherwise accompanying an individual*. If an article of food carried by or otherwise accompanying an individual arriving in the United States is not for personal use and is placed under hold under section 801(l) of the act because it is from a foreign facility that is not registered as required under section 415 of the act and subpart H of this part, the individual may arrange to have the food held at the port or exported. If such arrangements cannot be made, the article of food may be destroyed.

(i) *Post-hold submissions*. (1) To resolve a hold, if an article of food is held under paragraph (b) of this section because it is from a foreign facility that is not registered, the facility must be registered and a registration number must be obtained.

(2) The FDA Prior Notice Center must be notified of the applicable registration number in writing. The notification must provide the name and contact information for the person submitting the information. The notification may be delivered to FDA by fax or e-mail. The contact information for these delivery methods is listed at *http://www.fda.gov*—see Prior Notice. The notification should include the applicable CBP entry identifier.

(3) If FDA determines that the article is no longer subject to hold, it will notify the person who provided the registration information and CBP that the food is no longer subject to hold under section 801(l) of the act.

(j) *FDA review after hold*. (1) If an article of food has been placed under hold under section 801(l) of the act, a request may be submitted asking FDA to review whether the facility associated with the article is subject to the requirements of section 415 of the act. A request for review may not be submitted to obtain a registration number.

(2) A request may be submitted only by the carrier, submitter, importer, owner, or ultimate consignee of the article. A request must identify which one the requestor is.

(3) A request must be submitted in writing to FDA and delivered by fax or e-mail. The location for receipt of a request is listed at *http://www.fda.gov*—see Prior Notice. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each article under hold.

(4) The request must be submitted within 5-calendar days of the hold. FDA will review and respond within 5-calendar days of receiving the request.

(5) If FDA determines that the article is not from a facility subject to the requirements of section 415 of the act, it will notify the requestor and CBP that the food is no longer subject to hold under section 801(l) of the act.

(k) *International mail*. If an article of food that arrives by international mail is from a foreign facility that is not registered as required under section 415 of the act and subpart H of this part, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If the article is placed under hold under section 801(l) of the act and there is a return address, the parcel may be returned to sender marked ''No Registration—No Admission Permitted.'' If the article is under hold and there is no return address or FDA determines that the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender marked ''No Registration—No Admission Permitted'' or, if there is no return address, destroy the parcel, at FDA expense.

(l) *Prohibitions on delivery and transfer*. Notwithstanding section 801(b)

of the act, while an article of food is under hold under section 801(l) of the act, it may not be delivered to the importer, owner, or ultimate consignee. If an article of food is no longer subject to hold under section 801(l) of the act, entry may be made in accordance with law and regulation.

(m) *Relationship to other admissibility provisions.* A determination that an article of food is no longer subject to hold under section 801(l) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer under hold under section 801(l) of the act does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

Dated: October 29, 2008.

Michael Chertoff,

Secretary of Homeland Security.

Dated: July 1, 2008.

Michael O. Leavitt,

Secretary of Health and Human Services.

[FR Doc. E8–26282 Filed 10–31–08; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0487] (formerly Docket No. 2007D–0260]

Draft Compliance Policy Guide; ''Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft Compliance Policy Guide (CPG) entitled ''Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' The draft CPG provides written guidance to FDA's and Customs and Border Protection's (CBP's) staff on enforcement of section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulations, which require prior notice for food imported or offered for import into the United States. The final rule entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' is published elsewhere in this issue of the **Federal Register**.

DATES: Although you can comment on any CPG at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on the draft CPG before it begins work on the final version of the CPG, submit written or electronic comments concerning the draft CPG by December 8, 2008.

ADDRESSES: Submit written requests for single copies of the draft CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861.

Submit written comments on the draft CPG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

FOR FURTHER INFORMATION CONTACT: Laura Draski, Office of Regulatory Affairs (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 866–521–2297.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft CPG entitled ''Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' This guidance is issued with CBP concurrence and explains to FDA and CBP staff the FDA and CBP policies on enforcement of section 307 of the Bioterrorism Act and its implementing regulations, which require prior notice to FDA of all food imported or offered for import into the United States (21 CFR 1.276 through 1.285). The final regulation requiring that FDA receive prior notice of the importation of food is published elsewhere in this issue of the **Federal Register** and will take effect on May 6, 2009.

FDA is issuing this CPG as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent the agency's current thinking on its enforcement policy concerning prior notice. It does not create or confer any rights for or on any person and does not operate to bind FDA, or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic copies or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please not that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Electronic Access

An electronic version of the draft CPG is available on the Internet at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: October 10, 2008.

Michael A. Chappell,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. E8–26281 Filed 10–31–08; 11:15 am]

BILLING CODE 4160–01–S

Federal Register

Friday,
November 7, 2008

Part III

Department of the Treasury

31 CFR Part 103

Financial Crimes Enforcement Network

31 CFR Chapter X

Transfer and Reorganization of Bank Secrecy Act Regulations; Proposed Rule

DEPARTMENT OF THE TREASURY

31 CFR Part 103

Financial Crimes Enforcement Network

31 CFR Chapter X

RIN 1506–0092

Transfer and Reorganization of Bank Secrecy Act Regulations

AGENCY: Financial Crimes Enforcement Network (FinCEN), Department of the Treasury.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: FinCEN proposes to move Bank Secrecy Act (BSA) regulations to a new chapter in the Code of Federal Regulations (CFR). The new chapter would contain the BSA regulations, which would generally be reorganized by financial industry. Moving the BSA regulations to a new chapter and organizing the chapter by financial industry would create a user-friendly way to find regulations applicable to a particular financial industry. This new organization within the new chapter also allows for the renumbering of the BSA regulations in a manner that would make it easier to find regulatory requirements than under the numbering system currently used in the existing regulations. FinCEN also proposes to make minor technical changes to the BSA regulations such as updating mailing addresses and points of contact.

DATES: Written comments must be submitted on or before March 9, 2009.

ADDRESSES: Those submitting comments are encouraged to do so via the Internet. Comments submitted via the Internet may be submitted at *http://www.regulations.gov/search/index.jsp* with the caption in the body of the text, ''Attention: Chapter X.'' Comments may also be submitted by written mail to: Financial Crimes Enforcement Network, Department of the Treasury, P.O. Box 39, Vienna, VA 22183, Attention: Chapter X. Please submit comments by one method only. All comments submitted in response to this notice of proposed rulemaking will become a matter of public record; therefore, you should submit only information that you wish to make publicly available.

Inspection of comments: Comments may be inspected between 10 a.m. and 4 p.m. in the FinCEN reading room in Vienna, VA. Persons wishing to inspect the comments submitted must request an appointment with the Disclosure Officer by telephoning (703) 905–5034 (not a toll free call). In general, FinCEN will make all comments publicly available by posting them on *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory Helpline at (800) 949–2732 (toll-free number).

SUPPLEMENTARY INFORMATION:

I. Introduction

As part of its effort to increase the efficiency and effectiveness of BSA obligations, FinCEN proposes to move, without substantive change, the regulations promulgated under the BSA and the USA PATRIOT Act to a new chapter within the Code of Federal Regulations. Moving the regulations to a new chapter within Title 31 provides FinCEN with the opportunity to restructure its regulations to make them more easily identifiable by a particular regulated industry. Making the regulatory obligations more clear in their structure and more readily accessible to regulatory institutions will facilitate compliance and thereby advance the purposes of the BSA.

II. Background

In September 2005, the eRulemaking program launched the Federal Docket Management System (FDMS), greatly expanding public access to information and improving agency management of the rulemaking process. FDMS, publicly accessible at *http://www.regulations.gov*, serves as an electronic document repository, enabling departments and agencies to post all rulemaking and non-rulemaking documents for public access and comment. This access is revolutionizing the way the government involves the public in its decision-making by moving from paper-based processes to new e-government innovations, which will lead to more efficient interactions between government and the public.

Currently, FinCEN is included in FDMS as a departmental office of Treasury and FinCEN's rulemaking is included with all other departmental offices, not separately. By having its own chapter, FinCEN will be listed separately in FDMS. This separate FDMS listing will make it easier for the public to locate and comment on future FinCEN rulemaking documents.

Moving the regulations to a new chapter also provides the opportunity for FinCEN to organize the existing rules in a way that will add value to financial institutions, regulators, and law enforcement entities that deal with these rules by making them easier to find. FinCEN has not proposed any substantive amendments or revisions to the Part 103 regulations. The information collection, reporting, and recordkeeping requirements will remain the same for all regulated entities.[1] However, in addition to adding a new chapter and restructuring the organization of its regulations, FinCEN proposes to make necessary technical corrections, such as updating references, mailing addresses, and points of contact.

FinCEN has not published any of the Appendices in 31 CFR part 103 with this proposal. As explained in greater detail below, FinCEN proposes to publish the Appendices that will be part of Chapter X in a subsequent notice of proposed rulemaking.

III. Proposed Changes

A. Structure of Chapter X

FinCEN proposes to organize Chapter X by financial industry so as to create a user-friendly way to find regulations which apply to a particular industry. This methodology and format is currently used by several state jurisdictions. In this new structure, definitions and regulatory obligations applicable to all or a number of regulated persons and financial institutions will be located in a Part titled ''General Provisions.'' Regulatory obligations applicable to a particular industry will be located in an industry-specific Part. If a regulatory obligation in the General Provisions Part is applicable to a particular industry, there will be a statement in the industry-specific Part referring the industry to the obligation contained in the General Provisions Part. FinCEN is proposing this structure so that individuals interested in finding the rules applicable to a particular category of financial institution need only to look in two places. The proposed Parts are as follows:

1010 General Provisions
1020 Rules for Banks
1021 Rules for Casinos and Card Clubs
1022 Rules for Money Services Businesses
1023 Rules for Brokers or Dealers in Securities
1024 Rules for Mutual Funds
1025 Rules for Insurance Companies
1026 Rules for Futures Commission Merchants and Introducing Brokers in Commodities
1027 Rules for Dealers in Precious Metals, Precious Stones, or Jewels
1028 Rules for Operators of Credit Card Systems
1029–1099 [RESERVED]

[1] To the extent that the renumbering of regulations will require making changes to regulations referenced on various FinCEN information collection forms, it will not change the information fields in such forms and the manner in which the forms are completed will not be altered.

Additionally, FinCEN will use Chapter X to reorganize provisions currently divided into several layers of subparagraphs throughout a particular Part 103 subpart in a manner that will be simpler to follow. For example, FinCEN is proposing to divide the regulations relating to currency transaction reporting (CTR) regulations into separately numbered sections. Interested parties will be able to identify specific CTR requirements, including those relating to filing reports, identification, aggregation, and structured transactions, more readily as they have been grouped together, rather than throughout the subpart or in several subparagraphs within a section. Current CTR requirements for financial institutions other than casinos and card clubs will be located in the General Provisions Part because those regulations apply to several industries. CTR requirements for casinos and card clubs that use different language due to the unique nature of the industry will be located within Part 1021 only.

FinCEN is taking a tiered approach to removing the BSA regulations from 31 CFR part 103 and adding them in 31 CFR Chapter X. As part of this tiered approach, FinCEN intends to publish a subsequent notice of proposed rulemaking with any revisions or deletions necessary to move the Appendices contained in 31 CFR part 103 to 31 CFR Chapter X. Because the current notice is focusing on the restructuring effort, within this notice, FinCEN has proposed the new location of each 31 CFR part 103 Appendix in the Distribution Table below as well as in the table of contents contained in the proposed rulemaking. In the subsequent notice of proposed rulemaking, FinCEN will publish those Appendices that should be moved to 31 CFR Chapter X.

B. Renumbering Logic

FinCEN's proposed renumbering logic is designed to provide consistency and ease of access. By maintaining a consistent numbering and division of sections within subparts, regulatory requirements will be easier to find. For example, each regulatory section in each subpart A refers to definitions; each regulatory section in each Subpart B is numbered 10xx.2xx and refers to a program requirement; each regulatory section in each Subpart C is numbered 10xx.3xx and refers to a reporting requirement; and each regulatory section in each Subpart D is numbered 10xx.4xx and refers to a recordkeeping requirement. Therefore, if a regulation is numbered 10xx.3xx, such as 1010.310, it will be immediately recognizable as a reporting requirement. If the regulation is numbered 10xx.4xx, such as 1010.410, it will likewise be recognizable as a recordkeeping requirement. This renumbering, in conjunction with the restructuring, will eliminate confusion existing in the current structure. For instance, currently, § 103.29, pertaining to ''purchases of bank checks and drafts, cashier's checks, money orders and traveler's checks,'' is in Subpart B—Reports Required To Be Made; this specific regulation, however, is a recordkeeping requirement. In the proposed Chapter X, that regulatory obligation will be included in the subpart for recordkeeping requirements. FinCEN is reordering and renumbering the requirement to make this provision, and others, clearly identifiable and retrievable based on a logical format that will require less memorization. This renumbering logic will also allow financial institutions to search for a section in their relevant Part to determine quickly if there is in fact a current regulatory requirement. For example, each section that ends with .320 will always pertain to suspicious activity reporting (SAR) requirements. As specific examples, 1021.320 will be the SAR requirement for casinos and card clubs and 1023.320 will be the SAR requirement for broker or dealers in securities. If a financial institution, such as a dealer in precious metals, precious stones, or jewels views Part 1027, the institution will see that 1027.320 is ''Reserved.'' While dealers in precious metals, precious stones, or jewels are encouraged to file SARs, they are currently not required to do so.

C. Definitions

General BSA definitions will be found in § 1010.100, with further definitions in §§ 1010.505 and 1010.605, which are applicable to subparts E and F, respectively, of Part 1010. As indicated above, definitions specific to a particular financial industry will always be found in subpart A of that financial industry Part in a section ending with .100 (*e.g.,* § 1024.100 of Part 1024 and § 1026.100 of Part 1026).

Certain definitions that are not currently located in § 103.11, but which FinCEN intends to apply to the entire Chapter, unless otherwise indicated, have been moved into the General Definition § 1010.100. Additionally, definitions have been reordered in § 1010.100 to be consistent with the alphabetical system. These include the definitions for ''Attorney General,'' ''business day,'' ''commodity,'' ''contract of sale,'' ''Federal Functional Regulator,'' ''FinCEN,'' ''futures commission merchant,'' ''Indian Gaming Regulatory Act,'' ''intermediary bank,'' ''introducing broker-commodities,'' ''mutual fund,'' ''security,'' ''self-regulatory organization,'' ''state,'' ''stored value,'' ''taxpayer identification number,'' ''territories and insular provinces,'' ''transaction account,'' ''United States Postal Service,'' and ''U.S. person.'' General Definitions will apply to all FinCEN regulations, unless otherwise noted.

FinCEN proposes a definition for Bank Secrecy Act (BSA). Currently, the acronym ''BSA'' and the term ''Bank Secrecy Act'' is used throughout Part 103, but has not been defined. FinCEN has proposed a definition of Bank Secrecy Act so that it can be used consistently throughout the Chapter.

The definition of ''mutual fund'' has been moved from the substantive text of the regulations to the General Definitions section, as well as sections where the term is specified according to regulatory requirements. Where applicable, such as Special Measures requirements or Customer Identification Program requirements for mutual funds, the definitions of mutual fund have been reprinted as it was in those sections in current 31 CFR 103 and relocated as per the proposed Chapter X renumbering logic.

D. Technical Corrections

The following technical corrections to FinCEN regulations are being proposed:

1. FinCEN has updated references to its Web site by including ''*http://www.fincen.gov*'' where current references cite to ''*http://www.treas.gov/fincen.*''

2. The FinCEN mailing address has been changed to: P.O. Box 39, Vienna, Virginia, 22183.

3. When used to refer to Part 103, the word ''part'' or the phrase ''Part 103'' has been changed to ''chapter.''

4. The ''Office of Enforcement'' has been changed to ''FinCEN.''

5. ''Assistant Secretary (Enforcement)'' and ''Director, Office of Financial Enforcement'' have been updated to ''Director, FinCEN.''

6. ''The Office of the Assistant Secretary (Enforcement)'' has been changed to ''Director of FinCEN or his designee.''

7. ''Customs'' has been changed to ''Customs and Border Protection.''

8. FinCEN has replaced ''Commission'' with ''Commodity Futures Trading Commission'' when the term is used to refer to the Commodity Futures Trading Commission. The term ''Commission'' is now only used to refer to the Securities and Exchange Commission.

9. The definition of FinCEN has been updated to reflect that FinCEN is now a bureau rather than an office within the Treasury Department (i.e. proposed § 1010.100(s) versus the prior version § 103.11(qq)).

10. The name of the SAR form that brokers or dealers in securities and futures commission merchants and introducing brokers in commodities use to report suspicious transactions has been updated to reflect the correct name of the form.

11. The references to Treasury Form TD F 90–22.53 have been changed to FinCEN Form 110.

12. The reference to the New York Stock Exchange and the National Association of Securities Dealers has been changed to the Financial Industry Regulatory Authority.

13. Cross references to § 103.21 contained in § 103.22(d)(9) were not updated when the bank SAR rules were moved from § 103.21 to § 103.18. In Chapter X, the references have been fixed so that they refer to the bank SAR rules (proposed § 1020.320) rather than to the casino SAR rules (proposed § 1021.320).

14. Sections 103.27(a)(1) and 103.55(c)(1) incorrectly indicate that the transactions in currency reporting requirements are contained in § 103.22(a). Prior to 1998, the reporting obligations were contained in § 103.22(a), but per the *Amendments to the Bank Secrecy Act Regulations—Exemptions from the Requirement to Report Transactions in Currency—Phase II,* 63 FR 50147 (1998), the filing obligations were moved to § 103.22(b)(1) for financial institutions other than casinos and § 103.22(b)(2) for casinos. The cross references to § 103.22(a) in § 103.27(a)(1) (proposed § 1010.306(a)(1)) and § 103.55(c)(1) (proposed § 1010.970(c)(1)) have been corrected to include those Chapter X sections that contain transactions in currency transaction reporting obligations.

15. All references to ''subpart'' in § 103.38(a)–(d) were changed to ''chapter'' in proposed § 1010.430(a)–(d).

16. The reference to ''subpart'' in § 103.39 was changed to ''chapter'' in proposed § 1010.440.

17. The word ''Act'' from § 103.62 was changed to the ''Bank Secrecy Act'' in proposed § 1010.930.

18. The words ''Treasury Department'' in § 103.85 (proposed § 1010.715) have been changed to ''FinCEN,'' so that now the provision states that FinCEN will only be bound by a ruling if the request describes a specifically identified actual situation.

19. The cross reference contained in § 103.140(a)(4)(ii) to ''paragraph (a)(3)(i) of this section'' is incorrect because there is no (a)(3)(i) in that section. Because this should have been a reference to (a)(4)(i), the cross-reference should be to proposed § 1027.100(d)(1) in Chapter X.

20. Former § 103.170(c), currently proposed as § 1010.205(c), has been corrected by revising the beginning of the first sentence to read as follows: ''The exemptions described in paragraph (b) of this section * * *''. In Part 103, there was a reference to the exemptions contained in ''paragraphs (a)(2) and (b)'' of § 103.170. Paragraph (a)(2) was removed and reserved through Corrections published in the **Federal Register** (see 67 FR 68935 (Nov. 14, 2002)). Paragraph (b) is the only paragraph within this section that contains exemptions (see 67 FR at 67549 (Nov. 6, 2002)).

21. Paragraph (a)(2) of 31 CFR 103.27, which provided that ''A report required by § 103.22(g) shall be filed by the bank within 15 days after receiving a request for the report,'' is superfluous and has been deleted. Paragraph (g) of 31 CFR 103.22 was previously removed in 63 FR 50147.

IV. Part-by-Part Analysis

Part 1010 of Chapter X contains the general regulatory provisions of the Bank Secrecy Act and USA PATRIOT Act. General definitions are in Subpart A (§ 1010.100); programs are in Subpart B (§§ 1010.205–1010.220); reports required to be made by financial institutions are in Subpart C (§§ 1010.301–1010.370); records required to be maintained by financial institutions are in Subpart D (§§ 1010.401–1010.440); special information sharing procedures to deter money laundering and terrorist activity are in Subpart E (§§ 1010.505–1010.540); special standards of diligence; prohibitions; and special measures are in Subpart F (§§ 1010.605–1010.670); administrative rulings are in Subpart G (§§ 1010.710–1010.717); enforcement; penalties; and forfeiture provisions are in Subpart H (§§ 1010.810–1010.850); summons provisions are in Subpart I (§§ 1010.911–1010.917); miscellaneous provisions are in Subpart J (§§ 1010.920–1010.980).

Part 1020 of Chapter X contains regulatory provisions for banks. Definitions applicable to banks are in Subpart A (§ 1020.100); programs are in Subpart B (§§ 1020.210–1020.220); reports required to be made by banks are in Subpart C (§§ 1020.310–1020.320); records required to be maintained by banks are in Subpart D (§ 1020.410); special information sharing procedures to deter money laundering and terrorist activity for banks are in Subpart E, and special standards of diligence; prohibitions; and special measures for banks are in Subpart F.

Part 1021 of Chapter X contains regulatory provisions for casinos and card clubs. Definitions for casinos and card clubs are in Subpart A (§ 1021.100); programs are in Subpart B (§ 1021.210); reports required to be made by casinos are in Subpart C (§§ 1021.310–1021.320); records required to be maintained by casinos are in Subpart D (§ 1021.410); special information sharing procedures to deter money laundering and terrorist activity for casinos are in Subpart E; and special standards of diligence; prohibitions; and special measures for casinos are in Subpart F.

Part 1022 of Chapter X contains regulatory provisions for money services businesses. Definitions for money services business are in Subpart A (§ 1022.100); programs are in Subpart B (§ 1022.210); reports required to be made by money services businesses are in Subpart C (§§ 1022.310–1022.320); records required to be maintained by money services businesses are in Subpart D (§ 1022.410); special information sharing procedures to deter money laundering and terrorist activity for money services businesses are in Subpart E; and special standards of diligence; prohibitions; and special measures for money services businesses are in Subpart F.

Part 1023 of Chapter X contains regulatory provisions for brokers or dealers in securities. Definitions for brokers or dealers in securities are in Subpart A (§ 1023.100); programs are in Subpart B (§§ 1023.210–1023.220); reports required to be made by brokers or dealers in securities are in Subpart C (§§ 1023.310–1023.320); records required to be maintained by brokers or dealers in securities are in Subpart D (§ 1023.410); special information sharing procedures to deter money laundering and terrorist activity for brokers or dealers in securities are in Subpart E; and special standards of diligence; prohibitions; and special measures for money services businesses are in Subpart F.

Part 1024 of Chapter X contains regulatory provisions for mutual funds. Definitions for mutual funds are in Subpart A (§ 1024.100); programs are in Subpart B (§§ 1024.210–1024.220); reports required to be made by mutual funds are in Subpart C (§§ 1024.310–1024.330); records required to be maintained by mutual funds are in

Subpart D (§ 1024.410); special information sharing procedures to deter money laundering and terrorist activity for mutual funds are in Subpart E; and special standards of diligence; prohibitions; and special measures for mutual funds are in Subpart F.

Part 1025 of Chapter X contains regulatory provisions for insurance companies. Definitions for insurance companies are in Subpart A (§ 1025.100); programs are in Subpart B (§ 1025.210); reports required to be made by insurance companies are in Subpart C (§§ 1025.310–1025.330); records required to be maintained by insurance companies are in Subpart D (§ 1025.410); special information sharing procedures to deter money laundering and terrorist activity for insurance companies are in Subpart E; and special standards of diligence; prohibitions; and special measures for insurance companies are in Subpart F.

Part 1026 of Chapter X contains regulatory provisions for futures commission merchants and introducing brokers in commodities. Definitions for futures commission merchants and introducing brokers in commodities are in Subpart A (§ 1026.100); programs are in Subpart B (§§ 1026.210–1026.220); reports required to be made by futures commission merchants and introducing brokers in commodities are in Subpart C (§§ 1026.310–1026.330); records required to be maintained by futures commission merchants and introducing brokers in commodities are in Subpart D (§ 1026.410); special information sharing procedures to deter money laundering and terrorist activity for futures commission merchants and introducing brokers in commodities are in Subpart E; and special standards of diligence; prohibitions; and special measures for futures commission merchants and introducing brokers in commodities are in Subpart F.

Part 1027 of Chapter X contains regulatory provisions for dealers in precious metals, precious stones, or jewels. Definitions for dealers in precious metals, precious stones, or jewels are in Subpart A (§ 1027.100); programs are in Subpart B (§ 1027.210); reports required to be made by dealers in precious metals, precious stones, or jewels are in Subpart C (§§ 1027.310–1027.330); records required to be maintained by dealers in precious metals, precious stones, or jewels are in Subpart D (§ 1027.410); special information sharing procedures to deter money laundering and terrorist activity for dealers in precious metals, precious stones, or jewels are in Subpart E; and special standards of diligence; prohibitions; and special measures for dealers in precious metals, precious stones, or jewels are in Subpart F.

Part 1028 of Chapter X contains regulatory provisions for operators of credit card systems. Definitions for operators of credit card systems are in Subpart A (§ 1028.100); programs are in Subpart B (§ 1028.210); reports required to be made by operators of credit card systems are in Subpart C (§§ 1028.310–1028.330); records required to be maintained by operators of credit card systems are in Subpart D (§ 1028.410); special information sharing procedures to deter money laundering and terrorist activity for operators of credit card systems are in Subpart E; and special standards of diligence; prohibitions; and special measures for operators of credit card systems are in Subpart F.

At this time, Parts 1029–1099 of Chapter X are reserved and the Appendices to Chapter X will remain the same as those currently contained in title 31 CFR Part 103 until further notice.

For convenience, FinCEN is providing a table summarizing the redistribution of the 31 CFR Part 103 provisions to the proposed layout of Chapter X as follows:

DISTRIBUTION TABLE

31 CFR part 103 section	31 CFR parts 1000–1099 (Chapter X) section
103.11	1010.100.
103.12	1010.301.
103.15(a)–(g)	1024.320(a)–(g).
103.16(a)	Deleted.
103.16(b)–(i)	1025.320(a)–(h).
103.17(a)–(h)	1026.320(a)–(h).
103.18(a)–(f)	1020.320(a)–(f).
103.19(a)–(h)	1023.320(a)–(h).
103.20(a)–(f)	1022.320(a)–(f).
103.21(a)–(g)	1021.320(a)–(g).
103.22(a)	Deleted.
103.22(b)(1)	1010.311.
103.22(b)(2)(i)–(iii)	1021.311(a)–(c).
103.22(c)(1) & (2)	1010.313(a) & (b).
103.22(c)(3)	1021.313.
103.22(d)	1020.315(a)–(k).
103.23(a)–(d)	1010.340(a)–(d).
103.24	1010.350.
103.25(a)–(e)	1010.360(a)–(e).
103.26(a)–(d)	1010.370(a)–(d).
103.27(a)(1)	1010.306(a)(1).
103.27(a)(2)	Deleted.
103.27(a)(3) & (4)	1010.306(a)(2) & (3).
103.27(b)–(e)	1010.306(b)–(e).
103.28	1010.312.
103.29(a)–(c)	1010.415(a)–(c).
103.30(a)–(c)	1010.330(a)–(c).
103.30(d)(1)(i)–(iv)	1021.330(a)–(d).
103.30(d)(2)	1010.330(d)(2).
103.30(d)(3)	1010.330(d)(1).
103.30(e)	1010.330(e).
103.31	1010.401.
103.32	1010.420.
103.33(a)–(d)	1010.410(a)–(d).
103.33(e)	1020.410(a).
103.33(f) & (g)	1010.410(e) & (f).

DISTRIBUTION TABLE—Continued

31 CFR part 103 section	31 CFR parts 1000–1099 (Chapter X) section
103.34(a) & (b)	1020.410(b) & (c).
103.35(a) & (b)	1023.410(a) & (b).
103.36(a)–(c)	1021.410(a)–(c).
103.37(a)–(c)	1022.410(a)–(c).
103.38(a)–(d)	1010.430(a)–(d).
103.39	1010.440.
103.41(a)–(f)	1022.380(a)–(f).
103.51	1010.980.
103.52(a) & (b)	1010.940(a) & (b).
103.53(a)–(f)	1010.950(a)–(f).
103.54	1010.960.
103.55(a)–(c)	1010.970(a)–(c).
103.56(a)–(g)	1010.810(a)–(g).
103.57(a)–(h)	1010.820(a)–(h).
103.58	1010.830.
103.59(a)–(d)	1010.840(a)–(d).
103.60(a)–(c)	1010.850(a)–(c).
103.61	1010.920.
103.62(a)–(c)	1010.930(a)–(c).
103.63(a)–(c)	1010.314(a)–(c).
103.64(a)	1021.210(b).
103.64(b)(1)	1021.100(a).
103.64(b)(2)	1021.100(b).
103.64(b)(3)	1021.100(c).
103.64(b)(4)	1021.100(d).
103.64(b)(5)	1021.100(e).
103.71	1010.911.
103.72(a)–(c)	1010.912(a)–(c).
103.73(a) & (b)	1010.913(a) & (b).
103.74(a)–(c)	1010.914(a)–(c).
103.75(a)–(c)	1010.915(a)–(c).
103.76	1010.916.
103.77	1010.917.
103.80	1010.710.
103.81(a)–(e)	1010.711(a)–(e).
103.82	1010.712.
103.83(a) & (b)	1010.713(a) & (b).
103.84	1010.714.
103.85	1010.715.
103.86(a)–(d)	1010.716(a)–(d).
103.87(a) & (b)	1010.717(a) & (b).
103.90(a)	1010.505(b).
103.90(b)	1010.505(c).
103.90(c)	1010.505(a).
103.90(d)	1010.505(d).
103.100(a)(1) & (a)(3)	Deleted.
103.100(a)(2)	1010.520(a)(1).
103.100(b)	1010.520(b).
103.110(a)(1)	Deleted.
103.110(a)(2) & (3)	1010.540(a)(1) & (2).
103.110(b)–(d)	1010.540(b)–(d).
103.120(a)(1)	1020.100(d)(1). 1023.100(e)(1).
103.120(a)(2)	1010.100(r).
103.120(a)(3)	1010.100(tt).
103.120(a)(4)	Deleted.
103.120(b)	1020.210.
103.120(c)(1) & (2)	1023.210(a) & (b). 1026.210(b)(1) & (2).
103.120(d)	1021.210(a).
103.121(a)(1)	1020.100(a).
103.121(a)(2)	1020.100(b).
103.121(a)(3)	1020.100(c).
103.121(a)(4)	Deleted.
103.121(a)(5)	1020.100(d)(2).
103.121(a)(6)	1010.100(yy).
103.121(a)(7)	1010.100(iii).
103.121(a)(8)	1010.100(iii).
103.121(b)–(d)	1020.220(a)–(c).
103.122(a)(1)	1023.100(a).

DISTRIBUTION TABLE—Continued

31 CFR part 103 section	31 CFR parts 1000–1099 (Chapter X) section
103.122(a)(2)	1023.100(b).
103.122(a)(3)	1023.100(c).
103.122(a)(4)	1023.100(d).
103.122(a)(5)	Deleted.
103.122(a)(6)	1023.100(e).
103.122(a)(7)	Deleted.
103.122(a)(8)	Deleted.
103.122(a)(9)	Deleted.
103.122(b)–(d)	1023.220(a)–(c).
103.123(a)(1)	1026.100(a).
103.123(a)(2)	Deleted.
103.123(a)(3)	1026.100(b).
103.123(a)(4)	1026.100(c).
103.123(a)(5)	1026.100(d).
103.123(a)(6)	Deleted.
103.123(a)(7)	1026.100(e).
103.123(a)(8)	1026.100(f).
103.123(a)(9)	1026.100(g).
103.123(a)(10)	1026.100(h).
103.123(a)(11)	Deleted.
103.123(a)(12)	Deleted.
103.123(a)(13)	Deleted.
103.123(b)–(d)	1026.220(a)–(c).
103.125(a)–(e)	1022.210(a)–(e).
103.130(a)	1024.100(e)(1).
103.130(b) & (c)	1024.210(a) & (b).
103.131(a)(1)	1024.100(a).
103.131(a)(2)	1024.100(c).
103.131(a)(3)	1010.100(r).
103.131(a)(4)	1024.100(d).
103.131(a)(5)	1024.100(e)(2).
103.131(a)(6)	1010.100(iii).
103.131(a)(7)	1010.100(yy).
103.131(a)(8)	1010.100(iii).
103.131(b)–(d)	1024.220(a)–(c).
103.135(a)(1)	1028.100(e).
103.135(a)(2)	1028.100(d).
103.135(a)(3)	1028.100(a).
103.135(a)(4)	1028.100(f).
103.135(a)(5)	1028.100(b).
103.135(a)(6)	1028.100(c).
103.135(b) & (c)	1028.210(a) & (b).
103.137(a)(1)	1025.100(a).
103.137(a)(2)	Deleted.
103.137(a)(3)	Deleted.
103.137(a)(4)	1025.100(b).
103.137(a)(5)	1025.100(c).
103.137(a)(6)	1025.100(d).
103.137(a)(7)	1025.100(e).
103.137(a)(8)	1025.100(f).
103.137(a)(9)	1025.100(g).
103.137(a)(10)	1025.100(h).
103.137(a)(11)	Deleted.
103.137(a)(12)	Deleted.
103.137(b)–(e)	1025.210(a)–(d).
103.140(a)(1)	1027.100(a).
103.140(a)(2)	1027.100(b).
103.140(a)(3)	1027.100(c).
103.140(a)(4)	1027.100(d).
103.140(a)(5)	1027.100(e).
103.140(a)(6)	Deleted.
103.140(a)(7)	1027.100(f).
103.140(b)–(d)	1027.210(a)–(c).
103.170(a)–(d)	1010.205(a)–(d).
103.175(a)	1010.100(c).
103.175(b)	1010.605(a).
103.175(c)	1010.605(b).
103.175(d)	1010.605(c).
103.175(e)	1010.605(d).
103.175(f)	1010.605(e).

DISTRIBUTION TABLE—Continued

31 CFR part 103 section	31 CFR parts 1000–1099 (Chapter X) section
103.175(g)	Deleted.
103.175(h)	1010.605(f).
103.175(i)	1010.605(g).
103.175(j)	1010.605(h).
103.175(k)	1010.605(i).
103.175(l)	1010.605(j).
103.175(m)	1010.605(k).
103.175(n)	1010.605(l).
103.175(o)	1010.605(m).
103.175(p)	1010.605(n).
103.175(q)	1010.605(o).
103.175(r)	1010.605(p).
103.175(s)	Deleted.
103.175(t)	Deleted.
103.176(a)–(g)	1010.610(a)–(g).
103.177(a)–(f)	1010.630(a)–(f).
103.178(a)–(e)	1010.620(a)–(e).
103.185(a)–(f)	1010.670(a)–(f).
103.186(a)(1)	1010.651(a)(2).
103.186(a)(2)	1010.651(a)(3).
103.186(a)(3)	1010.651(a)(1).
103.186(b)	1010.651(b).
103.187(a)(1)	1010.652(a)(2).
103.187(a)(2)	1010.652(a)(3).
103.187(a)(3)	1010.652(a)(4).
103.187(a)(4)	1010.652(a)(1).
103.187(b)	1010.652(b).
103.188(a)(1)	1010.653(a)(1).
103.188(a)(2)	1010.653(a)(2).
103.188(a)(3)	1010.653(a)(3).
103.188(a)(4)	1010.653(a)(4).
103.188(b)	1010.653(b).
103.192(a)(1)	1010.654(a)(1).
103.192(a)(2)	1010.654(a)(2).
103.192(a)(3)	1010.654(a)(3).
103.192(a)(4)	1010.654(a)(4).
103.192(b)	1010.654(b).
103.193(a)(1)	1010.655(a)(1).
103.193(a)(2)	1010.655(a)(2).
103.193(a)(3)	1010.655(a)(3).
103.193(a)(4)	1010.655(a)(4).
103.193(b)	1010.655(b).
Appendix A to Subpart H.	Appendix A.
Appendix A to Subpart I.	Appendix C.
Appendix B to Subpart I.	Appendix D.
Appendix A to Part 103.	Appendix E.
Appendix B to Part 103.	Appendix B.
Appendix C to Part 103.	Appendix F.

V. Request for Comments

FinCEN invites comment on all aspects of the proposed restructuring of the regulations, and specifically seeks comment on the following issues:

1. Whether the structure and numbering logic of the sections and parts within Chapter X makes FinCEN regulations more easily accessible.

2. Whether alphabetical order and the maintenance of alphabetical order is clear, effective and of such value that FinCEN should renumber the definitions at this time and each time a new one is added.

VI. Regulatory Matters

A. Executive Order 12866

It has been determined that this proposed rule is not a significant regulatory action for purposes of Executive Order 12866. Accordingly, a regulatory impact analysis is not required.

B. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), Public Law 104–4 (March 22, 1995), requires that an agency prepare a budgetary impact statement before promulgating a rule that may result in expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 202 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. FinCEN has determined that it is not required to prepare a written statement under Section 202 and has concluded that on balance the proposals in the Notice of Proposed Rulemaking provide the most cost-effective and least burdensome alternative to achieve the objectives of the rule.

C. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 602 *et seq.*), FinCEN certifies that this proposed regulation would not have a significant economic impact on a substantial number of small entities. The proposed regulation merely restructures and re-codifies existing regulations.

FinCEN believes the costs that may arise as a result of restructuring these regulations will be confined to training, publication and computer programming. The new regulatory structure will require financial institution compliance personnel to be retrained to assure familiarity with the new numbering format. FinCEN has attempted to mitigate any substantial costs of retraining by providing two aids: (1) III Proposed Changes—D. Technical Corrections, and (2) IV Part by Part Analysis.

Publication costs incurred to reproduce informational materials supplied by financial institutions to customers and the public should be minimized by the time interval afforded between the proposed rule, analysis and publication of a final rule.

FinCEN's analysis of the small entities that are subject to this regulation indicates that the vast majority of such entities file paper reports with FinCEN. These entities should incur no additional filing costs because they will continue to obtain the most current copy of the form available on the FinCEN Web site to file a report. However, for small entities that utilize a computer system to generate reports, there may be some recoding or reprogramming of existing software or the purchase of new software to file under this regulation. A current survey of the size of the financial institutions that file electronically indicates that this would be a small number of the total filers.

D. Paperwork Reduction Act

This proposed rule contains no new information collection requirements subject to review and approval by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d), *et seq.*). The information collection requirements for the Bank Secrecy Act, currently codified at 31 CFR part 103, were previously approved by the Office of Management and Budget under OMB Control numbers 1506–0001 through 1506–0046.

List of Subjects in 31 CFR Part 103 and 31 CFR Parts 1010 and 1020 Through 1028

Administrative practice and procedure, Banks, banking, Brokers, Currency, Foreign banking, Foreign currencies, Gambling, Investigations, Penalties, Reporting and recordkeeping requirements, Securities, Terrorism.

Department of the Treasury

31 CFR Chapter I

Authority and Issuance

For the reasons set forth above, under the authority of 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5314, 5316–5332; title III, sec. 314, Pub. L. 107–56, 115 Stat. 307, Chapter I of Title 31 of the Code of Federal Regulations is proposed to be amended by removing Part 103.

Department of the Treasury

Financial Crimes Enforcement Network

31 CFR Chapter X

Authority and Issuance

For the reasons set forth above, Chapter X, consisting of parts 1000 through 1099, is proposed to be added to Title 31 to read as follows:

Chapter X—Financial Crimes Enforcement Network, Department of the Treasury

PARTS 1000–1009 [RESERVED]

PART 1010—GENERAL PROVISIONS

Subpart A—General Definitions

Sec.
1010.100 General definitions.

Subpart B—Programs

1010.200 General.
1010.205 Exempted anti-money laundering programs for certain financial institutions.
1010.210 Anti-money laundering programs.
1010.220 Customer identification program requirements.

Subpart C—Reports Required To Be Made

1010.300 General.
1010.301 Determination by the Secretary.
1010.305 [Reserved]
1010.306 Filing of reports.
1010.310 Reports of transactions in currency.
1010.311 Filing obligations for reports of transactions in currency.
1010.312 Identification required.
1010.313 Aggregation.
1010.314 Structured transactions.
1010.315 Exemptions for non-bank financial institutions.
1010.320 Reports of suspicious transactions.
1010.330 Reports relating to currency in excess of $10,000 received in a trade or business.
1010.340 Reports of transportation of currency or monetary instruments.
1010.350 Reports of foreign financial accounts.
1010.360 Reports of transactions with foreign financial agencies.
1010.370 Reports of certain domestic coin and currency transactions.

Subpart D—Records Required To Be Maintained

1010.400 General.
1010.401 Determination by the Secretary.
1010.405 [Reserved]
1010.410 Records to be made and retained by financial institutions.
1010.415 Purchases of bank checks and drafts, cashier's checks, money orders and traveler's checks.
1010.420 Records to be made and retained by persons having financial interests in foreign financial accounts.
1010.430 Nature of records and retention period.
1010.440 Person outside the United States.

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

1010.500 General.
1010.505 Definitions.
1010.520 Information sharing between Federal law enforcement agencies and financial institutions.
1010.530 [Reserved]
1010.540 Voluntary information sharing among financial institutions.

Subpart F—Special Standards of Diligence; Prohibitions; and Special Measures

1010.600 General.

Special Due Diligence for Correspondent Accounts and Private Banking Accounts

1010.605 Definitions.
1010.610 Due diligence programs for correspondent accounts for foreign financial institutions.
1010.620 Due diligence programs for private banking accounts.
1010.630 Prohibition on correspondent accounts for foreign shell banks; records concerning owners of foreign banks and agents for service of legal process.
1010.640 [Reserved]

Special Measures Under Section 311 of the USA PATRIOT Act and Law Enforcement Access to Foreign Bank Records

1010.651 Special measures against Burma.
1010.652 Special measures against Myanmar Mayflower Bank and Asia Wealth Bank.
1010.653 Special measures against Commercial Bank of Syria.
1010.654 Special measures against VEF Bank.
1010.655 Special measures against Banco Delta Asia.
1010.670 Summons or subpoena of foreign bank records; termination of correspondent relationship.

Subpart G—Administrative Rulings

1010.710 Scope.
1010.711 Submitting requests.
1010.712 Nonconforming requests.
1010.713 Oral communications.
1010.714 Withdrawing requests.
1010.715 Issuing rulings.
1010.716 Modifying or rescinding rulings.
1010.717 Disclosing information.

Subpart H—Enforcement; Penalties; and Forfeiture

1010.810 Enforcement.
1010.820 Civil penalty.
1010.830 Forfeiture of currency or monetary instruments.
1010.840 Criminal penalty.
1010.850 Enforcement authority with respect to transportation of currency or monetary instruments.

Subpart I—Summons

1010.911 General.
1010.912 Persons who may issue summons.
1010.913 Contents of summons.
1010.914 Service of summons.
1010.915 Examination of witnesses and records.
1010.916 Enforcement of summons.
1010.917 Payment of expenses.

Subpart J—Miscellaneous

1010.920 Access to records.
1010.930 Rewards for informants.
1010.940 Photographic or other reproductions of Government obligations.
1010.950 Availability of information.
1010.960 Disclosure.
1010.970 Exceptions, exemptions, and reports.

1010.980 Dollars as including foreign currency.

Authority: 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5314, 5316–5332; title III, sec. 314, Pub. L. 107–56, 115 Stat. 307.

Subpart A—General Definitions

§ 1010.100 General definitions.

When used in this chapter and in forms prescribed under this chapter, where not otherwise distinctly expressed or manifestly incompatible with the intent thereof, terms shall have the meanings ascribed in this subpart. Terms applicable to a particular type of financial institution or specific part or subpart of this chapter are located in that part or subpart. Terms may have different meanings in different parts or subparts.

(a) *Accept.* A receiving financial institution, other than the recipient's financial institution, accepts a transmittal order by executing the transmittal order. A recipient's financial institution accepts a transmittal order by paying the recipient, by notifying the recipient of the receipt of the order or by otherwise becoming obligated to carry out the order.

(b) *At one time.* For purposes of § 1010.340 of this part, a person who transports, mails, ships or receives; is about to or attempts to transport, mail or ship; or causes the transportation, mailing, shipment or receipt of monetary instruments, is deemed to do so ''at one time'' if:

(1) That person either alone, in conjunction with or on behalf of others;

(2) Transports, mails, ships or receives in any manner; is about to transport, mail or ship in any manner; or causes the transportation, mailing, shipment or receipt in any manner of;

(3) Monetary instruments;

(4) Into the United States or out of the United States;

(5) Totaling more than $10,000;

(6)(i) On one calendar day; or

(ii) If for the purpose of evading the reporting requirements of § 1010.340, on one or more days.

(c) *Attorney General.* The Attorney General of the United States.

(d) *Bank.* Each agent, agency, branch or office within the United States of any person doing business in one or more of the capacities listed below:

(1) A commercial bank or trust company organized under the laws of any State or of the United States;

(2) A private bank;

(3) A savings and loan association or a building and loan association organized under the laws of any State or of the United States;

(4) An insured institution as defined in section 401 of the National Housing Act;

(5) A savings bank, industrial bank or other thrift institution;

(6) A credit union organized under the law of any State or of the United States;

(7) Any other organization (except a money services business) chartered under the banking laws of any state and subject to the supervision of the bank supervisory authorities of a State;

(8) A bank organized under foreign law;

(9) Any national banking association or corporation acting under the provisions of section 25(a) of the Act of Dec. 23, 1913, as added by the Act of Dec. 24, 1919, ch. 18, 41 Stat. 378, as amended (12 U.S.C. 611–32).

(e) *Bank Secrecy Act.* The Currency and Foreign Transactions Reporting Act, its amendments, and the other statutes relating to the subject matter of that Act, have come to be referred to as the Bank Secrecy Act. These statutes are codified at 12 U.S.C. 1829b, 12 U.S.C. 1951–1959, 18 U.S.C. 1956, 18 U.S.C. 1957, 18 U.S.C. 1960, and 31 U.S.C. 5311–5314 and 5316–5332 and notes thereto.

(f) *Beneficiary.* The person to be paid by the beneficiary's bank.

(g) *Beneficiary's bank.* The bank or foreign bank identified in a payment order in which an account of the beneficiary is to be credited pursuant to the order or which otherwise is to make payment to the beneficiary if the order does not provide for payment to an account.

(h) *Broker or dealer in securities.* A broker or dealer in securities, registered or required to be registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934, except persons who register pursuant to section 15(b)(11) of the Securities Exchange Act of 1934.

(i) *Business day.* As used in this chapter with respect to banks, business day means that day, as normally communicated to its depository customers, on which a bank routinely posts a particular transaction to its customer's account.

(j) *Commodity.* Any good, article, service, right, or interest described in section 1a(4) of the Commodity Exchange Act (''CEA''), 7 U.S.C. 1a(4).

(k) *Common carrier.* Any person engaged in the business of transporting individuals or goods for a fee who holds himself out as ready to engage in such transportation for hire and who undertakes to do so indiscriminately for all persons who are prepared to pay the fee for the particular service offered.

(l) *Contract of sale.* Any sale, agreement of sale, or agreement to sell as described in section 1a(7) of the CEA, 7 U.S.C. 1a(7).

(m) *Currency.* The coin and paper money of the United States or of any other country that is designated as legal tender and that circulates and is customarily used and accepted as a medium of exchange in the country of issuance. Currency includes U.S. silver certificates, U.S. notes and Federal Reserve notes. Currency also includes official foreign bank notes that are customarily used and accepted as a medium of exchange in a foreign country.

(n) *Deposit account.* Deposit accounts include transaction accounts described in paragraph (ccc) of this section, savings accounts, and other time deposits.

(o) *Domestic.* When used herein, refers to the doing of business within the United States, and limits the applicability of the provision where it appears to the performance by such institutions or agencies of functions within the United States.

(p) *Established customer.* A person with an account with the financial institution, including a loan account or deposit or other asset account, or a person with respect to which the financial institution has obtained and maintains on file the person's name and address, as well as taxpayer identification number (*e.g.* , social security or employer identification number) or, if none, alien identification number or passport number and country of issuance, and to which the financial institution provides financial services relying on that information.

(q) *Execution date.* The day on which the receiving financial institution may properly issue a transmittal order in execution of the sender's order. The execution date may be determined by instruction of the sender but cannot be earlier than the day the order is received, and, unless otherwise determined, is the day the order is received. If the sender's instruction states a payment date, the execution date is the payment date or an earlier date on which execution is reasonably necessary to allow payment to the recipient on the payment date.

(r) *Federal functional regulator.*

(1) The Board of Governors of the Federal Reserve System;

(2) The Office of the Comptroller of the Currency;

(3) The Board of Directors of the Federal Deposit Insurance Corporation;

(4) The Office of Thrift Supervision;

(5) The National Credit Union Administration;

(6) The Securities and Exchange Commission; or

(7) The Commodity Futures Trading Commission.

(s) *FinCEN.* FinCEN means the Financial Crimes Enforcement Network, a bureau of the Department of the Treasury.

(t) *Financial institution.* Each agent, agency, branch, or office within the United States of any person doing business, whether or not on a regular basis or as an organized business concern, in one or more of the capacities listed below:

(1) A bank (except bank credit card systems);

(2) A broker or dealer in securities;

(3) A money services business as defined in paragraph (ff) of this section;

(4) A telegraph company;

(5)(i) *Casino.* A casino or gambling casino that: Is duly licensed or authorized to do business as such in the United States, whether under the laws of a State or of a Territory or Insular Possession of the United States, or under the Indian Gaming Regulatory Act or other federal, state, or tribal law or arrangement affecting Indian lands (including, without limitation, a casino operating on the assumption or under the view that no such authorization is required for casino operation on Indian lands); and has gross annual gaming revenue in excess of $1 million. The term includes the principal headquarters and every domestic branch or place of business of the casino.

(ii) For purposes of this paragraph (t)(5), ''gross annual gaming revenue'' means the gross gaming revenue received by a casino, during either the previous business year or the current business year of the casino. A casino or gambling casino which is a casino for purposes of this chapter solely because its gross annual gaming revenue exceeds $1,000,000 during its current business year, shall not be considered a casino for purposes of this chapter prior to the time in its current business year that its gross annual gaming revenue exceeds $1,000,000.

(iii) Any reference in this chapter, other than in this paragraph (t)(5) and in paragraph (t)(6) of this section, to a casino shall also include a reference to a card club, unless the provision in question contains specific language varying its application to card clubs or excluding card clubs from its application;

(6)(i) *Card club.* A card club, gaming club, card room, gaming room, or similar gaming establishment that is duly licensed or authorized to do business as such in the United States, whether under the laws of a State, of a Territory or Insular Possession of the United States, or of a political subdivision of any of the foregoing, or under the Indian Gaming Regulatory Act or other federal, state, or tribal law or arrangement affecting Indian lands (including, without limitation, an establishment operating on the assumption or under the view that no such authorization is required for operation on Indian lands for an establishment of such type), and that has gross annual gaming revenue in excess of $1,000,000. The term includes the principal headquarters and every domestic branch or place of business of the establishment. The term ''casino,'' as used in this chapter shall include a reference to ''card club'' to the extent provided in paragraph (t)(5)(iii) of this section.

(ii) For purposes of this paragraph (t)(6), ''gross annual gaming revenue'' means the gross revenue derived from or generated by customer gaming activity (whether in the form of per-game or per-table fees, however computed, rentals, or otherwise) and received by an establishment, during either the establishment's previous business year or its current business year. A card club that is a financial institution for purposes of this chapter solely because its gross annual revenue exceeds $1,000,000 during its current business year, shall not be considered a financial institution for purposes of this chapter prior to the time in its current business year when its gross annual revenue exceeds $1,000,000;

(7) A person subject to supervision by any state or federal bank supervisory authority;

(8) A futures commission merchant; or

(9) An introducing broker in commodities.

(u) *Foreign bank.* A bank organized under foreign law, or an agency, branch or office located outside the United States of a bank. The term does not include an agent, agency, branch or office within the United States of a bank organized under foreign law.

(v) *Foreign financial agency.* A person acting outside the United States for a person (except for a country, a monetary or financial authority acting as a monetary or financial authority, or an international financial institution of which the United States Government is a member) as a financial institution, bailee, depository trustee, or agent, or acting in a similar way related to money, credit, securities, gold, or a transaction in money, credit, securities, or gold.

(w) *Funds transfer.* The series of transactions, beginning with the originator's payment order, made for the purpose of making payment to the beneficiary of the order. The term includes any payment order issued by the originator's bank or an intermediary bank intended to carry out the originator's payment order. A funds transfer is completed by acceptance by the beneficiary's bank of a payment order for the benefit of the beneficiary of the originator's payment order. Funds transfers governed by the Electronic Fund Transfer Act of 1978 (Title XX, Pub. L. 95–630, 92 Stat. 3728, 15 U.S.C. 1693, *et seq.*), as well as any other funds transfers that are made through an automated clearinghouse, an automated teller machine, or a point-of-sale system, are excluded from this definition.

(x) *Futures commission merchant.* Any person registered or required to be registered as a futures commission merchant with the Commodity Futures Trading Commission \(''CFTC'') under the CEA, except persons who register pursuant to section 4f(a)(2) of the CEA, 7 U.S.C. 6f(a)(2).

(y) *Indian Gaming Regulatory Act.* The Indian Gaming Regulatory Act of 1988, codified at 25 U.S.C. 2701–2721 and 18 U.S.C. 1166–68.

(z) *Intermediary bank.* A receiving bank other than the originator's bank or the beneficiary's bank.

(aa) *Intermediary financial institution.* A receiving financial institution, other than the transmitter's financial institution or the recipient's financial institution. The term intermediary financial institution includes an intermediary bank.

(bb) *Introducing broker-commodities.* Any person registered or required to be registered as an introducing broker with the CFTC under the CEA, except persons who register pursuant to section 4f(a)(2) of the CEA, 7 U.S.C. 6f(a)(2).

(cc) *Investment security.* An instrument which:

(1) Is issued in bearer or registered form;

(2) Is of a type commonly dealt in upon securities exchanges or markets or commonly recognized in any area in which it is issued or dealt in as a medium for investment;

(3) Is either one of a class or series or by its terms is divisible into a class or series of instruments; and

(4) Evidences a share, participation or other interest in property or in an enterprise or evidences an obligation of the issuer.

(dd) *Monetary instruments.* (1) Monetary instruments include:

(i) Currency;

(ii) Traveler's checks in any form;

(iii) All negotiable instruments (including personal checks, business

checks, official bank checks, cashier's checks, third-party checks, promissory notes (as that term is defined in the Uniform Commercial Code), and money orders) that are either in bearer form, endorsed without restriction, made out to a fictitious payee (for the purposes of § 1010.340), or otherwise in such form that title thereto passes upon delivery;

(iv) Incomplete instruments (including personal checks, business checks, official bank checks, cashier's checks, third-party checks, promissory notes (as that term is defined in the Uniform Commercial Code), and money orders) signed but with the payee's name omitted; and

(v) Securities or stock in bearer form or otherwise in such form that title thereto passes upon delivery.

(2) Monetary instruments do not include warehouse receipts or bills of lading.

(ee) [Reserved]

(ff) *Money services business.* Each agent, agency, branch, or office within the United States of any person doing business, whether or not on a regular basis or as an organized business concern, in one or more of the capacities listed in paragraphs (ff)(1) through (ff)(6) of this section. Notwithstanding the preceding sentence, the term ''money services business'' shall not include a bank, nor shall it include a person registered with, and regulated or examined by, the Securities and Exchange Commission or the Commodity Futures Trading Commission.

(1) *Currency dealer or exchanger.* A currency dealer or exchanger (other than a person who does not exchange currency in an amount greater than $1,000 in currency or monetary or other instruments for any person on any day in one or more transactions).

(2) *Check casher.* A person engaged in the business of a check casher (other than a person who does not cash checks in an amount greater than $1,000 in currency or monetary or other instruments for any person on any day in one or more transactions).

(3) *Issuer of traveler's checks, money orders, or stored value.* An issuer of traveler's checks, money orders, or, stored value (other than a person who does not issue such checks or money orders or stored value in an amount greater than $1,000 in currency or monetary or other instruments to any person on any day in one or more transactions).

(4) *Seller or redeemer of traveler's checks, money orders, or stored value.* A seller or redeemer of traveler's checks, money orders, or stored value (other than a person who does not sell such checks or money orders or stored value in an amount greater than $1,000 in currency or monetary or other instruments to or redeem such instruments for an amount greater than $1,000 in currency or monetary or other instruments from, any person on any day in one or more transactions).

(5) *Money transmitter*—(i) *In general.* Money transmitter:

(A) Any person, whether or not licensed or required to be licensed, who engages as a business in accepting currency, or funds denominated in currency, and transmits the currency or funds, or the value of the currency or funds, by any means through a financial agency or institution, a Federal Reserve Bank or other facility of one or more Federal Reserve Banks, the Board of Governors of the Federal Reserve System, or both, or an electronic funds transfer network; or

(B) Any other person engaged as a business in the transfer of funds.

(ii) *Facts and circumstances; Limitation.* Whether a person ''engages as a business'' in the activities described in paragraph (ff)(5)(i) of this section is a matter of facts and circumstances. Generally, the acceptance and transmission of funds as an integral part of the execution and settlement of a transaction other than the funds transmission itself (for example, in connection with a bona fide sale of securities or other property), will not cause a person to be a money transmitter within the meaning of paragraph (ff)(5)(i) of this section.

(6) *U.S. Postal Service.* The United States Postal Service, except with respect to the sale of postage or philatelic products.

(gg) *Mutual fund.* An ''investment company'' (as the term is defined in section 3 of the Investment Company Act (15 U.S.C. 80a–3)) that is an ''open-end company'' (as that term is defined in section 5 of the Investment Company Act (15 U.S.C. 80a–5)) that is registered or is required to register with the Commission under section 8 of the Investment Company Act (15 U.S.C. 80a–8).

(hh) *Option on a commodity.* Any agreement, contract, or transaction described in section 1a(26) of the CEA, 7 U.S.C. 1a(26).

(ii) *Originator.* The sender of the first payment order in a funds transfer.

(jj) *Originator's bank.* The receiving bank to which the payment order of the originator is issued if the originator is not a bank or foreign bank, or the originator if the originator is a bank or foreign bank.

(kk) *Payment date.* The day on which the amount of the transmittal order is payable to the recipient by the recipient's financial institution. The payment date may be determined by instruction of the sender, but cannot be earlier than the day the order is received by the recipient's financial institution and, unless otherwise prescribed by instruction, is the date the order is received by the recipient's financial institution.

(ll) *Payment order.* An instruction of a sender to a receiving bank, transmitted orally, electronically, or in writing, to pay, or to cause another bank or foreign bank to pay, a fixed or determinable amount of money to a beneficiary if:

(1) The instruction does not state a condition to payment to the beneficiary other than time of payment;

(2) The receiving bank is to be reimbursed by debiting an account of, or otherwise receiving payment from, the sender; and

(3) The instruction is transmitted by the sender directly to the receiving bank or to an agent, funds transfer system, or communication system for transmittal to the receiving bank.

(mm) *Person.* An individual, a corporation, a partnership, a trust or estate, a joint stock company, an association, a syndicate, joint venture, or other unincorporated organization or group, an Indian Tribe (as that term is defined in the Indian Gaming Regulatory Act), and all entities cognizable as legal personalities.

(nn) *Receiving bank.* The bank or foreign bank to which the sender's instruction is addressed.

(oo) *Receiving financial institution.* The financial institution or foreign financial agency to which the sender's instruction is addressed. The term receiving financial institution includes a receiving bank.

(pp) *Recipient.* The person to be paid by the recipient's financial institution. The term recipient includes a beneficiary, except where the recipient's financial institution is a financial institution other than a bank.

(qq) *Recipient's financial institution.* The financial institution or foreign financial agency identified in a transmittal order in which an account of the recipient is to be credited pursuant to the transmittal order or which otherwise is to make payment to the recipient if the order does not provide for payment to an account. The term recipient's financial institution includes a beneficiary's bank, except where the beneficiary is a recipient's financial institution.

(rr) *Secretary.* The Secretary of the Treasury or any person duly authorized by the Secretary to perform the function mentioned.

(ss) *Security.* Security means any instrument or interest described in section 3(a)(10) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(10).

(tt) *Self-regulatory organization:*

(1) Shall have the same meaning as provided in section 3(a)(26) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(26)); and

(2) Means a ''registered entity'' or a ''registered futures association'' as provided in section 1a(29) or 17, respectively, of the Commodity Exchange Act (7 U.S.C. 1a(29), 21).

(uu) *Sender.* The person giving the instruction to the receiving financial institution.

(vv) *State.* The States of the United States and, wherever necessary to carry out the provisions of this chapter, the District of Columbia.

(ww) *Stored value.* Funds or monetary value represented in digital electronics format (whether or not specially encrypted) and stored or capable of storage on electronic media in such a way as to be retrievable and transferable electronically.

(xx) *Structure (structuring).* For purposes of § 1010.314, a person structures a transaction if that person, acting alone, or in conjunction with, or on behalf of, other persons, conducts or attempts to conduct one or more transactions in currency, in any amount, at one or more financial institutions, on one or more days, in any manner, for the purpose of evading the reporting requirements under §§ 1010.311, 1010.313, 1020.315, 1021.311 and 1021.313 of this chapter. ''In any manner'' includes, but is not limited to, the breaking down of a single sum of currency exceeding $10,000 into smaller sums, including sums at or below $10,000, or the conduct of a transaction, or series of currency transactions at or below $10,000. The transaction or transactions need not exceed the $10,000 reporting threshold at any single financial institution on any single day in order to constitute structuring within the meaning of this definition.

(yy) *Taxpayer Identification Number.* Taxpayer Identification Number (''TIN'') is defined by section 6109 of the Internal Revenue Code of 1986 (26 U.S.C. 6109) and the Internal Revenue Service regulations implementing that section (*e.g.,* Social Security number or employer identification number).

(zz) *Territories and Insular Possessions.* The Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, the Commonwealth of the Northern Mariana Islands, and all other territories and possessions of the United States other than the Indian lands and the District of Columbia.

(aaa) [Reserved]

(bbb) *Transaction.* (1) Except as provided in paragraph (bbb)(2) of this section, transaction means a purchase, sale, loan, pledge, gift, transfer, delivery, or other disposition, and with respect to a financial institution includes a deposit, withdrawal, transfer between accounts, exchange of currency, loan, extension of credit, purchase or sale of any stock, bond, certificate of deposit, or other monetary instrument, security, contract of sale of a commodity for future delivery, option on any contract of sale of a commodity for future delivery, option on a commodity, purchase or redemption of any money order, payment or order for any money remittance or transfer, purchase or redemption of casino chips or tokens, or other gaming instruments or any other payment, transfer, or delivery by, through, or to a financial institution, by whatever means effected.

(2) For purposes of §§ 1010.311, 1010.313, 1020.315, 1021.311, 1021.313, and other provisions of this chapter relating solely to the report required by those sections, the term ''transaction in currency'' shall mean a transaction involving the physical transfer of currency from one person to another. A transaction which is a transfer of funds by means of bank check, bank draft, wire transfer, or other written order, and which does not include the physical transfer of currency, is not a transaction in currency for this purpose.

(ccc) *Transaction account.* Transaction accounts include those accounts described in 12 U.S.C. 461(b)(1)(C), money market accounts and similar accounts that take deposits and are subject to withdrawal by check or other negotiable order.

(ddd) *Transmittal of funds.* A series of transactions beginning with the transmittor's transmittal order, made for the purpose of making payment to the recipient of the order. The term includes any transmittal order issued by the transmittor's financial institution or an intermediary financial institution intended to carry out the transmittor's transmittal order. The term transmittal of funds includes a funds transfer. A transmittal of funds is completed by acceptance by the recipient's financial institution of a transmittal order for the benefit of the recipient of the transmittor's transmittal order. Funds transfers governed by the Electronic Fund Transfer Act of 1978 (Title XX, Pub. L. 95–630, 92 Stat. 3728, 15 U.S.C. 1693, *et seq.*), as well as any other funds transfers that are made through an automated clearinghouse, an automated teller machine, or a point-of-sale system, are excluded from this definition.

(eee) *Transmittal order.* The term transmittal order includes a payment order and is an instruction of a sender to a receiving financial institution, transmitted orally, electronically, or in writing, to pay, or cause another financial institution or foreign financial agency to pay, a fixed or determinable amount of money to a recipient if:

(1) The instruction does not state a condition to payment to the recipient other than time of payment;

(2) The receiving financial institution is to be reimbursed by debiting an account of, or otherwise receiving payment from, the sender; and

(3) The instruction is transmitted by the sender directly to the receiving financial institution or to an agent or communication system for transmittal to the receiving financial institution.

(fff) *Transmittor.* The sender of the first transmittal order in a transmittal of funds. The term transmittor includes an originator, except where the transmittor's financial institution is a financial institution or foreign financial agency other than a bank or foreign bank.

(ggg) *Transmittor's financial institution.* The receiving financial institution to which the transmittal order of the transmittor is issued if the transmittor is not a financial institution or foreign financial agency, or the transmittor if the transmittor is a financial institution or foreign financial agency. The term transmittor's financial institution includes an originator's bank, except where the originator is a transmittor's financial institution other than a bank or foreign bank.

(hhh) *United States.* The States of the United States, the District of Columbia, the Indian lands (as that term is defined in the Indian Gaming Regulatory Act), and the Territories and Insular Possessions of the United States.

(iii) *U.S. person.* (1) A United States citizen; or (2) A person other than an individual (such as a corporation, partnership or trust), that is established or organized under the laws of a State or the United States. Non-U.S. person means a person that is not a U.S. person.

(jjj) *U.S. Postal Service.* The United States Postal Service, except with respect to the sale of postage or philatelic products.

Subpart B—Programs

§ 1010.200 General.

Financial institutions (as defined in 31 U.S.C. 5312(a)(2) or (c)(1)) should refer to Subpart B of their Chapter X Part for additional program

requirements specific to that particular category of financial institution. Unless otherwise indicated, the program requirements contained in this Subpart B apply to all financial institutions (as defined in 31 U.S.C. 5312(a)(2) or (c)(1)).

§ 1010.205 Exempted anti-money laundering programs for certain financial institutions.

(a) *Exempt financial institutions.* Subject to the provisions of paragraphs (c) and (d) of this section, the following financial institutions (as defined in 31 U.S.C. 5312(a)(2) or (c)(1)) are exempt from the requirement in 31 U.S.C. 5318(h)(1) concerning the establishment of anti-money laundering programs:

(1) An agency of the United States Government, or of a State or local government, carrying out a duty or power of a business described in 31 U.S.C. 5312(a)(2); and

(2) [Reserved]

(b) *Temporary exemption for certain financial institutions.* (1) Subject to the provisions of paragraphs (c) and (d) of this section, the following financial institutions (as defined in 31 U.S.C. 5312(a)(2) or (c)(1)) are exempt from the requirement in 31 U.S.C. 5318(h)(1) concerning the establishment of anti-money laundering programs:

(i) Pawnbroker;

(ii) Loan or finance company;

(iii) Travel agency;

(iv) Telegraph company;

(v) Seller of vehicles, including automobiles, airplanes, and boats;

(vi) Person involved in real estate closings and settlements;

(vii) Private banker;

(viii) Commodity pool operator;

(ix) Commodity trading advisor; or

(x) Investment company.

(2) Subject to the provisions of paragraphs (c) and (d) of this section, a bank (as defined in § 1010.100(d)) that is not subject to regulation by a Federal functional regulator (as defined in § 1010.100(r)) is exempt from the requirement in 31 U.S.C. 5318(h)(1) concerning the establishment of anti-money laundering programs.

(3) Subject to the provisions of paragraphs (c) and (d) of this section, a person described in § 1010.100(t)(7) is exempt from the requirement in 31 U.S.C. 5318(h)(1) concerning the establishment of anti-money laundering programs.

(c) *Limitation on exemption.* The exemptions described in paragraph (b) of this section shall not apply to any financial institution that is otherwise required to establish an anti-money laundering program by this chapter.

(d) *Compliance obligations of deferred financial institutions.* Nothing in this section shall be deemed to relieve an exempt financial institution from its responsibility to comply with any other applicable requirement of law or regulation, including title 31 of the U.S.C. and this chapter.

§ 1010.210 Anti-money laundering programs.

Financial institutions (as defined in 31 U.S.C. 5312(a)(2) or (c)(1)) should refer to Subpart B of their Chapter X Part for anti-money laundering program requirements specific to that particular category of financial institution.

§ 1010.220 Customer identification program requirements.

Financial institutions (as defined in 31 U.S.C. 5312(a)(2) or (c)(1)) should refer to Subpart B of their Chapter X Part for customer identification program requirements specific to that particular category of financial institution.

Subpart C—Reports Required To Be Made

§ 1010.300 General.

Financial institutions (as defined in 31 U.S.C. 5312(a)(2) or (c)(1)) should refer to their Chapter X Part for additional reporting requirements specific to that particular category of financial institution. Unless otherwise indicated, the reporting requirements contained in this Subpart C apply to all financial institutions.

§ 1010.301 Determination by the Secretary.

The Secretary hereby determines that the reports required by this chapter have a high degree of usefulness in criminal, tax, or regulatory investigations or proceedings.

§ 1010.305 [Reserved]

§ 1010.306 Filing of reports.

(a)(1) A report required by § 1010.311 or § 1021.311, shall be filed by the financial institution within 15 days following the day on which the reportable transaction occurred.

(2) A copy of each report filed pursuant to §§ 1010.311, 1010.313, 1020.315, 1021.311 and 1021.313 shall be retained by the financial institution for a period of five years from the date of the report.

(3) All reports required to be filed by §§ 1010.311, 1010.313, 1020.315, 1021.311 and 1021.313 shall be filed with the Commissioner of Internal Revenue, unless otherwise specified.

(b)(1) A report required by § 1010.340(a) shall be filed at the time of entry into the United States or at the time of departure, mailing or shipping from the United States, unless otherwise specified by the Commissioner of Customs and Border Protection.

(2) A report required by § 1010.340(b) shall be filed within 15 days after receipt of the currency or other monetary instruments.

(3) All reports required by § 1010.340 shall be filed with the Customs officer in charge at any port of entry or departure, or as otherwise specified by the Commissioner of Customs and Border Protection. Reports required by § 1010.340(a) for currency or other monetary instruments not physically accompanying a person entering or departing from the United States, may be filed by mail on or before the date of entry, departure, mailing or shipping. All reports required by § 1010.340(b) may also be filed by mail. Reports filed by mail shall be addressed to the Commissioner of Customs and Border Protection, Attention: Currency Transportation Reports, Washington, DC 20229.

(c) Reports required to be filed by § 1010.350 shall be filed with the Commissioner of Internal Revenue on or before June 30 of each calendar year with respect to foreign financial accounts exceeding $10,000 maintained during the previous calendar year.

(d) Reports required by § 1010.311, § 1010.313, § 1010.340, § 1010.350, § 1020.315, § 1021.311 or § 1021.313 shall be filed on forms prescribed by the Secretary. All information called for in such forms shall be furnished.

(e) Forms to be used in making the reports required by § 1010.311, § 1010.313, § 1010.350, § 1020.315, § 1021.311 or § 1021.313 may be obtained from the Internal Revenue Service. Forms to be used in making the reports required by § 1010.340 may be obtained from the U.S. Customs and Border Protection.

(Approved by the Office of Management and Budget under control number 1505–0063)

§ 1010.310 Reports of transactions in currency.

Sections 1010.310 through 1010.314 set forth the rules for the reporting by financial institutions of transactions in currency. Unless otherwise indicated, the transactions in currency reporting requirements in §§ 1010.310 through 1010.314 apply to all financial institutions. All financial institutions should refer to Subpart C of their Chapter X Part for additional transactions in currency reporting requirements specific to that particular financial institution category.

§ 1010.311 Filing obligations for reports of transactions in currency.

Each financial institution other than a casino shall file a report of each deposit, withdrawal, exchange of currency or other payment or transfer, by, through, or to such financial institution which involves a transaction in currency of more than $10,000, except as otherwise provided in this section. In the case of the U.S. Postal Service, the obligation contained in the preceding sentence shall not apply to payments or transfers made solely in connection with the purchase of postage or philatelic products.

§ 1010.312 Identification required.

Before concluding any transaction with respect to which a report is required under § 1010.311, § 1010.313, § 1020.315, § 1021.311 or § 1021.313, a financial institution shall verify and record the name and address of the individual presenting a transaction, as well as record the identity, account number, and the social security or taxpayer identification number, if any, of any person or entity on whose behalf such transaction is to be effected. Verification of the identity of an individual who indicates that he or she is an alien or is not a resident of the United States must be made by passport, alien identification card, or other official document evidencing nationality or residence (*e.g.*, a Provincial driver's license with indication of home address). Verification of identity in any other case shall be made by examination of a document, other than a bank signature card, that is normally acceptable within the banking community as a means of identification when cashing checks for nondepositors (*e.g.*, a driver's license or credit card). A bank signature card may be relied upon only if it was issued after documents establishing the identity of the individual were examined and notation of the specific information was made on the signature card. In each instance, the specific identifying information (*i.e.*, the account number of the credit card, the driver's license number, etc.) used in verifying the identity of the customer shall be recorded on the report, and the mere notation of ''known customer'' or ''bank signature card on file'' on the report is prohibited.

(Approved by the Office of Management and Budget under control number 1505–0063.)

§ 1010.313 Aggregation.

(a) *Multiple branches.* A financial institution includes all of its domestic branch offices, and any recordkeeping facility, wherever located, that contains records relating to the transactions of the institution's domestic offices, for purposes of the transactions in currency reporting requirements in this chapter.

(b) *Multiple transactions.* In the case of financial institutions other than casinos, for purposes of the transactions in currency reporting requirements in this chapter, multiple currency transactions shall be treated as a single transaction if the financial institution has knowledge that they are by or on behalf of any person and result in either cash in or cash out totaling more than $10,000 during any one business day (or in the case of the U.S. Postal Service, any one day). Deposits made at night or over a weekend or holiday shall be treated as if received on the next business day following the deposit.

§ 1010.314 Structured transactions.

No person shall for the purpose of evading the transactions in currency reporting requirements of this chapter with respect to such transaction:

(a) Cause or attempt to cause a domestic financial institution to fail to file a report required under the transactions in currency reporting requirements of this chapter;

(b) Cause or attempt to cause a domestic financial institution to file a report required under the transactions in currency reporting requirements of this chapter that contains a material omission or misstatement of fact; or

(c) Structure (as that term is defined in § 1010.100(xx)) or assist in structuring, or attempt to structure or assist in structuring, any transaction with one or more domestic financial institutions.

§ 1010.315 Exemptions for non-bank financial institutions.

A non-bank financial institution is not required to file a report otherwise required by § 1010.311 with respect to a transaction in currency between the institution and a commercial bank.

§ 1010.320 Reports of suspicious transactions.

Financial institutions (as defined in 31 U.S.C. 5312(a)(2) or (c)(1)) should refer to subpart C of their financial institution part for suspicious transaction reporting requirements specific to that particular category of financial institution.

§ 1010.330 Reports relating to currency in excess of $10,000 received in a trade or business.

(a) *Reporting requirement*—(1) *Reportable transactions*—(i) *In general.* Any person (solely for purposes of section 5331 of title 31, United States Code and this section, ''person'' shall have the same meaning as under 26 U.S.C. 7701 (a)(1)) who, in the course of a trade or business in which such person is engaged, receives currency in excess of $10,000 in 1 transaction (or 2 or more related transactions) shall, except as otherwise provided, make a report of information with respect to the receipt of currency. This section does not apply to amounts received in a transaction reported under 31 U.S.C. 5313 and §§ 1010.311, 1010.313, 1020.315, 1021.311 or 1021.313 of this chapter.

(ii) *Certain financial transactions.* Section 60501 of title 26 of the United States Code requires persons to report information about financial transactions to the IRS, and 31 U.S.C. 5331 requires persons to report similar information about certain transactions to FinCEN. This information shall be reported on the same form as prescribed by the Secretary.

(2) *Currency received for the account of another.* Currency in excess of $10,000 received by a person for the account of another must be reported under this section. Thus, for example, a person who collects delinquent accounts receivable for an automobile dealer must report with respect to the receipt of currency in excess of $10,000 from the collection of a particular account even though the proceeds of the collection are credited to the account of the automobile dealer (*i.e.*, where the rights to the proceeds from the account are retained by the automobile dealer and the collection is made on a fee-for-service basis).

(3) *Currency received by agents*—(i) *General rule.* Except as provided in paragraph (a)(3)(ii) of this section, a person who in the course of a trade or business acts as an agent (or in some other similar capacity) and receives currency in excess of $10,000 from a principal must report the receipt of currency under this section.

(ii) *Exception.* An agent who receives currency from a principal and uses all of the currency within 15 days in a currency transaction (the ''second currency transaction'') which is reportable under section 5312 of title 31, or 31 U.S.C. 5331 and this section, and who discloses the name, address, and TIN of the principal to the recipient in the second currency transaction need not report the initial receipt of currency under this section. An agent will be deemed to have met the disclosure requirements of this paragraph (a)(3)(ii) if the agent discloses only the name of the principal and the agent knows that the recipient has the principal's address and taxpayer identification number.

(iii) *Example.* The following example illustrates the application of the rules in paragraphs (a)(3)(i) and (ii) of this section:

Example. B, the principal, gives D, an attorney, $75,000 in currency to purchase real property on behalf of B. Within 15 days D purchases real property for currency from E, a real estate developer, and discloses to E, B's name, address, and taxpayer identification number. Because the transaction qualifies for the exception provided in paragraph (a)(3)(ii) of this section, D need not report with respect to the initial receipt of currency under this section. The exception does not apply, however, if D pays E by means other than currency, or effects the purchase more than 15 days following receipt of the currency from B, or fails to disclose B's name, address, and taxpayer identification number (assuming D does not know that E already has B's address and taxpayer identification number), or purchases the property from a person whose sale of the property is not in the course of that person's trade or business. In any such case, D is required to report the receipt of currency from B under this section.

(b) *Multiple payments.* The receipt of multiple currency deposits or currency installment payments (or other similar payments or prepayments) relating to a single transaction (or two or more related transactions), is reported as set forth in paragraphs (b)(1) through (b)(3) of this section.

(1) *Initial payment in excess of $10,000.* If the initial payment exceeds $10,000, the recipient must report the initial payment within 15 days of its receipt.

(2) *Initial payment of $10,000 or less.* If the initial payment does not exceed $10,000, the recipient must aggregate the initial payment and subsequent payments made within one year of the initial payment until the aggregate amount exceeds $10,000, and report with respect to the aggregate amount within 15 days after receiving the payment that causes the aggregate amount to exceed $10,000.

(3) *Subsequent payments.* In addition to any other required report, a report must be made each time that previously unreportable payments made within a 12-month period with respect to a single transaction (or two or more related transactions), individually or in the aggregate, exceed $10,000. The report must be made within 15 days after receiving the payment in excess of $10,000 or the payment that causes the aggregate amount received in the 12-month period to exceed $10,000. (If more than one report would otherwise be required for multiple currency payments within a 15-day period that relate to a single transaction (or two or more related transactions), the recipient may make a single combined report with respect to the payments. The combined report must be made no later than the date by which the first of the separate reports would otherwise be required to be made.)

(4) *Example.* The following example illustrates the application of the rules in paragraphs (b)(1) through (b)(3) of this section:

Example. On January 10, Year 1, M receives an initial payment in currency of $11,000 with respect to a transaction. M receives subsequent payments in currency with respect to the same transaction of $4,000 on February 15, Year 1, $6,000 on March 20, Year 1, and $12,000 on May 15, Year 1. M must make a report with respect to the payment received on January 10, Year 1, by January 25, Year 1. M must also make a report with respect to the payments totaling $22,000 received from February 15, Year 1, through May 15, Year 1. This report must be made by May 30, Year 1, that is, within 15 days of the date that the subsequent payments, all of which were received within a 12-month period, exceeded $10,000.

(c) *Meaning of terms.* The following definitions apply for purposes of this section—

(1) *Currency.* Solely for purposes of 31 U.S.C. 5331 and this section, *currency* means—

(i) The coin and currency of the United States or of any other country, which circulate in and are customarily used and accepted as money in the country in which issued; and

(ii) A cashier's check (by whatever name called, including ''treasurer's check'' and ''bank check''), bank draft, traveler's check, or money order having a face amount of not more than $10,000—

(A) Received in a designated reporting transaction as defined in paragraph (c)(2) of this section (except as provided in paragraphs (c)(3), (4), and (5) of this section), or

(B) Received in any transaction in which the recipient knows that such instrument is being used in an attempt to avoid the reporting of the transaction under section 5331 and this section.

(2) *Designated reporting transaction.* A designated reporting transaction is a retail sale (or the receipt of funds by a broker or other intermediary in connection with a retail sale) of—

(i) A consumer durable,

(ii) A collectible, or

(iii) A travel or entertainment activity.

(3) *Exception for certain loans.* A cashier's check, bank draft, traveler's check, or money order received in a designated reporting transaction is not treated as currency pursuant to paragraph (c)(1)(ii)(A) of this section if the instrument constitutes the proceeds of a loan from a bank. The recipient may rely on a copy of the loan document, a written statement from the bank, or similar documentation (such as a written lien instruction from the issuer of the instrument) to substantiate that the instrument constitutes loan proceeds.

(4) *Exception for certain installment sales.* A cashier's check, bank draft, traveler's check, or money order received in a designated reporting transaction is not treated as currency pursuant to paragraph (c)(1)(ii)(A) of this section if the instrument is received in payment on a promissory note or an installment sales contract (including a lease that is considered to be a sale for Federal income tax purposes). However, the preceding sentence applies only if—

(i) Promissory notes or installment sales contracts with the same or substantially similar terms are used in the ordinary course of the recipient's trade or business in connection with sales to ultimate consumers; and

(ii) The total amount of payments with respect to the sale that are received on or before the 60th day after the date of the sale does not exceed 50 percent of the purchase price of the sale.

(5) *Exception for certain down payment plans.* A cashier's check, bank draft, traveler's check, or money order received in a designated reporting transaction is not treated as currency pursuant to paragraph (c)(1)(ii)(A) of this section if the instrument is received pursuant to a payment plan requiring one or more down payments and the payment of the balance of the purchase price by a date no later than the date of the sale (in the case of an item of travel or entertainment, a date no later than the earliest date that any item of travel or entertainment pertaining to the same trip or event is furnished). However, the preceding sentence applies only if—

(i) The recipient uses payment plans with the same or substantially similar terms in the ordinary course of its trade or business in connection with sales to ultimate consumers; and

(ii) The instrument is received more than 60 days prior to the date of the sale (in the case of an item of travel or entertainment, the date on which the final payment is due).

(6) *Examples.* The following examples illustrate the definition of ''currency'' set forth in paragraphs (c)(1) through (c)(5) of this section:

Example 1. D, an individual, purchases gold coins from M, a coin dealer, for $13,200. D tenders to M in payment United States currency in the amount of $6,200 and a cashier's check in the face amount of $7,000 which D had purchased. Because the sale is a designated reporting transaction, the cashier's check is treated as currency for

purposes of 31 U.S.C. 5331 and this section. Therefore, because M has received more than $10,000 in currency with respect to the transaction, M must make the report required by 31 U.S.C. 5331 and this section.

Example 2. E, an individual, purchases an automobile from Q, an automobile dealer, for $11,500. E tenders to Q in payment United States currency in the amount of $2,000 and a cashier's check payable to E and Q in the amount of $9,500. The cashier's check constitutes the proceeds of a loan from the bank issuing the check. The origin of the proceeds is evident from provisions inserted by the bank on the check that instruct the dealer to cause a lien to be placed on the vehicle as security for the loan. The sale of the automobile is a designated reporting transaction. However, under paragraph (c)(3) of this section, because E has furnished Q documentary information establishing that the cashier's check constitutes the proceeds of a loan from the bank issuing the check, the cashier's check is not treated as currency pursuant to paragraph (c)(1)(ii)(A) of this section.

Example 3. F, an individual, purchases an item of jewelry from S, a retail jeweler, for $12,000. F gives S traveler's checks totaling $2,400 and pays the balance with a personal check payable to S in the amount of $9,600. Because the sale is a designated reporting transaction, the traveler's checks are treated as currency for purposes of section 5331 and this section. However, because the personal check is not treated as currency for purposes of section 5331 and this section, S has not received more than $10,000 in currency in the transaction and no report is required to be filed under section 5331 and this section.

Example 4. G, an individual, purchases a boat from T, a boat dealer, for $16,500. G pays T with a cashier's check payable to T in the amount of $16,500. The cashier's check is not treated as currency because the face amount of the check is more than $10,000. Thus, no report is required to be made by T under section 5331 and this section.

Example 5. H, an individual, arranges with W, a travel agent, for the chartering of a passenger aircraft to transport a group of individuals to a sports event in another city. H also arranges with W for hotel accommodations for the group and for admission tickets to the sports event. In payment, H tenders to W money orders which H had previously purchased. The total amount of the money orders, none of which individually exceeds $10,000 in face amount, exceeds $10,000. Because the transaction is a designated reporting transaction, the money orders are treated as currency for purposes of section 5331 and this section. Therefore, because W has received more than $10,000 in currency with respect to the transaction, W must make the report required by section 5331 and this section.

(7) *Consumer durable.* The term *consumer durable* means an item of tangible personal property of a type that is suitable under ordinary usage for personal consumption or use, that can reasonably be expected to be useful for at least 1 year under ordinary usage, and that has a sales price of more than $10,000. Thus, for example, a $20,000 automobile is a consumer durable (whether or not it is sold for business use), but a $20,000 dump truck or a $20,000 factory machine is not.

(8) *Collectible.* The term *collectible* means an item described in paragraphs (A) through (D) of section 408(m)(2) of title 26 of the United States Code (determined without regard to section 408(m)(3) of title 26 of the United States Code).

(9) *Travel or entertainment activity.* The term *travel or entertainment activity* means an item of travel or entertainment (within the meaning of 26 CFR 1.274–2(b)(1)) pertaining to a single trip or event where the aggregate sales price of the item and all other items pertaining to the same trip or event that are sold in the same transaction (or related transactions) exceeds $10,000.

(10) *Retail sale.* The term *retail sale* means any sale (whether for resale or for any other purpose) made in the course of a trade or business if that trade or business principally consists of making sales to ultimate consumers.

(11) *Trade or business.* The term *trade or business* has the same meaning as under section 162 of title 26, United States Code.

(12) *Transaction.* (i) Solely for purposes of 31 U.S.C. 5331 and this section, the term *transaction* means the underlying event precipitating the payer's transfer of currency to the recipient. In this context, transactions include (but are not limited to) a sale of goods or services; a sale of real property; a sale of intangible property; a rental of real or personal property; an exchange of currency for other currency; the establishment or maintenance of or contribution to a custodial, trust, or escrow arrangement; a payment of a preexisting debt; a conversion of currency to a negotiable instrument; a reimbursement for expenses paid; or the making or repayment of a loan. A transaction may not be divided into multiple transactions in order to avoid reporting under this section.

(ii) The term *related transactions* means any transaction conducted between a payer (or its agent) and a recipient of currency in a 24-hour period. Additionally, transactions conducted between a payer (or its agent) and a currency recipient during a period of more than 24 hours are related if the recipient knows or has reason to know that each transaction is one of a series of connected transactions.

(iii) The following examples illustrate the definition of paragraphs (c)(12)(i) and (ii) of this section:

Example 1. A person has a tacit agreement with a gold dealer to purchase $36,000 in gold bullion. The $36,000 purchase represents a single transaction under paragraph (c)(12)(i) of this section and the reporting requirements of this section cannot be avoided by recasting the single sales transaction into 4 separate $9,000 sales transactions.

Example 2. An attorney agrees to represent a client in a criminal case with the attorney's fee to be determined on an hourly basis. In the first month in which the attorney represents the client, the bill for the attorney's services comes to $8,000 which the client pays in currency. In the second month in which the attorney represents the client, the bill for the attorney's services comes to $4,000, which the client again pays in currency. The aggregate amount of currency paid ($12,000) relates to a single transaction as defined in paragraph (c)(12)(i) of this section, the sale of legal services relating to the criminal case, and the receipt of currency must be reported under this section.

Example 3. A person intends to contribute a total of $45,000 to a trust fund, and the trustee of the fund knows or has reason to know of that intention. The $45,000 contribution is a single transaction under paragraph (c)(12)(i) of this section and the reporting requirement of this section cannot be avoided by the grantor's making five separate $9,000 contributions of currency to a single fund or by making five $9,000 contributions of currency to five separate funds administered by a common trustee.

Example 4. K, an individual, attends a one day auction and purchases for currency two items, at a cost of $9,240 and $1,732.50 respectively (tax and buyer's premium included). Because the transactions are related transactions as defined in paragraph (c)(12)(ii) of this section, the auction house is required to report the aggregate amount of currency received from the related sales ($10,972.50), even though the auction house accounts separately on its books for each item sold and presents the purchaser with separate bills for each item purchased.

Example 5. F, a coin dealer, sells for currency $9,000 worth of gold coins to an individual on three successive days. Under paragraph (c)(12)(ii) of this section the three $9,000 transactions are related transactions aggregating $27,000 if F knows, or has reason to know, that each transaction is one of a series of connected transactions.

(13) *Recipient.* (i) The term *recipient* means the person receiving the currency. Except as provided in paragraph (c)(13)(ii) of this section, each store, division, branch, department, headquarters, or office (''branch'') (regardless of physical location) comprising a portion of a person's trade or business shall for purposes of this section be deemed a separate recipient.

(ii) A branch that receives currency payments will not be deemed a separate recipient if the branch (or a central unit linking such branch with other branches) would in the ordinary course of business have reason to know the

identity of payers making currency payments to other branches of such person.

(iii) *Examples.* The following examples illustrate the application of the rules in paragraphs (c)(13)(i) and (ii) of this section:

Example 1. N, an individual, purchases regulated futures contracts at a cost of $7,500 and $5,000, respectively, through two different branches of Commodities Broker X on the same day. N pays for each purchase with currency. Each branch of Commodities Broker X transmits the sales information regarding each of N's purchases to a central unit of Commodities Broker X (which settles the transactions against N's account). Under paragraph (c)(13)(ii) of this section the separate branches of Commodities Broker X are not deemed to be separate recipients; therefore, Commodities Broker X must report with respect to the two related regulated futures contracts sales in accordance with this section.

Example 2. P, a corporation, owns and operates a racetrack. P's racetrack contains 100 betting windows at which pari-mutuel wagers may be made. R, an individual, places currency wagers of $3,000 each at five separate betting windows. Assuming that in the ordinary course of business each betting window (or a central unit linking windows) does not have reason to know the identity of persons making wagers at other betting windows, each betting window would be deemed to be a separate currency recipient under paragraph (c)(13)(i) of this section. As no individual recipient received currency in excess of $10,000, no report need be made by P under this section.

(d) *Exceptions to the reporting requirements of 31 U.S.C. 5331*—(1) *Receipt is made with respect to a foreign currency transaction*—(i) *In general.* Generally, there is no requirement to report with respect to a currency transaction if the entire transaction occurs outside the United States (the fifty states and the District of Columbia). An entire transaction consists of both the transaction as defined in paragraph (c)(12)(i) of this section and the receipt of currency by the recipient. If, however, any part of an entire transaction occurs in the Commonwealth of Puerto Rico or a possession or territory of the United States and the recipient of currency in that transaction is subject to the general jurisdiction of the Internal Revenue Service under title 26 of the United States Code, the recipient is required to report the transaction under this section.

(ii) *Example.* The following example illustrates the application of the rules in paragraph (d)(1)(i) of this section:

Example. W, an individual engaged in the trade or business of selling aircraft, reaches an agreement to sell an airplane to a U.S. citizen living in Mexico. The agreement, no portion of which is formulated in the United States, calls for a purchase price of $125,000 and requires delivery of and payment for the airplane to be made in Mexico. Upon delivery of the airplane in Mexico, W receives $125,000 in currency. W is not required to report under 31 U.S.C. 5331 or this section because the exception provided in paragraph (d)(1)(i) of this section (''foreign transaction exception'') applies. If, however, any part of the agreement to sell had been formulated in the United States, the foreign transaction exception would not apply and W would be required to report the receipt of currency under 31 U.S.C. 5331 and this section.

(2) *Receipt of currency not in the course of the recipient's trade or business.* The receipt of currency in excess of $10,000 by a person other than in the course of the person's trade or business is not reportable under 31 U.S.C. 5331. Thus, for example, F, an individual in the trade or business of selling real estate, sells a motorboat for $12,000, the purchase price of which is paid in currency. F did not use the motorboat in any trade or business in which F was engaged. F is not required to report under 31 U.S.C. 5331 or this section because the exception provided in this paragraph (d)(2) applies.

(e) *Time, manner, and form of reporting*—(1) *In general.* The reports required by paragraph (a) of this section must be made by filing a Form 8300, as specified in 26 CFR 1.6050I–1(e)(2). The reports must be filed at the time and in the manner specified in 26 CFR 1.6050I–1(e)(1) and (3) respectively.

(2) *Verification.* A person making a report of information under this section must verify the identity of the person from whom the reportable currency is received. Verification of the identity of a person who purports to be an alien must be made by examination of such person's passport, alien identification card, or other official document evidencing nationality or residence. Verification of the identity of any other person may be made by examination of a document normally acceptable as a means of identification when cashing or accepting checks (for example, a driver's license or a credit card). In addition, a report will be considered incomplete if the person required to make a report knows (or has reason to know) that an agent is conducting the transaction for a principal, and the return does not identify both the principal and the agent.

(3) *Retention of reports.* A person required to make a report under this section must keep a copy of each report filed for five years from the date of filing.

§ 1010.340 Reports of transportation of currency or monetary instruments.

(a) Each person who physically transports, mails, or ships, or causes to be physically transported, mailed, or shipped, or attempts to physically transport, mail or ship, or attempts to cause to be physically transported, mailed or shipped, currency or other monetary instruments in an aggregate amount exceeding $10,000 at one time from the United States to any place outside the United States, or into the United States from any place outside the United States, shall make a report thereof. A person is deemed to have caused such transportation, mailing or shipping when he aids, abets, counsels, commands, procures, or requests it to be done by a financial institution or any other person.

(b) Each person who receives in the U.S. currency or other monetary instruments in an aggregate amount exceeding $10,000 at one time which have been transported, mailed, or shipped to such person from any place outside the United States with respect to which a report has not been filed under paragraph (a) of this section, whether or not required to be filed thereunder, shall make a report thereof, stating the amount, the date of receipt, the form of monetary instruments, and the person from whom received.

(c) This section shall not require reports by:

(1) A Federal Reserve;

(2) A bank, a foreign bank, or a broker or dealer in securities, in respect to currency or other monetary instruments mailed or shipped through the postal service or by common carrier;

(3) A commercial bank or trust company organized under the laws of any State or of the United States with respect to overland shipments of currency or monetary instruments shipped to or received from an established customer maintaining a deposit relationship with the bank, in amounts which the bank may reasonably conclude do not exceed amounts commensurate with the customary conduct of the business, industry or profession of the customer concerned;

(4) A person who is not a citizen or resident of the United States in respect to currency or other monetary instruments mailed or shipped from abroad to a bank or broker or dealer in securities through the postal service or by common carrier;

(5) A common carrier of passengers in respect to currency or other monetary instruments in the possession of its passengers;

(6) A common carrier of goods in respect to shipments of currency or monetary instruments not declared to be such by the shipper;

(7) A travelers' check issuer or its agent in respect to the transportation of travelers' checks prior to their delivery to selling agents for eventual sale to the public;

(8) By a person with respect to a restrictively endorsed traveler's check that is in the collection and reconciliation process after the traveler's check has been negotiated;

(9) Nor by a person engaged as a business in the transportation of currency, monetary instruments and other commercial papers with respect to the transportation of currency or other monetary instruments overland between established offices of banks or brokers or dealers in securities and foreign persons.

(d) A transfer of funds through normal banking procedures which does not involve the physical transportation of currency or monetary instruments is not required to be reported by this section. This section does not require that more than one report be filed covering a particular transportation, mailing or shipping of currency or other monetary instruments with respect to which a complete and truthful report has been filed by a person. However, no person required by paragraph (a) or (b) of this section to file a report shall be excused from liability for failure to do so if, in fact, a complete and truthful report has not been filed.

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§ 1010.350 Reports of foreign financial accounts.

Each person subject to the jurisdiction of the United States (except a foreign subsidiary of a U.S. person) having a financial interest in, or signature or other authority over, a bank, securities or other financial account in a foreign country shall report such relationship to the Commissioner of the Internal Revenue for each year in which such relationship exists, and shall provide such information as shall be specified in a reporting form prescribed by the Secretary to be filed by such persons. Persons having a financial interest in 25 or more foreign financial accounts need only note that fact on the form. Such persons will be required to provide detailed information concerning each account when so requested by the Secretary or his delegate.

§ 1010.360 Reports of transactions with foreign financial agencies.

(a) *Promulgation of reporting requirements.* The Secretary, when he deems appropriate, may promulgate regulations requiring specified financial institutions to file reports of certain transactions with designated foreign financial agencies. If any such regulation is issued as a final rule without notice and opportunity for public comment, then a finding of good cause for dispensing with notice and comment in accordance with 5 U.S.C. 553(b) will be included in the regulation. If any such regulation is not published in the **Federal Register**, then any financial institution subject to the regulation will be named and personally served or otherwise given actual notice in accordance with 5 U.S.C. 553(b). If a financial institution is given notice of a reporting requirement under this section by means other than publication in the **Federal Register**, the Secretary may prohibit disclosure of the existence or provisions of that reporting requirement to the designated foreign financial agency or agencies and to any other party.

(b) *Information subject to reporting requirements.* A regulation promulgated pursuant to paragraph (a) of this section shall designate one or more of the following categories of information to be reported:

(1) Checks or drafts, including traveler's checks, received by respondent financial institution for collection or credit to the account of a foreign financial agency, sent by respondent financial institution to a foreign country for collection or payment, drawn by respondent financial institution on a foreign financial agency, drawn by a foreign financial agency on respondent financial institution—including the following information.

(i) Name of maker or drawer;

(ii) Name of drawee or drawee financial institution;

(iii) Name of payee;

(iv) Date and amount of instrument;

(v) Names of all endorsers.

(2) Transmittal orders received by a respondent financial institution from a foreign financial agency or sent by respondent financial institution to a foreign financial agency, including all information maintained by that institution pursuant to §§ 1010.410 and 1020.410.

(3) Loans made by respondent financial institution to or through a foreign financial agency—including the following information:

(i) Name of borrower;

(ii) Name of person acting for borrower;

(iii) Date and amount of loan;

(iv) Terms of repayment;

(v) Name of guarantor;

(vi) Rate of interest;

(vii) Method of disbursing proceeds;

(viii) Collateral for loan.

(4) Commercial paper received or shipped by the respondent financial institution—including the following information:

(i) Name of maker;

(ii) Date and amount of paper;

(iii) Due date;

(iv) Certificate number;

(v) Amount of transaction.

(5) Stocks received or shipped by respondent financial institution—including the following information:

(i) Name of corporation;

(ii) Type of stock;

(iii) Certificate number;

(iv) Number of shares;

(v) Date of certificate;

(vi) Name of registered holder;

(vii) Amount of transaction.

(6) Bonds received or shipped by respondent financial institution—including the following information:

(i) Name of issuer;

(ii) Bond number;

(iii) Type of bond series;

(iv) Date issued;

(v) Due date;

(vi) Rate of interest;

(vii) Amount of transaction;

(viii) Name of registered holder.

(7) Certificates of deposit received or shipped by respondent financial institution—including the following information:

(i) Name and address of issuer;

(ii) Date issued;

(iii) Dollar amount;

(iv) Name of registered holder;

(v) Due date;

(vi) Rate of interest;

(vii) Certificate number;

(viii) Name and address of issuing agent.

(c) *Scope of reports.* In issuing regulations as provided in paragraph (a) of this section, the Secretary will prescribe:

(1) A reasonable classification of financial institutions subject to or exempt from a reporting requirement;

(2) A foreign country to which a reporting requirement applies if the Secretary decides that applying the requirement to all foreign countries is unnecessary or undesirable;

(3) The magnitude of transactions subject to a reporting requirement; and

(4) The kind of transaction subject to or exempt from a reporting requirement.

(d) *Form of reports.* Regulations issued pursuant to paragraph (a) of this section may prescribe the manner in which the information is to be reported.

However, the Secretary may authorize a designated financial institution to report in a different manner if the institution demonstrates to the Secretary that the form of the required report is unnecessarily burdensome on the institution as prescribed; that a report in a different form will provide all the information the Secretary deems necessary; and that submission of the information in a different manner will not unduly hinder the effective administration of this chapter.

(e) *Limitations.* (1) In issuing regulations under paragraph (a) of this section, the Secretary shall consider the need to avoid impeding or controlling the export or import of monetary instruments and the need to avoid burdening unreasonably a person making a transaction with a foreign financial agency.

(2) The Secretary shall not issue a regulation under paragraph (a) of this section for the purpose of obtaining individually identifiable account information concerning a customer, as defined by the Right to Financial Privacy Act (12 U.S.C. 3401 *et seq.*), where that customer is already the subject of an ongoing investigation for possible violation of the Currency and Foreign Transactions Reporting Act, or is known by the Secretary to be the subject of an investigation for possible violation of any other Federal law.

(3) The Secretary may issue a regulation pursuant to paragraph (a) of this section requiring a financial institution to report transactions completed prior to the date it received notice of the reporting requirement. However, with respect to completed transactions, a financial institution may be required to provide information only from records required to be maintained pursuant to the requirements of this chapter, or any other provision of state or Federal law, or otherwise maintained in the regular course of business.

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§ 1010.370 Reports of certain domestic coin and currency transactions.

(a) If the Secretary of the Treasury finds, upon the Secretary's own initiative or at the request of an appropriate Federal or State law enforcement official, that reasonable grounds exist for concluding that additional recordkeeping and/or reporting requirements are necessary to carry out the purposes of this chapter and to prevent persons from evading the reporting/recordkeeping requirements of this chapter, the Secretary may issue an order requiring any domestic financial institution or group of domestic financial institutions in a geographic area and any other person participating in the type of transaction to file a report in the manner and to the extent specified in such order. The order shall contain such information as the Secretary may describe concerning any transaction in which such financial institution is involved for the payment, receipt, or transfer of United States coins or currency (or such other monetary instruments as the Secretary may describe in such order) the total amounts or denominations of which are equal to or greater than an amount which the Secretary may prescribe.

(b) An order issued under paragraph (a) of this section shall be directed to the Chief Executive Officer of the financial institution and shall designate one or more of the following categories of information to be reported: Each deposit, withdrawal, exchange of currency or other payment or transfer, by, through or to such financial institution specified in the order, which involves all or any class of transactions in currency and/or monetary instruments equal to or exceeding an amount to be specified in the order.

(c) In issuing an order under paragraph (a) of this section, the Secretary will prescribe:

(1) The dollar amount of transactions subject to the reporting requirement in the order;

(2) The type of transaction or transactions subject to or exempt from a reporting requirement in the order;

(3) The appropriate form for reporting the transactions required in the order;

(4) The address to which reports required in the order are to be sent or from which they will be picked up;

(5) The starting and ending dates by which such transactions specified in the order are to be reported;

(6) The name of a Treasury official to be contacted for any additional information or questions;

(7) The amount of time the reports and records of reports generated in response to the order will have to be retained by the financial institution; and

(8) Any other information deemed necessary to carry out the purposes of the order.

(d)(1) No order issued pursuant to paragraph (a) of this section shall prescribe a reporting period of more than 60 days unless renewed pursuant to the requirements of paragraph (a).

(2) Any revisions to an order issued under this section will not be effective until made in writing by the Secretary.

(3) Unless otherwise specified in the order, a bank receiving an order under this section may continue to use the exemptions granted under § 1020.315 of this chapter prior to the receipt of the order, but may not grant additional exemptions.

(4) For purposes of this section, the term *geographic area* means any area in one or more States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, the Commonwealth of the Northern Mariana Islands, American Samoa, the Trust Territory of the Pacific Islands, the territories and possessions of the United States, and/or political subdivision or subdivisions thereof, as specified in an order issued pursuant to paragraph (a) of this section.

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Subpart D—Records Required To Be Maintained

§ 1010.400 General.

Financial institutions (as defined in 31 U.S.C. 5312(a)(2) or (c)(1)) should refer to their Chapter X Part for additional recordkeeping requirements specific to that particular category of financial institution. Unless otherwise indicated, the recordkeeping requirements contained in this Subpart D apply to all financial institutions.

§ 1010.401 Determination by the Secretary.

The Secretary hereby determines that the records required to be kept by this chapter have a high degree of usefulness in criminal, tax, or regulatory investigations or proceedings.

§ 1010.405 [Reserved]

§ 1010.410 Records to be made and retained by financial institutions.

Each financial institution shall retain either the original or a microfilm or other copy or reproduction of each of the following:

(a) A record of each extension of credit in an amount in excess of $10,000, except an extension of credit secured by an interest in real property, which record shall contain the name and address of the person to whom the extension of credit is made, the amount thereof, the nature or purpose thereof, and the date thereof;

(b) A record of each advice, request, or instruction received or given regarding any transaction resulting (or intended to result and later canceled if such a record is normally made) in the transfer of currency or other monetary instruments, funds, checks, investment securities, or credit, of more than $10,000 to or from any person, account, or place outside the United States.

(c) A record of each advice, request, or instruction given to another financial institution or other person located within or without the United States, regarding a transaction intended to result in the transfer of funds, or of currency, other monetary instruments, checks, investment securities, or credit, of more than $10,000 to a person, account or place outside the United States.

(d) A record of such information for such period of time as the Secretary may require in an order issued under § 1010.370(a), not to exceed five years.

(e) *Nonbank financial institutions.* Each agent, agency, branch, or office located within the United States of a financial institution other than a bank is subject to the requirements of this paragraph (e) with respect to a transmittal of funds in the amount of $3,000 or more:

(1) *Recordkeeping requirements.* (i) For each transmittal order that it accepts as a transmittor's financial institution, a financial institution shall obtain and retain either the original or a microfilm, other copy, or electronic record of the following information relating to the transmittal order:

(A) The name and address of the transmittor;

(B) The amount of the transmittal order;

(C) The execution date of the transmittal order;

(D) Any payment instructions received from the transmittor with the transmittal order;

(E) The identity of the recipient's financial institution;

(F) As many of the following items as are received with the transmittal order: [2]

(*1*) The name and address of the recipient;

(*2*) The account number of the recipient; and

(*3*) Any other specific identifier of the recipient; and

(G) Any form relating to the transmittal of funds that is completed or signed by the person placing the transmittal order.

(ii) For each transmittal order that it accepts as an intermediary financial institution, a financial institution shall retain either the original or a microfilm, other copy, or electronic record of the transmittal order.

(iii) For each transmittal order that it accepts as a recipient's financial institution, a financial institution shall retain either the original or a microfilm, other copy, or electronic record of the transmittal order.

(2) *Transmittors other than established customers.* In the case of a transmittal order from a transmittor that is not an established customer, in addition to obtaining and retaining the information required in paragraph (e)(1)(i) of this section:

(i) If the transmittal order is made in person, prior to acceptance the transmittor's financial institution shall verify the identity of the person placing the transmittal order. If it accepts the transmittal order, the transmittor's financial institution shall obtain and retain a record of the name and address, the type of identification reviewed, and the number of the identification document (*e.g.*, driver's license), as well as a record of the person's taxpayer identification number (*e.g.*, social security or employer identification number) or, if none, alien identification number or passport number and country of issuance, or a notation in the record of the lack thereof. If the transmittor's financial institution has knowledge that the person placing the transmittal order is not the transmittor, the transmittor's financial institution shall obtain and retain a record of the transmittor's taxpayer identification number (*e.g.*, social security or employer identification number) or, if none, alien identification number or passport number and country of issuance, if known by the person placing the order, or a notation in the record of the lack thereof.

(ii) If the transmittal order accepted by the transmittor's financial institution is not made in person, the transmittor's financial institution shall obtain and retain a record of the name and address of the person placing the transmittal order, as well as the person's taxpayer identification number (*e.g.*, social security or employer identification number) or, if none, alien identification number or passport number and country of issuance, or a notation in the record of the lack thereof, and a copy or record of the method of payment (*e.g.*, check or credit card transaction) for the transmittal of funds. If the transmittor's financial institution has knowledge that the person placing the transmittal order is not the transmittor, the transmittor's financial institution shall obtain and retain a record of the transmittor's taxpayer identification number (*e.g.*, social security or employer identification number) or, if none, alien identification number or passport number and country of issuance, if known by the person placing the order, or a notation in the record of the lack thereof.

(3) *Recipients other than established customers.* For each transmittal order that it accepts as a recipient's financial institution for a recipient that is not an established customer, in addition to obtaining and retaining the information required in paragraph (e)(1)(iii) of this section:

(i) If the proceeds are delivered in person to the recipient or its representative or agent, the recipient's financial institution shall verify the identity of the person receiving the proceeds and shall obtain and retain a record of the name and address, the type of identification reviewed, and the number of the identification document (*e.g.*, driver's license), as well as a record of the person's taxpayer identification number (*e.g.*, social security or employer identification number) or, if none, alien identification number or passport number and country of issuance, or a notation in the record of the lack thereof. If the recipient's financial institution has knowledge that the person receiving the proceeds is not the recipient, the recipient's financial institution shall obtain and retain a record of the recipient's name and address, as well as the recipient's taxpayer identification number (*e.g.*, social security or employer identification number) or, if none, alien identification number or passport number and country of issuance, if known by the person receiving the proceeds, or a notation in the record of the lack thereof.

(ii) If the proceeds are delivered other than in person, the recipient's financial institution shall retain a copy of the check or other instrument used to effect payment, or the information contained thereon, as well as the name and address of the person to which it was sent.

(4) *Retrievability.* The information that a transmittor's financial institution must retain under paragraphs (e)(1)(i) and (e)(2) of this section shall be retrievable by the transmittor's financial institution by reference to the name of the transmittor. If the transmittor is an established customer of the transmittor's financial institution and has an account used for transmittals of funds, then the information also shall be retrievable by account number. The information that a recipient's financial institution must retain under paragraphs (e)(1)(iii) and (e)(3) of this section shall be retrievable by the recipient's financial institution by reference to the name of the recipient. If the recipient is an established customer of the recipient's financial institution and has an account

[2] For transmittals of funds effected through the Federal Reserve's Fedwire funds transfer system by a domestic broker or dealers in securities, only one of the items is required to be retained, if received with the transmittal order, until such time as the bank that sends the order to the Federal Reserve Bank completes its conversion to the expanded Fedwire message format.

used for transmittals of funds, then the information also shall be retrievable by account number. This information need not be retained in any particular manner, so long as the financial institution is able to retrieve the information required by this paragraph, either by accessing transmittal of funds records directly or through reference to some other record maintained by the financial institution.

(5) *Verification.* Where verification is required under paragraphs (e)(2) and (e)(3) of this section, a financial institution shall verify a person's identity by examination of a document (other than a customer signature card), preferably one that contains the person's name, address, and photograph, that is normally acceptable by financial institutions as a means of identification when cashing checks for persons other than established customers. Verification of the identity of an individual who indicates that he or she is an alien or is not a resident of the United States may be made by passport, alien identification card, or other official document evidencing nationality or residence (*e.g.*, a foreign driver's license with indication of home address).

(6) *Exceptions.* The following transmittals of funds are not subject to the requirements of this section:

(i) Transmittals of funds where the transmittor and the recipient are any of the following:

(A) A bank;

(B) A wholly-owned domestic subsidiary of a bank chartered in the United States;

(C) A broker or dealer in securities;

(D) A wholly-owned domestic subsidiary of a broker or dealer in securities;

(E) A futures commission merchant or an introducing broker in commodities;

(F) A wholly-owned domestic subsidiary of a futures commission merchant or an introducing broker in commodities;

(G) The United States;

(H) A state or local government; or

(I) A federal, state or local government agency or instrumentality; and

(ii) Transmittals of funds where both the transmittor and the recipient are the same person and the transmittor's financial institution and the recipient's financial institution are the same broker or dealer in securities.

(f) Any transmittor's financial institution or intermediary financial institution located within the United States shall include in any transmittal order for a transmittal of funds in the amount of $3,000 or more, information as required in this paragraph (f):

(1) A transmittor's financial institution shall include in a transmittal order, at the time it is sent to a receiving financial institution, the following information:

(i) The name and, if the payment is ordered from an account, the account number of the transmittor;

(ii) The address of the transmittor, except for a transmittal order through Fedwire until such time as the bank that sends the order to the Federal Reserve Bank completes its conversion to the expanded Fedwire format;

(iii) The amount of the transmittal order;

(iv) The execution date of the transmittal order;

(v) The identity of the recipient's financial institution;

(vi) As many of the following items as are received with the transmittal order: [3]

(A) The name and address of the recipient;

(B) The account number of the recipient;

(C) Any other specific identifier of the recipient; and

(vii) Either the name and address or numerical identifier of the transmittor's financial institution.

(2) A receiving financial institution that acts as an intermediary financial institution, if it accepts a transmittal order, shall include in a corresponding transmittal order at the time it is sent to the next receiving financial institution, the following information, if received from the sender:

(i) The name and the account number of the transmittor;

(ii) The address of the transmittor, except for a transmittal order through Fedwire until such time as the bank that sends the order to the Federal Reserve Bank completes its conversion to the expanded Fedwire format;

(iii) The amount of the transmittal order;

(iv) The execution date of the transmittal order;

(v) The identity of the recipient's financial institution;

(vi) As many of the following items as are received with the transmittal order: [4]

(A) The name and address of the recipient;

(B) The account number of the recipient;

(C) Any other specific identifier of the recipient; and

(vii) Either the name and address or numerical identifier of the transmittor's financial institution.

(3) *Safe harbor for transmittals of funds prior to conversion to the expanded Fedwire message format.* The following provisions apply to transmittals of funds effected through the Federal Reserve's Fedwire funds transfer system or otherwise by a financial institution before the bank that sends the order to the Federal Reserve Bank or otherwise completes its conversion to the expanded Fedwire message format.

(i) *Transmittor's financial institution.* A transmittor's financial institution will be deemed to be in compliance with the provisions of paragraph (f)(1) of this section if it:

(A) Includes in the transmittal order, at the time it is sent to the receiving financial institution, the information specified in paragraphs (f)(1)(iii) through (v), and the information specified in paragraph (f)(1)(vi) of this section to the extent that such information has been received by the financial institution, and

(B) Provides the information specified in paragraphs (f)(1)(i), (ii) and (vii) of this section to a financial institution that acted as an intermediary financial institution or recipient's financial institution in connection with the transmittal order, within a reasonable time after any such financial institution makes a request therefor in connection with the requesting financial institution's receipt of a lawful request for such information from a federal, state, or local law enforcement or financial regulatory agency, or in connection with the requesting financial institution's own Bank Secrecy Act compliance program.

(ii) *Intermediary financial institution.* An intermediary financial institution will be deemed to be in compliance with the provisions of paragraph (f)(2) of this section if it:

(A) Includes in the transmittal order, at the time it is sent to the receiving financial institution, the information specified in paragraphs (f)(2)(iii) through (f)(2)(vi) of this section, to the extent that such information has been received by the intermediary financial institution; and

(B) Provides the information specified in paragraphs (f)(2)(i), (ii) and (vii) of this section, to the extent that such information has been received by the

[3] For transmittals of funds effected through the Federal Reserve's Fedwire funds transfer system by a financial institution, only one of the items is required to be included in the transmittal order, if received with the sender's transmittal order, until such time as the bank that sends the order to the Federal Reserve Bank completes its conversion to the expanded Fedwire message format.

[4] For transmittals of funds effected through the Federal Reserve's Fedwire funds transfer system by a financial institution, only one of the items is required to be included in the transmittal order, if received with the sender's transmittal order, until such time as the bank that sends the order to the Federal Reserve Bank completes its conversion to the expanded Fedwire message format.

intermediary financial institution, to a financial institution that acted as an intermediary financial institution or recipient's financial institution in connection with the transmittal order, within a reasonable time after any such financial institution makes a request therefor in connection with the requesting financial institution's receipt of a lawful request for such information from a federal, state, or local law enforcement or regulatory agency, or in connection with the requesting financial institution's own Bank Secrecy Act compliance program.

(iii) *Obligation of requesting financial institution.* Any information requested under paragraph (f)(3)(i)(B) or (f)(3)(ii)(B) of this section shall be treated by the requesting institution, once received, as if it had been included in the transmittal order to which such information relates.

(4) *Exceptions.* The requirements of this paragraph (f) shall not apply to transmittals of funds that are listed in paragraph (e)(6) of this section or § 1020.410(a)(6) of this chapter.

(Approved by the Office of Management and Budget under control number 1505–0063)

§ 1010.415 Purchases of bank checks and drafts, cashier's checks, money orders and traveler's checks.

(a) No financial institution may issue or sell a bank check or draft, cashier's check, money order or traveler's check for $3,000 or more in currency unless it maintains records of the following information, which must be obtained for each issuance or sale of one or more of these instruments to any individual purchaser which involves currency in amounts of $3,000–$10,000 inclusive:

(1) If the purchaser has a deposit account with the financial institution:

(i)(A) The name of the purchaser;

(B) The date of purchase;

(C) The type(s) of instrument(s) purchased;

(D) The serial number(s) of each of the instrument(s) purchased; and

(E) The amount in dollars of each of the instrument(s) purchased.

(ii) In addition, the financial institution must verify that the individual is a deposit accountholder or must verify the individual's identity. Verification may be either through a signature card or other file or record at the financial institution provided the deposit accountholder's name and address were verified previously and that information was recorded on the signature card or other file or record; or by examination of a document which is normally acceptable within the banking community as a means of identification when cashing checks for nondepositors and which contains the name and address of the purchaser. If the deposit accountholder's identity has not been verified previously, the financial institution shall verify the deposit accountholder's identity by examination of a document which is normally acceptable within the banking community as a means of identification when cashing checks for nondepositors and which contains the name and address of the purchaser, and shall record the specific identifying information (*e.g.*, State of issuance and number of driver's license).

(2) If the purchaser does not have a deposit account with the financial institution:

(i)(A) The name and address of the purchaser;

(B) The social security number of the purchaser, or if the purchaser is an alien and does not have a social security number, the alien identification number;

(C) The date of birth of the purchaser;

(D) The date of purchase;

(E) The type(s) of instrument(s) purchased;

(F) The serial number(s) of the instrument(s) purchased; and

(G) The amount in dollars of each of the instrument(s) purchased.

(ii) In addition, the financial institution shall verify the purchaser's name and address by examination of a document which is normally acceptable within the banking community as a means of identification when cashing checks for nondepositors and which contains the name and address of the purchaser, and shall record the specific identifying information (*e.g.*, State of issuance and number of driver's license).

(b) Contemporaneous purchases of the same or different types of instruments totaling $3,000 or more shall be treated as one purchase. Multiple purchases during one business day totaling $3,000 or more shall be treated as one purchase if an individual employee, director, officer, or partner of the financial institution has knowledge that these purchases have occurred.

(c) Records required to be kept shall be retained by the financial institution for a period of five years and shall be made available to the Secretary upon request at any time.

§ 1010.420 Records to be made and retained by persons having financial interests in foreign financial accounts.

Records of accounts required by § 1010.350 to be reported to the Commissioner of Internal Revenue shall be retained by each person having a financial interest in or signature or other authority over any such account. Such records shall contain the name in which each such account is maintained, the number or other designation of such account, the name and address of the foreign bank or other person with whom such account is maintained, the type of such account, and the maximum value of each such account during the reporting period. Such records shall be retained for a period of 5 years and shall be kept at all times available for inspection as authorized by law. In the computation of the period of 5 years, there shall be disregarded any period beginning with a date on which the taxpayer is indicted or information instituted on account of the filing of a false or fraudulent Federal income tax return or failing to file a Federal income tax return, and ending with the date on which final disposition is made of the criminal proceeding.

§ 1010.430 Nature of records and retention period.

(a) Wherever it is required that there be retained either the original or a microfilm or other copy or reproduction of a check, draft, monetary instrument, investment security, or other similar instrument, there shall be retained a copy of both front and back of each such instrument or document, except that no copy need be retained of the back of any instrument or document which is entirely blank or which contains only standardized printed information, a copy of which is on file.

(b) Records required by this chapter to be retained by financial institutions may be those made in the ordinary course of business by a financial institution. If no record is made in the ordinary course of business of any transaction with respect to which records are required to be retained by this chapter, then such a record shall be prepared in writing by the financial institution.

(c) The rules and regulations issued by the Internal Revenue Service under 26 U.S.C. 6109 determine what constitutes a taxpayer identification number and whose number shall be obtained in the case of an account maintained by one or more persons.

(d) All records that are required to be retained by this chapter shall be retained for a period of five years. Records or reports required to be kept pursuant to an order issued under § 1010.370 of this chapter shall be retained for the period of time specified in such order, not to exceed five years. All such records shall be filed or stored in such a way as to be accessible within a reasonable period of time, taking into consideration the nature of the record,

and the amount of time expired since the record was made.

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§ 1010.440 Person outside the United States.

For the purposes of this chapter, a remittance or transfer of funds, or of currency, other monetary instruments, checks, investment securities, or credit to the domestic account of a person whose address is known by the person making the remittance or transfer, to be outside the United States, shall be deemed to be a remittance or transfer to a person outside the United States, except that, unless otherwise directed by the Secretary, this section shall not apply to a transaction on the books of a domestic financial institution involving the account of a customer of such institution whose address is within approximately 50 miles of the location of the institution, or who is known to be temporarily outside the United States.

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

§ 1010.500 General.

Sections 1010.505 through 1010.540 of this Subpart E were issued pursuant to the requirements of section 314 of the USA PATRIOT Act. Financial institutions (as defined in 31 U.S.C. 5312(a)(2) or (c)(1)) should refer to their Chapter X Part for additional requirements specific to that particular category of financial institution.

§ 1010.505 Definitions.

For purposes of this Subpart E, the following definitions apply:

(a) *Account* means a formal banking or business relationship established to provide regular services, dealings, and other financial transactions, and includes, but is not limited to, a demand deposit, savings deposit, or other transaction or asset account and a credit account or other extension of credit.

(b) *Money laundering* means an activity criminalized by 18 U.S.C. 1956 or 1957.

(c) *Terrorist activity* means an act of domestic terrorism or international terrorism as those terms are defined in 18 U.S.C. 2331.

(d) *Transaction.* (1) Except as provided in paragraph (d)(2) of this section, the term ''transaction'' shall have the same meaning as provided in § 1010.100(bbb).

(2) For purposes of § 1010.520, a transaction shall not mean any transaction conducted through an account.

§ 1010.520 Information sharing between Federal law enforcement agencies and financial institutions.

(a) *Definitions.* For purposes of this section:

(1) *Financial institution* means any financial institution described in 31 U.S.C. 5312(a)(2).

(2) [Reserved]

(b) *Information requests based on credible evidence concerning terrorist activity or money laundering*—(1) *In general.* A Federal law enforcement agency investigating terrorist activity or money laundering may request that FinCEN solicit, on the investigating agency's behalf, certain information from a financial institution or a group of financial institutions. When submitting such a request to FinCEN, the Federal law enforcement agency shall provide FinCEN with a written certification, in such form and manner as FinCEN may prescribe. At a minimum, such certification must: State that each individual, entity, or organization about which the Federal law enforcement agency is seeking information is engaged in, or is reasonably suspected based on credible evidence of engaging in, terrorist activity or money laundering; include enough specific identifiers, such as date of birth, address, and social security number, that would permit a financial institution to differentiate between common or similar names; and identify one person at the agency who can be contacted with any questions relating to its request. Upon receiving the requisite certification from the requesting Federal law enforcement agency, FinCEN may require any financial institution to search its records to determine whether the financial institution maintains or has maintained accounts for, or has engaged in transactions with, any specified individual, entity, or organization.

(2) *Obligations of a financial institution receiving an information request*—(i) *Record search.* Upon receiving an information request from FinCEN under this section, a financial institution shall expeditiously search its records to determine whether it maintains or has maintained any account for, or has engaged in any transaction with, each individual, entity, or organization named in FinCEN's request. A financial institution may contact the Federal law enforcement agency named in the information request provided to the institution by FinCEN with any questions relating to the scope or terms of the request. Except as otherwise provided in the information request, a financial institution shall only be required to search its records for:

(A) Any current account maintained for a named suspect;

(B) Any account maintained for a named suspect during the preceding twelve months; and

(C) Any transaction, as defined by § 1010.505(d), conducted by or on behalf of a named suspect, or any transmittal of funds conducted in which a named suspect was either the transmittor or the recipient, during the preceding six months that is required under law or regulation to be recorded by the financial institution or is recorded and maintained electronically by the institution.

(ii) *Report to FinCEN.* If a financial institution identifies an account or transaction identified with any individual, entity, or organization named in a request from FinCEN, it shall report to FinCEN, in the manner and in the time frame specified in FinCEN's request, the following information:

(A) The name of such individual, entity, or organization;

(B) The number of each such account, or in the case of a transaction, the date and type of each such transaction; and

(C) Any Social Security number, taxpayer identification number, passport number, date of birth, address, or other similar identifying information provided by the individual, entity, or organization when each such account was opened or each such transaction was conducted.

(iii) *Designation of contact person.* Upon receiving an information request under this section, a financial institution shall designate one person to be the point of contact at the institution regarding the request and to receive similar requests for information from FinCEN in the future. When requested by FinCEN, a financial institution shall provide FinCEN with the name, title, mailing address, e-mail address, telephone number, and facsimile number of such person, in such manner as FinCEN may prescribe. A financial institution that has provided FinCEN with contact information must promptly notify FinCEN of any changes to such information.

(iv) *Use and security of information request.* (A) A financial institution shall not use information provided by FinCEN pursuant to this section for any purpose other than:

(*1*) Reporting to FinCEN as provided in this section;

(*2*) Determining whether to establish or maintain an account, or to engage in a transaction; or

(*3*) Assisting the financial institution in complying with any requirement of this chapter.

(B)(*1*) A financial institution shall not disclose to any person, other than FinCEN or the Federal law enforcement agency on whose behalf FinCEN is requesting information, the fact that FinCEN has requested or has obtained information under this section, except to the extent necessary to comply with such an information request.

(*2*) Notwithstanding paragraph (b)(2)(iv)(B)(1) of this section, a financial institution authorized to share information under § 1010.540 may share information concerning an individual, entity, or organization named in a request from FinCEN in accordance with the requirements of such section. However, such sharing shall not disclose the fact that FinCEN has requested information concerning such individual, entity, or organization.

(C) Each financial institution shall maintain adequate procedures to protect the security and confidentiality of requests from FinCEN for information under this section. The requirements of this paragraph (b)(2)(iv)(C) shall be deemed satisfied to the extent that a financial institution applies to such information procedures that the institution has established to satisfy the requirements of section 501 of the Gramm-Leach-Bliley Act (15 U.S.C. 6801), and applicable regulations issued thereunder, with regard to the protection of its customers' nonpublic personal information.

(v) *No other action required.* Nothing in this section shall be construed to require a financial institution to take any action, or to decline to take any action, with respect to an account established for, or a transaction engaged in with, an individual, entity, or organization named in a request from FinCEN, or to decline to establish an account for, or to engage in a transaction with, any such individual, entity, or organization. Except as otherwise provided in an information request under this section, such a request shall not require a financial institution to report on future account opening activity or transactions or to treat a suspect list received under this section as a government list for purposes of section 326 of Public Law 107–56.

(3) *Relation to the Right to Financial Privacy Act and the Gramm-Leach-Bliley Act.* The information that a financial institution is required to report pursuant to paragraph (b)(2)(ii) of this section is information required to be reported in accordance with a Federal statute or rule promulgated thereunder, for purposes of subsection 3413(d) of the Right to Financial Privacy Act (12 U.S.C. 3413(d)) and subsection 502(e)(8) of the Gramm-Leach-Bliley Act (15 U.S.C. 6802(e)(8)).

(4) *No effect on law enforcement or regulatory investigations.* Nothing in this subpart affects the authority of a Federal agency or officer to obtain information directly from a financial institution.

§ 1010.530 [Reserved]

§ 1010.540 Voluntary information sharing among financial institutions.

(a) *Definitions.* For purposes of this section:

(1) *Financial institution.* (i) Except as provided in paragraph (a)(1)(ii) of this section, the term ''financial institution'' means any financial institution described in 31 U.S.C. 5312(a)(2) that is required under this chapter to establish and maintain an anti-money laundering program, or is treated under this chapter as having satisfied the requirements of 31 U.S.C. 5318(h)(1).

(ii) For purposes of this section, a financial institution shall not mean any institution included within a class of financial institutions that FinCEN has designated as ineligible to share information under this section.

(2) *Association of financial institutions* means a group or organization the membership of which is comprised entirely of financial institutions as defined in paragraph (a)(1) of this section.

(b) *Voluntary information sharing among financial institutions*—(1) *In general.* Subject to paragraphs (b)(2), (b)(3), and (b)(4) of this section, a financial institution or an association of financial institutions may, under the protection of the safe harbor from liability described in paragraph (b)(5) of this section, transmit, receive, or otherwise share information with any other financial institution or association of financial institutions regarding individuals, entities, organizations, and countries for purposes of identifying and, where appropriate, reporting activities that the financial institution or association suspects may involve possible terrorist activity or money laundering.

(2) *Notice requirement.* A financial institution or association of financial institutions that intends to share information as described in paragraph (b)(1) of this section shall submit to FinCEN a notice described in Appendix A to this chapter. Each notice provided pursuant to this paragraph (b)(2) shall be effective for the one year period beginning on the date of the notice. In order to continue to engage in the sharing of information after the end of the one year period, a financial institution or association of financial institutions must submit a new notice. Completed notices may be submitted to FinCEN by accessing FinCEN's Internet Web site, *http://www.fincen.gov,* and entering the appropriate information as directed, or, if a financial institution does not have Internet access, by mail to: FinCEN, P.O. Box 39, Vienna, VA 22183.

(3) *Verification requirement.* Prior to sharing information as described in paragraph (b)(1) of this section, a financial institution or an association of financial institutions must take reasonable steps to verify that the other financial institution or association of financial institutions with which it intends to share information has submitted to FinCEN the notice required by paragraph (b)(2) of this section. A financial institution or an association of financial institutions may satisfy this paragraph (b)(3) by confirming that the other financial institution or association of financial institutions appears on a list that FinCEN will periodically make available to financial institutions or associations of financial institutions that have filed a notice with it, or by confirming directly with the other financial institution or association of financial institutions that the requisite notice has been filed.

(4) *Use and security of information.* (i) Information received by a financial institution or an association of financial institutions pursuant to this section shall not be used for any purpose other than:

(A) Identifying and, where appropriate, reporting on money laundering or terrorist activities;

(B) Determining whether to establish or maintain an account, or to engage in a transaction; or

(C) Assisting the financial institution in complying with any requirement of this chapter.

(ii) Each financial institution or association of financial institutions that engages in the sharing of information pursuant to this section shall maintain adequate procedures to protect the security and confidentiality of such information. The requirements of this paragraph (b)(4)(ii) shall be deemed satisfied to the extent that a financial institution applies to such information procedures that the institution has established to satisfy the requirements of section 501 of the Gramm-Leach-Bliley Act (15 U.S.C. 6801), and applicable regulations issued

thereunder, with regard to the protection of its customers' nonpublic personal information.

(5) *Safe harbor from certain liability*—(i) *In general.* A financial institution or association of financial institutions that shares information pursuant to paragraph (b) of this section shall be protected from liability for such sharing, or for any failure to provide notice of such sharing, to an individual, entity, or organization that is identified in such sharing, to the full extent provided in subsection 314(b) of Public Law 107–56.

(ii) *Limitation.* Paragraph (b)(5)(i) of this section shall not apply to a financial institution or association of financial institutions to the extent such institution or association fails to comply with paragraphs (b)(2), (b)(3), or (b)(4) of this section.

(c) *Information sharing between financial institutions and the Federal Government.* If, as a result of information shared pursuant to this section, a financial institution knows, suspects, or has reason to suspect that an individual, entity, or organization is involved in, or may be involved in terrorist activity or money laundering, and such institution is subject to a suspicious activity reporting requirement under this chapter or other applicable regulations, the institution shall file a Suspicious Activity Report in accordance with those regulations. In situations involving violations requiring immediate attention, such as when a reportable violation involves terrorist activity or is ongoing, the financial institution shall immediately notify, by telephone, an appropriate law enforcement authority and financial institution supervisory authorities in addition to filing timely a Suspicious Activity Report. A financial institution that is not subject to a suspicious activity reporting requirement is not required to file a Suspicious Activity Report or otherwise to notify law enforcement of suspicious activity that is detected as a result of information shared pursuant to this section. Such a financial institution is encouraged, however, to voluntarily report such activity to FinCEN.

(d) *No effect on financial institution reporting obligations.* Nothing in this subpart affects the obligation of a financial institution to file a Suspicious Activity Report pursuant to this chapter or any other applicable regulations, or to otherwise contact directly a Federal agency concerning individuals or entities suspected of engaging in terrorist activity or money laundering.

Subpart F—Special Standards of Diligence; Prohibitions; and Special Measures

§ 1010.600 General.

Financial institutions (as defined in 31 U.S.C. 5312(a)(2) or (c)(1)) should refer to their Chapter X Part for additional special standards of diligence; prohibitions; and special measures requirements specific to that particular category of financial institution.

Special Due Diligence for Correspondent Accounts and Private Banking Accounts

§ 1010.605 Definitions.

Except as otherwise provided, the following definitions apply for purposes of §§ 1010.610 through 1010.630 and § 1010.670:

(a) *Beneficial owner* of an account means an individual who has a level of control over, or entitlement to, the funds or assets in the account that, as a practical matter, enables the individual, directly or indirectly, to control, manage or direct the account. The ability to fund the account or the entitlement to the funds of the account alone, however, without any corresponding authority to control, manage or direct the account (such as in the case of a minor child beneficiary), does not cause the individual to be a beneficial owner.

(b) *Certification and recertification* mean the certification and recertification forms described in appendices B and C, respectively, to this chapter.

(c) *Correspondent account.* (1) The term *correspondent account* means:

(i) For purposes of § 1010.610(a), (d) and (e), an account established for a foreign financial institution to receive deposits from, or to make payments or other disbursements on behalf of, the foreign financial institution, or to handle other financial transactions related to such foreign financial institution; and

(ii) For purposes of §§ 1010.610(b) and (c), 1010.630 and 1010.670, an account established for a foreign bank to receive deposits from, or to make payments or other disbursements on behalf of, the foreign bank, or to handle other financial transactions related to such foreign bank.

(2) For purposes of this definition, the term *account:*

(i) As applied to banks (as set forth in paragraphs (e)(1)(i) through (vii) of this section):

(A) Means any formal banking or business relationship established by a bank to provide regular services, dealings, and other financial transactions; and

(B) Includes a demand deposit, savings deposit, or other transaction or asset account and a credit account or other extension of credit;

(ii) As applied to brokers or dealers in securities (as set forth in paragraph (e)(1)(viii) of this section) means any formal relationship established with a broker or dealer in securities to provide regular services to effect transactions in securities, including, but not limited to, the purchase or sale of securities and securities loaned and borrowed activity, and to hold securities or other assets for safekeeping or as collateral;

(iii) As applied to futures commission merchants and introducing brokers (as set forth in paragraph (e)(1)(ix) of this section) means any formal relationship established by a futures commission merchant to provide regular services, including, but not limited to, those established to effect transactions in contracts of sale of a commodity for future delivery, options on any contract of sale of a commodity for future delivery, or options on a commodity; and

(iv) As applied to mutual funds (as set forth in paragraph (e)(1)(x) of this section) means any contractual or other business relationship established between a person and a mutual fund to provide regular services to effect transactions in securities issued by the mutual fund, including the purchase or sale of securities.

(d) *Correspondent relationship* has the same meaning as correspondent account for purposes of §§ 1010.630 and 1010.670.

(e) *Covered financial institution* means: (1) For purposes of § 1010.610 and 1010.620:

(i) An insured bank (as defined in section 3(h) of the Federal Deposit Insurance Act (12 U.S.C. 1813(h)));

(ii) A commercial bank;

(iii) An agency or branch of a foreign bank in the United States;

(iv) A federally insured credit union;

(v) A savings association;

(vi) A corporation acting under section 25A of the Federal Reserve Act (12 U.S.C. 611 *et seq.*);

(vii) A trust bank or trust company that is federally regulated and is subject to an anti-money laundering program requirement;

(viii) A broker or dealer in securities registered, or required to be registered, with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), except persons who register pursuant to section 15(b)(11) of the Securities Exchange Act of 1934;

(ix) A futures commission merchant or an introducing broker registered, or required to be registered, with the Commodity Futures Trading Commission under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*), except persons who register pursuant to section 4(f)(a)(2) of the Commodity Exchange Act; and

(x) A mutual fund;

(2) For purposes of §§ 1010.630 and 1010.670:

(i) An insured bank (as defined in section 3(h) of the Federal Deposit Insurance Act (12 U.S.C. 1813(h)));

(ii) A commercial bank or trust company;

(iii) A private banker;

(iv) An agency or branch of a foreign bank in the United States;

(v) A credit union;

(vi) A savings association;

(vii) A corporation acting under section 25A of the Federal Reserve Act (12 U.S.C. 611 *et seq.*); and

(viii) A broker or dealer in securities registered, or required to be registered, with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), except persons who register pursuant to section 15(b)(11) of the Securities Exchange Act of 1934.

(f) *Foreign financial institution.* (1) The term *foreign financial institution* means:

(i) A foreign bank;

(ii) Any branch or office located outside the United States of any covered financial institution described in paragraphs (e)(1)(viii) through (x) of this section;

(iii) Any other person organized under foreign law (other than a branch or office of such person in the United States) that, if it were located in the United States, would be a covered financial institution described in paragraphs (e)(1)(viii) through (x) of this section; and

(iv) Any person organized under foreign law (other than a branch or office of such person in the United States) that is engaged in the business of, and is readily identifiable as:

(A) A currency dealer or exchanger; or

(B) A money transmitter.

(2) For purposes of paragraph (f)(1)(iv) of this section, a person is not ''engaged in the business'' of a currency dealer, a currency exchanger or a money transmitter if such transactions are merely incidental to the person's business.

(g) *Foreign shell bank* means a foreign bank without a physical presence in any country.

(h) *Non-United States person or non-U.S. person* means a natural person who is neither a United States citizen nor is accorded the privilege of residing permanently in the United States pursuant to title 8 of the United States Code. For purposes of this paragraph (h), the definition of *person* in § 1010.100(mm) does not apply, notwithstanding paragraph (k) of this section.

(i) *Offshore banking license* means a license to conduct banking activities that prohibits the licensed entity from conducting banking activities with the citizens of, or in the local currency of, the jurisdiction that issued the license.

(j) *Owner.* (1) The term *owner* means any person who, directly or indirectly:

(i) Owns, controls, or has the power to vote 25 percent or more of any class of voting securities or other voting interests of a foreign bank; or

(ii) Controls in any manner the election of a majority of the directors (or individuals exercising similar functions) of a foreign bank.

(2) For purposes of this definition:

(i) Members of the same family shall be considered to be one person.

(ii) The term *same family* means parents, spouses, children, siblings, uncles, aunts, grandparents, grandchildren, first cousins, stepchildren, stepsiblings, parents-in-law, and spouses of any of the foregoing.

(iii) Each member of the same family who has an ownership interest in a foreign bank must be identified if the family is an owner as a result of aggregating the ownership interests of the members of the family. In determining the ownership interests of the same family, any voting interest of any family member shall be taken into account.

(iv) *Voting securities or other voting interests* means securities or other interests that entitle the holder to vote for or to select directors (or individuals exercising similar functions).

(k) *Person* has the meaning provided in § 1010.100(mm).

(l) *Physical presence* means a place of business that:

(1) Is maintained by a foreign bank;

(2) Is located at a fixed address (other than solely an electronic address or a post-office box) in a country in which the foreign bank is authorized to conduct banking activities, at which location the foreign bank:

(i) Employs one or more individuals on a full-time basis; and

(ii) Maintains operating records related to its banking activities; and

(3) Is subject to inspection by the banking authority that licensed the foreign bank to conduct banking activities.

(m) *Private banking account* means an account (or any combination of accounts) maintained at a covered financial institution that:

(1) Requires a minimum aggregate deposit of funds or other assets of not less than $1,000,000;

(2) Is established on behalf of or for the benefit of one or more non-U.S. persons who are direct or beneficial owners of the account; and

(3) Is assigned to, or is administered or managed by, in whole or in part, an officer, employee, or agent of a covered financial institution acting as a liaison between the covered financial institution and the direct or beneficial owner of the account.

(n) *Regulated affiliate.* (1) The term *regulated affiliate* means a foreign shell bank that:

(i) Is an affiliate of a depository institution, credit union, or foreign bank that maintains a physical presence in the United States or a foreign country, as applicable; and

(ii) Is subject to supervision by a banking authority in the country regulating such affiliated depository institution, credit union, or foreign bank.

(2) For purposes of this definition:

(i) *Affiliate* means a foreign bank that is controlled by, or is under common control with, a depository institution, credit union, or foreign bank.

(ii) *Control* means:

(A) Ownership, control, or power to vote 50 percent or more of any class of voting securities or other voting interests of another company; or

(B) Control in any manner the election of a majority of the directors (or individuals exercising similar functions) of another company.

(o) *Secretary* means the Secretary of the Treasury.

(p) *Senior foreign political figure.* (1) The term *senior foreign political figure* means:

(i) A current or former:

(A) Senior official in the executive, legislative, administrative, military, or judicial branches of a foreign government (whether elected or not);

(B) Senior official of a major foreign political party; or

(C) Senior executive of a foreign government-owned commercial enterprise;

(ii) A corporation, business, or other entity that has been formed by, or for the benefit of, any such individual;

(iii) An immediate family member of any such individual; and

(iv) A person who is widely and publicly known (or is actually known by the relevant covered financial institution) to be a close associate of such individual.

(2) For purposes of this definition:

(i) *Senior official or executive* means an individual with substantial authority over policy, operations, or the use of government-owned resources; and

(ii) *Immediate family member* means spouses, parents, siblings, children and a spouse's parents and siblings.

§ 1010.610 Due diligence programs for correspondent accounts for foreign financial institutions.

(a) *In general.* A covered financial institution shall establish a due diligence program that includes appropriate, specific, risk-based, and, where necessary, enhanced policies, procedures, and controls that are reasonably designed to enable the covered financial institution to detect and report, on an ongoing basis, any known or suspected money laundering activity conducted through or involving any correspondent account established, maintained, administered, or managed by such covered financial institution in the United States for a foreign financial institution. The due diligence program required by this section shall be a part of the anti-money laundering program otherwise required by this chapter. Such policies, procedures, and controls shall include:

(1) Determining whether any such correspondent account is subject to paragraph (b) of this section;

(2) Assessing the money laundering risk presented by such correspondent account, based on a consideration of all relevant factors, which shall include, as appropriate:

(i) The nature of the foreign financial institution's business and the markets it serves;

(ii) The type, purpose, and anticipated activity of such correspondent account;

(iii) The nature and duration of the covered financial institution's relationship with the foreign financial institution (and any of its affiliates);

(iv) The anti-money laundering and supervisory regime of the jurisdiction that issued the charter or license to the foreign financial institution, and, to the extent that information regarding such jurisdiction is reasonably available, of the jurisdiction in which any company that is an owner of the foreign financial institution is incorporated or chartered; and

(v) Information known or reasonably available to the covered financial institution about the foreign financial institution's anti-money laundering record; and

(3) Applying risk-based procedures and controls to each such correspondent account reasonably designed to detect and report known or suspected money laundering activity, including a periodic review of the correspondent account activity sufficient to determine consistency with information obtained about the type, purpose, and anticipated activity of the account.

(b) *Enhanced due diligence for certain foreign banks.* In the case of a correspondent account established, maintained, administered, or managed in the United States for a foreign bank described in paragraph (c) of this section, the due diligence program required by paragraph (a) of this section shall include enhanced due diligence procedures designed to ensure that the covered financial institution, at a minimum, takes reasonable steps to:

(1) Conduct enhanced scrutiny of such correspondent account to guard against money laundering and to identify and report any suspicious transactions in accordance with applicable law and regulation. This enhanced scrutiny shall reflect the risk assessment of the account and shall include, as appropriate:

(i) Obtaining and considering information relating to the foreign bank's anti-money laundering program to assess the risk of money laundering presented by the foreign bank's correspondent account;

(ii) Monitoring transactions to, from, or through the correspondent account in a manner reasonably designed to detect money laundering and suspicious activity; and

(iii)(A) Obtaining information from the foreign bank about the identity of any person with authority to direct transactions through any correspondent account that is a payable-through account, and the sources and beneficial owner of funds or other assets in the payable-through account.

(B) For purposes of paragraph (b)(1)(iii)(A) of this section, a *payable-through account* means a correspondent account maintained by a covered financial institution for a foreign bank by means of which the foreign bank permits its customers to engage, either directly or through a subaccount, in banking activities usual in connection with the business of banking in the United States.

(2) Determine whether the foreign bank for which the correspondent account is established or maintained in turn maintains correspondent accounts for other foreign banks that use the foreign correspondent account established or maintained by the covered financial institution and, if so, take reasonable steps to obtain information relevant to assess and mitigate money laundering risks associated with the foreign bank's correspondent accounts for other foreign banks, including, as appropriate, the identity of those foreign banks.

(3)(i) Determine, for any correspondent account established or maintained for a foreign bank whose shares are not publicly traded, the identity of each owner of the foreign bank and the nature and extent of each owner's ownership interest.

(ii) For purposes of paragraph (b)(3)(i) of this section:

(A) *Owner* means any person who directly or indirectly owns, controls, or has the power to vote 10 percent or more of any class of securities of a foreign bank. For purposes of this paragraph (b)(3)(ii)(A):

(*1*) Members of the same family shall be considered to be one person; and

(*2*) *Same family* has the meaning provided in § 1010.605(j)(2)(ii).

(B) *Publicly traded* means shares that are traded on an exchange or an organized over-the-counter market that is regulated by a foreign securities authority as defined in section 3(a)(50) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(50)).

(c) *Foreign banks to be accorded enhanced due diligence.* The due diligence procedures described in paragraph (b) of this section are required for any correspondent account maintained for a foreign bank that operates under:

(1) An offshore banking license;

(2) A banking license issued by a foreign country that has been designated as non-cooperative with international anti-money laundering principles or procedures by an intergovernmental group or organization of which the United States is a member and with which designation the U.S. representative to the group or organization concurs; or

(3) A banking license issued by a foreign country that has been designated by the Secretary as warranting special measures due to money laundering concerns.

(d) *Special procedures when due diligence or enhanced due diligence cannot be performed.* The due diligence program required by paragraphs (a) and (b) of this section shall include procedures to be followed in circumstances in which a covered financial institution cannot perform appropriate due diligence or enhanced due diligence with respect to a correspondent account, including when the covered financial institution should refuse to open the account, suspend transaction activity, file a suspicious activity report, or close the account.

(e) *Applicability rules for general due diligence.* The provisions of paragraph

(a) of this section apply to covered financial institutions as follows:

(1) *General rules*—(i) *Correspondent accounts established on or after July 5, 2006.* Effective July 5, 2006, the requirements of paragraph (a) of this section shall apply to each correspondent account established on or after that date.

(ii) *Correspondent accounts established before July 5, 2006.* Effective October 2, 2006, the requirements of paragraph (a) of this section shall apply to each correspondent account established before July 5, 2006.

(2) *Special rules for certain banks.* Until the requirements of paragraph (a) of this section become applicable as set forth in paragraph (e)(1) of this section, the due diligence requirements of 31 U.S.C. 5318(i)(1) shall continue to apply to any covered financial institution listed in § 1010.605(e)(1)(i) through (vi).

(3) *Special rules for all other covered financial institutions.* The due diligence requirements of 31 U.S.C. 5318(i)(1) shall not apply to a covered financial institution listed in § 1010.605(e)(1)(vii) through (x) until the requirements of paragraph (a) of this section become applicable as set forth in paragraph (e)(1) of this section.

(f) *Applicability rules for enhanced due diligence.* The provisions of paragraph (b) of this section apply to covered financial institutions as follows:

(1) *General rules*—(i) *Correspondent accounts established on or after February 5, 2008.* Effective February 5, 2008, the requirements of paragraph (b) of this section shall apply to each correspondent account established on or after such date.

(ii) *Correspondent accounts established before February 5, 2008.* Effective May 5, 2008, the requirements of paragraph (b) of this section shall apply to each correspondent account established before February 5, 2008.

(2) *Special rules for certain banks.* Until the requirements of paragraph (b) of this section become applicable as set forth in paragraph (f)(1) of this section, the enhanced due diligence requirements of 31 U.S.C. 5318(i)(2) shall continue to apply to any covered financial institutions listed in § 1010.605(e)(1)(i) through (vi).

(3) *Special rules for all other covered financial institutions.* The enhanced due diligence requirements of 31 U.S.C. 5318(i)(2) shall not apply to a covered financial institution listed in § 1010.605(e)(1)(vii) through (x) until the requirements of paragraph (b) of this section become applicable, as set forth in paragraph (f)(1) of this section.

(g) *Exemptions*—(1) *Exempt financial institutions.* Except as provided in this section, a financial institution defined in 31 U.S.C. 5312(a)(2) or (c)(1), or § 1010.100(t) is exempt from the requirements of 31 U.S.C. 5318(i)(1) and (i)(2) pertaining to correspondent accounts.

(2) *Other compliance obligations of financial institutions unaffected.* Nothing in paragraph (g) of this section shall be construed to relieve a financial institution from its responsibility to comply with any other applicable requirement of law or regulation, including title 31, United States Code, and this chapter.

§ 1010.620 Due diligence programs for private banking accounts.

(a) *In general.* A covered financial institution shall maintain a due diligence program that includes policies, procedures, and controls that are reasonably designed to detect and report any known or suspected money laundering or suspicious activity conducted through or involving any private banking account that is established, maintained, administered, or managed in the United States by such financial institution. The due diligence program required by this section shall be a part of the anti-money laundering program otherwise required by this chapter.

(b) *Minimum requirements.* The due diligence program required by paragraph (a) of this section shall be designed to ensure, at a minimum, that the financial institution takes reasonable steps to:

(1) Ascertain the identity of all nominal and beneficial owners of a private banking account;

(2) Ascertain whether any person identified under paragraph (b)(1) of this section is a senior foreign political figure;

(3) Ascertain the source(s) of funds deposited into a private banking account and the purpose and expected use of the account; and

(4) Review the activity of the account to ensure that it is consistent with the information obtained about the client's source of funds, and with the stated purpose and expected use of the account, as needed to guard against money laundering, and to report, in accordance with applicable law and regulation, any known or suspected money laundering or suspicious activity conducted to, from, or through a private banking account.

(c) *Special requirements for senior foreign political figures.* (1) In the case of a private banking account for which a senior foreign political figure is a nominal or beneficial owner, the due diligence program required by paragraph (a) of this section shall include enhanced scrutiny of such account that is reasonably designed to detect and report transactions that may involve the proceeds of foreign corruption.

(2) For purposes of this paragraph (c), the term *proceeds of foreign corruption* means any asset or property that is acquired by, through, or on behalf of a senior foreign political figure through misappropriation, theft, or embezzlement of public funds, the unlawful conversion of property of a foreign government, or through acts of bribery or extortion, and shall include any other property into which any such assets have been transformed or converted.

(d) *Special procedures when due diligence cannot be performed.* The due diligence program required by paragraph (a) of this section shall include procedures to be followed in circumstances in which a covered financial institution cannot perform appropriate due diligence with respect to a private banking account, including when the covered financial institution should refuse to open the account, suspend transaction activity, file a suspicious activity report, or close the account.

(e) *Applicability rules.* The provisions of this section apply to covered financial institutions as follows:

(1) *General rules*—(i) Private banking accounts established on or after July 5, 2006. Effective July 5, 2006, the requirements of this section shall apply to each private banking account established on or after such date.

(ii) Private banking accounts established before July 5, 2006. Effective October 2, 2006, the requirements of this section shall apply to each private banking account established before July 5, 2006.

(2) *Special rules for certain banks and for brokers or dealers in securities, futures commission merchants, and introducing brokers.* Until the requirements of this section become applicable as set forth in paragraph (e)(1) of this section, the requirements of 31 U.S.C. 5318(i)(3) shall continue to apply to a covered financial institution listed in § 1010.605(e)(1)(i) through (vi), (viii), or (ix).

(3) *Special rules for federally regulated trust banks or trust companies, and mutual funds.* Until the requirements of this section become applicable as set forth in paragraph (e)(1) of this section, the requirements of 31 U.S.C. 5318(i)(3) shall not apply to a covered financial institution listed in § 1010.605(e)(1)(vii) or (x).

(4) *Exemptions*—(i) *Exempt financial institutions*. Except as provided in this section, a financial institution defined in 31 U.S.C. 5312(a)(2) or (c)(1) or § 1010.100(t) is exempt from the requirements of 31 U.S.C. 5318(i)(3) pertaining to private banking accounts.

(ii) *Other compliance obligations of financial institutions unaffected*. Nothing in paragraph (e)(4) of this section shall be construed to relieve a financial institution from its responsibility to comply with any other applicable requirement of law or regulation, including title 31, United States Code, and this chapter.

§ 1010.630 Prohibition on correspondent accounts for foreign shell banks; records concerning owners of foreign banks and agents for service of legal process.

(a) *Requirements for covered financial institutions*—(1) *Prohibition on correspondent accounts for foreign shell banks*. (i) A covered financial institution shall not establish, maintain, administer, or manage a correspondent account in the United States for, or on behalf of, a foreign shell bank.

(ii) A covered financial institution shall take reasonable steps to ensure that any correspondent account established, maintained, administered, or managed by that covered financial institution in the United States for a foreign bank is not being used by that foreign bank to indirectly provide banking services to a foreign shell bank.

(iii) Nothing in paragraph (a)(1) of this section prohibits a covered financial institution from providing a correspondent account or banking services to a regulated affiliate.

(2) *Records of owners and agents*. (i) Except as provided in paragraph (a)(2)(ii) of this section, a covered financial institution that maintains a correspondent account in the United States for a foreign bank shall maintain records in the United States identifying the owners of each such foreign bank whose shares are not publicly traded and the name and street address of a person who resides in the United States and is authorized, and has agreed to be an agent to accept service of legal process for records regarding each such account.

(ii) A covered financial institution need not maintain records of the owners of any foreign bank that is required to have on file with the Federal Reserve Board a Form FR Y–7 that identifies the current owners of the foreign bank as required by such form.

(iii) For purposes of paragraph (a)(2)(i) of this section, *publicly traded* refers to shares that are traded on an exchange or on an organized over-the-counter market that is regulated by a foreign securities authority as defined in section 3(a)(50) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(50)).

(b) *Safe harbor*. Subject to paragraphs (c) and (d) of this section, a covered financial institution will be deemed to be in compliance with the requirements of paragraph (a) of this section with respect to a foreign bank if the covered financial institution obtains, at least once every three years, a certification or recertification from the foreign bank.

(c) *Interim verification*. If at any time a covered financial institution knows, suspects, or has reason to suspect, that any information contained in a certification or recertification provided by a foreign bank, or otherwise relied upon by the covered financial institution for purposes of this section, is no longer correct, the covered financial institution shall request that the foreign bank verify or correct such information, or shall take other appropriate measures to ascertain the accuracy of the information or to obtain correct information, as appropriate. See paragraph (d)(3) of this section for additional requirements if a foreign bank fails to verify or correct the information or if a covered financial institution cannot ascertain the accuracy of the information or obtain correct information.

(d) *Closure of correspondent accounts*—(1) *Accounts existing on October 28, 2002*. In the case of any correspondent account that was in existence on October 28, 2002, if the covered financial institution has not obtained a certification (or recertification) from the foreign bank, or has not otherwise obtained documentation of the information required by such certification (or recertification), on or before March 31, 2003, and at least once every three years thereafter, the covered financial institution shall close all correspondent accounts with such foreign bank within a commercially reasonable time, and shall not permit the foreign bank to establish any new positions or execute any transaction through any such account, other than transactions necessary to close the account.

(2) *Accounts established after October 28, 2002*. In the case of any correspondent account established after October 28, 2002, if the covered financial institution has not obtained a certification (or recertification), or has not otherwise obtained documentation of the information required by such certification (or recertification) within 30 calendar days after the date the account is established, and at least once every three years thereafter, the covered financial institution shall close all correspondent accounts with such foreign bank within a commercially reasonable time, and shall not permit the foreign bank to establish any new positions or execute any transaction through any such account, other than transactions necessary to close the account.

(3) *Verification of previously provided information*. In the case of a foreign bank with respect to which the covered financial institution undertakes to verify information pursuant to paragraph (c) of this section, if the covered financial institution has not obtained, from the foreign bank or otherwise, verification of the information or corrected information within 90 calendar days after the date of undertaking the verification, the covered financial institution shall close all correspondent accounts with such foreign bank within a commercially reasonable time, and shall not permit the foreign bank to establish any new positions or execute any transaction through any such account, other than transactions necessary to close the account.

(4) *Reestablishment of closed accounts and establishment of new accounts*. A covered financial institution shall not reestablish any account closed pursuant to this paragraph (d), and shall not establish any other correspondent account with the concerned foreign bank, until it obtains from the foreign bank the certification or the recertification, as appropriate.

(5) *Limitation on liability*. A covered financial institution shall not be liable to any person in any court or arbitration proceeding for terminating a correspondent account in accordance with this paragraph (d).

(e) *Recordkeeping requirement*. A covered financial institution shall retain the original of any document provided by a foreign bank, and the original or a copy of any document otherwise relied upon by the covered financial institution, for purposes of this section, for at least 5 years after the date that the covered financial institution no longer maintains any correspondent account for such foreign bank. A covered financial institution shall retain such records with respect to any foreign bank for such longer period as the Secretary may direct.

(f) *Special rules concerning information requested prior to October 28, 2002*—(1) *Definition*. For purposes of this paragraph (f) the term ''Interim Guidance'' means:

(i) The Interim Guidance of the Department of the Treasury dated November 20, 2001 and published in

the **Federal Register** on November 27, 2001; or

(ii) The guidance issued in a document published in the **Federal Register** on December 28, 2001.

(2) *Use of Interim Guidance certification*. In the case of a correspondent account in existence on October 28, 2002, the term ''certification'' as used in paragraphs (b), (c), (d)(1), and (d)(3) of this section shall also include the certification appended to the Interim Guidance, provided that such certification was requested prior to October 28, 2002 and obtained by the covered financial institution on or before December 26, 2002.

(3) *Recordkeeping requirement*. Paragraph (e) of this section shall apply to any document provided by a foreign bank, or otherwise relied upon by a covered financial institution, for purposes of the Interim Guidance.

(Approved by the Office of Management and Budget under Control Number 1505–0184.)

§ 1010.640 [Reserved]

Special Measures Under Section 311 of the USA PATRIOT Act and Law Enforcement Access to Foreign Bank Records

§ 1010.651 Special measures against Burma.

(a) *Definitions*. For purposes of this section:

(1) *Burmese banking institution* means any foreign bank, as that term is defined in § 1010.100(u), chartered or licensed by Burma, including branches and offices located outside Burma.

(2) *Correspondent account* has the same meaning as provided in § 1010.605(c).

(3) *Covered financial institution* has the same meaning as provided in § 1010.605(e)(2) and also includes the following:

(i) A futures commission merchant or an introducing broker registered, or required to register, with the Commodity Futures Trading Commission under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*); and

(ii) An investment company (as defined in section 3 of the Investment Company Act of 1940 (15 U.S.C. 80a–5)) that is an open-end company (as defined in section 5 of the Investment Company Act (15 U.S.C. 80a–5)) and that is registered, or required to register, with the Securities and Exchange Commission pursuant to that Act.

(b) *Requirements for covered financial institutions*—(1) *Prohibition on correspondent accounts*. A covered financial institution shall terminate any correspondent account that is established, maintained, administered, or managed in the United States for, or on behalf of, a Burmese banking institution.

(2) *Prohibition on indirect correspondent accounts*. (i) If a covered financial institution has or obtains knowledge that a correspondent account established, maintained, administered, or managed by that covered financial institution in the United States for a foreign bank is being used by the foreign bank to provide banking services indirectly to a Burmese banking institution, the covered financial institution shall ensure that the correspondent account is no longer used to provide such services, including, where necessary, terminating the correspondent account; and

(ii) A covered financial institution required to terminate an account pursuant to paragraph (b)(2)(i) of this section:

(A) Shall do so within a commercially reasonable time, and shall not permit the foreign bank to establish any new positions or execute any transactions through such account, other than those necessary to close the account; and

(B) May reestablish an account closed pursuant to this paragraph if it determines that the account will not be used to provide banking services indirectly to a Burmese banking institution.

(3) *Exception*. The provisions of paragraphs (b)(1) and (2) of this section shall not apply to a correspondent account provided that the operation of such account is not prohibited by Executive Order 13310 and the transactions involving Burmese banking institutions that are conducted through the correspondent account are limited solely to transactions that are exempted from, or otherwise authorized by regulation, order, directive, or license pursuant to Executive Order 13310.

(4) *Reporting and recordkeeping not required*. Nothing in this section shall require a covered financial institution to maintain any records, obtain any certification, or report any information not otherwise required by law or regulation.

§ 1010.652 Special measures against Myanmar Mayflower Bank and Asia Wealth Bank.

(a) *Definitions*. For purposes of this section:

(1) *Asia Wealth Bank* means all headquarters, branches, and offices of Asia Wealth Bank operating in Burma or in any jurisdiction.

(2) *Correspondent account* has the same meaning as provided in § 1010.605(c).

(3) *Covered financial institution* has the same meaning as provided in § 1010.605(e)(2) and also includes the following:

(i) A futures commission merchant or an introducing broker registered, or required to register, with the Commodity Futures Trading Commission under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*); and

(ii) An investment company (as defined in section 3 of the Investment Company Act of 1940 (15 U.S.C. 80a–5)) that is an open-end company (as defined in section 5 of the Investment Company Act (15 U.S.C. 80a–5)) and that is registered, or required to register, with the Securities and Exchange Commission pursuant to that Act.

(4) *Myanmar Mayflower Bank* means all headquarters, branches, and offices of Myanmar Mayflower Bank operating in Burma or in any jurisdiction.

(b) *Requirements for covered financial institutions*—(1) *Prohibition on correspondent accounts*. A covered financial institution shall terminate any correspondent account that is established, maintained, administered, or managed in the United States for, or on behalf of, Myanmar Mayflower Bank or Asia Wealth Bank.

(2) *Prohibition on indirect correspondent accounts*. (i) If a covered financial institution has or obtains knowledge that a correspondent account established, maintained, administered, or managed by that covered financial institution in the United States for a foreign bank is being used by the foreign bank to provide banking services indirectly to Myanmar Mayflower Bank or Asia Wealth Bank, the covered financial institution shall ensure that the correspondent account is no longer used to provide such services, including, where necessary, terminating the correspondent account; and

(ii) A covered financial institution required to terminate an account pursuant to paragraph (b)(2)(i) of this section:

(A) Shall do so within a commercially reasonable time, and shall not permit the foreign bank to establish any new positions or execute any transactions through such account, other than those necessary to close the account; and

(B) May reestablish an account closed pursuant to this paragraph if it determines that the account will not be used to provide banking services indirectly to Myanmar Mayflower Bank or Asia Wealth Bank.

(3) *Reporting and recordkeeping not required*. Nothing in this section shall

require a covered financial institution to maintain any records, obtain any certification, or to report any information not otherwise required by law or regulation.

§ 1010.653 Special measures against Commercial Bank of Syria.

(a) *Definitions.* For purposes of this section:

(1) *Commercial Bank of Syria* means any branch, office, or subsidiary of Commercial Bank of Syria operating in Syria or in any other jurisdiction, including Syrian Lebanese Commercial Bank.

(2) *Correspondent account* has the same meaning as provided in § 1010.605(c)(1)(ii).

(3) *Covered financial institution* includes:

(i) An insured bank (as defined in section 3(h) of the Federal Deposit Insurance Act (12 U.S.C. 1813(h)));

(ii) A commercial bank;

(iii) An agency or branch of a foreign bank in the United States;

(iv) A federally insured credit union;

(v) A savings association;

(vi) A corporation acting under section 25A of the Federal Reserve Act (12 U.S.C. 611 *et seq.*);

(vii) A trust bank or trust company that is federally regulated and is subject to an anti-money laundering program requirement;

(viii) A broker or dealer in securities registered, or required to be registered, with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), except persons who register pursuant to section 15(b)(11) of the Securities Exchange Act of 1934;

(ix) A futures commission merchant or an introducing broker registered, or required to be registered, with the Commodity Futures Trading Commission under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*), except persons who register pursuant to section 4(f)(a)(2) of the Commodity Exchange Act; and

(x) A mutual fund, which means an investment company (as defined in section 3(a)(1) of the Investment Company Act of 1940 ((''Investment Company Act'') (15 U.S.C. 80a–3(a)(1))) that is an open-end company (as defined in section 5(a)(1) of the Investment Company Act (15 U.S.C. 80a–5(a)(1))) and that is registered, or is required to register with the Securities and Exchange Commission pursuant to the Investment Company Act.

(4) *Subsidiary* means a company of which more than 50 percent of the voting stock or analogous equity interest is owned by another company.

(b) *Requirements for covered financial institutions*—(1) *Prohibition on direct use of correspondent accounts.* A covered financial institution shall terminate any correspondent account that is open or maintained in the United States for, or on behalf of, Commercial Bank of Syria.

(2) *Due diligence of correspondent accounts to prohibit indirect use.* (i) A covered financial institution shall apply due diligence to its correspondent accounts that is reasonably designed to guard against their indirect use by Commercial Bank of Syria. At a minimum, that due diligence must include:

(A) Notifying correspondent account holders that the correspondent account may not be used to provide Commercial Bank of Syria with access to the covered financial institution; and

(B) Taking reasonable steps to identify any indirect use of its correspondent accounts by Commercial Bank of Syria, to the extent that such indirect use can be determined from transactional records maintained in the covered financial institution's normal course of business.

(ii) A covered financial institution shall take a risk-based approach when deciding what, if any, additional due diligence measures it should adopt to guard against the indirect use of its correspondent accounts by Commercial Bank of Syria.

(iii) A covered financial institution that obtains knowledge that a correspondent account is being used by the foreign bank to provide indirect access to Commercial Bank of Syria shall take all appropriate steps to prevent such indirect access, including, where necessary, terminating the correspondent account.

(iv) A covered financial institution required to terminate a correspondent account pursuant to paragraph (b)(2)(iii) of this section:

(A) Should do so within a commercially reasonable time, and should not permit the foreign bank to establish any new positions or execute any transaction through such correspondent account, other than those necessary to close the correspondent account; and

(B) May reestablish a correspondent account closed pursuant to this paragraph if it determines that the correspondent account will not be used to provide banking services indirectly to Commercial Bank of Syria.

(3) *Recordkeeping and reporting.* (i) A covered financial institution is required to document its compliance with the notice requirement set forth in paragraph (b)(2)(i)(A) of this section.

(ii) Nothing in this section shall require a covered financial institution to report any information not otherwise required to be reported by law or regulation.

§ 1010.654 Special measures against VEF Bank.

(a) *Definitions.* For purposes of this section:

(1) *Correspondent account* has the same meaning as provided in § 1010.605(c)(1)(ii).

(2) *Covered financial institution* includes:

(i) An insured bank (as defined in section 3(h) of the Federal Deposit Insurance Act (12 U.S.C. 1813(h)));

(ii) A commercial bank;

(iii) An agency or branch of a foreign bank in the United States;

(iv) A federally insured credit union;

(v) A savings association;

(vi) A corporation acting under section 25A of the Federal Reserve Act (12 U.S.C. 611 *et seq.*);

(vii) A trust bank or trust company that is federally regulated and is subject to an anti-money laundering program requirement;

(viii) A broker or dealer in securities registered, or required to be registered, with the U.S. Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), except persons who register pursuant to section 15(b)(11) of the Securities Exchange Act of 1934;

(ix) A futures commission merchant or an introducing broker registered, or required to be registered, with the Commodity Futures Trading Commission under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*), except persons who register pursuant to section 4(f)(a)(2) of the Commodity Exchange Act; and

(x) A mutual fund, which means an investment company (as defined in section 3(a)(1) of the Investment Company Act of 1940 ((''Investment Company Act'') (15 U.S.C. 80a–3(a)(1))) that is an open-end company (as defined in section 5(a)(1) of the Investment Company Act (15 U.S.C. 80a–5(a)(1))) and that is registered, or is required to register with the Securities and Exchange Commission pursuant to the Investment Company Act.

(3) *Subsidiary* means a company of which more than 50 percent of the voting stock or analogous equity interest is owned by another company.

(4) *VEF Bank* means any branch, office, or subsidiary of joint stock company VEF Banka operating in the Republic of Latvia or in any other jurisdiction. The one known VEF Bank subsidiary, Veiksmes līzings, and any

branches or offices, are included in the definition.

(b) *Requirements for covered financial institutions*—(1) *Prohibition on direct use of correspondent accounts.* A covered financial institution shall terminate any correspondent account that is opened or maintained in the United States for, or on behalf of, VEF Bank.

(2) *Due diligence of correspondent accounts to prohibit indirect use.* (i) A covered financial institution shall apply due diligence to its correspondent accounts that is reasonably designed to guard against their indirect use by VEF Bank. At a minimum, that due diligence must include:

(A) Notifying correspondent accountholders that the correspondent account may not be used to provide VEF Bank with access to the covered financial institution; and

(B) Taking reasonable steps to identify any indirect use of its correspondent accounts by VEF Bank, to the extent that such indirect use can be determined from transactional records maintained in the covered financial institution's normal course of business.

(ii) A covered financial institution shall take a risk-based approach when deciding what, if any, additional due diligence measures it should adopt to guard against the indirect use of its correspondent accounts by VEF Bank.

(iii) A covered financial institution that obtains knowledge that a correspondent account is being used by the foreign bank to provide indirect access to VEF Bank shall take all appropriate steps to prevent such indirect access, including, where necessary, terminating the correspondent account.

(iv) A covered financial institution required to terminate a correspondent account pursuant to paragraph (b)(2)(iii) of this section:

(A) Should do so within a commercially reasonable time, and should not permit the foreign bank to establish any new positions or execute any transaction through such correspondent account, other than those necessary to close the correspondent account; and

(B) May reestablish a correspondent account closed pursuant to this paragraph if it determines that the correspondent account will not be used to provide banking services indirectly to VEF Bank.

(3) *Recordkeeping and reporting.* (i) A covered financial institution is required to document its compliance with the notice requirement set forth in paragraph (b)(2)(i)(A) of this section.

(ii) Nothing in this section shall require a covered financial institution to report any information not otherwise required to be reported by law or regulation.

§ 1010.655 Special measures against Banco Delta Asia.

(a) *Definitions.* For purposes of this section:

(1) *Banco Delta Asia* means all branches, offices, and subsidiaries of Banco Delta Asia operating in any jurisdiction, including its subsidiaries Delta Asia Credit Limited and Delta Asia Insurance Limited.

(2) *Correspondent account* has the same meaning as provided in § 1010.605(c)(1)(ii).

(3) *Covered financial institution* includes:

(i) An insured bank (as defined in section 3(h) of the Federal Deposit Insurance Act (12 U.S.C. 1813(h)));

(ii) A commercial bank;

(iii) An agency or branch of a foreign bank in the United States;

(iv) A federally insured credit union;

(v) A savings association;

(vi) A corporation acting under section 25A of the Federal Reserve Act (12 U.S.C. 611 *et seq.*);

(vii) A trust bank or trust company that is federally regulated and is subject to an anti-money laundering program requirement;

(viii) A broker or dealer in securities registered, or required to be registered, with the U.S. Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), except persons who register pursuant to section 15(b)(11) of the Securities Exchange Act of 1934;

(ix) A futures commission merchant or an introducing broker registered, or required to register, with the Commodity Futures Trading Commission under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*), except persons who register pursuant to section 4(f)(a)(2) of the Commodity Exchange Act; and

(x) A mutual fund, which means an investment company (as defined in section 3(a)(1) of the Investment Company Act of 1940 ((''Investment Company Act'') (15 U.S.C. 80a–3(a)(1))) that is an open-end company (as defined in section 5(a)(1) of the Investment Company Act (15 U.S.C. 80a–5(a)(1))) and that is registered, or is required to register with the Securities and Exchange Commission pursuant to the Investment Company Act.

(4) *Subsidiary* means a company of which more than 50 percent of the voting stock or analogous equity interest is owned by another company.

(b) *Requirements for covered financial institutions*—(1) *Prohibition on direct use of correspondent accounts.* A covered financial institution shall terminate any correspondent account that is established, maintained, administered, or managed in the United States for, or on behalf of, Banco Delta Asia.

(2) *Due diligence of correspondent accounts to prohibit indirect use.*

(i) A covered financial institution shall apply due diligence to its correspondent accounts that is reasonably designed to guard against their indirect use by Banco Delta Asia. At a minimum, that due diligence must include:

(A) Notifying correspondent accountholders the correspondent account may not be used to provide Banco Delta Asia with access to the covered financial institution; and

(B) Taking reasonable steps to identify any indirect use of its correspondent accounts by Banco Delta Asia, to the extent that such indirect use can be determined from transactional records maintained in the covered financial institution's normal course of business.

(ii) A covered financial institution shall take a risk-based approach when deciding what, if any, additional due diligence measures it should adopt to guard against the indirect use of its correspondent accounts by Banco Delta Asia.

(iii) A covered financial institution that obtains knowledge that a correspondent account is being used by the foreign bank to provide indirect access to Banco Delta Asia shall take all appropriate steps to prevent such indirect access, including, where necessary, terminating the correspondent account.

(iv) A covered financial institution required to terminate a correspondent account pursuant to paragraph (b)(2)(iii) of this section:

(A) Should do so within a commercially reasonable time, and should not permit the foreign bank to establish any new positions or execute any transaction through such correspondent account, other than those necessary to close the correspondent account; and

(B) May reestablish a correspondent account closed pursuant to this paragraph if it determines that the correspondent account will not be used to provide banking services indirectly to Banco Delta Asia.

(3) *Recordkeeping and reporting.* (i) A covered financial institution is required to document its compliance with the notice requirement set forth in paragraph (b)(2)(i)(A) of this section.

(ii) Nothing in this section shall require a covered financial institution to report any information not otherwise required to be reported by law or regulation.

§ 1010.670 Summons or subpoena of foreign bank records; termination of correspondent relationship.

(a) *Definitions.* The definitions in § 1010.605 apply to this section.

(b) *Issuance to foreign banks.* The Secretary or the Attorney General may issue a summons or subpoena to any foreign bank that maintains a correspondent account in the United States and may request records related to such correspondent account, including records maintained outside of the United States relating to the deposit of funds into the foreign bank. The summons or subpoena may be served on the foreign bank in the United States if the foreign bank has a representative in the United States, or in a foreign country pursuant to any mutual legal assistance treaty, multilateral agreement, or other request for international law enforcement assistance.

(c) *Issuance to covered financial institutions.* Upon receipt of a written request from a Federal law enforcement officer for information required to be maintained by a covered financial institution under paragraph (a)(2) of § 1010.630, the covered financial institution shall provide the information to the requesting officer not later than 7 days after receipt of the request.

(d) *Termination upon receipt of notice.* A covered financial institution shall terminate any correspondent relationship with a foreign bank not later than 10 business days after receipt of written notice from the Secretary or the Attorney General (in each case, after consultation with the other) that the foreign bank has failed:

(1) To comply with a summons or subpoena issued under paragraph (b) of this section; or

(2) To initiate proceedings in a United States court contesting such summons or subpoena.

(e) *Limitation on liability.* A covered financial institution shall not be liable to any person in any court or arbitration proceeding for terminating a correspondent relationship in accordance with paragraph (d) of this section.

(f) *Failure to terminate relationship.* Failure to terminate a correspondent relationship in accordance with this section shall render the covered financial institution liable for a civil penalty of up to $10,000 per day until the correspondent relationship is so terminated.

Subpart G—Administrative Rulings

§ 1010.710 Scope.

This subpart provides that the Director, FinCEN, or his designee, either unilaterally or upon request, may issue administrative rulings interpreting the application of this chapter.

§ 1010.711 Submitting requests.

(a) Each request for an administrative ruling must be in writing and contain the following information:

(1) A complete description of the situation for which the ruling is requested,

(2) A complete statement of all material facts related to the subject transaction,

(3) A concise and unambiguous question to be answered,

(4) A statement certifying, to the best of the requestor's knowledge and belief, that the question to be answered is not applicable to any ongoing state or federal investigation, litigation, grand jury proceeding, or proceeding before any other governmental body involving either the requestor, any other party to the subject transaction, or any other party with whom the requestor has an agency relationship,

(5) A statement identifying any information in the request that the requestor considers to be exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552, and the reason therefor,

(6) If the subject situation is hypothetical, a statement justifying why the particular situation described warrants the issuance of a ruling,

(7) The signature of the person making the request, or

(8) If an agent makes the request, the signature of the agent and a statement certifying the authority under which the request is made.

(b) A request filed by a corporation shall be signed by a corporate officer and a request filed by a partnership shall be signed by a partner.

(c) A request may advocate a particular proposed interpretation and may set forth the legal and factual basis for that interpretation.

(d) Requests shall be addressed to: Director, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183.

(e) The requester shall advise the Director, FinCEN, immediately in writing of any subsequent change in any material fact or statement submitted with a ruling request in conformity with paragraph (a) of this section.

(Approved by the Office of Management and Budget under control number 1505–0105.)

§ 1010.712 Nonconforming requests.

The Director, FinCEN, or his designee shall notify the requester if the ruling request does not conform with the requirements of § 1010.711. The notice shall be in writing and shall describe the requirements that have not been met. A request that is not brought into conformity with such requirements within 30 days from the date of such notice, unless extended for good cause by FinCEN, shall be treated as though it were withdrawn.

(Approved by the Office of Management and Budget under control number 1505–0105.)

§ 1010.713 Oral communications.

(a) The Director of FinCEN or his designee will not issue administrative rulings in response to oral requests. Oral opinions or advice by Treasury, Customs and Border Protection, the Internal Revenue Service, the Office of the Comptroller of the Currency, or any other bank supervisory agency personnel, regarding the interpretation and application of this chapter, do not bind FinCEN and carry no precedential value.

(b) A person who has made a ruling request in conformity with § 1010.711 may request an opportunity for oral discussion of the issues presented in the request. The request should be made to the Director, FinCEN, and any decision to grant such a conference is wholly within the discretion of the Director. Personal conferences or telephone conferences may be scheduled only for the purpose of affording the requester an opportunity to discuss freely and openly the matters set forth in the administrative ruling request. Accordingly, the conferees will not be bound by any argument or position advocated or agreed to, expressly or impliedly, during the conference. Any new arguments or facts put forth by the requester at the meeting must be reduced to writing by the requester and submitted in conformity with § 1010.711 before they may be considered in connection with the request.

(Approved by the Office of Management and Budget under control number 1505–0105.)

§ 1010.714 Withdrawing requests.

A person may withdraw a request for an administrative ruling at any time before the ruling has been issued.

§ 1010.715 Issuing rulings.

The Director, FinCEN, or his designee may issue a written ruling interpreting the relationship between this chapter and each situation for which such a ruling has been requested in conformity with § 1010.711. A ruling issued under this section shall bind FinCEN only in the event that the request describes a specifically identified actual situation. A ruling issued under this section shall have precedential value, and hence may be relied upon by others similarly situated, only if it is published or will be published by FinCEN in the **Federal Register**. Rulings with precedential value will be published periodically in the **Federal Register** and yearly in Appendix D to this chapter. All rulings with precedential value will be available by mail to any person upon written request specifically identifying the ruling sought. FinCEN will make every effort to respond to each requestor within 90 days of receiving a request.

(Approved by the Office of Management and Budget under control number 1505–0105.)

§ 1010.716 Modifying or rescinding rulings.

(a) The Director, FinCEN, or his designee may modify or rescind any ruling made pursuant to § 1010.715:

(1) When, in light of changes in the statute or regulations, the ruling no longer sets forth the interpretation of the Director, FinCEN with respect to the described situation,

(2) When any fact or statement submitted in the original ruling request is found to be materially inaccurate or incomplete, or

(3) For other good cause.

(b) Any person may submit to the Director, FinCEN a written request that an administrative ruling be modified or rescinded. The request should conform to the requirements of § 1010.711, explain why rescission or modification is warranted, and refer to any reasons in paragraph (a) of this section that are relevant. The request may advocate an alternative interpretation and may set forth the legal and factual basis for that interpretation.

(c) FinCEN shall modify an existing administrative ruling by issuing a new ruling that rescinds the relevant prior ruling. Once rescinded, an administrative ruling shall no longer have any precedential value.

(d) An administrative ruling may be modified or rescinded retroactively with respect to one or more parties to the original ruling request if the Director, FinCEN determines that:

(1) A fact or statement in the original ruling request was materially inaccurate or incomplete,

(2) The requestor failed to notify in writing FinCEN of a material change to any fact or statement in the original request, or

(3) A party to the original request acted in bad faith when relying upon the ruling.

(Approved by the Office of Management and Budget under control number 1505–0105.)

§ 1010.717 Disclosing information.

(a) Any part of any administrative ruling, including names, addresses, or information related to the business transactions of private parties, may be disclosed pursuant to a request under the Freedom of Information Act, 5 U.S.C. 552. If the request for an administrative ruling contains information which the requestor wishes to be considered for exemption from disclosure under the Freedom of Information Act, the requestor should clearly identify such portions of the request and the reasons why such information should be exempt from disclosure.

(b) A requestor claiming an exemption from disclosure will be notified, at least 10 days before the administrative ruling is issued, of a decision not to exempt any of such information from disclosure so that the underlying request for an administrative ruling can be withdrawn if the requestor so chooses.

(Approved by the Office of Management and Budget under control number 1505–0105.)

Subpart H—Enforcement; Penalties; and Forfeiture

§ 1010.810 Enforcement.

(a) Overall authority for enforcement and compliance, including coordination and direction of procedures and activities of all other agencies exercising delegated authority under this chapter, is delegated to the Director, FinCEN.

(b) Authority to examine institutions to determine compliance with the requirements of this chapter is delegated as follows:

(1) To the Comptroller of the Currency with respect to those financial institutions regularly examined for safety and soundness by national bank examiners;

(2) To the Board of Governors of the Federal Reserve System with respect to those financial institutions regularly examined for safety and soundness by Federal Reserve bank examiners;

(3) To the Federal Deposit Insurance Corporation with respect to those financial institutions regularly examined for safety and soundness by FDIC bank examiners;

(4) To the Federal Home Loan Bank Board with respect to those financial institutions regularly examined for safety and soundness by FHLBB bank examiners;

(5) To the Chairman of the Board of the National Credit Union Administration with respect to those financial institutions regularly examined for safety and soundness by NCUA examiners.

(6) To the Securities and Exchange Commission with respect to brokers and dealers in securities and investment companies as that term is defined in the Investment Company Act of 1940 (15 U.S.C. 80–1 *et seq.*);

(7) To the Commissioner of Customs and Border Protection with respect to §§ 1010.340 and 1010.830;

(8) To the Commissioner of Internal Revenue with respect to all financial institutions, except brokers or dealers in securities, futures commission merchants, introducing brokers in commodities, and commodity trading advisors, not currently examined by Federal bank supervisory agencies for soundness and safety; and

(9) To the Commodity Futures Trading Commission with respect to futures commission merchants, introducing brokers in commodities, and commodity trading advisors.

(c) Authority for investigating criminal violations of this chapter is delegated as follows:

(1) To the Commissioner of Customs and Border Protection with respect to § 1010.340;

(2) To the Commissioner of Internal Revenue except with respect to § 1010.340.

(d) Authority for the imposition of civil penalties for violations of this chapter lies with the Director of FinCEN.

(e) Periodic reports shall be made to the Director, FinCEN by each agency to which compliance authority has been delegated under paragraph (b) of this section. These reports shall be in such a form and submitted at such intervals as the Director, FinCEN may direct. Evidence of specific violations of any of the requirements of this chapter may be submitted to the Director, FinCEN at any time.

(f) The Director, FinCEN or his delegate, and any agency to which compliance has been delegated under paragraph (b) of this section, may examine any books, papers, records, or other data of domestic financial institutions relevant to the

recordkeeping or reporting requirements of this chapter.

(g) The authority to enforce the provisions of 31 U.S.C. 5314 and §§ 1010.350 and 1010.420 of this chapter has been redelegated from FinCEN to the Commissioner of Internal Revenue by means of a Memorandum of Agreement between FinCEN and IRS. Such authority includes, with respect to 31 U.S.C. 5314 and §§ 1010.350 and 1010.420 of this chapter, the authority to: Assess and collect civil penalties under 31 U.S.C. 5321 and 31 CFR 1010.820; investigate possible civil violations of these provisions (in addition to the authority already provided at paragraph (c)(2) of this section); employ the summons power of subpart I of this part 1010; issue administrative rulings under subpart G of this part 1010; and take any other action reasonably necessary for the enforcement of these and related provisions, including pursuit of injunctions.

§ 1010.820 Civil penalty.

(a) For any willful violation, committed on or before October 12, 1984, of any reporting requirement for financial institutions under this chapter or of any recordkeeping requirements of §§ 1010.311, 1010.313, 1020.315, 1021.311 or 1021.313, the Secretary may assess upon any domestic financial institution, and upon any partner, director, officer, or employee thereof who willfully participates in the violation, a civil penalty not to exceed $1,000.

(b) For any willful violation committed after October 12, 1984 and before October 28, 1986, of any reporting requirement for financial institutions under this chapter or of the recordkeeping requirements of § 1010.420, the Secretary may assess upon any domestic financial institution, and upon any partner, director, officer, or employee thereof who willfully participates in the violation, a civil penalty not to exceed $10,000.

(c) For any willful violation of any recordkeeping requirement for financial institutions, except violations of § 1010.420, under this chapter, the Secretary may assess upon any domestic financial institution, and upon any partner, director, officer, or employee thereof who willfully participates in the violation, a civil penalty not to exceed $1,000.

(d) For any failure to file a report required under § 1010.340 or for filing such a report containing any material omission or misstatement, the Secretary may assess a civil penalty up to the amount of the currency or monetary instruments transported, mailed or shipped, less any amount forfeited under § 1010.830.

(e) For any willful violation of § 1010.314 committed after January 26, 1987, the Secretary may assess upon any person a civil penalty not to exceed the amount of coins and currency involved in the transaction with respect to which such penalty is imposed. The amount of any civil penalty assessed under this paragraph shall be reduced by the amount of any forfeiture to the United States in connection with the transaction for which the penalty was imposed.

(f) For any willful violation committed after October 27, 1986, of any reporting requirement for financial institutions under this chapter (except § 1010.350, § 1010.360 or § 1010.420), the Secretary may assess upon any domestic financial institution, and upon any partner, director, officer, or employee thereof who willfully participates in the violation, a civil penalty not to exceed the greater of the amount (not to exceed $100,000) involved in the transaction or $25,000.

(g) For any willful violation committed after October 27, 1986, of any requirement of § 1010.350, § 1010.360 or § 1010.420, the Secretary may assess upon any person, a civil penalty:

(1) In the case of a violation of § 1010.360 involving a transaction, a civil penalty not to exceed the greater of the amount (not to exceed $100,000) of the transaction, or $25,000; and

(2) In the case of a violation of § 1010.350 or § 1010.420 involving a failure to report the existence of an account or any identifying information required to be provided with respect to such account, a civil penalty not to exceed the greater of the amount (not to exceed $100,000) equal to the balance in the account at the time of the violation, or $25,000.

(h) For each negligent violation of any requirement of this chapter, committed after October 27, 1986, the Secretary may assess upon any financial institution a civil penalty not to exceed $500.

§ 1010.830 Forfeiture of currency or monetary instruments.

Any currency or other monetary instruments which are in the process of any transportation with respect to which a report is required under § 1010.340 are subject to seizure and forfeiture to the United States if such report has not been filed as required in § 1010.360, or contains material omissions or misstatements. The Secretary may, in his sole discretion, remit or mitigate any such forfeiture in whole or in part upon such terms and conditions as he deems reasonable.

§ 1010.840 Criminal penalty.

(a) Any person who willfully violates any provision of Title I of Public Law 91–508, or of this chapter authorized thereby may, upon conviction thereof, be fined not more than $1,000 or be imprisoned not more than 1 year, or both. Such person may in addition, if the violation is of any provision authorized by Title I of Public Law 91–508 and if the violation is committed in furtherance of the commission of any violation of Federal law punishable by imprisonment for more than 1 year, be fined not more than $10,000 or be imprisoned not more than 5 years, or both.

(b) Any person who willfully violates any provision of Title II of Public Law 91–508, or of this chapter authorized thereby, may, upon conviction thereof, be fined not more than $250,000 or be imprisoned not more than 5 years, or both.

(c) Any person who willfully violates any provision of Title II of Pub. L. 91–508, or of this chapter authorized thereby, where the violation is either

(1) Committed while violating another law of the United States, or

(2) Committed as part of a pattern of any illegal activity involving more than $100,000 in any 12-month period, may, upon conviction thereof, be fined not more than $500,000 or be imprisoned not more than 10 years, or both.

(d) Any person who knowingly makes any false, fictitious or fraudulent statement or representation in any report required by this chapter may, upon conviction thereof, be fined not more than $10,000 or be imprisoned not more than 5 years, or both.

§ 1010.850 Enforcement authority with respect to transportation of currency or monetary instruments.

(a) If a customs officer has reasonable cause to believe that there is a monetary instrument being transported without the filing of the report required by §§ 1010.340 and 1010.360 of this chapter, he may stop and search, without a search warrant, a vehicle, vessel, aircraft, or other conveyance, envelope or other container, or person entering or departing from the United States with respect to which or whom the officer reasonably believes is transporting such instrument.

(b) If the Secretary has reason to believe that currency or monetary instruments are in the process of transportation and with respect to which a report required under

§ 1010.340 has not been filed or contains material omissions or misstatements, he may apply to any court of competent jurisdiction for a search warrant. Upon a showing of probable cause, the court may issue a warrant authorizing the search of any or all of the following:

(1) One or more designated persons.

(2) One or more designated or described places or premises.

(3) One or more designated or described letters, parcels, packages, or other physical objects.

(4) One or more designated or described vehicles. Any application for a search warrant pursuant to this section shall be accompanied by allegations of fact supporting the application.

(c) This section is not in derogation of the authority of the Secretary under any other law or regulation.

Subpart I—Summons

§ 1010.911 General.

For any investigation for the purpose of civil enforcement of violations of the Bank Secrecy Act, or any regulation issued pursuant to the Bank Secrecy Act, the Secretary or delegate of the Secretary may summon a financial institution or an officer or employee of a financial institution (including a former officer or employee), or any person having possession, custody, or care of any of the records and reports required under the Bank Secrecy Act or this chapter to appear before the Secretary or his delegate, at a time and place named in the summons, and to give testimony, under oath, and be examined, and to produce such books, papers, records, or other data as may be relevant or material to such investigation.

§ 1010.912 Persons who may issue summons.

For purposes of this chapter, the following officials are hereby designated as delegates of the Secretary who are authorized to issue a summons under § 1010.911, solely for the purposes of civil enforcement of this chapter:

(a) *FinCEN.* The Director, FinCEN.

(b) *Internal Revenue Service.* Except with respect to § 1010.340 of this chapter, the Commissioner, the Deputy Commissioner, or a delegate of either official, and, for the purposes of perfecting seizures and forfeitures related to civil enforcement of this chapter, the Chief (Criminal Investigation) or a delegate.

(c) *Customs and Border Protection.* With respect to § 1010.340 of this chapter, the Commissioner, the Deputy Commissioner, the Assistant Commissioner (Enforcement), Regional Commissioners, Assistant Regional Commissioners (Enforcement), and Special Agents in Charge.

§ 1010.913 Contents of summons.

(a) *Summons for testimony.* Any summons issued under § 1010.911 of this chapter to compel the appearance and testimony of a person shall state:

(1) The name, title, address, and telephone number of the person before whom the appearance shall take place (who may be a person other than the persons who are authorized to issue such a summons under § 1010.912 of this chapter);

(2) The address to which the person summoned shall report for the appearance;

(3) The date and time of the appearance; and

(4) The name, title, address, and telephone number of the person who has issued the summons.

(b) *Summons of books, papers, records, or data.* Any summons issued under § 1010.911 of this chapter to require the production of books, papers, records, or other data shall describe the materials to be produced with reasonable specificity, and shall state:

(1) The name, title, address, and telephone number of the person to whom the materials shall be produced (who may be a person other than the persons who are authorized to issue such a summons under § 1010.912 of this chapter);

(2) The address at which the person summoned shall produce the materials, not to exceed 500 miles from any place where the financial institution operates or conducts business in the United States;

(3) The specific manner of production, whether by personal delivery, by mail, or by messenger service;

(4) The date and time for production; and

(5) The name, title, address, and telephone number of the person who has issued the summons.

§ 1010.914 Service of summons.

(a) *Who may serve.* Any delegate of the Secretary authorized under § 1010.912 of this chapter to issue a summons, or any other person authorized by law to serve summonses or other process, is hereby authorized to serve a summons issued under this chapter.

(b) *Manner of service.* Service of a summons may be made—

(1) Upon any person, by registered mail, return receipt requested, directed to the person summoned;

(2) Upon a natural person by personal delivery; or

(3) Upon any other person by delivery to an officer, managing or general agent, or any other agent authorized to receive service of process.

(c) *Certificate of service.* The summons shall contain a certificate of service to be signed by the server of the summons. On the hearing of an application for enforcement of the summons, the certificate of service signed by the person serving the summons shall be evidence of the facts it states.

§ 1010.915 Examination of witnesses and records.

(a) *General.* Any delegate of the Secretary authorized under § 1010.912 of this chapter to issue a summons, or any officer or employee of the Treasury Department or any component thereof who is designated by that person (whether in the summons or otherwise), is hereby authorized to receive evidence and to examine witnesses pursuant to the summons. Any person authorized by law may administer any oaths and affirmations that may be required under this subpart.

(b) *Testimony taken under oath.* Testimony of any person under this chapter may be taken under oath, and shall be taken down in writing by the person examining the person summoned or shall be otherwise transcribed. After the testimony of a witness has been transcribed, a copy of that transcript shall be made available to the witness upon request, unless for good cause the person issuing the summons determines, under 5 U.S.C. 555, that a copy should not be provided. If such a determination has been made, the witness shall be limited to inspection of the official transcript of the testimony.

(c) *Disclosure of summons, testimony, or records.* Unless the Secretary or a delegate of the Secretary listed under § 1010.912(a) of this chapter so authorizes in writing, or it is otherwise required by law, no delegate of the Secretary listed under § 1010.912(b) or (c) of this chapter or other officer or employee of the Treasury Department or any component thereof shall—

(1) Make public the name of any person to whom a summons has been issued under this chapter, or release any information to the public concerning that person or the issuance of a summons to that person prior to the time and date set for that person's appearance or production of records; or

(2) Disclose any testimony taken (including the name of the witness) or material presented pursuant to the

summons, to any person other than an officer or employee of the Treasury Department or of any component thereof. Nothing in the preceding sentence shall preclude a delegate of the Secretary, or other officer or employee of the Treasury Department or any component thereof, from disclosing testimony taken, or material presented pursuant to a summons issued under this chapter, to any person in order to obtain necessary information for investigative purposes relating to the performance of official duties, or to any officer or employee of the Department of Justice in connection with a possible violation of Federal law.

§ 1010.916 Enforcement of summons.

In the case of contumacy by, or refusal to obey a summons issued to, any person under this chapter, the Secretary or any delegate of the Secretary listed under § 1010.912 of this chapter shall refer the matter to the Attorney General or delegate of the Attorney General (including any United States Attorney or Assistant United States Attorney, as appropriate), who may bring an action to compel compliance with the summons in any court of the United States within the jurisdiction of which the investigation which gave rise to the summons being or has been carried on, the jurisdiction in which the person summoned is a resident, or the jurisdiction in which the person summoned carries on business or may be found. When a referral is made by a delegate of the Secretary other than a delegate named in § 1010.912(a) of this chapter, prompt notification of the referral must be made to the Director, FinCEN. The court may issue an order requiring the person summoned to appear before the Secretary or delegate of the Secretary to produce books, papers, records, or other data, to give testimony as may be necessary in order to explain how such material was compiled and maintained, and to pay the costs of the proceeding. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any case under this section may be served in any judicial district in which such person may be found.

§ 1010.917 Payment of expenses.

Persons summoned under this chapter shall be paid the same fees and mileage for travel in the United States that are paid witnesses in the courts of the United States. The United States shall not be liable for any other expense incurred in connection with the production of books, papers, records, or other data under this chapter.

Subpart J—Miscellaneous

§ 1010.920 Access to records.

Except as provided in §§ 1020.410(b)(1), 1021.410(a), and 1023.410(a)(1), and except for the purpose of assuring compliance with the recordkeeping and reporting requirements of this chapter, this chapter does not authorize the Secretary or any other person to inspect or review the records required to be maintained by this chapter. Other inspection, review or access to such records is governed by other applicable law.

§ 1010.930 Rewards for informants.

(a) If an individual provides original information which leads to a recovery of a criminal fine, civil penalty, or forfeiture, which exceeds $50,000, for a violation of the provisions of the Bank Secrecy Act or of this chapter, the Secretary may pay a reward to that individual.

(b) The Secretary shall determine the amount of the reward to be paid under this section; however, any reward paid may not be more than 25 percent of the net amount of the fine, penalty or forfeiture collected, or $150,000, whichever is less.

(c) An officer or employee of the United States, a State, or a local government who provides original information described in paragraph (a) in the performance of official duties is not eligible for a reward under this section.

§ 1010.940 Photographic or other reproductions of Government obligations.

Nothing herein contained shall require or authorize the microfilming or other reproduction of

(a) Currency or other obligation or security of the United States as defined in 18 U.S.C. 8, or

(b) Any obligation or other security of any foreign government, the reproduction of which is prohibited by law.

§ 1010.950 Availability of information.

(a) The Secretary may within his discretion disclose information reported under this chapter for any reason consistent with the purposes of the Bank Secrecy Act, including those set forth in paragraphs (b) through (d) of this section.

(b) The Secretary may make any information set forth in any report received pursuant to this chapter available to another agency of the United States, to an agency of a state or local government or to an agency of a foreign government, upon the request of the head of such department or agency made in writing and stating the particular information desired, the criminal, tax or regulatory purpose for which the information is sought, and the official need for the information.

(c) The Secretary may make any information set forth in any report received pursuant to this chapter available to the Congress, or any committee or subcommittee thereof, upon a written request stating the particular information desired, the criminal, tax or regulatory purpose for which the information is sought, and the official need for the information.

(d) The Secretary may make any information set forth in any report received pursuant to this chapter available to any other department or agency of the United States that is a member of the Intelligence Community, as defined by Executive Order 12333 or any succeeding executive order, upon the request of the head of such department or agency made in writing and stating the particular information desired, the national security matter with which the information is sought and the official need therefor.

(e) Any information made available under this section to other department or agencies of the United States, any state or local government, or any foreign government shall be received by them in confidence, and shall not be disclosed to any person except for official purposes relating to the investigation, proceeding or matter in connection with which the information is sought.

(f) The Secretary may require that a state or local government department or agency requesting information under paragraph (b) of this section pay fees to reimburse the Department of the Treasury for costs incidental to such disclosure. The amount of such fees will be set in accordance with the statute on fees for government services, 31 U.S.C. 9701.

(Approved by the Office of Management and Budget under control number 1505–0104.)

§ 1010.960 Disclosure.

All reports required under this chapter and all records of such reports are specifically exempted from disclosure under section 552 of Title 5, United States Code.

§ 1010.970 Exceptions, exemptions, and reports.

(a) The Secretary, in his sole discretion, may by written order or authorization make exceptions to or grant exemptions from the requirements of this chapter. Such exceptions or exemptions may be conditional or unconditional, may apply to particular

persons or to classes of persons, and may apply to particular transactions or classes of transactions. They shall, however, be applicable only as expressly stated in the order of authorization, and they shall be revocable in the sole discretion of the Secretary.

(b) The Secretary shall have authority to further define all terms used herein.

(c)(1) The Secretary may, as an alternative to the reporting and recordkeeping requirements for casinos in §§ 1010.306(a), 1021.311, and 1021.410, grant exemptions to the casinos in any state whose regulatory system substantially meets the reporting and recordkeeping requirements of this chapter.

(2) In order for a state regulatory system to qualify for an exemption on behalf of its casinos, the state must provide:

(i) That the Treasury Department be allowed to evaluate the effectiveness of the state's regulatory system by periodic oversight review of that system;

(ii) That the reports required under the state's regulatory system be submitted to the Treasury Department within 15 days of receipt by the state;

(iii) That any records required to be maintained by the casinos relevant to any matter under this chapter and to which the state has access or maintains under its regulatory system be made available to the Treasury Department within 30 days of request;

(iv) That the Treasury Department be provided with periodic status reports on the state's compliance efforts and findings;

(v) That all but minor violations of the state requirements be reported to Treasury within 15 days of discovery; and

(vi) That the state will initiate compliance examinations of specific institutions at the request of Treasury within a reasonable time, not to exceed 90 days where appropriate, and will provide reports of these examinations to Treasury within 15 days of completion or periodically during the course of the examination upon the request of the Secretary. If for any reason the state were not able to conduct an investigation within a reasonable time, the state will permit Treasury to conduct the investigation.

(3) Revocation of any exemption under this subsection shall be in the sole discretion of the Secretary.

§ 1010.980 Dollars as including foreign currency.

Wherever in this chapter an amount is stated in dollars, it shall be deemed to mean also the equivalent amount in any foreign currency.

PARTS 1011–1019 [RESERVED]

PART 1020—RULES FOR BANKS

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Subpart A—Definitions

§ 1020.100 Definitions.

Refer to § 1010.100 of this chapter for general definitions not noted herein. To the extent there is a differing definition in § 1010.100, the definition in this Section is what applies to Part 1020.

Unless otherwise indicated, for purposes of this Part:

(a) *Account.* For purposes of § 1020.220:

(1) *Account* means a formal banking relationship established to provide or engage in services, dealings, or other financial transactions including a deposit account, a transaction or asset account, a credit account, or other extension of credit. *Account* also includes a relationship established to provide a safety deposit box or other safekeeping services, or cash management, custodian, and trust services.

(2) *Account* does not include:

(i) A product or service where a formal banking relationship is not established with a person, such as check-cashing, wire transfer, or sale of a check or money order;

(ii) An account that the bank acquires through an acquisition, merger, purchase of assets, or assumption of liabilities; or

(iii) An account opened for the purpose of participating in an employee benefit plan established under the Employee Retirement Income Security Act of 1974.

(b) *Bank.* For the purposes of § 1020.220, means:

(1) A bank, as that term is defined in § 1010.100(d), that is subject to regulation by a Federal functional regulator; and

(2) A credit union, private bank, and trust company, as set forth in § 1010.100(d) of this chapter, that does not have a Federal functional regulator.

(c) *Customer.* For the purposes of § 1020.220:

(1) *Customer* means:

(i) A person that opens a new account; and

(ii) An individual who opens a new account for:

(A) An individual who lacks legal capacity, such as a minor; or

(B) An entity that is not a legal person, such as a civic club.

(2) *Customer* does not include:

(i) A financial institution regulated by a Federal functional regulator or a bank regulated by a state bank regulator;

(ii) A person described in § 1020.315(b)(2) through (b)(4); or

(iii) A person that has an existing account with the bank, provided that the bank has a reasonable belief that it knows the true identity of the person.

(d) *Financial institution* means:

(1) For the purposes of § 1020.210, a financial institution defined in 31 U.S.C. 5312(a)(2) or (c)(1) that is subject

to regulation by a Federal functional regulator or a self-regulatory organization.

(2) For the purposes of § 1020.220, financial institution is defined at 31 U.S.C. 5312(a)(2) and (c)(1).

Subpart B—Programs

§ 1020.200 General.

Banks are subject to the program requirements set forth and cross referenced in this subpart. Banks should also refer to Subpart B of Part 1010 of this chapter for program requirements contained in that subpart which apply to banks.

§ 1020.210 Anti-money laundering program requirements for financial institutions regulated only by a Federal functional regulator, including banks, savings associations, and credit unions.

A financial institution regulated by a Federal functional regulator that is not subject to the regulations of a self regulatory organization shall be deemed to satisfy the requirements of 31 U.S.C. 5318(h)(1) if it implements and maintains an anti-money laundering program that complies with the requirements of §§ 1010.610 and 1010.620 of this chapter and the regulation of its Federal functional regulator governing such programs.

§ 1020.220 Customer Identification Programs for banks, savings associations, credit unions, and certain non-Federally regulated banks.

(a) *Customer Identification Program: minimum requirements*—(1) *In general.* A bank must implement a written Customer Identification Program (CIP) appropriate for its size and type of business that, at a minimum, includes each of the requirements of paragraphs (a)(1) through (5) of this section. If a bank is required to have an anti-money laundering compliance program under the regulations implementing 31 U.S.C. 5318(h), 12 U.S.C. 1818(s), or 12 U.S.C. 1786(q)(1), then the CIP must be a part of the anti-money laundering compliance program. Until such time as credit unions, private banks, and trust companies without a Federal functional regulator are subject to such a program, their CIPs must be approved by their boards of directors.

(2) *Identity verification procedures.* The CIP must include risk-based procedures for verifying the identity of each customer to the extent reasonable and practicable. The procedures must enable the bank to form a reasonable belief that it knows the true identity of each customer. These procedures must be based on the bank's assessment of the relevant risks, including those presented by the various types of accounts maintained by the bank, the various methods of opening accounts provided by the bank, the various types of identifying information available, and the bank's size, location, and customer base. At a minimum, these procedures must contain the elements described in this paragraph (a)(2).

(i) *Customer information required*—(A) *In general.* The CIP must contain procedures for opening an account that specify the identifying information that will be obtained from each customer. Except as permitted by paragraphs (a)(2)(i)(B) and (C) of this section, the bank must obtain, at a minimum, the following information from the customer prior to opening an account:

(1) Name;

(2) Date of birth, for an individual;

(3) Address, which shall be:

(i) For an individual, a residential or business street address;

(ii) For an individual who does not have a residential or business street address, an Army Post Office (APO) or Fleet Post Office (FPO) box number, or the residential or business street address of next of kin or of another contact individual; or

(iii) For a person other than an individual (such as a corporation, partnership, or trust), a principal place of business, local office, or other physical location; and

(4) Identification number, which shall be:

(i) For a U.S. person, a taxpayer identification number; or

(ii) For a non-U.S. person, one or more of the following: a taxpayer identification number; passport number and country of issuance; alien identification card number; or number and country of issuance of any other government-issued document evidencing nationality or residence and bearing a photograph or similar safeguard.

Note to Paragraph (a)(2)(i)(A)(*4*)(*ii*): When opening an account for a foreign business or enterprise that does not have an identification number, the bank must request alternative government-issued documentation certifying the existence of the business or enterprise.

(B) *Exception for persons applying for a taxpayer identification number.* Instead of obtaining a taxpayer identification number from a customer prior to opening the account, the CIP may include procedures for opening an account for a customer that has applied for, but has not received, a taxpayer identification number. In this case, the CIP must include procedures to confirm that the application was filed before the customer opens the account and to obtain the taxpayer identification number within a reasonable period of time after the account is opened.

(C) *Credit card accounts.* In connection with a customer who opens a credit card account, a bank may obtain the identifying information about a customer required under paragraph (a)(2)(i)(A) by acquiring it from a third-party source prior to extending credit to the customer.

(ii) *Customer verification.* The CIP must contain procedures for verifying the identity of the customer, using information obtained in accordance with paragraph (a)(2)(i) of this section, within a reasonable time after the account is opened. The procedures must describe when the bank will use documents, non-documentary methods, or a combination of both methods as described in this paragraph (a)(2)(ii).

(A) *Verification through documents.* For a bank relying on documents, the CIP must contain procedures that set forth the documents that the bank will use. These documents may include:

(1) For an individual, unexpired government-issued identification evidencing nationality or residence and bearing a photograph or similar safeguard, such as a driver's license or passport; and

(2) For a person other than an individual (such as a corporation, partnership, or trust), documents showing the existence of the entity, such as certified articles of incorporation, a government-issued business license, a partnership agreement, or trust instrument.

(B) *Verification through non-documentary methods.* For a bank relying on non-documentary methods, the CIP must contain procedures that describe the non-documentary methods the bank will use.

(1) These methods may include contacting a customer; independently verifying the customer's identity through the comparison of information provided by the customer with information obtained from a consumer reporting agency, public database, or other source; checking references with other financial institutions; and obtaining a financial statement.

(2) The bank's non-documentary procedures must address situations where an individual is unable to present an unexpired government-issued identification document that bears a photograph or similar safeguard; the bank is not familiar with the documents presented; the account is opened without obtaining documents; the customer opens the account without appearing in person at the bank; and where the bank is otherwise presented

with circumstances that increase the risk that the bank will be unable to verify the true identity of a customer through documents.

(C) *Additional verification for certain customers.* The CIP must address situations where, based on the bank's risk assessment of a new account opened by a customer that is not an individual, the bank will obtain information about individuals with authority or control over such account, including signatories, in order to verify the customer's identity. This verification method applies only when the bank cannot verify the customer's true identity using the verification methods described in paragraphs (a)(2)(ii)(A) and (B) of this section.

(iii) *Lack of verification.* The CIP must include procedures for responding to circumstances in which the bank cannot form a reasonable belief that it knows the true identity of a customer. These procedures should describe:

(A) When the bank should not open an account;

(B) The terms under which a customer may use an account while the bank attempts to verify the customer's identity;

(C) When the bank should close an account, after attempts to verify a customer's identity have failed; and

(D) When the bank should file a Suspicious Activity Report in accordance with applicable law and regulation.

(3) *Recordkeeping.* The CIP must include procedures for making and maintaining a record of all information obtained under the procedures implementing paragraph (a) of this section.

(i) *Required records.* At a minimum, the record must include:

(A) All identifying information about a customer obtained under paragraph (a)(2)(i) of this section;

(B) A description of any document that was relied on under paragraph (a)(2)(ii)(A) of this section noting the type of document, any identification number contained in the document, the place of issuance and, if any, the date of issuance and expiration date;

(C) A description of the methods and the results of any measures undertaken to verify the identity of the customer under paragraph (a)(2)(ii)(B) or (C) of this section; and

(D) A description of the resolution of any substantive discrepancy discovered when verifying the identifying information obtained.

(ii) *Retention of records.* The bank must retain the information in paragraph (a)(3)(i)(A) of this section for five years after the date the account is closed or, in the case of credit card accounts, five years after the account is closed or becomes dormant. The bank must retain the information in paragraphs (a)(3)(i)(B), (C), and (D) of this section for five years after the record is made.

(4) *Comparison with government lists.* The CIP must include procedures for determining whether the customer appears on any list of known or suspected terrorists or terrorist organizations issued by any Federal government agency and designated as such by Treasury in consultation with the Federal functional regulators. The procedures must require the bank to make such a determination within a reasonable period of time after the account is opened, or earlier, if required by another Federal law or regulation or Federal directive issued in connection with the applicable list. The procedures must also require the bank to follow all Federal directives issued in connection with such lists.

(5)(i) *Customer notice.* The CIP must include procedures for providing bank customers with adequate notice that the bank is requesting information to verify their identities.

(ii) *Adequate notice.* Notice is adequate if the bank generally describes the identification requirements of this section and provides the notice in a manner reasonably designed to ensure that a customer is able to view the notice, or is otherwise given notice, before opening an account. For example, depending upon the manner in which the account is opened, a bank may post a notice in the lobby or on its Web site, include the notice on its account applications, or use any other form of written or oral notice.

(iii) *Sample notice.* If appropriate, a bank may use the following sample language to provide notice to its customers:

Important Information About Procedures for Opening a New Account

To help the government fight the funding of terrorism and money laundering activities, Federal law requires all financial institutions to obtain, verify, and record information that identifies each person who opens an account.

What this means for you: When you open an account, we will ask for your name, address, date of birth, and other information that will allow us to identify you. We may also ask to see your driver's license or other identifying documents.

(6) *Reliance on another financial institution.* The CIP may include procedures specifying when a bank will rely on the performance by another financial institution (including an affiliate) of any procedures of the bank's CIP, with respect to any customer of the bank that is opening, or has opened, an account or has established a similar formal banking or business relationship with the other financial institution to provide or engage in services, dealings, or other financial transactions, provided that:

(i) Such reliance is reasonable under the circumstances;

(ii) The other financial institution is subject to a rule implementing 31 U.S.C. 5318(h) and is regulated by a Federal functional regulator; and

(iii) The other financial institution enters into a contract requiring it to certify annually to the bank that it has implemented its anti-money laundering program, and that it will perform (or its agent will perform) the specified requirements of the bank's CIP.

(b) *Exemptions.* The appropriate Federal functional regulator, with the concurrence of the Secretary, may, by order or regulation, exempt any bank or type of account from the requirements of this section. The Federal functional regulator and the Secretary shall consider whether the exemption is consistent with the purposes of the Bank Secrecy Act and with safe and sound banking, and may consider other appropriate factors. The Secretary will make these determinations for any bank or type of account that is not subject to the authority of a Federal functional regulator.

(c) *Other requirements unaffected.* Nothing in this section relieves a bank of its obligation to comply with any other provision in this chapter, including provisions concerning information that must be obtained, verified, or maintained in connection with any account or transaction.

Subpart C—Reports Required To Be Made by Banks

§ 1020.300 General.

Banks are subject to the reporting requirements set forth and cross referenced in this subpart. Banks should also refer to Subpart C of Part 1010 for reporting requirements contained in that subpart which apply to banks.

§ 1020.310 Reports of transactions in currency.

The reports of transactions in currency requirements for banks are located in subpart C of Part 1010 of this chapter and this subpart.

§ 1020.311 Filing obligations.

Refer to § 1010.311 of this chapter for reports of transactions in currency filing obligations for banks.

§ 1020.312 Identification required.

Refer to § 1010.312 of this chapter for identification requirements for reports of transactions in currency filed by banks.

§ 1020.313 Aggregation.

Refer to § 1010.313 of this chapter for reports of transactions in currency aggregation requirements for banks.

§ 1020.314 Structured transactions.

Refer to § 1010.314 of this chapter for rules regarding structured transactions for banks.

§ 1020.315 Transactions of exempt persons.

(a) *General.* No bank is required to file a report otherwise required by § 1010.311 of this chapter with respect to any transaction in currency between an exempt person and such bank, or, to the extent provided in paragraph (f)(6) of this section, between such exempt person and other banks affiliated with such bank. (A limitation on the exemption described in this paragraph (a) is set forth in paragraph (g) of this section.)

(b) *Exempt person.* For purposes of this section, an exempt person is:

(1) A bank, to the extent of such bank's domestic operations;

(2) A department or agency of the United States, of any State, or of any political subdivision of any State;

(3) Any entity established under the laws of the United States, of any State, or of any political subdivision of any State, or under an interstate compact between two or more States, that exercises governmental authority on behalf of the United States or any such State or political subdivision;

(4) Any entity, other than a bank, whose common stock or analogous equity interests are listed on the New York Stock Exchange or the American Stock Exchange or whose common stock or analogous equity interests have been designated as a Nasdaq National Market Security listed on the Nasdaq Stock Market (except stock or interests listed under the separate ''Nasdaq Small-Cap Issues'' heading), provided that, for purposes of this paragraph (b)(4), a person that is a financial institution, other than a bank, is an exempt person only to the extent of its domestic operations;

(5) Any subsidiary, other than a bank, of any entity described in paragraph (b)(4) of this section (a ''listed entity'') that is organized under the laws of the United States or of any State and at least 51 percent of whose common stock or analogous equity interest is owned by the listed entity, provided that, for purposes of this paragraph (b)(5), a person that is a financial institution, other than a bank, is an exempt person only to the extent of its domestic operations;

(6) To the extent of its domestic operations and only with respect to transactions conducted through its exemptible accounts, any other commercial enterprise (for purposes of this section, a ''non-listed business''), other than an enterprise specified in paragraph (f)(8) of this section, that:

(i) Has maintained a transaction account, as defined in paragraph (f)(9) of this section, at the bank for at least 12 months;

(ii) Frequently engages in transactions in currency with the bank in excess of $10,000; and

(iii) Is incorporated or organized under the laws of the United States or a State, or is registered as and eligible to do business within the United States or a State; or

(7) With respect solely to withdrawals for payroll purposes from existing exemptible accounts, any other person (for purposes of this section, a ''payroll customer'') that:

(i) Has maintained a transaction account, as defined in paragraph (f)(9) of this section, at the bank for at least 12 months;

(ii) Operates a firm that regularly withdraws more than $10,000 in order to pay its United States employees in currency; and

(iii) Is incorporated or organized under the laws of the United States or a State, or is registered as and eligible to do business within the United States or a State.

(c) *Initial designation of exempt persons*—(1) *General.* A bank must designate each exempt person with which it engages in transactions in currency by the close of the 30-day period beginning after the day of the first reportable transaction in currency with that person sought to be exempted from reporting under the terms of this section. Except as provided in paragraph (c)(2) of this section, designation by a bank of an exempt person shall be made by a single filing of FinCEN Form 110. (A bank is not required to file a FinCEN Form 110 with respect to the transfer of currency to or from any of the twelve Federal Reserve Banks.) The designation must be made separately by each bank that treats the person in question as an exempt person, except as provided in paragraph (f)(6) of this section. The designation requirements of this paragraph (c) apply whether or not the particular exempt person to be designated has previously been treated as exempt from the reporting requirements of prior § 103.22(a) under the rules contained in 31 CFR 103.22(a) through (g), as in effect on October 20, 1998 (see 31 CFR Parts 0 to 199 revised as of July 1, 1998). A special transitional rule, which extends the time for initial designation for customers that have been previously treated as exempt under such prior rules, is contained in paragraph (k) of this section.

(2) *Special rules for banks.* When designating another bank as an exempt person, a bank must either make the filing required by paragraph (c)(1) of this section or file, in such a format and manner as FinCEN may specify, a current list of its domestic bank customers. In the event that a bank files its current list of domestic bank customers, the bank must make the filing as described in paragraph (c)(1) of this section for each bank that is a new customer and for which an exemption is sought under this section.

(d) *Annual review.* The information supporting each designation of an exempt person, and the application to each account of an exempt person described in paragraphs (b)(6) or (b)(7) of this section of the monitoring system required to be maintained by paragraph (i)(2) of this section, must be reviewed and verified at least once each year.

(e) *Biennial filing with respect to certain exempt persons*—(1) *General.* A biennial filing, as described in paragraph (e)(2) of this section, is required for continuation of the treatment as an exempt person of a customer described in paragraph (b)(6) or (7) of this section. No biennial filing is required for continuation of the treatment as an exempt person of a customer described in paragraphs (b)(1) through (5) of this section.

(2) *Non-listed businesses and payroll customers.* The designation of a non-listed business or a payroll customer as an exempt person must be renewed biennially, beginning on March 15 of the second calendar year following the year in which the first designation of such customer as an exempt person is made, and every other March 15 thereafter, on FinCEN Form 110. Biennial renewals must include a statement certifying that the bank's system of monitoring the transactions in currency of an exempt person for suspicious activity, required to be maintained by paragraph (i)(2) of this section, has been applied as necessary, but at least annually, to the account of the exempt person to whom the biennial renewal applies. Biennial renewals also must include information about any change in control of the exempt person

involved of which the bank knows (or should know on the basis of its records).

(f) *Operating rules*—(1) *General rule*. Subject to the specific rules of this section, a bank must take such steps to assure itself that a person is an exempt person (within the meaning of the applicable provision of paragraph (b) of this section), to document the basis for its conclusions, and document its compliance, with the terms of this section, that a reasonable and prudent bank would take and document to protect itself from loan or other fraud or loss based on misidentification of a person's status, and in the case of the monitoring system requirement set forth in paragraph (i)(2) of this section, such steps that a reasonable and prudent bank would take and document to identify suspicious transactions as required by paragraph (i)(2) of this section.

(2) *Governmental departments and agencies*. A bank may treat a person as a governmental department, agency, or entity if the name of such person reasonably indicates that it is described in paragraph (b)(2) or (b)(3) of this section, or if such person is known generally in the community to be a State, the District of Columbia, a tribal government, a Territory or Insular Possession of the United States, or a political subdivision or a wholly-owned agency or instrumentality of any of the foregoing. An entity generally exercises governmental authority on behalf of the United States, a State, or a political subdivision, for purposes of paragraph (b)(3) of this section, only if its authorities include one or more of the powers to tax, to exercise the authority of eminent domain, or to exercise police powers with respect to matters within its jurisdiction. Examples of entities that exercise governmental authority include, but are not limited to, the New Jersey Turnpike Authority and the Port Authority of New York and New Jersey.

(3) *Stock exchange listings*. In determining whether a person is described in paragraph (b)(4) of this section, a bank may rely on any New York, American or Nasdaq Stock Market listing published in a newspaper of general circulation, on any commonly accepted or published stock symbol guide, on any information contained in the Securities and Exchange Commission ''Edgar'' System, or on any information contained on an Internet World-Wide Web site or sites maintained by the American Stock Exchange or The Financial Industry Regulatory Authority.

(4) *Listed company subsidiaries*. In determining whether a person is described in paragraph (b)(5) of this section, a bank may rely upon:

(i) Any reasonably authenticated corporate officer's certificate;

(ii) Any reasonably authenticated photocopy of Internal Revenue Service Form 851 (Affiliation Schedule) or the equivalent thereof for the appropriate tax year; or

(iii) A person's Annual Report or Form 10–K, as filed in each case with the Securities and Exchange Commission.

(5) *Aggregated accounts*. In determining the qualification of a customer as a non-listed business or a payroll customer, a bank may treat all exemptible accounts of the customer as a single account. If a bank elects to treat all exemptible accounts of a customer as a single account, the bank must continue to treat such accounts consistently as a single account for purposes of determining the qualification of the customer as a non-listed business or payroll customer.

(6) *Affiliated banks*. The designation required by paragraph (c) of this section may be made by a parent bank holding company or one of its bank subsidiaries on behalf of all bank subsidiaries of the holding company, so long as the designation lists each bank subsidiary to which the designation shall apply.

(7) *Sole proprietorships*. A sole proprietorship may be treated as a non-listed business if it otherwise meets the requirements of paragraph (b)(6) of this section, as applicable. In addition, a sole proprietorship may be treated as a payroll customer if it otherwise meets the requirements of paragraph (b)(7) of this section, as applicable.

(8) *Ineligible businesses*. A business engaged primarily in one or more of the following activities may not be treated as a non-listed business for purposes of this section: Serving as financial institutions or agents of financial institutions of any type; purchase or sale to customers of motor vehicles of any kind, vessels, aircraft, farm equipment or mobile homes; the practice of law, accountancy, or medicine; auctioning of goods; chartering or operation of ships, buses, or aircraft; gaming of any kind (other than licensed parimutuel betting at race tracks); investment advisory services or investment banking services; real estate brokerage; pawn brokerage; title insurance and real estate closing; trade union activities; and any other activities that may be specified by FinCEN. A business that engages in multiple business activities may be treated as a non-listed business so long as no more than 50% of its gross revenues is derived from one or more of the ineligible business activities listed in this paragraph (f)(8).

(9) *Exemptible accounts of a non-listed business or payroll customer*. The exemptible accounts of a non-listed business or payroll customer include transaction accounts and money market deposit accounts. However, money market deposit accounts maintained other than in connection with a commercial enterprise are not exemptible accounts. A transaction account, for purposes of this section, is any account described in section 19(b)(1)(C) of the Federal Reserve Act, 12 U.S.C. 461(b)(1)(C), and its implementing regulations (12 CFR part 204). A money market deposit account, for purposes of this section, is any interest-bearing account that is described as a money market deposit account in 12 CFR 204.2(d)(2).

(10) *Documentation*. The records maintained by a bank to document its compliance with and administration of the rules of this section shall be maintained in accordance with the provisions of § 1010.430 of this chapter.

(g) *Limitation on exemption*. A transaction carried out by an exempt person as an agent for another person who is the beneficial owner of the funds that are the subject of a transaction in currency is not subject to the exemption from reporting contained in paragraph (a) of this section.

(h) *Limitation on liability*. (1) No bank shall be subject to penalty under this chapter for failure to file a report required by § 1010.311 of this chapter with respect to a transaction in currency by an exempt person with respect to which the requirements of this section have been satisfied, unless the bank:

(i) Knowingly files false or incomplete information with respect to the transaction or the customer engaging in the transaction; or

(ii) Has reason to believe that the customer does not meet the criteria established by this section for treatment of the transactor as an exempt person or that the transaction is not a transaction of the exempt person.

(2) Subject to the specific terms of this section, and absent any specific knowledge of information indicating that a customer no longer meets the requirements of an exempt person, a bank satisfies the requirements of this section to the extent it continues to treat that customer as an exempt person until the date of that customer's next periodic review, which, as required by paragraph (d) of this section, shall occur no less than once each year.

(3) A bank that files a report with respect to a currency transaction by an exempt person rather than treating such

person as exempt shall remain subject, with respect to each such report, to the rules for filing reports, and the penalties for filing false or incomplete reports that are applicable to reporting of transactions in currency by persons other than exempt persons.

(i) *Obligations to file suspicious activity reports and maintain system for monitoring transactions in currency.* (1) Nothing in this section relieves a bank of the obligation, or reduces in any way such bank's obligation, to file a report required by § 1020.320 with respect to any transaction, including any transaction in currency that a bank knows, suspects, or has reason to suspect is a transaction or attempted transaction that is described in § 1020.320(a)(2)(i), (ii), or (iii), or relieves a bank of any reporting or recordkeeping obligation imposed by this chapter (except the obligation to report transactions in currency pursuant to this chapter to the extent provided in this section). Thus, for example, a sharp increase from one year to the next in the gross total of currency transactions made by an exempt customer, or similarly anomalous transaction trends or patterns, may trigger the obligations of a bank under § 1020.320.

(2) Consistent with its annual review obligations under paragraph (d) of this section, a bank shall establish and maintain a monitoring system that is reasonably designed to detect, for each account of a non-listed business or payroll customer, those transactions in currency involving such account that would require a bank to file a suspicious transaction report. The statement in the preceding sentence with respect to accounts of non-listed and payroll customers does not limit the obligation of banks generally to take the steps necessary to satisfy the terms of paragraph (i)(1) of this section and § 1020.320 with respect to all exempt persons.

(j) *Revocation.* The status of any person as an exempt person under this section may be revoked by FinCEN by written notice, which may be provided by publication in the **Federal Register** in appropriate situations, on such terms as are specified in such notice. Without any action on the part of the Treasury Department and subject to the limitation on liability contained in paragraph (h)(2) of this section:

(1) The status of an entity as an exempt person under paragraph (b)(4) of this section ceases once such entity ceases to be listed on the applicable stock exchange; and

(2) The status of a subsidiary as an exempt person under paragraph (b)(5) of this section ceases once such subsidiary ceases to have at least 51 percent of its common stock or analogous equity interest owned by a listed entity.

(k) *Transitional rule.* (1) No accounts may be newly granted an exemption or placed on an exempt list on or after October 21, 1998, under the rules contained in 31 CFR 103.22(b) through (g), as in effect on October 20, 1998 (see 31 CFR Parts 0 to 199 revised as of July 1, 1998).

(2) If a bank properly treated an account (a ''previously exempted account'') as exempt on October 20, 1998 under the rules contained in 31 CFR 103.22(b) through (g), as in effect on October 20, 1998 (see 31 CFR Parts 0 to 199 revised as of July 1, 1998), it may continue to treat such account as exempt under such prior rules with respect to transactions in currency occurring on or before June 30, 2000, provided that it does so consistently until the earlier of June 30, 2000, and the date on which the bank makes the designation or the determination described in paragraph (k)(3) of this section. A bank that continues to treat a previously exempted account as exempt under the prior rules, and for the period, specified in the preceding sentence, shall remain subject to such prior rules, and to the penalties for failing to comply therewith, with respect to transactions in currency occurring during such period.

(3) A bank must, on or before July 1, 2000, either designate the holder of a previously exempted account as an exempt person under paragraph (b) of this section or determine that it may not or will not treat such holder as an exempt person under paragraph (b) of this section (so that it will be required to make reports under § 1010.311 with respect to transactions in currency by such person occurring on or after the date of determination, but no later than July 1, 2000). A bank that initially does not designate the holder of a previously exempted account as an exempt person for periods beginning after June 30, 2000, may later make such a designation, to the extent otherwise permitted to do so by this section, for periods after the effective date of such designation.

(Approved by the Office of Management and Budget under control number 1506–0009.)

§ 1020.320 Reports by banks of suspicious transactions.

(a) *General.* (1) Every bank shall file with the Treasury Department, to the extent and in the manner required by this section, a report of any suspicious transaction relevant to a possible violation of law or regulation. A bank may also file with the Treasury Department by using the Suspicious Activity Report specified in paragraph (b)(1) of this section or otherwise, a report of any suspicious transaction that it believes is relevant to the possible violation of any law or regulation but whose reporting is not required by this section.

(2) A transaction requires reporting under the terms of this section if it is conducted or attempted by, at, or through the bank, it involves or aggregates at least $5,000 in funds or other assets, and the bank knows, suspects, or has reason to suspect that:

(i) The transaction involves funds derived from illegal activities or is intended or conducted in order to hide or disguise funds or assets derived from illegal activities (including, without limitation, the ownership, nature, source, location, or control of such funds or assets) as part of a plan to violate or evade any federal law or regulation or to avoid any transaction reporting requirement under federal law or regulation;

(ii) The transaction is designed to evade any requirements of this chapter or of any other regulations promulgated under the Bank Secrecy Act; or

(iii) The transaction has no business or apparent lawful purpose or is not the sort in which the particular customer would normally be expected to engage, and the bank knows of no reasonable explanation for the transaction after examining the available facts, including the background and possible purpose of the transaction.

(b) *Filing procedures*—(1) *What to file.* A suspicious transaction shall be reported by completing a Suspicious Activity Report (''SAR''), and collecting and maintaining supporting documentation as required by paragraph (d) of this section.

(2) *Where to file.* The SAR shall be filed with FinCEN in a central location, to be determined by FinCEN, as indicated in the instructions to the SAR.

(3) *When to file.* A bank is required to file a SAR no later than 30 calendar days after the date of initial detection by the bank of facts that may constitute a basis for filing a SAR. If no suspect was identified on the date of the detection of the incident requiring the filing, a bank may delay filing a SAR for an additional 30 calendar days to identify a suspect. In no case shall reporting be delayed more than 60 calendar days after the date of initial detection of a reportable transaction. In situations involving violations that require immediate attention, such as, for example, ongoing money laundering schemes, the bank shall immediately notify, by telephone,

an appropriate law enforcement authority in addition to filing timely a SAR.

(c) *Exceptions*. A bank is not required to file a SAR for a robbery or burglary committed or attempted that is reported to appropriate law enforcement authorities, or for lost, missing, counterfeit, or stolen securities with respect to which the bank files a report pursuant to the reporting requirements of 17 CFR 240.17f–1.

(d) *Retention of records*. A bank shall maintain a copy of any SAR filed and the original or business record equivalent of any supporting documentation for a period of five years from the date of filing the SAR. Supporting documentation shall be identified, and maintained by the bank as such, and shall be deemed to have been filed with the SAR. A bank shall make all supporting documentation available to FinCEN and any appropriate law enforcement agencies or bank supervisory agencies upon request.

(e) *Confidentiality of reports; limitation of liability*. No bank or other financial institution, and no director, officer, employee, or agent of any bank or other financial institution, who reports a suspicious transaction under this chapter, may notify any person involved in the transaction that the transaction has been reported. Thus, any person subpoenaed or otherwise requested to disclose a SAR or the information contained in a SAR, except where such disclosure is requested by FinCEN or an appropriate law enforcement or bank supervisory agency, shall decline to produce the SAR or to provide any information that would disclose that a SAR has been prepared or filed, citing this paragraph (e) and 31 U.S.C. 5318(g)(2), and shall notify FinCEN of any such request and its response thereto. A bank, and any director, officer, employee, or agent of such bank, that makes a report pursuant to this section (whether such report is required by this section or is made voluntarily) shall be protected from liability for any disclosure contained in, or for failure to disclose the fact of such report, or both, to the full extent provided by 31 U.S.C. 5318(g)(3).

(f) *Compliance*. Compliance with this section shall be audited by the Department of the Treasury, through FinCEN or its delegees under the terms of the Bank Secrecy Act. Failure to satisfy the requirements of this section may be a violation of the reporting rules of the Bank Secrecy Act and of this chapter. Such failure may also violate provisions of Title 12 of the Code of Federal Regulations.

Subpart D—Records Required To Be Maintained by Banks

§ 1020.400 General.

Banks are subject to the recordkeeping requirements set forth and cross referenced in this subpart. Banks should also refer to Subpart D of Part 1010 of this chapter for recordkeeping requirements contained in that subpart which apply to banks.

§ 1020.410 Records to be made and retained by banks.

(a) Each agent, agency, branch, or office located within the United States of a bank is subject to the requirements of this paragraph (a) with respect to a funds transfer in the amount of $3,000 or more, and is required to retain either the original or a microfilm or other copy or reproduction of each of the following:

(1) *Recordkeeping requirements*. (i) For each payment order that it accepts as an originator's bank, a bank shall obtain and retain either the original or a microfilm, other copy, or electronic record of the following information relating to the payment order:

(A) The name and address of the originator;

(B) The amount of the payment order;

(C) The execution date of the payment order;

(D) Any payment instructions received from the originator with the payment order;

(E) The identity of the beneficiary's bank; and

(F) As many of the following items as are received with the payment order: [5]

(*1*) The name and address of the beneficiary;

(*2*) The account number of the beneficiary; and

(*3*) Any other specific identifier of the beneficiary.

(ii) For each payment order that it accepts as an intermediary bank, a bank shall retain either the original or a microfilm, other copy, or electronic record of the payment order.

(iii) For each payment order that it accepts as a beneficiary's bank, a bank shall retain either the original or a microfilm, other copy, or electronic record of the payment order.

(2) *Originators other than established customers*. In the case of a payment order from an originator that is not an established customer, in addition to obtaining and retaining the information required in paragraph (a)(1)(i) of this section:

(i) If the payment order is made in person, prior to acceptance the originator's bank shall verify the identity of the person placing the payment order. If it accepts the payment order, the originator's bank shall obtain and retain a record of the name and address, the type of identification reviewed, the number of the identification document (*e.g.*, driver's license), as well as a record of the person's taxpayer identification number (*e.g.*, Social Security or employer identification number) or, if none, alien identification number or passport number and country of issuance, or a notation in the record of the lack thereof. If the originator's bank has knowledge that the person placing the payment order is not the originator, the originator's bank shall obtain and retain a record of the originator's taxpayer identification number (*e.g.*, Social Security or employer identification number) or, if none, alien identification number or passport number and country of issuance, if known by the person placing the order, or a notation in the record of the lack thereof.

(ii) If the payment order accepted by the originator's bank is not made in person, the originator's bank shall obtain and retain a record of name and address of the person placing the payment order, as well as the person's taxpayer identification number (*e.g.*, Social Security or employer identification number) or, if none, alien identification number or passport number and country of issuance, or a notation in the record of the lack thereof, and a copy or record of the method of payment (*e.g.*, check or credit card transaction) for the funds transfer. If the originator's bank has knowledge that the person placing the payment order is not the originator, the originator's bank shall obtain and retain a record of the originator's taxpayer identification number (*e.g.*, Social Security or employer identification number) or, if none, alien identification number or passport number and country of issuance, if known by the person placing the order, or a notation in the record of the lack thereof.

(3) *Beneficiaries other than established customers*. For each payment order that it accepts as a beneficiary's bank for a beneficiary that is not an established customer, in addition to obtaining and retaining the information required in paragraph (a)(1)(iii) of this section:

(i) If the proceeds are delivered in person to the beneficiary or its representative or agent, the beneficiary's

[5] For funds transfers effected through the Federal Reserve's Fedwire funds transfer system, only one of the items is required to be retained, if received with the payment order, until such time as the bank that sends the order to the Federal Reserve Bank completes its conversion to the expanded Fedwire message format.

bank shall verify the identity of the person receiving the proceeds and shall obtain and retain a record of the name and address, the type of identification reviewed, and the number of the identification document (*e.g.*, driver's license), as well as a record of the person's taxpayer identification number (*e.g.*, Social Security or employer identification number) or, if none, alien identification number or passport number and country of issuance, or a notation in the record of the lack thereof. If the beneficiary's bank has knowledge that the person receiving the proceeds is not the beneficiary, the beneficiary's bank shall obtain and retain a record of the beneficiary's name and address, as well as the beneficiary's taxpayer identification number (*e.g.*, Social Security or employer identification number) or, if none, alien identification number or passport number and country of issuance, if known by the person receiving the proceeds, or a notation in the record of the lack thereof.

(ii) If the proceeds are delivered other than in person, the beneficiary's bank shall retain a copy of the check or other instrument used to effect payment, or the information contained thereon, as well as the name and address of the person to which it was sent.

(4) *Retrievability*. The information that an originator's bank must retain under paragraphs (a)(1)(i) and (a)(2) of this section shall be retrievable by the originator's bank by reference to the name of the originator. If the originator is an established customer of the originator's bank and has an account used for funds transfers, then the information also shall be retrievable by account number. The information that a beneficiary's bank must retain under paragraphs (a)(1)(iii) and (a)(3) of this section shall be retrievable by the beneficiary's bank by reference to the name of the beneficiary. If the beneficiary is an established customer of the beneficiary's bank and has an account used for funds transfers, then the information also shall be retrievable by account number. This information need not be retained in any particular manner, so long as the bank is able to retrieve the information required by this paragraph, either by accessing funds transfer records directly or through reference to some other record maintained by the bank.

(5) *Verification*. Where verification is required under paragraphs (a)(2) and (a)(3) of this section, a bank shall verify a person's identity by examination of a document (other than a bank signature card), preferably one that contains the person's name, address, and photograph, that is normally acceptable by financial institutions as a means of identification when cashing checks for persons other than established customers. Verification of the identity of an individual who indicates that he or she is an alien or is not a resident of the United States may be made by passport, alien identification card, or other official document evidencing nationality or residence (*e.g.*, a foreign driver's license with indication of home address).

(6) *Exceptions*. The following funds transfers are not subject to the requirements of this section:

(i) Funds transfers where the originator and beneficiary are any of the following:

(A) A bank;

(B) A wholly-owned domestic subsidiary of a bank chartered in the United States;

(C) A broker or dealer in securities;

(D) A wholly-owned domestic subsidiary of a broker or dealer in securities;

(E) A futures commission merchant or an introducing broker in commodities;

(F) A wholly-owned domestic subsidiary of a futures commission merchant or an introducing broker in commodities;

(G) The United States;

(H) A state or local government; or

(I) A federal, state or local government agency or instrumentality; and

(ii) Funds transfers where both the originator and the beneficiary are the same person and the originator's bank and the beneficiary's bank are the same bank.

(b)(1) With respect to each certificate of deposit sold or redeemed after May 31, 1978, and before October 1, 2003, or each deposit or share account opened with a bank after June 30, 1972, and before October 1, 2003, a bank shall, within 30 days from the date such a transaction occurs or an account is opened, secure and maintain a record of the taxpayer identification number of the customer involved; or where the account or certificate is in the names of two or more persons, the bank shall secure the taxpayer identification number of a person having a financial interest in the certificate or account. In the event that a bank has been unable to secure, within the 30-day period specified, the required identification, it shall nevertheless not be deemed to be in violation of this section if it has made a reasonable effort to secure such identification, and it maintains a list containing the names, addresses, and account numbers of those persons from whom it has been unable to secure such identification, and makes the names, addresses, and account numbers of those persons available to the Secretary as directed by him. A bank acting as an agent for another person in the purchase or redemption of a certificate of deposit issued by another bank is responsible for obtaining and recording the required taxpayer identification, as well as for maintaining the records referred to in paragraphs (c)(11) and (12) of this section. The issuing bank can satisfy the recordkeeping requirement by recording the name and address of the agent together with a description of the instrument and the date of the transaction. Where a person is a non-resident alien, the bank shall also record the person's passport number or a description of some other government document used to verify his identity.

(2) The 30-day period provided for in paragraph (b)(1) of this section shall be extended where the person opening the account has applied for a taxpayer identification or social security number on Form SS–4 or SS–5, until such time as the person maintaining the account has had a reasonable opportunity to secure such number and furnish it to the bank.

(3) A taxpayer identification number required under paragraph (b)(1) of this section need not be secured for accounts or transactions with the following:

(i) Agencies and instrumentalities of Federal, state, local or foreign governments;

(ii) Judges, public officials, or clerks of courts of record as custodians of funds in controversy or under the control of the court;

(iii) Aliens who are ambassadors, ministers, career diplomatic or consular officers, or naval, military or other attachés of foreign embassies and legations, and for the members of their immediate families;

(iv) Aliens who are accredited representatives of international organizations which are entitled to enjoy privileges, exemptions and immunities as an international organization under the International Organization Immunities Act of December 29, 1945 (22 U.S.C. 288), and the members of their immediate families;

(v) Aliens temporarily residing in the United States for a period not to exceed 180 days;

(vi) Aliens not engaged in a trade or business in the United States who are attending a recognized college or university or any training program, supervised or conducted by any agency of the Federal Government;

(vii) Unincorporated subordinate units of a tax exempt central

organization which are covered by a group exemption letter,

(viii) A person under 18 years of age with respect to an account opened as a part of a school thrift savings program, provided the annual interest is less than $10;

(ix) A person opening a Christmas club, vacation club and similar installment savings programs provided the annual interest is less than $10; and

(x) Non-resident aliens who are not engaged in a trade or business in the United States.

(4) In instances described in paragraphs (b)(3), (viii) and (ix) of this section, the bank shall, within 15 days following the end of any calendar year in which the interest accrued in that year is $10 or more use its best effort to secure and maintain the appropriate taxpayer identification number or application form therefor.

(5) The rules and regulations issued by the Internal Revenue Service under section 6109 of the Internal Revenue Code of 1954 shall determine what constitutes a taxpayer identification number and whose number shall be obtained in the case of an account maintained by one or more persons.

(c) Each bank shall, in addition, retain either the original or a microfilm or other copy or reproduction of each of the following:

(1) Each document granting signature authority over each deposit or share account, including any notations, if such are normally made, of specific identifying information verifying the identity of the signer (such as a driver's license number or credit card number);

(2) Each statement, ledger card or other record on each deposit or share account, showing each transaction in, or with respect to, that account;

(3) Each check, clean draft, or money order drawn on the bank or issued and payable by it, except those drawn for $100 or less or those drawn on accounts which can be expected to have drawn on them an average of at least 100 checks per month over the calendar year or on each occasion on which such checks are issued, and which are:

(i) Dividend checks,

(ii) Payroll checks,

(iii) Employee benefit checks,

(iv) Insurance claim checks,

(v) Medical benefit checks,

(vi) Checks drawn on government agency accounts,

(vii) Checks drawn by brokers or dealers in securities,

(viii) Checks drawn on fiduciary accounts,

(ix) Checks drawn on other financial institutions, or

(x) Pension or annuity checks;

(4) Each item in excess of $100 (other than bank charges or periodic charges made pursuant to agreement with the customer), comprising a debit to a customer's deposit or share account, not required to be kept, and not specifically exempted, under paragraph (c)(3) of this section;

(5) Each item, including checks, drafts, or transfers of credit, of more than $10,000 remitted or transferred to a person, account or place outside the United States;

(6) A record of each remittance or transfer of funds, or of currency, other monetary instruments, checks, investment securities, or credit, of more than $10,000 to a person, account or place outside the United States;

(7) Each check or draft in an amount in excess of $10,000 drawn on or issued by a foreign bank which the domestic bank has paid or presented to a nonbank drawee for payment;

(8) Each item, including checks, drafts or transfers of credit, of more than $10,000 received directly and not through a domestic financial institution, by letter, cable or any other means, from a bank, broker or dealer in foreign exchange outside the United States;

(9) A record of each receipt of currency, other monetary instruments, investment securities or checks, and of each transfer of funds or credit, of more than $10,000 received on any one occasion directly and not through a domestic financial institution, from a bank, broker or dealer in foreign exchange outside the United States; and

(10) Records prepared or received by a bank in the ordinary course of business, which would be needed to reconstruct a transaction account and to trace a check in excess of $100 deposited in such account through its domestic processing system or to supply a description of a deposited check in excess of $100. This subparagraph shall be applicable only with respect to demand deposits.

(11) A record containing the name, address, and taxpayer identification number as determined under section 6109 of the Internal Revenue Code of 1986, if available, of the purchaser of each certificate of deposit, as well as a description of the instrument, a notation of the method of payment, and the date of the transaction.

(12) A record containing the name, address and taxpayer identification number as determined under section 6109 of the Internal Revenue Code of 1986, if available, of any person presenting a certificate of deposit for payment, as well as a description of the instrument and the date of the transaction.

(13) Each deposit slip or credit ticket reflecting a transaction in excess of $100 or the equivalent record for direct deposit or other wire transfer deposit transactions. The slip or ticket shall record the amount of any currency involved.

(Approved by the Office of Management and Budget under control number 1505–0063)

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

§ 1020.500 General.

Banks are subject to the special information sharing procedures to deter money laundering and terrorist activity requirements set forth and cross referenced in this subpart. Banks should also refer to Subpart E of Part 1010 of this chapter for special information sharing procedures to deter money laundering and terrorist activity contained in that subpart which apply to banks.

§ 1020.520 Special information sharing procedures to deter money laundering and terrorist activity for banks.

(a) Refer to § 1010.520 of this chapter.

(b) [Reserved]

§ 1020.530 [Reserved]

§ 1020.540 Voluntary information sharing among financial institutions.

(a) Refer to § 1010.540 of this chapter.

(b) [Reserved]

Subpart F—Special Standards of Diligence; Prohibitions; and Special Measures

§ 1020.600 General.

Banks are subject to the special standards of diligence; prohibitions; and special measures requirements set forth and cross referenced in this subpart. Banks should also refer to Subpart F of Part 1010 of this chapter for special standards of diligence; prohibitions; and special measures contained in that subpart which apply to banks.

§ 1020.610 Due diligence programs for correspondent accounts for foreign financial institutions.

(a) Refer to § 1010.610 of this chapter.

(b) [Reserved]

§ 1020.620 Due diligence programs for private banking accounts.

(a) Refer to § 1010.620 of this chapter.

(b) [Reserved]

§ 1020.630 Prohibition on correspondent accounts for foreign shell banks; records concerning owners of foreign banks and agents for service of legal process.

(a) Refer to § 1010.630 of this chapter.

(b) [Reserved]

§ 1020.640 [Reserved]

§ 1020.670 Summons or subpoena of foreign bank records; Termination of correspondent relationship.

(a) Refer to § 1010.670 of this chapter.

(b) [Reserved]

PART 1021—RULES FOR CASINOS AND CARD CLUBS

Subpart A—Definitions

Sec.
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1021.400 General.
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1021.500 General.
1021.520 Special information sharing procedures to deter money laundering and terrorist activity for casinos and card clubs.
1021.530 [Reserved]
1021.540 Voluntary information sharing among financial institutions.

Subpart F—Special Standards of Diligence; Prohibitions, and Special Measures for Casinos and Card Clubs

1021.600 General.
1021.610 Due diligence programs for correspondent accounts for foreign financial institutions.
1021.620 Due diligence programs for private banking accounts.
1021.630 Prohibition on correspondent accounts for foreign shell banks; records concerning owners of foreign banks and agents for service of legal process.
1021.640 [Reserved]
1021.670 Summons or subpoena of foreign bank records; Termination of correspondent relationship.

Subpart A—Definitions

§ 1021.100 Definitions.

Refer to § 1010.100 of this chapter for general definitions not noted herein. To the extent there is a differing definition in § 1010.100 of this chapter, the definition in this Section is what applies to Part 1021. Unless otherwise indicated, for purposes of this Part:

(a) *Business year* means the annual accounting period, such as a calendar or fiscal year, by which a casino maintains its books and records for purposes of subtitle A of title 26 of the United States Code.

(b) *Casino account number* means any and all numbers by which a casino identifies a customer.

(c) *Customer* includes every person who is involved in a transaction to which this chapter applies with a casino, whether or not that person participates, or intends to participate, in the gaming activities offered by that casino.

(d) *Gaming day* means the normal business day of a casino. For a casino that offers 24-hour gaming, the term means that 24-hour period by which the casino keeps its books and records for business, accounting, and tax purposes. For purposes of the regulations contained in this chapter, each casino may have only one gaming day, common to all of its divisions.

(e) *Machine-readable* means capable of being read by an automated data processing system.

Subpart B—Programs

§ 1021.200 General.

Casinos and card clubs are subject to the program requirements set forth and cross referenced in this subpart. Casinos and card clubs should also refer to Subpart B of Part 1010 of this chapter for program requirements contained in that subpart which apply to casinos and card clubs.

§ 1021.210 Anti-money laundering program requirements for casinos.

(a) *Requirements for casinos.* A casino shall be deemed to satisfy the requirements of 31 U.S.C. 5318(h)(1) if it implements and maintains a compliance program described in paragraph (b) of this section.

(b) *Compliance programs.* (1) Each casino shall develop and implement a written program reasonably designed to assure and monitor compliance with the requirements set forth in 31 U.S.C. chapter 53, subchapter II and the regulations contained in this chapter.

(2) At a minimum, each compliance program shall provide for:

(i) A system of internal controls to assure ongoing compliance;

(ii) Internal and/or external independent testing for compliance. The scope and frequency of the testing shall be commensurate with the money laundering and terrorist financing risks posed by the products and services provided by the casino;

(iii) Training of casino personnel, including training in the identification of unusual or suspicious transactions, to the extent that the reporting of such transactions is required by this chapter, by other applicable law or regulation, or by the casino's own administrative and compliance policies;

(iv) An individual or individuals to assure day-to-day compliance;

(v) Procedures for using all available information to determine:

(A) When required by this chapter, the name, address, social security number, and other information, and verification of the same, of a person;

(B) The occurrence of any transactions or patterns of transactions required to be reported pursuant to § 1021.320;

(C) Whether any record as described in subpart D of Part 1010 of this chapter or subpart D of this Part 1021 must be made and retained; and

(vi) For casinos that have automated data processing systems, the use of automated programs to aid in assuring compliance.

Subpart C—Reports Required To Be Made by Casinos and Card Clubs

§ 1021.300 General.

Casinos and card clubs are subject to the reporting requirements set forth and cross referenced in this subpart. Casinos and card clubs should also refer to Subpart C of Part 1010 of this chapter for reporting requirements contained in that subpart which apply to casinos and card clubs.

§ 1021.310 Reports of transactions in currency.

The reports of transactions in currency requirements for casinos are located in subpart C of Part 1010 of this chapter and this subpart.

§ 1021.311 Filing obligations.

Each casino shall file a report of each transaction in currency, involving either cash in or cash out, of more than $10,000.

(a) Transactions in currency involving cash in include, but are not limited to:

(1) Purchases of chips, tokens, and other gaming instruments;

(2) Front money deposits;

(3) Safekeeping deposits;

(4) Payments on any form of credit, including markers and counter checks;

(5) Bets of currency, including money plays;

(6) Currency received by a casino for transmittal of funds through wire transfer for a customer;

(7) Purchases of a casino's check;

(8) Exchanges of currency for currency, including foreign currency; and

(9) Bills inserted into electronic gaming devices.

(b) Transactions in currency involving cash out include, but are not limited to:

(1) Redemptions of chips, tokens, tickets, and other gaming instruments;

(2) Front money withdrawals;

(3) Safekeeping withdrawals;

(4) Advances on any form of credit, including markers and counter checks;

(5) Payments on bets;

(6) Payments by a casino to a customer based on receipt of funds through wire transfers;

(7) Cashing of checks or other negotiable instruments;

(8) Exchanges of currency for currency, including foreign currency;

(9) Travel and complimentary expenses and gaming incentives; and

(10) Payment for tournament, contests, and other promotions.

(c) Other provisions of this chapter notwithstanding, casinos are exempted from the reporting obligations found in this section and § 1021.313 for the following transactions in currency or currency transactions:

(1) Transactions between a casino and a currency dealer or exchanger, or between a casino and a check casher, as those terms are defined in § 1010.100(ff) of this chapter, so long as such transactions are conducted pursuant to a contractual or other arrangement with a casino covering the financial services in paragraphs (a)(8), (b)(7), and (b)(8) of this section;

(2) Cash out transactions to the extent the currency is won in a money play and is the same currency the customer wagered in the money play, or cash in transactions to the extent the currency is the same currency the customer previously wagered in a money play on the same table game without leaving the table;

(3) Bills inserted into electronic gaming devices in multiple transactions (unless a casino has knowledge pursuant to § 1021.313 in which case this exemption would not apply); and

(4) Jackpots from slot machines or video lottery terminals.

§ 1021.312 Identification required.

Refer to § 1010.312 of this chapter for identification requirements for reports of transaction in currency filed by casinos and card clubs.

§ 1021.313 Aggregation.

In the case of a casino, multiple currency transactions shall be treated as a single transaction if the casino has knowledge that they are by or on behalf of any person and result in either cash in or cash out totaling more than $10,000 during any gaming day. For purposes of this section, a casino shall be deemed to have the knowledge described in the preceding sentence, if: Any sole proprietor, partner, officer, director, or employee of the casino, acting within the scope of his or her employment, has knowledge that such multiple currency transactions have occurred, including knowledge from examining the books, records, logs, information retained on magnetic disk, tape or other machine-readable media, or in any manual system, and similar documents and information, which the casino maintains pursuant to any law or regulation or within the ordinary course of its business, and which contain information that such multiple currency transactions have occurred.

§ 1021.314 Structured transactions.

Refer to § 1010.314 of this chapter for rules regarding structured transactions for casinos.

§ 1021.315 Exemptions.

Refer to § 1010.315 of this chapter for exemptions from the obligation to file reports of transactions in currency for casinos.

§ 1021.320 Reports by casinos of suspicious transactions.

(a) *General.* (1) Every casino shall file with FinCEN, to the extent and in the manner required by this section, a report of any suspicious transaction relevant to a possible violation of law or regulation. A casino may also file with FinCEN, by using the form specified in paragraph (b)(1) of this section, or otherwise, a report of any suspicious transaction that it believes is relevant to the possible violation of any law or regulation but whose reporting is not required by this section.

(2) A transaction requires reporting under the terms of this section if it is conducted or attempted by, at, or through a casino, and involves or aggregates at least $5,000 in funds or other assets, and the casino knows, suspects, or has reason to suspect that the transaction (or a pattern of transactions of which the transaction is a part):

(i) Involves funds derived from illegal activity or is intended or conducted in order to hide or disguise funds or assets derived from illegal activity (including, without limitation, the ownership, nature, source, location, or control of such funds or assets) as part of a plan to violate or evade any federal law or regulation or to avoid any transaction reporting requirement under federal law or regulation;

(ii) Is designed, whether through structuring or other means, to evade any requirements of this chapter or of any other regulations promulgated under the Bank Secrecy Act;

(iii) Has no business or apparent lawful purpose or is not the sort in which the particular customer would normally be expected to engage, and the casino knows of no reasonable explanation for the transaction after examining the available facts, including the background and possible purpose of the transaction; or

(iv) Involves use of the casino to facilitate criminal activity.

(b) *Filing procedures*—(1) *What to file.* A suspicious transaction shall be reported by completing a Suspicious Activity Report by Casinos (''SARC''), and collecting and maintaining supporting documentation as required by paragraph (d) of this section.

(2) *Where to file.* The SARC shall be filed with FinCEN in a central location, to be determined by FinCEN, as indicated in the instructions to the SARC.

(3) *When to file.* A SARC shall be filed no later than 30 calendar days after the date of the initial detection by the casino of facts that may constitute a basis for filing a SARC under this section. If no suspect is identified on the date of such initial detection, a casino may delay filing a SARC for an additional 30 calendar days to identify a suspect, but in no case shall reporting be delayed more than 60 calendar days after the date of such initial detection. In situations involving violations that require immediate attention, such as ongoing money laundering schemes, the casino shall immediately notify by telephone an appropriate law enforcement authority in addition to filing timely a SARC. Casinos wishing voluntarily to report suspicious transactions that may relate to terrorist activity may call FinCEN's Financial Institutions Hotline at 1–866–556–3974 in addition to filing timely a SARC if required by this section.

(c) *Exceptions.* A casino is not required to file a SARC for a robbery or burglary committed or attempted that is reported to appropriate law enforcement authorities.

(d) *Retention of records.* A casino shall maintain a copy of any SARC filed and the original or business record equivalent of any supporting documentation for a period of five years

from the date of filing the SARC. Supporting documentation shall be identified as such and maintained by the casino, and shall be deemed to have been filed with the SARC. A casino shall make all supporting documentation available to FinCEN, any other appropriate law enforcement agencies or federal, state, local, or tribal gaming regulators upon request.

(e) *Confidentiality of reports; limitation of liability.* No casino, and no director, officer, employee, or agent of any casino, who reports a suspicious transaction under this chapter, may notify any person involved in the transaction that the transaction has been reported. Thus, any person subpoenaed or otherwise requested to disclose a SARC or the information contained in a SARC, except where such disclosure is requested by FinCEN or another appropriate law enforcement or regulatory agency, shall decline to produce the SARC or to provide any information that would disclose that a SARC has been prepared or filed, citing this paragraph (e) and 31 U.S.C. 5318(g)(2), and shall notify FinCEN of any such request and its response thereto. A casino, and any director, officer, employee, or agent of such casino, that makes a report pursuant to this section (whether such report is required by this section or made voluntarily) shall be protected from liability for any disclosure contained in, or for failure to disclose the fact of, such report, or both, to the extent provided by 31 U.S.C. 5318(g)(3).

(f) *Compliance.* Compliance with this section shall be audited by the Department of the Treasury, through FinCEN or its delegees, under the terms of the Bank Secrecy Act. Failure to satisfy the requirements of this section may constitute a violation of the reporting rules of the Bank Secrecy Act and of this chapter.

(g) *Applicability date.* This section applies to transactions occurring after March 25, 2003.

§ 1021.330 Exceptions to the reporting requirements of 31 U.S.C. 5331.

(a) *Receipt of currency by certain casinos having gross annual gaming revenue in excess of $1,000,000—In general.* If a casino receives currency in excess of $10,000 and is required to report the receipt of such currency directly to the Treasury Department under § 1010.306, § 1021.311, or § 1021.313 and is subject to the recordkeeping requirements of § 1021.410, then the casino is not required to make a report with respect to the receipt of such currency under 31 U.S.C. 5331 and this section.

(b) *Casinos exempt under § 1010.970(c).* Pursuant to § 1010.970, the Secretary may exempt from the reporting and recordkeeping requirements under § 1010.306, § 1021.311, § 1021.313 or § 1021.410 casinos in any state whose regulatory system substantially meets the reporting and recordkeeping requirements of this chapter. Such casinos shall not be required to report receipt of currency under 31 U.S.C. 5331 and this section.

(c) *Reporting of currency received in a non-gaming business.* Non-gaming businesses (such as shops, restaurants, entertainment, and hotels) at casino hotels and resorts are separate trades or businesses in which the receipt of currency in excess of $10,000 is reportable under section 5331 and these regulations. Thus, a casino exempt under paragraph (a) or (b) of this section must report with respect to currency in excess of $10,000 received in its non-gaming businesses.

(d) *Example.* The following example illustrates the application of the rules in paragraphs (a) and (c) of this section:

Example. A and B are casinos having gross annual gaming revenue in excess of $1,000,000. C is a casino with gross annual gaming revenue of less than $1,000,000. Casino A receives $15,000 in currency from a customer with respect to a gaming transaction which the casino reports to the Treasury Department under §§ 1010.306, 1021.311, and 1021.313. Casino B receives $15,000 in currency from a customer in payment for accommodations provided to that customer at Casino B's hotel. Casino C receives $15,000 in currency from a customer with respect to a gaming transaction. Casino A is not required to report the transaction under 31 U.S.C. 5331 or this section because the exception for certain casinos provided in paragraph (a) of this section (''the casino exception'') applies. Casino B is required to report under 31 U.S.C. 5331 and this section because the casino exception does not apply to the receipt of currency from a nongaming activity. Casino C is required to report under 31 U.S.C. 5331 and this section because the casino exception does not apply to casinos having gross annual gaming revenue of $1,000,000 or less which do not have to report to the Treasury Department under §§ 1010.306, 1021.311, and 1021.313.

Subpart D—Records Required To Be Maintained by Casinos and Card Clubs

§ 1021.400 General.

Casinos and card clubs are subject to the recordkeeping requirements set forth and cross referenced in this subpart. Casinos and card clubs should also refer to Subpart D of Part 1010 for recordkeeping requirements contained in that subpart which apply to casinos and card clubs.

§ 1021.410 Additional records to be made and retained by casinos.

(a) With respect to each deposit of funds, account opened or line of credit extended after the effective date of these regulations, a casino shall, at the time the funds are deposited, the account is opened or credit is extended, secure and maintain a record of the name, permanent address, and social security number of the person involved. Where the deposit, account or credit is in the names of two or more persons, the casino shall secure the name, permanent address, and social security number of each person having a financial interest in the deposit, account or line of credit. The name and address of such person shall be verified by the casino at the time the deposit is made, account opened, or credit extended. The verification shall be made by examination of a document of the type described in § 1010.312, of this chapter and the specific identifying information shall be recorded in the manner described in § 1010.312 of this chapter. In the event that a casino has been unable to secure the required social security number, it shall not be deemed to be in violation of this section if it has made a reasonable effort to secure such number and it maintains a list containing the names and permanent addresses of those persons from who it has been unable to obtain social security numbers and makes the names and addresses of those persons available to the Secretary upon request. Where a person is a nonresident alien, the casino shall also record the person's passport number or a description of some other government document used to verify his identity.

(b) In addition, each casino shall retain either the original or a microfilm or other copy or reproduction of each of the following:

(1) A record of each receipt (including but not limited to funds for safekeeping or front money) of funds by the casino for the account (credit or deposit) of any person. The record shall include the name, permanent address and social security number of the person from whom the funds were received, as well as the date and amount of the funds received. If the person from whom the funds were received is a non-resident alien, the person's passport number or a description of some other government document used to verify the person's identity shall be obtained and recorded;

(2) A record of each bookkeeping entry comprising a debit or credit to a customer's deposit account or credit account with the casino;

(3) Each statement, ledger card or other record of each deposit account or

credit account with the casino, showing each transaction (including deposits, receipts, withdrawals, disbursements or transfers) in or with respect to, a customer's deposit account or credit account with the casino;

(4) A record of each extension of credit in excess of $2,500, the terms and conditions of such extension of credit, and repayments. The record shall include the customer's name, permanent address, social security number, and the date and amount of the transaction (including repayments). If the customer or person for whom the credit extended is a non-resident alien, his passport number or description of some other government document used to verify his identity shall be obtained and recorded;

(5) A record of each advice, request or instruction received or given by the casino for itself or another person with respect to a transaction involving a person, account or place outside the United States (including but not limited to communications by wire, letter, or telephone). If the transfer outside the United States is on behalf of a third party, the record shall include the third party's name, permanent address, social security number, signature, and the date and amount of the transaction. If the transfer is received from outside the United States on behalf of a third party, the record shall include the third party's name, permanent address, social security number, signature, and the date and amount of the transaction. If the person for whom the transaction is being made is a non-resident alien the record shall also include the person's name, his passport number or a description of some other government document used to verify his identity;

(6) Records prepared or received by the casino in the ordinary course of business which would be needed to reconstruct a person's deposit account or credit account with the casino or to trace a check deposited with the casino through the casino's records to the bank of deposit;

(7) All records, documents or manuals required to be maintained by a casino under state and local laws or regulations, regulations of any governing Indian tribe or tribal government, or terms of (or any regulations issued under) any Tribal-State compacts entered into pursuant to the Indian Gaming Regulatory Act, with respect to the casino in question.

(8) All records which are prepared or used by a casino to monitor a customer's gaming activity.

(9)(i) A separate record containing a list of each transaction between the casino and its customers involving the following types of instruments having a face value of $3,000 or more:

(A) Personal checks (excluding instruments which evidence credit granted by a casino strictly for gaming, such as markers);

(B) Business checks (including casino checks);

(C) Official bank checks;

(D) Cashier's checks;

(E) Third-party checks;

(F) Promissory notes;

(G) Traveler's checks; and

(H) Money orders.

(ii) The list will contain the time, date, and amount of the transaction; the name and permanent address of the customer; the type of instrument; the name of the drawee or issuer of the instrument; all reference numbers (*e.g.*, casino account number, personal check number, etc.); and the name or casino license number of the casino employee who conducted the transaction. Applicable transactions will be placed on the list in the chronological order in which they occur.

(10) A copy of the compliance program described in § 1021.210(b).

(11) In the case of card clubs only, records of all currency transactions by customers, including without limitation, records in the form of currency transaction logs and multiple currency transaction logs, and records of all activity at cages or similar facilities, including, without limitation, cage control logs.

(c)(1) Casinos which input, store, or retain, in whole or in part, for any period of time, any record required to be maintained by § 1010.410 of this chapter or this section on computer disk, tape, or other machine-readable media shall retain the same on computer disk, tape, or machine-readable media.

(2) All indexes, books, programs, record layouts, manuals, formats, instructions, file descriptions, and similar materials which would enable a person readily to access and review the records that are described in § 1010.410 of this chapter and this section and that are input, stored, or retained on computer disk, tape, or other machine-readable media shall be retained for the period of time such records are required to be retained.

(Approved by the Office of Management and Budget under control numbers 1505–0087 and 1505–0063)

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity for Casinos and Card Clubs

§ 1021.500 General.

Casinos and card clubs are subject to the special information sharing procedures to deter money laundering and terrorist activity requirements set forth and cross referenced in this subpart. Casinos and card clubs should also refer to Subpart E of Part 1010 of this chapter for special information sharing procedures to deter money laundering and terrorist activity contained in that subpart which apply to casinos and card clubs.

§ 1021.520 Special information sharing procedures to deter money laundering and terrorist activity for casinos and card clubs.

(a) Refer to § 1010.520 of this chapter.
(b) [Reserved]

§ 1021.530 [Reserved]

§ 1021.540 Voluntary information sharing among financial institutions.

(a) Refer to § 1010.540 of this chapter.
(b) [Reserved]

Subpart F—Special Standards of Diligence; Prohibitions; and Special Measures for Casinos and Card Clubs

§ 1021.600 General.

Casinos and card clubs are subject to the special standards of diligence; prohibitions; and special measures requirements set forth and cross referenced in this subpart. Casinos and card clubs should also refer to Subpart F of Part 1010 of this chapter for special standards of diligence; prohibitions; and special measures contained in that subpart which apply to casinos and card clubs.

§ 1021.610 Due diligence programs for correspondent accounts for foreign financial institutions.

(a) Refer to § 1010.610 of this chapter.
(b) [Reserved]

§ 1021.620 Due diligence programs for private banking accounts.

(a) Refer to § 1010.620 of this chapter.
(b) [Reserved]

§ 1021.630 Prohibition on correspondent accounts for foreign shell banks; records concerning owners of foreign banks and agents for service of legal process.

(a) Refer to § 1010.630 of this chapter.
(b) [Reserved]

§ 1021.640 [Reserved]

§ 1021.670 Summons or subpoena of foreign bank records; Termination of correspondent relationship.

(a) Refer to § 1010.670 of this chapter.

(b) [Reserved]

PART 1022—RULES FOR MONEY SERVICES BUSINESSES

Subpart A—Definitions

Sec.
1022.100 Definitions.

Subpart B—Programs

1022.200 General.
1022.210 Anti-money laundering programs for money services businesses.

Subpart C—Reports Required To Be Made by Money Services Businesses

1022.300 General.
1022.310 Reports of transactions in currency.
1022.311 Filing obligations.
1022.312 Identification required.
1022.313 Aggregation.
1022.314 Structured transactions.
1022.315 Exemptions.
1022.320 Reports by money services businesses of suspicious transactions.
1022.380 Registration of money services businesses.

Subpart D—Records Required To Be Maintained by Money Services Businesses

1022.400 General.
1022.410 Additional records to be made and retained by currency dealers or exchangers.

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

1022.500 General.
1022.520 Special information sharing procedures to deter money laundering and terrorist activity for money services businesses.
1022.530 [Reserved]
1022.540 Voluntary information sharing among financial institutions.

Subpart F—Special Standards of Diligence; Prohibitions, and Special Measures for Money Services Businesses

1022.600 General.
1022.610 [Reserved]
1022.620 [Reserved]
1022.630 [Reserved]
1022.640 [Reserved]
1022.670 [Reserved]

Subpart A—Definitions

§ 1022.100 Definitions.

Refer to § 1010.100 of this chapter for general definitions not noted herein.

Subpart B—Programs

§ 1022.200 General.

Money services businesses are subject to the program requirements set forth and cross referenced in this subpart. Money services businesses should also refer to Subpart B of Part 1010 of this chapter for program requirements contained in that subpart which apply to money services businesses.

§ 1022.210 Anti-money laundering programs for money services businesses.

(a) Each money services business, as defined by § 1010.100(ff) of this chapter, shall develop, implement, and maintain an effective anti-money laundering program. An effective anti-money laundering program is one that is reasonably designed to prevent the money services business from being used to facilitate money laundering and the financing of terrorist activities.

(b) The program shall be commensurate with the risks posed by the location and size of, and the nature and volume of the financial services provided by, the money services business.

(c) The program shall be in writing, and a money services business shall make copies of the anti-money laundering program available for inspection to the Department of the Treasury upon request.

(d) At a minimum, the program shall:

(1) Incorporate policies, procedures, and internal controls reasonably designed to assure compliance with this chapter.

(i) Policies, procedures, and internal controls developed and implemented under this section shall include provisions for complying with the requirements of this chapter including, to the extent applicable to the money services business, requirements for:

(A) Verifying customer identification;

(B) Filing reports;

(C) Creating and retaining records; and

(D) Responding to law enforcement requests.

(ii) Money services businesses that have automated data processing systems should integrate their compliance procedures with such systems.

(iii) A person that is a money services business solely because it is an agent for another money services business as set forth in § 1022.380(a)(2), and the money services business for which it serves as agent, may by agreement allocate between them responsibility for development of policies, procedures, and internal controls required by this paragraph (d)(1). Each money services business shall remain solely responsible for implementation of the requirements set forth in this section, and nothing in this paragraph (d)(1) relieves any money services business from its obligation to establish and maintain an effective anti-money laundering program.

(2) Designate a person to assure day to day compliance with the program and this chapter. The responsibilities of such person shall include assuring that:

(i) The money services business properly files reports, and creates and retains records, in accordance with applicable requirements of this chapter;

(ii) The compliance program is updated as necessary to reflect current requirements of this chapter, and related guidance issued by the Department of the Treasury; and

(iii) The money services business provides appropriate training and education in accordance with paragraph (d)(3) of this section.

(3) Provide education and/or training of appropriate personnel concerning their responsibilities under the program, including training in the detection of suspicious transactions to the extent that the money services business is required to report such transactions under this chapter.

(4) Provide for independent review to monitor and maintain an adequate program. The scope and frequency of the review shall be commensurate with the risk of the financial services provided by the money services business. Such review may be conducted by an officer or employee of the money services business so long as the reviewer is not the person designated in paragraph (d)(2) of this section.

(e) *Compliance date.* A money services business must develop and implement an anti-money laundering program that complies with the requirements of this section on or before the later of July 24, 2002, and the end of the 90-day period beginning on the day following the date the business is established.

Subpart C—Reports Required To Be Made by Money Services Businesses

§ 1022.300 General.

Money services businesses are subject to the reporting requirements set forth and cross referenced in this subpart. Money services businesses should also refer to Subpart C of Part 1010 of this chapter for reporting requirements contained in that subpart which apply to money services businesses.

§ 1022.310 Reports of transactions in currency.

The reports of transactions in currency requirements for money services businesses are located in subpart C of Part 1010 of this chapter and this subpart.

§ 1022.311 Filing obligations.

Refer to § 1010.311 of this chapter for reports of transactions in currency filing obligations for money services businesses.

§ 1022.312 Identification required.

Refer to § 1010.312 of this chapter for identification requirements for reports of transactions in currency filed by money services businesses.

§ 1022.313 Aggregation.

Refer to § 1010.313 of this chapter for reports of transactions in currency aggregation requirements for money services businesses.

§ 1022.314 Structured transactions.

Refer to § 1010.314 of this chapter for rules regarding structured transactions for money services businesses.

§ 1022.315 Exemptions.

Refer to § 1010.315 of this chapter for exemptions from the obligation to file reports of transactions in currency for money services businesses.

§ 1022.320 Reports by money services businesses of suspicious transactions.

(a) *General.* (1) Every money services business, described in § 1010.100(ff) (1), (3), (4), (5), or (6) of this chapter, shall file with the Treasury Department, to the extent and in the manner required by this section, a report of any suspicious transaction relevant to a possible violation of law or regulation. Any money services business may also file with the Treasury Department, by using the form specified in paragraph (b)(1) of this section, or otherwise, a report of any suspicious transaction that it believes is relevant to the possible violation of any law or regulation but whose reporting is not required by this section.

(2) A transaction requires reporting under the terms of this section if it is conducted or attempted by, at, or through a money services business, involves or aggregates funds or other assets of at least $2,000 (except as provided in paragraph (a)(3) of this section), and the money services business knows, suspects, or has reason to suspect that the transaction (or a pattern of transactions of which the transaction is a part):

(i) Involves funds derived from illegal activity or is intended or conducted in order to hide or disguise funds or assets derived from illegal activity (including, without limitation, the ownership, nature, source, location, or control of such funds or assets) as part of a plan to violate or evade any federal law or regulation or to avoid any transaction reporting requirement under federal law or regulation;

(ii) Is designed, whether through structuring or other means, to evade any requirements of this chapter or of any other regulations promulgated under the Bank Secrecy Act; or

(iii) Serves no business or apparent lawful purpose, and the reporting money services business knows of no reasonable explanation for the transaction after examining the available facts, including the background and possible purpose of the transaction.

(iv) Involves use of the money services business to facilitate criminal activity.

(3) To the extent that the identification of transactions required to be reported is derived from a review of clearance records or other similar records of money orders or traveler's checks that have been sold or processed, an issuer of money orders or traveler's checks shall only be required to report a transaction or pattern of transactions that involves or aggregates funds or other assets of at least $5,000.

(4) The obligation to identify and properly and timely to report a suspicious transaction rests with each money services business involved in the transaction, provided that no more than one report is required to be filed by the money services businesses involved in a particular transaction (so long as the report filed contains all relevant facts). Whether, in addition to any liability on its own for failure to report, a money services business that issues the instrument or provides the funds transfer service involved in the transaction may be liable for the failure of another money services business involved in the transaction to report that transaction depends upon the nature of the contractual or other relationship between the businesses, and the legal effect of the facts and circumstances of the relationship and transaction involved, under general principles of the law of agency.

(5) Notwithstanding the provisions of this section, a transaction that involves solely the issuance, or facilitation of the transfer of stored value, or the issuance, sale, or redemption of stored value, shall not be subject to reporting under this paragraph (a), until the promulgation of rules specifically relating to such reporting.

(b) *Filing procedures*—(1) *What to file.* A suspicious transaction shall be reported by completing a Suspicious Activity Report—MSB (''SAR–MSB''), and collecting and maintaining supporting documentation as required by paragraph (c) of this section.

(2) *Where to file.* The SAR–MSB shall be filed in a central location to be determined by FinCEN, as indicated in the instructions to the SAR–MSB.

(3) *When to file.* A money services business subject to this section is required to file each SAR–MSB no later than 30 calendar days after the date of the initial detection by the money services business of facts that may constitute a basis for filing a SAR–MSB under this section. In situations involving violations that require immediate attention, such as ongoing money laundering schemes, the money services business shall immediately notify by telephone an appropriate law enforcement authority in addition to filing a SAR–MSB. Money services businesses wishing voluntarily to report suspicious transactions that may relate to terrorist activity may call FinCEN's Financial Institutions Hotline at 1–866–556–3974 in addition to filing timely a SAR–MSB if required by this section.

(c) *Retention of records.* A money services business shall maintain a copy of any SAR–MSB filed and the original or business record equivalent of any supporting documentation for a period of five years from the date of filing the SAR–MSB. Supporting documentation shall be identified as such and maintained by the money services business, and shall be deemed to have been filed with the SAR–MSB. A money services business shall make all supporting documentation available to FinCEN and any other appropriate law enforcement agencies or supervisory agencies upon request.

(d) *Confidentiality of reports; limitation of liability.* No financial institution, and no director, officer, employee, or agent of any financial institution, who reports a suspicious transaction under this chapter, may notify any person involved in the transaction that the transaction has been reported. Thus, any person subpoenaed or otherwise requested to disclose a SAR–MSB or the information contained in a SAR–MSB, except where such disclosure is requested by FinCEN or an appropriate law enforcement or supervisory agency, shall decline to produce the SAR–MSB or to provide any information that would disclose that a SAR–MSB has been prepared or filed, citing this paragraph (d) and 31 U.S.C. 5318(g)(2), and shall notify FinCEN of any such request and its response thereto. A reporting money services business, and any director, officer, employee, or agent of such reporting money services business, that makes a report pursuant to this section (whether such report is required by this section or made voluntarily) shall be protected from liability for any disclosure contained in, or for failure to disclose the fact of, such report, or both, to the extent provided by 31 U.S.C. 5318(g)(3).

(e) *Compliance.* Compliance with this section shall be audited by the Department of the Treasury, through

FinCEN or its delegees under the terms of the Bank Secrecy Act. Failure to satisfy the requirements of this section may constitute a violation of the reporting rules of the Bank Secrecy Act and of this chapter.

(f) *Applicabilty date.* This section applies to transactions occurring after December 31, 2001.

§ 1022.380 Registration of money services businesses.

(a) *Registration requirement*—(1) *In general.* Except as provided in paragraph (a)(2) of this section, relating to agents, each money services business (whether or not licensed as a money services business by any State) must register with the Department of the Treasury and, as part of that registration, maintain a list of its agents as required by 31 U.S.C. 5330 and this section. This section does not apply to the U.S. Postal Service, to agencies of the United States, of any State, or of any political subdivision of a State, or to a person to the extent that the person is an issuer, seller, or redeemer of stored value.

(2) *Agents.* A person that is a money services business solely because that person serves as an agent of another money services business, see § 1010.100(ff) of this chapter, is not required to register under this section, but a money services business that engages in activities described in § 1010.100(ff) of this chapter both on its own behalf and as an agent for others must register under this section. For example, a supermarket corporation that acts as an agent for an issuer of money orders and performs no other services of a nature and value that would cause the corporation to be a money services business, is not required to register; the answer would be the same if the supermarket corporation served as an agent both of a money order issuer and of a money transmitter. However, registration would be required if the supermarket corporation, in addition to acting as an agent of an issuer of money orders, cashed checks or exchanged currencies (other than as an agent for another business) in an amount greater than $1,000 in currency or monetary or other instruments for any person on any day, in one or more transactions.

(3) *Agency status.* The determination whether a person is an agent depends on all the facts and circumstances.

(b) *Registration procedures*—(1) *In general.* (i) A money services business must be registered by filing such form as FinCEN may specify with the Enterprise Computing Center in Detroit of the Internal Revenue Service (or such other location as the form may specify). The information required by 31 U.S.C. 5330(b) and any other information required by the form must be reported in the manner and to the extent required by the form.

(ii) A branch office of a money services business is not required to file its own registration form. A money services business must, however, report information about its branch locations or offices as provided by the instructions to the registration form.

(iii) A money services business must retain a copy of any registration form filed under this section and any registration number that may be assigned to the business at a location in the United States and for the period specified in § 1010.430(d) of this chapter.

(2) *Registration period.* A money services business must be registered for the initial registration period and each renewal period. The initial registration period is the two-calendar-year period beginning with the calendar year in which the money services business is first required to be registered. However, the initial registration period for a money services business required to register by December 31, 2001 (see paragraph (b)(3) of this section) is the two-calendar-year period beginning 2002. Each two-calendar-year period following the initial registration period is a renewal period.

(3) *Due date.* The registration form for the initial registration period must be filed on or before the later of December 31, 2001, and the end of the 180-day period beginning on the day following the date the business is established. The registration form for a renewal period must be filed on or before the last day of the calendar year preceding the renewal period.

(4) *Events requiring re-registration.* If a money services business registered as such under the laws of any State experiences a change in ownership or control that requires the business to be re-registered under State law, the money services business must also be re-registered under this section. In addition, if there is a transfer of more than 10 percent of the voting power or equity interests of a money services business (other than a money services business that must report such transfer to the Securities and Exchange Commission), the money services business must be re-registered under this section. Finally, if a money services business experiences a more than 50-percent increase in the number of its agents during any registration period, the money services business must be re-registered under this section. The registration form must be filed not later than 180 days after such change in ownership, transfer of voting power or equity interests, or increase in agents. The calendar year in which the change, transfer, or increase occurs is treated as the first year of a new two-year registration period.

(c) *Persons required to file the registration form.* Under 31 U.S.C. 5330(a), any person who owns or controls a money services business is responsible for registering the business; however, only one registration form is required to be filed for each registration period. A person is treated as owning or controlling a money services business for purposes of filing the registration form only to the extent provided by the form. If more than one person owns or controls a money services business, the owning or controlling persons may enter into an agreement designating one of them to register the business. The failure of the designated person to register the money services business does not, however, relieve any of the other persons who own or control the business of liability for the failure to register the business. See paragraph (e) of this section, relating to consequences of the failure to comply with 31 U.S.C. 5330 or this section.

(d) *List of agents*—(1) *In general.* A money services business must prepare and maintain a list of its agents. The initial list of agents must be prepared by January 1, 2002, and must be revised each January 1, for the immediately preceding 12-month period; for money services businesses established after December 31, 2001, the initial agent list must be prepared by the due date of the initial registration form and must be revised each January 1 for the immediately preceding 12-month period. The list is not filed with the registration form but must be maintained at the location in the United States reported on the registration form under paragraph (b)(1) of this section. Upon request, a money services business must make its list of agents available to FinCEN and any other appropriate law enforcement agency (including, without limitation, the examination function of the Internal Revenue Service in its capacity as delegee of Bank Secrecy Act examination authority). Requests for information made pursuant to the preceding sentence shall be coordinated through FinCEN in the manner and to the extent determined by FinCEN. The original list of agents and any revised list must be retained for the period specified in § 1010.430(d) of this chapter.

(2) *Information included on the list of agents*—(i) *In general.* Except as provided in paragraph (d)(2)(ii) of this

section, a money services business must include the following information with respect to each agent on the list (including any revised list) of its agents—

(A) The name of the agent, including any trade names or doing-business-as names;

(B) The address of the agent, including street address, city, state, and ZIP code;

(C) The telephone number of the agent;

(D) The type of service or services (money orders, traveler's checks, check sales, check cashing, currency exchange, and money transmitting) the agent provides;

(E) A listing of the months in the 12 months immediately preceding the date of the most recent agent list in which the gross transaction amount of the agent with respect to financial products or services issued by the money services business maintaining the agent list exceeded $100,000. For this purpose, the money services gross transaction amount is the agent's gross amount (excluding fees and commissions) received from transactions of one or more businesses described in § 1010.100(ff) of this chapter;

(F) The name and address of any depository institution at which the agent maintains a transaction account (as defined in 12 U.S.C. 461(b)(1)(C)) for all or part of the funds received in or for the financial products or services issued by the money services business maintaining the list, whether in the agent's or the business principal's name;

(G) The year in which the agent first became an agent of the money services business; and

(H) The number of branches or subagents the agent has.

(ii) *Special rules.* Information about agent volume must be current within 45 days of the due date of the agent list. The information described by paragraphs (d)(2)(i)(G) and (d)(2)(i)(H) of this section is not required to be included in an agent list with respect to any person that is an agent of the money services business maintaining the list before the first day of the month beginning after February 16, 2000 so long as the information described by paragraphs (d)(2)(i)(G) and (d)(2)(i)(H) of this section is made available upon the request of FinCEN and any other appropriate law enforcement agency (including, without limitation, the examination function of the Internal Revenue Service in its capacity as delegee of Bank Secrecy Act examination authority).

(e) *Consequences of failing to comply with 31 U.S.C. 5330 or the regulations thereunder.* It is unlawful to do business without complying with 31 U.S.C. 5330 and this section. A failure to comply with the requirements of 31 U.S.C 5330 or this section includes the filing of false or materially incomplete information in connection with the registration of a money services business. Any person who fails to comply with any requirement of 31 U.S.C. 5330 or this section shall be liable for a civil penalty of $5,000 for each violation. Each day a violation of 31 U.S.C. 5330 or this section continues constitutes a separate violation. In addition, under 31 U.S.C. 5320, the Secretary of the Treasury may bring a civil action to enjoin the violation. See 18 U.S.C. 1960 for a criminal penalty for failure to comply with the registration requirements of 31 U.S.C. 5330 or this section.

(f) *Applicability date.* This section is applicable September 20, 1999. Registration of money services businesses under this section will not be required prior to December 31, 2001.

Subpart D—Records Required To Be Maintained by Money Services Businesses

§ 1022.400 General.

Money services businesses are subject to the recordkeeping requirements set forth and cross referenced in this subpart. Money services businesses should also refer to Subpart D of Part 1010 of this chapter for recordkeeping requirements contained in that subpart which apply to money services businesses.

§ 1022.410 Additional records to be made and retained by currency dealers or exchangers.

(a)(1) After July 7, 1987, each currency dealer or exchanger shall secure and maintain a record of the taxpayer identification number of each person for whom a transaction account is opened or a line of credit is extended within 30 days after such account is opened or credit line extended. Where a person is a non-resident alien, the currency dealer or exchanger shall also record the person's passport number or a description of some other government document used to verify his identity. Where the account or credit line is in the names of two or more persons, the currency dealer or exchanger shall secure the taxpayer identification number of a person having a financial interest in the account or credit line. In the event that a currency dealer or exchanger has been unable to secure the identification required within the 30-day period specified, it shall nevertheless not be deemed to be in violation of this section if:

(i) It has made a reasonable effort to secure such identification, and

(ii) It maintains a list containing the names, addresses, and account or credit line numbers of those persons from whom it has been unable to secure such identification, and makes the names, addresses, and account or credit line numbers of those persons available to the Secretary as directed by him.

(2) The 30-day period provided for in paragraph (a)(1) of this section shall be extended where the person opening the account or credit line has applied for a taxpayer identification or social security number on Form SS–4 or SS–5, until such time as the person maintaining the account or credit line has had a reasonable opportunity to secure such number and furnish it to the currency dealer or exchanger.

(3) A taxpayer identification number for an account or credit line required under paragraph (a)(1) of this section need not be secured in the following instances:

(i) Accounts for public funds opened by agencies and instrumentalities of Federal, state, local or foreign governments,

(ii) Accounts for aliens who are—

(A) Ambassadors, ministers, career diplomatic or consular officers, or

(B) Naval, military or other attaches of foreign embassies, and legations, and for members of their immediate families,

(iii) Accounts for aliens who are accredited representatives to international organizations which are entitled to enjoy privileges, exemptions, and immunities as an international organization under the International Organizations Immunities Act of December 29, 1945 (22 U.S.C. 288), and for the members of their immediate families,

(iv) Aliens temporarily residing in the United States for a period not to exceed 180 days,

(v) Aliens not engaged in a trade or business in the United States who are attending a recognized college or any training program, supervised or conducted by any agency of the Federal Government, and

(vi) Unincorporated subordinate units of a tax exempt central organization which are covered by a group exemption letter.

(b) Each currency dealer or exchanger shall retain either the original or a microfilm or other copy or reproduction of each of the following:

(1) Statements of accounts from banks, including paid checks, charges or other debit entry memoranda, deposit slips and other credit memoranda

representing the entries reflected on such statements;

(2) Daily work records, including purchase and sales slips or other memoranda needed to identify and reconstruct currency transactions with customers and foreign banks;

(3) A record of each exchange of currency involving transactions in excess of $1000, including the name and address of the customer (and passport number or taxpayer identification number unless received by mail or common carrier) date and amount of the transaction and currency name, country, and total amount of each foreign currency;

(4) Signature cards or other documents evidencing signature authority over each deposit or security account, containing the name of the depositor, street address, taxpayer identification number (TIN) or employer identification number (EIN) and the signature of the depositor or of a person authorized to sign on the account (if customer accounts are maintained in a code name, a record of the actual owner of the account);

(5) Each item, including checks, drafts, or transfers of credit, of more than $10,000 remitted or transferred to a person, account or place outside the United States;

(6) A record of each receipt of currency, other monetary instruments, investment securities and checks, and of each transfer of funds or credit, or more than $10,000 received on any one occasion directly and not through a domestic financial institution, from any person, account or place outside the United States;

(7) Records prepared or received by a dealer in the ordinary course of business, that would be needed to reconstruct an account and trace a check in excess of $100 deposited in such account through its internal recordkeeping system to its depository institution, or to supply a description of a deposited check in excess of $100;

(8) A record maintaining the name, address and taxpayer identification number, if available, of any person presenting a certificate of deposit for payment, as well as a description of the instrument and date of transaction;

(9) A system of books and records that will enable the currency dealer or exchanger to prepare an accurate balance sheet and income statement.

(c) This section does not apply to banks that offer services in dealing or changing currency to their customers as an adjunct to their regular service.

(Approved by the Office of Management and Budget under control number 1505–0063)

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

§ 1022.500 General.

Money services businesses are subject to the special information sharing procedures to deter money laundering and terrorist activity requirements set forth and cross referenced in this subpart. Money services businesses should also refer to Subpart E of Part 1010 of this chapter for special information sharing procedures to deter money laundering and terrorist activity contained in that subpart which apply to money services businesses.

§ 1022.520 Special information sharing procedures to deter money laundering and terrorist activity for money services businesses.

(a) Refer to § 1010.520 of this chapter.

(b) [Reserved]

§ 1022.530 [Reserved]

§ 1022.540 Voluntary information sharing among financial institutions.

(a) Refer to § 1010.540 of this chapter.

(b) [Reserved]

Subpart F—Special Standards of Diligence; Prohibitions; and Special Measures for Money Services Businesses

§ 1022.600 General.

Money services businesses are subject to the special standards of diligence; prohibitions; and special measures requirements set forth and cross referenced in this subpart. Money services businesses should also refer to Subpart F of Part 1010 of this chapter for special standards of diligence; prohibitions; and special measures contained in that subpart which apply to money services businesses.

§ 1022.610 [Reserved]

§ 1022.620 [Reserved]

§ 1022.630 [Reserved]

§ 1022.640 [Reserved]

§ 1022.670 [Reserved]

PART 1023—RULES FOR BROKERS OR DEALERS IN SECURITIES

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Subpart A—Definitions

§ 1023.100 Definitions.

Refer to § 1010.100 of this chapter for general definitions not noted herein. To the extent there is a differing definition in § 1010.100 of this chapter, the definition in this Section is what applies to Part 1023. Unless otherwise indicated, for purposes of this Part:

(a) *Account*. For purposes of § 1023.220:

(1) Account means a formal relationship with a broker-dealer established to effect transactions in securities, including, but not limited to, the purchase or sale of securities and securities loaned and borrowed activity, and to hold securities or other assets for safekeeping or as collateral.

(2) *Account* does not include:

(i) An account that the broker-dealer acquires through any acquisition,

merger, purchase of assets, or assumption of liabilities; or

(ii) An account opened for the purpose of participating in an employee benefit plan established under the Employee Retirement Income Security Act of 1974.

(b) *Broker-dealer* means a person registered or required to be registered as a broker or dealer with the Commission under the Securities Exchange Act of 1934 (15 U.S.C. 77a *et seq.*), except persons who register pursuant to 15 U.S.C. 78o(b)(11).

(c) *Commission* means, for the purposes of § 1023.220, the United States Securities and Exchange Commission.

(d) *Customer*. For purposes of § 1023.220:

(1) *Customer* means:

(i) A person that opens a new account; and

(ii) An individual who opens a new account for:

(A) An individual who lacks legal capacity; or

(B) an entity that is not a legal person.

(2) *Customer* does not include:

(i) A financial institution regulated by a Federal functional regulator or a bank regulated by a state bank regulator;

(ii) A person described in § 1020.315(b)(2) through (4) of this chapter; or

(iii) A person that has an existing account with the broker-dealer, provided the broker-dealer has a reasonable belief that it knows the true identity of the person.

(e) *Financial institution* is defined at 31 U.S.C. 5312(a)(2) and (c)(1).

Subpart B—Programs

§ 1023.200 General.

Brokers or dealers in securities are subject to the program requirements set forth and cross referenced in this subpart. Brokers or dealers in securities should also refer to Subpart B of Part 1010 of this chapter for program requirements contained in that subpart which apply to brokers or dealers in securities.

§ 1023.210 Anti-money laundering program requirements for brokers or dealers in securities.

A financial institution regulated by a self-regulatory organization shall be deemed to satisfy the requirements of 31 U.S.C. 5318(h)(1) if:

(a) The financial institution complies with the requirements of §§ 1010.610 and 1010.620 of this chapter and any applicable regulation of its Federal functional regulator governing the establishment and implementation of anti-money laundering programs; and

(b)(1) The financial institution implements and maintains an anti-money laundering program that complies with the rules, regulations, or requirements of its self-regulatory organization governing such programs; and

(2) The rules, regulations, or requirements of the self-regulatory organization have been approved, if required, by the appropriate Federal functional regulator.

§ 1023.220 Customer identification programs for broker-dealers.

(a) *Customer identification program: minimum requirements*—(1) *In general*. A broker-dealer must establish, document, and maintain a written Customer Identification Program (''CIP'') appropriate for its size and business that, at a minimum, includes each of the requirements of paragraphs (a)(1) through (a)(5) of this section. The CIP must be a part of the broker-dealer's anti-money laundering compliance program required under 31 U.S.C. 5318(h).

(2) *Identity verification procedures*. The CIP must include risk-based procedures for verifying the identity of each customer to the extent reasonable and practicable. The procedures must enable the broker-dealer to form a reasonable belief that it knows the true identity of each customer. The procedures must be based on the broker-dealer's assessment of the relevant risks, including those presented by the various types of accounts maintained by the broker-dealer, the various methods of opening accounts provided by the broker-dealer, the various types of identifying information available and the broker-dealer's size, location and customer base. At a minimum, these procedures must contain the elements described in this paragraph (a)(2).

(i)(A) *Customer information required*. The CIP must contain procedures for opening an account that specify identifying information that will be obtained from each customer. Except as permitted by paragraph (a)(2)(i)(B) of this section, the broker-dealer must obtain, at a minimum, the following information prior to opening an account:

(*1*) Name;

(*2*) Date of birth, for an individual;

(*3*) Address, which shall be:

(*i*) For an individual, a residential or business street address;

(*ii*) for an individual who does not have a residential or business street address, an Army Post Office (APO) or Fleet Post Office (FPO) box number, or the residential or business street address of a next of kin or another contact individual; or

(*iii*) for a person other than an individual (such as a corporation, partnership or trust), a principal place of business, local office or other physical location; and

(*4*) Identification number, which shall be:

(*i*) For a U.S. person, a taxpayer identification number; or

(*ii*) for a non-U.S. person, one or more of the following: a taxpayer identification number, a passport number and country of issuance, an alien identification card number, or the number and country of issuance of any other government-issued document evidencing nationality or residence and bearing a photograph or similar safeguard.

Note to Paragraph (a)(2)(i)(A)*(4)(ii)***:** When opening an account for a foreign business or enterprise that does not have an identification number, the broker-dealer must request alternative government-issued documentation certifying the existence of the business or enterprise.

(B) *Exception for persons applying for a taxpayer identification number*. Instead of obtaining a taxpayer identification number from a customer prior to opening an account, the CIP may include procedures for opening an account for a customer that has applied for, but has not received, a taxpayer identification number. In this case, the CIP must include procedures to confirm that the application was filed before the customer opens the account and to obtain the taxpayer identification number within a reasonable period of time after the account is opened.

(ii) *Customer verification*. The CIP must contain procedures for verifying the identity of each customer, using information obtained in accordance with paragraph (a)(2)(i) of this section, within a reasonable time before or after the customer's account is opened. The procedures must describe when the broker-dealer will use documents, non-documentary methods, or a combination of both methods, as described in this paragraph (a)(2)(ii).

(A) *Verification through documents*. For a broker-dealer relying on documents, the CIP must contain procedures that set forth the documents the broker-dealer will use. These documents may include:

(*1*) For an individual, an unexpired government-issued identification evidencing nationality or residence and bearing a photograph or similar safeguard, such as a driver's license or passport; and

(*2*) For a person other than an individual (such as a corporation,

partnership or trust), documents showing the existence of the entity, such as certified articles of incorporation, a government-issued business license, a partnership agreement, or a trust instrument.

(B) *Verification through non-documentary methods.* For a broker-dealer relying on non-documentary methods, the CIP must contain procedures that set forth the non-documentary methods the broker-dealer will use.

(*1*) These methods may include contacting a customer; independently verifying the customer's identity through the comparison of information provided by the customer with information obtained from a consumer reporting agency, public database, or other source; checking references with other financial institutions; or obtaining a financial statement.

(*2*) The broker-dealer's non-documentary procedures must address situations where an individual is unable to present an unexpired government-issued identification document that bears a photograph or similar safeguard; the broker-dealer is not familiar with the documents presented; the account is opened without obtaining documents; the customer opens the account without appearing in person at the broker-dealer; and where the broker-dealer is otherwise presented with circumstances that increase the risk that the broker-dealer will be unable to verify the true identity of a customer through documents.

(C) *Additional verification for certain customers.* The CIP must address situations where, based on the broker-dealer's risk assessment of a new account opened by a customer that is not an individual, the broker-dealer will obtain information about individuals with authority or control over such account. This verification method applies only when the broker-dealer cannot verify the customer's true identity using the verification methods described in paragraphs (a)(2)(ii)(A) and (B) of this section.

(iii) *Lack of verification.* The CIP must include procedures for responding to circumstances in which the broker-dealer cannot form a reasonable belief that it knows the true identity of a customer. These procedures should describe:

(A) When the broker-dealer should not open an account;

(B) The terms under which a customer may conduct transactions while the broker-dealer attempts to verify the customer's identity;

(C) When the broker-dealer should close an account after attempts to verify a customer's identity fail; and

(D) When the broker-dealer should file a Suspicious Activity Report in accordance with applicable law and regulation.

(3) *Recordkeeping.* The CIP must include procedures for making and maintaining a record of all information obtained under procedures implementing paragraph (a) of this section.

(i) *Required records.* At a minimum, the record must include:

(A) All identifying information about a customer obtained under paragraph (a)(2)(i) of this section,

(B) A description of any document that was relied on under paragraph (a)(2)(ii)(A) of this section noting the type of document, any identification number contained in the document, the place of issuance, and if any, the date of issuance and expiration date;

(C) A description of the methods and the results of any measures undertaken to verify the identity of a customer under paragraphs (a)(2)(ii)(B) and (C) of this section; and

(D) A description of the resolution of each substantive discrepancy discovered when verifying the identifying information obtained.

(ii) *Retention of records.* The broker-dealer must retain the records made under paragraph (a)(3)(i)(A) of this section for five years after the account is closed and the records made under paragraphs (a)(3)(i)(B), (C) and (D) of this section for five years after the record is made. In all other respects, the records must be maintained pursuant to the provisions of 17 CFR 240.17a–4.

(4) *Comparison with government lists.* The CIP must include procedures for determining whether a customer appears on any list of known or suspected terrorists or terrorist organizations issued by any Federal government agency and designated as such by the Treasury in consultation with the Federal functional regulators. The procedures must require the broker-dealer to make such a determination within a reasonable period of time after the account is opened, or earlier if required by another Federal law or regulation or Federal directive issued in connection with the applicable list. The procedures also must require the broker-dealer to follow all Federal directives issued in connection with such lists.

(5)(i) *Customer notice.* The CIP must include procedures for providing customers with adequate notice that the broker-dealer is requesting information to verify their identities.

(ii) *Adequate notice.* Notice is adequate if the broker-dealer generally describes the identification requirements of this section and provides such notice in a manner reasonably designed to ensure that a customer is able to view the notice, or is otherwise given notice, before opening an account. For example, depending upon the manner in which the account is opened, a broker-dealer may post a notice in the lobby or on its Web site, include the notice on its account applications or use any other form of oral or written notice.

(iii) *Sample notice.* If appropriate, a broker-dealer may use the following sample language to provide notice to its customers:

Important Information About Procedures for Opening a New Account

To help the government fight the funding of terrorism and money laundering activities, Federal law requires all financial institutions to obtain, verify, and record information that identifies each person who opens an account.

What this means for you: When you open an account, we will ask for your name, address, date of birth and other information that will allow us to identify you. We may also ask to see your driver's license or other identifying documents.

(6) *Reliance on another financial institution.* The CIP may include procedures specifying when the broker-dealer will rely on the performance by another financial institution (including an affiliate) of any procedures of the broker-dealer's CIP, with respect to any customer of the broker-dealer that is opening an account or has established an account or similar business relationship with the other financial institution to provide or engage in services, dealings, or other financial transactions, provided that:

(i) Such reliance is reasonable under the circumstances;

(ii) The other financial institution is subject to a rule implementing 31 U.S.C. 5318(h), and regulated by a Federal functional regulator; and

(iii) The other financial institution enters into a contract requiring it to certify annually to the broker-dealer that it has implemented its anti-money laundering program, and that it will perform (or its agent will perform) specified requirements of the broker-dealer's CIP.

(b) *Exemptions.* The Commission, with the concurrence of the Secretary, may by order or regulation exempt any broker-dealer that registers with the Commission pursuant to 15 U.S.C. 78o or 15 U.S.C. 78o–4 or any type of account from the requirements of this section. The Secretary, with the concurrence of the Commission, may

exempt any broker-dealer that registers with the Commission pursuant to 15 U.S.C. 78o–5. In issuing such exemptions, the Commission and the Secretary shall consider whether the exemption is consistent with the purposes of the Bank Secrecy Act, and in the public interest, and may consider other necessary and appropriate factors.

(c) *Other requirements unaffected.* Nothing in this section relieves a broker-dealer of its obligation to comply with any other provision of this chapter, including provisions concerning information that must be obtained, verified, or maintained in connection with any account or transaction.

Subpart C—Reports Required To Be Made by Brokers or Dealers in Securities

§ 1023.300 General.

Brokers or dealers in securities are subject to the reporting requirements set forth and cross referenced in this subpart. Brokers or dealers in securities should also refer to Subpart C of Part 1010 of this chapter for reporting requirements contained in that subpart which apply to brokers or dealers in securities.

§ 1023.310 Reports of transactions in currency.

The reports of transactions in currency requirements for brokers or dealers in securities are located in subpart C of Part 1010 of this chapter and this subpart.

§ 1023.311 Filing obligations.

Refer to § 1010.311 of this chapter for reports of transactions in currency filing obligations for brokers or dealers in securities.

§ 1023.312 Identification required.

Refer to § 1010.312 of this chapter for identification requirements for reports of transactions in currency filed by brokers or dealers in securities.

§ 1023.313 Aggregation.

Refer to § 1010.313 of this chapter for reports of transactions in currency aggregation requirements for brokers or dealers in securities.

§ 1023.314 Structured transactions.

Refer to § 1010.314 of this chapter for rules regarding structured transactions for brokers or dealers in securities.

§ 1023.315 Exemptions.

Refer to § 1010.315 of this chapter for exemptions from the obligation to file reports of transactions in currency for brokers or dealers in securities.

§ 1023.320 Reports by brokers or dealers in securities of suspicious transactions.

(a) *General.* (1) Every broker or dealer in securities within the United States (for purposes of this section, a ''broker-dealer'') shall file with FinCEN, to the extent and in the manner required by this section, a report of any suspicious transaction relevant to a possible violation of law or regulation. A broker-dealer may also file with FinCEN a report of any suspicious transaction that it believes is relevant to the possible violation of any law or regulation but whose reporting is not required by this section. Filing a report of a suspicious transaction does not relieve a broker-dealer from the responsibility of complying with any other reporting requirements imposed by the Securities and Exchange Commission or a self-regulatory organization (''SRO'') (as defined in section 3(a)(26) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(26)).

(2) A transaction requires reporting under the terms of this section if it is conducted or attempted by, at, or through a broker-dealer, it involves or aggregates funds or other assets of at least $5,000, and the broker-dealer knows, suspects, or has reason to suspect that the transaction (or a pattern of transactions of which the transaction is a part):

(i) Involves funds derived from illegal activity or is intended or conducted in order to hide or disguise funds or assets derived from illegal activity (including, without limitation, the ownership, nature, source, location, or control of such funds or assets) as part of a plan to violate or evade any federal law or regulation or to avoid any transaction reporting requirement under federal law or regulation;

(ii) Is designed, whether through structuring or other means, to evade any requirements of this chapter or of any other regulations promulgated under the Bank Secrecy Act;

(iii) Has no business or apparent lawful purpose or is not the sort in which the particular customer would normally be expected to engage, and the broker-dealer knows of no reasonable explanation for the transaction after examining the available facts, including the background and possible purpose of the transaction; or

(iv) Involves use of the broker-dealer to facilitate criminal activity.

(3) The obligation to identify and properly and timely to report a suspicious transaction rests with each broker-dealer involved in the transaction, provided that no more than one report is required to be filed by the broker-dealers involved in a particular transaction (so long as the report filed contains all relevant facts).

(b) *Filing procedures*—(1) *What to file.* A suspicious transaction shall be reported by completing a Suspicious Activity Report by the Securities and Futures Industry (''SAR–SF''), and collecting and maintaining supporting documentation as required by paragraph (d) of this section.

(2) *Where to file.* The SAR–SF shall be filed with FinCEN in a central location, to be determined by FinCEN, as indicated in the instructions to the SAR–SF.

(3) *When to file.* A SAR–SF shall be filed no later than 30 calendar days after the date of the initial detection by the reporting broker-dealer of facts that may constitute a basis for filing a SAR–SF under this section. If no suspect is identified on the date of such initial detection, a broker-dealer may delay filing a SAR–SF for an additional 30 calendar days to identify a suspect, but in no case shall reporting be delayed more than 60 calendar days after the date of such initial detection. In situations involving violations that require immediate attention, such as terrorist financing or ongoing money laundering schemes, the broker-dealer shall immediately notify by telephone an appropriate law enforcement authority in addition to filing timely a SAR–SF. Broker-dealers wishing voluntarily to report suspicious transactions that may relate to terrorist activity may call FinCEN's Financial Institutions Hotline at 1–866–556–3974 in addition to filing timely a SAR–SF if required by this section. The broker-dealer may also, but is not required to, contact the Securities and Exchange Commission to report in such situations.

(c) *Exceptions.* (1) A broker-dealer is not required to file a SAR–SF to report:

(i) A robbery or burglary committed or attempted of the broker-dealer that is reported to appropriate law enforcement authorities, or for lost, missing, counterfeit, or stolen securities with respect to which the broker-dealer files a report pursuant to the reporting requirements of 17 CFR 240.17f–1;

(ii) A violation otherwise required to be reported under this section of any of the federal securities laws or rules of an SRO by the broker-dealer or any of its officers, directors, employees, or other registered representatives, other than a violation of 17 CFR 240.17a–8 or 17 CFR 405.4, so long as such violation is appropriately reported to the SEC or an SRO.

(2) A broker-dealer may be required to demonstrate that it has relied on an exception in paragraph (c)(1) of this section, and must maintain records of

its determinations to do so for the period specified in paragraph (d) of this section. To the extent that a Form RE–3, Form U–4, or Form U–5 concerning the transaction is filed consistent with the SRO rules, a copy of that form will be a sufficient record for purposes of this paragraph (c)(2).

(3) For the purposes of this paragraph (c) the term ''federal securities laws'' means the ''securities laws,'' as that term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47), and the rules and regulations promulgated by the Securities and Exchange Commission under such laws.

(d) *Retention of records.* A broker-dealer shall maintain a copy of any SAR–SF filed and the original or business record equivalent of any supporting documentation for a period of five years from the date of filing the SAR–SF. Supporting documentation shall be identified as such and maintained by the broker-dealer, and shall be deemed to have been filed with the SAR–SF. A broker-dealer shall make all supporting documentation available to FinCEN, any other appropriate law enforcement agencies or federal or state securities regulators, and for purposes of paragraph (g) of this section, to an SRO registered with the Securities and Exchange Commission, upon request.

(e) *Confidentiality of reports.* No financial institution, and no director, officer, employee, or agent of any financial institution, who reports a suspicious transaction under this chapter, may notify any person involved in the transaction that the transaction has been reported, except to the extent permitted by paragraph (a)(3) of this section. Thus, any person subpoenaed or otherwise requested to disclose a SAR–SF or the information contained in a SAR–SF, except where such disclosure is requested by FinCEN, the Securities and Exchange Commission, or another appropriate law enforcement or regulatory agency, or for purposes of paragraph (g) of this section, an SRO registered with the Securities and Exchange Commission, shall decline to produce the SAR–SF or to provide any information that would disclose that a SAR–SF has been prepared or filed, citing this paragraph (e) and 31 U.S.C. 5318(g)(2), and shall notify FinCEN of any such request and its response thereto.

(f) *Limitation of liability.* A broker-dealer, and any director, officer, employee, or agent of such broker-dealer, that makes a report of any possible violation of law or regulation pursuant to this section or any other authority (or voluntarily) shall not be liable to any person under any law or regulation of the United States (or otherwise to the extent also provided in 31 U.S.C. 5318(g)(3), including in any arbitration proceeding) for any disclosure contained in, or for failure to disclose the fact of, such report.

(g) *Examination and enforcement.* Compliance with this section shall be examined by the Department of the Treasury, through FinCEN or its delegees, under the terms of the Bank Secrecy Act. Reports filed under this section shall be made available to an SRO registered with the Securities and Exchange Commission examining a broker-dealer for compliance with the requirements of this section. Failure to satisfy the requirements of this section may constitute a violation of the reporting rules of the Bank Secrecy Act and of this chapter.

(h) *Applicability date.* This section applies to transactions occurring after December 30, 2002.

Subpart D—Records Required To Be Maintained by Brokers or Dealers in Securities

§ 1023.400 General.

Brokers or dealers in securities are subject to the recordkeeping requirements set forth and cross referenced in this subpart. Brokers or dealers in securities should also refer to Subpart D of Part 1010 of this chapter for recordkeeping requirements contained in that subpart which apply to brokers or dealers in securities.

§ 1023.410 Additional records to be made and retained by brokers or dealers in securities.

(a)(1) With respect to each brokerage account opened with a broker or dealer in securities after June 30, 1972, and before October 1, 2003, by a person residing or doing business in the United States or a citizen of the United States, such broker or dealer shall within 30 days from the date such account is opened, secure and maintain a record of the taxpayer identification number of the person maintaining the account; or in the case of an account of one or more individuals, such broker or dealer shall secure and maintain a record of the social security number of an individual having a financial interest in that account. In the event that a broker or dealer has been unable to secure the identification required within the 30-day period specified, it shall nevertheless not be deemed to be in violation of this section if: it has made a reasonable effort to secure such identification, and it maintains a list containing the names, addresses, and account numbers of those persons from whom it has been unable to secure such identification, and makes the names, addresses, and account numbers of those persons available to the Secretary as directed by him. Where a person is a non-resident alien, the broker or dealer in securities shall also record the person's passport number or a description of some other government document used to verify his identity.

(2) The 30-day period provided for in paragraph (a)(1) of this section shall be extended where the person opening the account has applied for a taxpayer identification or social security number on Form SS–4 or SS–5, until such time as the person maintaining the account has had a reasonable opportunity to secure such number and furnish it to the broker or dealer.

(3) A taxpayer identification number for a deposit or share account required under paragraph (a)(1) of this section need not be secured in the following instances:

(i) Accounts for public funds opened by agencies and instrumentalities of Federal, state, local, or foreign governments,

(ii) Accounts for aliens who are ambassadors, ministers, career diplomatic or consular officers, or naval, military or other attaches of foreign embassies, and legations, and for the members of their immediate families,

(iii) Accounts for aliens who are accredited representatives to international organizations which are entitled to enjoy privileges, exemptions, and immunities as an international organization under the International Organizations Immunities Act of December 29, 1945 (22 U.S.C. 288), and for the members of their immediate families, (iv) aliens temporarily residing in the United States for a period not to exceed 180 days, (v) aliens not engaged in a trade or business in the United States who are attending a recognized college or university or any training program, supervised or conducted by any agency of the Federal Government, and

(vi) Unincorporated subordinate units of a tax exempt central organization which are covered by a group exemption letter.

(b) Every broker or dealer in securities shall, in addition, retain either the original or a microfilm or other copy or reproduction of each of the following:

(1) Each document granting signature or trading authority over each customer's account;

(2) Each record described in 17 CFR 240.17a–3(a) (1), (2), (3), (5), (6), (7), (8), and (9);

(3) A record of each remittance or transfer of funds, or of currency, checks, other monetary instruments, investment securities, or credit, of more than $10,000 to a person, account, or place, outside the United States;

(4) A record of each receipt of currency, other monetary instruments, checks, or investment securities and of each transfer of funds or credit, of more than $10,000 received on any one occasion directly and not through a domestic financial institution, from any person, account or place outside the United States.

(Approved by the Office of Management and Budget under control number 1505–0063.)

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

§ 1023.500 General.

Brokers or dealers in securities are subject to the special information sharing procedures to deter money laundering and terrorist activity requirements set forth and cross referenced in this subpart. Brokers or dealers in securities should also refer to Subpart E of Part 1010 of this chapter for special information sharing procedures to deter money laundering and terrorist activity contained in that subpart which apply to brokers or dealers in securities.

§ 1023.520 Special information sharing procedures to deter money laundering and terrorist activity for brokers or dealers in securities.

(a) Refer to § 1010.520 of this chapter.

(b) [Reserved]

§ 1023.530 [Reserved]

§ 1023.540 Voluntary information sharing among financial institutions.

(a) Refer to § 1010.540 of this chapter.

(b) [Reserved]

Subpart F—Special Standards of Diligence; Prohibitions; and Special Measures for Brokers or Dealers in Securities

§ 1023.600 General.

Brokers or dealers in securities are subject to the special standards of diligence; prohibitions; and special measures requirements set forth and cross referenced in this subpart. Brokers or dealers in securities should also refer to Subpart F of Part 1010 of this chapter for special standards of diligence; prohibitions; and special measures contained in that subpart which apply to brokers or dealers in securities.

§ 1023.610 Due diligence programs for correspondent accounts for foreign financial institutions.

(a) Refer to § 1010.610 of this chapter.

(b) [Reserved]

§ 1023.620 Due diligence programs for private banking accounts.

(a) Refer to § 1010.620 of this chapter.

(b) [Reserved]

§ 1023.630 Prohibition on correspondent accounts for foreign shell banks; records concerning owners of foreign banks and agents for service of legal process.

(a) Refer to § 1010.630 of this chapter.

(b) [Reserved]

§ 1023.640 [Reserved]

§ 1023.670 Summons or subpoena of foreign bank records; Termination of correspondent relationship.

(a) Refer to § 1010.670 of this chapter.

(b) [Reserved]

PART 1024—RULES FOR MUTUAL FUNDS

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Subpart A—Definitions

§ 1024.100 Definitions.

Refer to § 1010.100 for general definitions not noted herein. To the extent there is a differing definition in § 1010.100 of this chapter, the definition in this Section is what applies to Part 1024. Unless otherwise indicated, for purposes of this Part:

(a) *Account.* For purposes of § 1024.220:

(1) *Account* means any contractual or other business relationship between a person and a mutual fund established to effect transactions in securities issued by the mutual fund, including the purchase or sale of securities.

(2) *Account* does not include:

(i) An account that a mutual fund acquires through any acquisition, merger, purchase of assets, or assumption of liabilities; or

(ii) An account opened for the purpose of participating in an employee benefit plan established under the Employee Retirement Income Security Act of 1974.

(b) *Commission* means the United States Securities and Exchange Commission.

(c) *Customer.* For purposes of § 1024.220:

(1) *Customer* means:

(i) A person that opens a new account; and

(ii) An individual who opens a new account for:

(A) An individual who lacks legal capacity, such as a minor; or

(B) An entity that is not a legal person, such as a civic club.

(2) *Customer* does not include:

(i) A financial institution regulated by a federal functional regulator or a bank regulated by a state bank regulator;

(ii) A person described in § 1020.315(b)(2) through (4) of this chapter; or

(iii) A person that has an existing account with the mutual fund, provided that the mutual fund has a reasonable belief that it knows the true identity of the person.

(d) *Financial institution* is defined at 31 U.S.C. 5312(a)(2) and (c)(1).

(e) *Mutual fund* means:

(1) For the purposes of § 1024.210, an open-end company as defined in section 5(a)(1) of the Investment Company act of 1940 (15 U.S.C. 80a–5(a)(1).

(2) For the purposes of § 1024.220, an ''investment company'' (as the term is

defined in section 3 of the Investment Company Act (15 U.S.C. 80a–3)) that is an ''open-end company'' (as that term is defined in section 5 of the Investment Company Act (15 U.S.C. 80a–5)) that is registered or is required to register with the Commission under section 8 of the Investment Company Act (15 U.S.C. 80a–8).

Subpart B—Programs

§ 1024.200 General.

Mutual funds are subject to the program requirements set forth and cross referenced in this subpart. Mutual funds should also refer to Subpart B of Part 1010 of this chapter for program requirements contained in that subpart which apply to mutual funds.

§ 1024.210 Anti-money laundering programs for mutual funds.

(a) Effective July 24, 2002, each mutual fund shall develop and implement a written anti-money laundering program reasonably designed to prevent the mutual fund from being used for money laundering or the financing of terrorist activities and to achieve and monitor compliance with the applicable requirements of the Bank Secrecy Act (31 U.S.C. 5311, *et seq.*), and the implementing regulations promulgated thereunder by the Department of the Treasury. Each mutual fund's anti-money laundering program must be approved in writing by its board of directors or trustees. A mutual fund shall make its anti-money laundering program available for inspection by the Commission.

(b) The anti-money laundering program shall at a minimum:

(1) Establish and implement policies, procedures, and internal controls reasonably designed to prevent the mutual fund from being used for money laundering or the financing of terrorist activities and to achieve compliance with the applicable provisions of the Bank Secrecy Act and the implementing regulations thereunder;

(2) Provide for independent testing for compliance to be conducted by the mutual fund's personnel or by a qualified outside party;

(3) Designate a person or persons responsible for implementing and monitoring the operations and internal controls of the program; and

(4) Provide ongoing training for appropriate persons.

§ 1024.220 Customer identification programs for mutual funds.

(a) *Customer identification program: minimum requirements*—(1) In general. A mutual fund must implement a written Customer Identification Program (''CIP'') appropriate for its size and type of business that, at a minimum, includes each of the requirements of paragraphs (a)(1) through (5) of this section. The CIP must be a part of the mutual fund's anti-money laundering program required under the regulations implementing 31 U.S.C. 5318(h).

(2) *Identity verification procedures.* The CIP must include risk-based procedures for verifying the identity of each customer to the extent reasonable and practicable. The procedures must enable the mutual fund to form a reasonable belief that it knows the true identity of each customer. The procedures must be based on the mutual fund's assessment of the relevant risks, including those presented by the manner in which accounts are opened, fund shares are distributed, and purchases, sales and exchanges are effected, the various types of accounts maintained by the mutual fund, the various types of identifying information available, and the mutual fund's customer base. At a minimum, these procedures must contain the elements described in this paragraph (a)(2).

(i) *Customer information required*—(A) *In general.* The CIP must contain procedures for opening an account that specify the identifying information that will be obtained with respect to each customer. Except as permitted by paragraph (a)(2)(i)(B) of this section, a mutual fund must obtain, at a minimum, the following information prior to opening an account:

(*1*) Name;

(*2*) Date of birth, for an individual;

(*3*) Address, which shall be:

(*i*) For an individual, a residential or business street address;

(*ii*) For an individual who does not have a residential or business street address, an Army Post Office (APO) or Fleet Post Office (FPO) box number, or the residential or business street address of next of kin or of another contact individual; or

(*iii*) For a person other than an individual (such as a corporation, partnership, or trust), a principal place of business, local office or other physical location; and

(*4*) Identification number, which shall be:

(*i*) For a U.S. person, a taxpayer identification number; or

(*ii*) For a non-U.S. person, one or more of the following: A taxpayer identification number; passport number and country of issuance; alien identification card number; or number and country of issuance of any other government-issued document evidencing nationality or residence and bearing a photograph or similar safeguard.

Note to Paragraph (a)(2)(i)(A)(*4*)(*ii*): When opening an account for a foreign business or enterprise that does not have an identification number, the mutual fund must request alternative government-issued documentation certifying the existence of the business or enterprise.

(B) *Exception for persons applying for a taxpayer identification number.* Instead of obtaining a taxpayer identification number from a customer prior to opening an account, the CIP may include procedures for opening an account for a person that has applied for, but has not received, a taxpayer identification number. In this case, the CIP must include procedures to confirm that the application was filed before the person opens the account and to obtain the taxpayer identification number within a reasonable period of time after the account is opened.

(ii) *Customer verification.* The CIP must contain procedures for verifying the identity of the customer, using the information obtained in accordance with paragraph (a)(2)(i) of this section, within a reasonable time after the account is opened. The procedures must describe when the mutual fund will use documents, non-documentary methods, or a combination of both methods as described in this paragraph (a)(2)(ii).

(A) *Verification through documents.* For a mutual fund relying on documents, the CIP must contain procedures that set forth the documents that the mutual fund will use. These documents may include:

(*1*) For an individual, unexpired government-issued identification evidencing nationality or residence and bearing a photograph or similar safeguard, such as a driver's license or passport; and

(*2*) For a person other than an individual (such as a corporation, partnership, or trust), documents showing the existence of the entity, such as certified articles of incorporation, a government-issued business license, a partnership agreement, or trust instrument.

(B) *Verification through non-documentary methods.* For a mutual fund relying on non-documentary methods, the CIP must contain procedures that describe the non-documentary methods the mutual fund will use.

(*1*) These methods may include contacting a customer; independently verifying the customer's identity through the comparison of information provided by the customer with information obtained from a consumer reporting agency, public database, or

other source; checking references with other financial institutions; and obtaining a financial statement.

(*2*) The mutual fund's non-documentary procedures must address situations where an individual is unable to present an unexpired government-issued identification document that bears a photograph or similar safeguard; the mutual fund is not familiar with the documents presented; the account is opened without obtaining documents; the customer opens the account without appearing in person; and where the mutual fund is otherwise presented with circumstances that increase the risk that the mutual fund will be unable to verify the true identity of a customer through documents.

(C) *Additional verification for certain customers*. The CIP must address situations where, based on the mutual fund's risk assessment of a new account opened by a customer that is not an individual, the mutual fund will obtain information about individuals with authority or control over such account, including persons authorized to effect transactions in the shareholder of record's account, in order to verify the customer's identity. This verification method applies only when the mutual fund cannot verify the customer's true identity using the verification methods described in paragraphs (a)(2)(ii)(A) and (B) of this section.

(iii) *Lack of verification*. The CIP must include procedures for responding to circumstances in which the mutual fund cannot form a reasonable belief that it knows the true identity of a customer. These procedures should describe:

(A) When the mutual fund should not open an account;

(B) The terms under which a customer may use an account while the mutual fund attempts to verify the customer's identity;

(C) When the mutual fund should file a Suspicious Activity Report in accordance with applicable law and regulation; and

(D) When the mutual fund should close an account, after attempts to verify a customer's identity have failed.

(3) *Recordkeeping*. The CIP must include procedures for making and maintaining a record of all information obtained under paragraph (a) of this section.

(i) *Required records*. At a minimum, the record must include:

(A) All identifying information about a customer obtained under paragraph (a)(2)(i) of this section;

(B) A description of any document that was relied on under paragraph (a)(2)(ii)(A) of this section noting the type of document, any identification number contained in the document, the place of issuance, and if any, the date of issuance and expiration date;

(C) A description of the methods and the results of any measures undertaken to verify the identity of the customer under paragraph (a)(2)(ii)(B) or (C) of this section; and

(D) A description of the resolution of any substantive discrepancy discovered when verifying the identifying information obtained.

(ii) *Retention of records*. The mutual fund must retain the information in paragraph (a)(3)(i)(A) of this section for five years after the date the account is closed. The mutual fund must retain the information in paragraphs (a)(3)(i)(B), (C), and (D) of this section for five years after the record is made.

(4) *Comparison with government lists*. The CIP must include procedures for determining whether the customer appears on any list of known or suspected terrorists or terrorist organizations issued by any federal government agency and designated as such by the Department of the Treasury in consultation with the federal functional regulators. The procedures must require the mutual fund to make such a determination within a reasonable period of time after the account is opened, or earlier, if required by another federal law or regulation or federal directive issued in connection with the applicable list. The procedures must also require the mutual fund to follow all federal directives issued in connection with such lists.

(5)(i) *Customer notice*. The CIP must include procedures for providing mutual fund customers with adequate notice that the mutual fund is requesting information to verify their identities.

(ii) *Adequate notice*. Notice is adequate if the mutual fund generally describes the identification requirements of this section and provides the notice in a manner reasonably designed to ensure that a customer is able to view the notice, or is otherwise given notice, before opening an account. For example, depending on the manner in which the account is opened, a mutual fund may post a notice on its Web site, include the notice on its account applications, or use any other form of written or oral notice.

(iii) *Sample notice*. If appropriate, a mutual fund may use the following sample language to provide notice to its customers:

Important Information About Procedures for Opening a New Account

To help the government fight the funding of terrorism and money laundering activities, Federal law requires all financial institutions to obtain, verify, and record information that identifies each person who opens an account.

What this means for you: When you open an account, we will ask for your name, address, date of birth, and other information that will allow us to identify you. We may also ask to see your driver's license or other identifying documents.

(6) *Reliance on other financial institutions*. The CIP may include procedures specifying when a mutual fund will rely on the performance by another financial institution (including an affiliate) of any procedures of the mutual fund's CIP, with respect to any customer of the mutual fund that is opening, or has opened, an account or has established a similar formal business relationship with the other financial institution to provide or engage in services, dealings, or other financial transactions, provided that:

(i) Such reliance is reasonable under the circumstances;

(ii) The other financial institution is subject to a rule implementing 31 U.S.C. 5318(h) and is regulated by a federal functional regulator; and

(iii) The other financial institution enters into a contract requiring it to certify annually to the mutual fund that it has implemented its anti-money laundering program, and that it (or its agent) will perform the specific requirements of the mutual fund's CIP.

(b) *Exemptions*. The Commission, with the concurrence of the Secretary, may, by order or regulation, exempt any mutual fund or type of account from the requirements of this section. The Commission and the Secretary shall consider whether the exemption is consistent with the purposes of the Bank Secrecy Act and is in the public interest, and may consider other appropriate factors.

(c) *Other requirements unaffected*. Nothing in this section relieves a mutual fund of its obligation to comply with any other provision in this chapter, including provisions concerning information that must be obtained, verified, or maintained in connection with any account or transaction.

Subpart C—Reports Required To Be Made by Mutual Funds

§ 1024.300 General.

Mutual funds are subject to the reporting requirements set forth and cross referenced in this subpart. Mutual funds should also refer to Subpart C of Part 1010 of this chapter for reporting requirements contained in that subpart which apply to mutual funds.

§ 1024.310 [Reserved]

§ 1024.315 [Reserved]

§ 1024.320 Reports by mutual funds of suspicious transactions.

(a) *General*. (1) Every investment company (as defined in section 3 of the Investment Company Act of 1940 (15 U.S.C. 80a–3) (''Investment Company Act'') that is an open-end company (as defined in section 5 of the Investment Company Act (15 U.S.C. 80a–5)) and that is registered, or is required to register, with the Securities and Exchange Commission pursuant to that Act (for purposes of this section, a ''mutual fund''), shall file with the Financial Crimes Enforcement Network, to the extent and in the manner required by this section, a report of any suspicious transaction relevant to a possible violation of law or regulation. A mutual fund may also file with the Financial Crimes Enforcement Network a report of any suspicious transaction that it believes is relevant to the possible violation of any law or regulation, but whose reporting is not required by this section. Filing a report of a suspicious transaction does not relieve a mutual fund from the responsibility of complying with any other reporting requirements imposed by the Securities and Exchange Commission.

(2) A transaction requires reporting under this section if it is conducted or attempted by, at, or through a mutual fund, it involves or aggregates funds or other assets of at least $5,000, and the mutual fund knows, suspects, or has reason to suspect that the transaction (or a pattern of transactions of which the transaction is a part):

(i) Involves funds derived from illegal activity or is intended or conducted in order to hide or disguise funds or assets derived from illegal activity (including, without limitation, the ownership, nature, source, location, or control of such funds or assets) as part of a plan to violate or evade any Federal law or regulation or to avoid any transaction reporting requirement under Federal law or regulation;

(ii) Is designed, whether through structuring or other means, to evade any requirements of this chapter or any other regulations promulgated under the Bank Secrecy Act;

(iii) Has no business or apparent lawful purpose or is not the sort in which the particular customer would normally be expected to engage, and the mutual fund knows of no reasonable explanation for the transaction after examining the available facts, including the background and possible purpose of the transaction; or

(iv) Involves use of the mutual fund to facilitate criminal activity.

(3) More than one mutual fund may have an obligation to report the same transaction under this section, and other financial institutions may have separate obligations to report suspicious activity with respect to the same transaction pursuant to other provisions of this chapter. In those instances, no more than one report is required to be filed by the mutual fund(s) and other financial institution(s) involved in the transaction, provided that the report filed contains all relevant facts, including the name of each financial institution and the words ''joint filing'' in the narrative section, and each institution maintains a copy of the report filed, along with any supporting documentation.

(b) *Filing and notification procedures*—(1) *What to file*. A suspicious transaction shall be reported by completing a Suspicious Activity Report by Securities and Futures Industries (''SAR–SF''), and collecting and maintaining supporting documentation as required by paragraph (c) of this section.

(2) *Where to file*. Form SAR–SF shall be filed with the Financial Crimes Enforcement Network in accordance with the instructions to the Form SAR–SF.

(3) *When to file*. A Form SAR–SF shall be filed no later than 30 calendar days after the date of the initial detection by the reporting mutual fund of facts that may constitute a basis for filing a Form SAR–SF under this section. If no suspect is identified on the date of such initial detection, a mutual fund may delay filing a Form SAR–SF for an additional 30 calendar days to identify a suspect, but in no case shall reporting be delayed more than 60 calendar days after the date of such initial detection.

(4) *Mandatory notification to law enforcement*. In situations involving violations that require immediate attention, such as suspected terrorist financing or ongoing money laundering schemes, a mutual fund shall immediately notify by telephone an appropriate law enforcement authority in addition to filing timely a Form SAR–SF.

(5) *Voluntary notification to the Financial Crimes Enforcement Network or the Securities and Exchange Commission*. Mutual funds wishing voluntarily to report suspicious transactions that may relate to terrorist activity may call the Financial Crimes Enforcement Network's Financial Institutions Hotline at 1–866–556–3974 in addition to filing timely a Form SAR–SF if required by this section. The mutual fund may also, but is not required to, contact the Securities and Exchange Commission to report in such situations.

(c) *Retention of records*. A mutual fund shall maintain a copy of any Form SAR–SF filed by the fund or on its behalf (including joint reports), and the original (or business record equivalent) of any supporting documentation concerning any Form SAR–SF that it files (or is filed on its behalf), for a period of five years from the date of filing the Form SAR–SF. Supporting documentation shall be identified as such and maintained by the mutual fund, and shall be deemed to have been filed with the Form SAR–SF. The mutual fund shall make all supporting documentation available to the Financial Crimes Enforcement Network, any other appropriate law enforcement agencies or federal or state securities regulators, and for purposes of an examination of a broker-dealer pursuant to § 1023.320(g) regarding a joint report, to a self-regulatory organization (as defined in section 3(a)(26) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(26)) registered with the Securities and Exchange Commission, upon request.

(d) *Confidentiality of reports*. No mutual fund, and no director, officer, employee, or agent of any mutual fund, who reports a suspicious transaction under this chapter (whether such a report is required by this section or made voluntarily), may notify any person involved in the transaction that the transaction has been reported, except to the extent permitted by paragraph (a)(3) of this section. Any person subpoenaed or otherwise required to disclose a Form SAR–SF or the information contained in a Form SAR–SF, including a Form SAR–SF filed jointly with another financial institution involved in the same transaction (except where such disclosure is requested by the Financial Crimes Enforcement Network, the Securities and Exchange Commission, another appropriate law enforcement or regulatory agency, or, in the case of a joint report involving a broker-dealer, a self-regulatory organization registered with the Securities and Exchange Commission conducting an examination of such broker-dealer pursuant to § 1023.320(g)), shall decline to produce Form SAR–SF or to provide any information that would disclose that a Form SAR–SF has been prepared or filed, citing this paragraph (d) and 31 U.S.C. 5318(g)(2), and shall notify the Financial Crimes Enforcement Network

of any such request and its response thereto.

(e) *Limitation of liability*. A mutual fund, and any director, officer, employee, or agent of such mutual fund, that makes a report of any possible violation of law or regulation pursuant to this section, including a joint report (whether such report is required by this section or made voluntarily) shall be protected from liability for any disclosure contained in, or for failure to disclose the fact of, such report, or both, to the extent provided in 31 U.S.C. 5318(g)(3).

(f) *Examinations and enforcement*. Compliance with this section shall be examined by the Department of the Treasury, through the Financial Crimes Enforcement Network or its delegees, under the terms of the Bank Secrecy Act. Failure to satisfy the requirements of this section may constitute a violation of the reporting rules of the Bank Secrecy Act and of this chapter.

(g) *Applicability date*. This section applies to transactions occurring after October 31, 2006.

§ 1024.330 Reports relating to currency in excess of $10,000 received in a trade or business.

Refer to § 1010.330 of this chapter for rules regarding the filing of reports relating to currency in excess of $10,000 received by mutual funds.

Subpart D—Records Required To Be Maintained by Mutual Funds

§ 1024.400 General.

Mutual funds are subject to the recordkeeping requirements set forth and cross referenced in this subpart. Mutual funds should also refer to Subpart D of Part 1010 of this chapter for recordkeeping requirements contained in that subpart which apply to mutual funds.

§ 1024.410 Recordkeeping.

Refer to § 1010.410 of this chapter.

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

§ 1024.500 General.

Mutual funds are subject to the special information sharing procedures to deter money laundering and terrorist activity requirements set forth and cross referenced in this subpart. Mutual funds should also refer to Subpart E of Part 1010 of this chapter for special information sharing procedures to deter money laundering and terrorist activity contained in that subpart which apply to mutual funds.

§ 1024.520 Special information sharing procedures to deter money laundering and terrorist activity for mutual funds.

(a) Refer to § 1010.520 of this chapter.

(b) [Reserved]

§ 1024.530 [Reserved]

§ 1024.540 Voluntary information sharing among financial institutions.

(a) Refer to § 1010.540 of this chapter.

(b) [Reserved]

Subpart F—Special Standards of Diligence; Prohibitions; and Special Measures for Mutual Funds

§ 1024.600 General.

Mutual funds are subject to the special standards of diligence; prohibitions; and special measures requirements set forth and cross referenced in this subpart. Mutual funds should also refer to Subpart F of Part 1010 of this chapter for special standards of diligence; prohibitions; and special measures contained in that subpart which apply to mutual funds.

§ 1024.610 Due diligence programs for correspondent accounts for foreign financial institutions.

(a) Refer to § 1010.610 of this chapter.

(b) [Reserved]

§ 1024.620 Due diligence programs for private banking accounts.

(a) Refer to § 1010.620 of this chapter.

(b) [Reserved]

§ 1024.630 Prohibition on correspondent accounts for foreign shell banks; records concerning owners of foreign banks and agents for service of legal process.

(a) Refer to § 1010.630 of this chapter.

(b) [Reserved]

§ 1024.640 [Reserved]

§ 1024.670 [Reserved]

PART 1025—RULES FOR INSURANCE COMPANIES

Subpart A—Definitions

Sec.
1025.100 Definitions.

Subpart B—Programs

1025.200 General.
1025.210 Anti-money laundering programs for insurance companies.

Subpart C—Reports Required To Be Made by Insurance Companies

1025.300 General.
1025.310 [Reserved]
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1025.320 Reports by insurance companies of suspicious transactions.
1025.330 Reports relating to currency in excess of $10,000 received in a trade or business.

Subpart D—Records Required To Be Maintained by Insurance Companies

1025.400 General.
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Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

1025.500 General.
1025.520 Special information sharing procedures to deter money laundering and terrorist activity for insurance companies.
1025.530 [Reserved]
1025.540 Voluntary information sharing among financial institutions.

Subpart F—Special Standards of Diligence; Prohibitions, and Special Measures for Insurance Companies

1025.600 [Reserved]
1025.610 [Reserved]
1025.620 [Reserved]
1025.630 [Reserved]
1025.640 [Reserved]
1025.670 [Reserved]

Subpart A—Definitions

§ 1025.100 Definitions.

Refer to § 1010.100 for general definitions not noted herein. To the extent there is a differing definition in § 1010.100 of this chapter, the definition in this Section is what applies to Part 1025. Unless otherwise indicated, for purposes of this Part:

(a) *Annuity contract* means any agreement between the insurer and the contract owner whereby the insurer promises to pay out a fixed or variable income stream for a period of time.

(b) *Covered product* means:

(1) A permanent life insurance policy, other than a group life insurance policy;

(2) An annuity contract, other than a group annuity contract; or

(3) Any other insurance product with features of cash value or investment.

(c) *Group annuity contract* means a master contract providing annuities to a group of persons under a single contract.

(d) *Group life insurance policy* means any life insurance policy under which a number of persons and their dependents, if appropriate, are insured under a single policy.

(e) *Insurance agent* means a sales and/or service representative of an insurance company. The term ''insurance agent'' encompasses any person that sells, markets, distributes, or services an insurance company's covered products, including, but not limited to, a person who represents only one insurance company, a person who represents more than one insurance company, and a bank or broker-dealer in securities that sells any covered product of an insurance company.

(f) *Insurance broker* means a person who, by acting as the customer's representative, arranges and/or services covered products on behalf of the customer.

(g) *Insurance company or insurer.* (1) Except as provided in paragraph (g)(2) of this section, the term ''insurance company'' or ''insurer'' means any person engaged within the United States as a business in the issuing or underwriting of any covered product.

(2) The term ''insurance company'' or ''insurer'' does not include an insurance agent or insurance broker.

(h) *Permanent life insurance policy* means an agreement that contains a cash value or investment element and that obligates the insurer to indemnify or to confer a benefit upon the insured or beneficiary to the agreement contingent upon the death of the insured.

Subpart B—Programs

§ 1025.200 General.

Insurance companies are subject to the program requirements set forth and cross referenced in this subpart. Insurance companies should also refer to Subpart B of Part 1010 of this chapter for program requirements contained in that subpart which apply to insurance companies.

§ 1025.210 Anti-money laundering programs for insurance companies.

(a) *In general.* Not later than May 2, 2006, each insurance company shall develop and implement a written anti-money laundering program applicable to its covered products that is reasonably designed to prevent the insurance company from being used to facilitate money laundering or the financing of terrorist activities. The program must be approved by senior management. An insurance company shall make a copy of its anti-money laundering program available to the Department of the Treasury, the Financial Crimes Enforcement Network, or their designee upon request.

(b) *Minimum requirements.* At a minimum, the program required by paragraph (a) of this section shall:

(1) Incorporate policies, procedures, and internal controls based upon the insurance company's assessment of the money laundering and terrorist financing risks associated with its covered products. Policies, procedures, and internal controls developed and implemented by an insurance company under this section shall include provisions for complying with the applicable requirements of subchapter II of chapter 53 of title 31, United States Code and this chapter, integrating the company's insurance agents and insurance brokers into its anti-money laundering program, and obtaining all relevant customer-related information necessary for an effective anti-money laundering program.

(2) Designate a compliance officer who will be responsible for ensuring that:

(i) The anti-money laundering program is implemented effectively, including monitoring compliance by the company's insurance agents and insurance brokers with their obligations under the program;

(ii) The anti-money laundering program is updated as necessary; and

(iii) Appropriate persons are educated and trained in accordance with paragraph (b)(3) of this section.

(3) Provide for on-going training of appropriate persons concerning their responsibilities under the program. An insurance company may satisfy this requirement with respect to its employees, insurance agents, and insurance brokers by directly training such persons or verifying that persons have received training by another insurance company or by a competent third party with respect to the covered products offered by the insurance company.

(4) Provide for independent testing to monitor and maintain an adequate program, including testing to determine compliance of the company's insurance agents and insurance brokers with their obligations under the program. The scope and frequency of the testing shall be commensurate with the risks posed by the insurance company's covered products. Such testing may be conducted by a third party or by any officer or employee of the insurance company, other than the person designated in paragraph (b)(2) of this section.

(c) *Anti-money laundering program requirements for insurance companies registered or required to register with the Securities and Exchange Commission as broker-dealers in securities.* An insurance company that is registered or required to register with the Securities and Exchange Commission as a broker-dealer in securities shall be deemed to have satisfied the requirements of this section for its broker-dealer activities to the extent that the company is required to establish and has established an anti-money laundering program pursuant to § 1023.210 of this chapter and complies with such program.

(d) *Compliance.* Compliance with this section shall be examined by the Department of the Treasury, through the Financial Crimes Enforcement Network or its delegees, under the terms of the Bank Secrecy Act. Failure to comply with the requirements of this section may constitute a violation of the Bank Secrecy Act and of this chapter.

Subpart C—Reports Required To Be Made by Insurance Companies

§ 1025.300 General.

Insurance companies are subject to the reporting requirements set forth and cross referenced in this subpart. Insurance companies should also refer to Subpart C of Part 1010 of this chapter for reporting requirements contained in that subpart which apply to insurance companies.

§ 1025.310 [Reserved]

§ 1025.315 [Reserved]

§ 1025.320 Reports by insurance companies of suspicious transactions.

(a) *General.* (1) Each insurance company shall file with the Financial Crimes Enforcement Network, to the extent and in the manner required by this section, a report of any suspicious transaction involving a covered product that is relevant to a possible violation of law or regulation. An insurance company may also file with the Financial Crimes Enforcement Network by using the form specified in paragraph (b)(1) of this section or otherwise, a report of any suspicious transaction that it believes is relevant to the possible violation of any law or regulation but the reporting of which is not required by this section.

(2) A transaction requires reporting under this section if it is conducted or attempted by, at, or through an insurance company, and involves or aggregates at least $5,000 in funds or other assets, and the insurance company knows, suspects, or has reason to suspect that the transaction (or a pattern of transactions of which the transaction is a part):

(i) Involves funds derived from illegal activity or is intended or conducted in order to hide or disguise funds or assets derived from illegal activity (including, without limitation, the ownership, nature, source, location, or control of such funds or assets) as part of a plan to violate or evade any federal law or regulation or to avoid any transaction reporting requirement under federal law or regulation;

(ii) Is designed, whether through structuring or other means, to evade any requirements of this chapter or of any other regulations promulgated under the Bank Secrecy Act;

(iii) Has no business or apparent lawful purpose or is not the sort in which the particular customer would

normally be expected to engage, and the insurance company knows of no reasonable explanation for the transaction after examining the available facts, including the background and possible purpose of the transaction; or

(iv) Involves use of the insurance company to facilitate criminal activity.

(3)(i) An insurance company is responsible for reporting suspicious transactions conducted through its insurance agents and insurance brokers. Accordingly, an insurance company shall establish and implement policies and procedures reasonably designed to obtain customer-related information necessary to detect suspicious activity from all relevant sources, including from its insurance agents and insurance brokers, and shall report suspicious activity based on such information.

(ii) Certain insurance agents may have a separate obligation to report suspicious activity pursuant to other provisions of this chapter. In those instances, no more than one report is required to be filed by the financial institutions involved in the transaction, as long as the report filed contains all relevant facts, including the names of both institutions and the words ''joint filing'' in the narrative section, and both institutions maintain a copy of the report filed, along with any supporting documentation.

(iii) An insurance company that issues variable insurance products funded by separate accounts that meet the definition of a mutual fund in § 1024.320(a)(1) of this chapter shall file reports of suspicious transactions pursuant to § 1024.320.

(b) *Filing procedures*—(1) *What to file.* A suspicious transaction shall be reported by completing a Suspicious Activity Report by Insurance Companies (SAR–IC), and collecting and maintaining supporting documentation as required by paragraph (d) of this section.

(2) *Where to file.* The SAR–IC shall be filed with the Financial Crimes Enforcement Network as indicated in the instructions to the SAR–IC.

(3) *When to file.* A SAR–IC shall be filed no later than 30 calendar days after the date of the initial detection by the insurance company of facts that may constitute a basis for filing a SAR–IC under this section. If no suspect is identified on the date of such initial detection, an insurance company may delay filing a SAR–IC for an additional 30 calendar days to identify a suspect, but in no case shall reporting be delayed more than 60 calendar days after the date of such initial detection. In situations that require immediate attention, such as terrorist financing or ongoing money laundering schemes, the insurance company shall immediately notify by telephone an appropriate law enforcement authority in addition to filing timely a SAR–IC. Insurance companies wishing voluntarily to report suspicious transactions that may relate to terrorist activity may call the Financial Crimes Enforcement Network's Financial Institutions Hotline at 1–866–556–3974 in addition to filing timely a SAR–IC if required by this section.

(c) *Exception.* An insurance company is not required to file a SAR–IC to report the submission to it of false or fraudulent information to obtain a policy or make a claim, unless the company has reason to believe that the false or fraudulent submission relates to money laundering or terrorist financing.

(d) *Retention of records.* An insurance company shall maintain a copy of any SAR–IC filed and the original or business record equivalent of any supporting documentation for a period of five years from the date of filing the SAR–IC. Supporting documentation shall be identified as such and maintained by the insurance company and shall be deemed to have been filed with the SAR–IC. When an insurance company has filed or is identified as a filer in a joint Suspicious Activity Report, the insurance company shall maintain a copy of such joint report (together with copies of any supporting documentation) for a period of five years from the date of filing. An insurance company shall make all supporting documentation available to the Financial Crimes Enforcement Network and any other appropriate law enforcement agencies or supervisory agencies upon request.

(e) *Confidentiality of reports; limitation of liability.* No insurance company, and no director, officer, employee, agent, or broker of any insurance company, who reports a suspicious transaction under this chapter (whether such a report is required by this section or made voluntarily), may notify any person involved in the transaction that the transaction has been reported, except to the extent permitted by paragraph (a)(3) of this section. Thus, any insurance company subpoenaed or otherwise requested to disclose a SAR–IC or the information contained in a SAR–IC (or a copy of a joint Suspicious Activity Report filed with another financial institution involved in the same transaction, including an insurance agent), except where such disclosure is requested by the Financial Crimes Enforcement Network or another appropriate law enforcement or supervisory agency, shall decline to produce the Suspicious Activity Report or to provide any information that would disclose that a Suspicious Activity Report has been prepared or filed, citing as authority 31 CFR 1025.320 and 31 U.S.C. 5318(g)(2), and shall notify the Financial Crimes Enforcement Network of any such request and its response thereto. An insurance company, and any director, officer, employee, agent, or broker of such insurance company, that makes a report pursuant to this section, including a joint report (whether such report is required by this section or made voluntarily) shall be protected from liability for any disclosure contained in, or for failure to disclose the fact of, such report, or both, to the extent provided by 31 U.S.C. 5318(g)(3).

(f) *Compliance.* Compliance with this section shall be examined by the Department of the Treasury, through the Financial Crimes Enforcement Network or its delegees, under the terms of the Bank Secrecy Act. Failure to comply with the requirements of this section may constitute a violation of the reporting rules of the Bank Secrecy Act and of this chapter.

(g) *Suspicious transaction reporting requirements for insurance companies registered or required to register with the Securities and Exchange Commission as broker-dealers in securities.* An insurance company that is registered or required to register with the Securities and Exchange Commission as a broker-dealer in securities shall be deemed to have satisfied the requirements of this section for its broker-dealer activities to the extent that the company complies with the reporting requirements applicable to such activities pursuant to § 1023.320 of this chapter.

(h) *Applicability date.* This section applies to transactions occurring after May 2, 2006.

§ 1025.330 Reports relating to currency in excess of $10,000 received in a trade or business.

Refer to § 1010.330 of this chapter for rules regarding the filing of reports relating to currency in excess of $10,000 received by insurance companies.

Subpart D—Records Required To Be Maintained by Insurance Companies

§ 1025.400 General.

Insurance companies are subject to the recordkeeping requirements set forth and cross referenced in this subpart. Insurance companies should also refer to Subpart D of Part 1010 of this chapter for recordkeeping requirements contained in that subpart which apply to insurance companies.

§ 1025.410 Recordkeeping.

Refer to § 1010.410 of this chapter.

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

§ 1025.500 General.

Insurance companies are subject to the special information sharing procedures to deter money laundering and terrorist activity requirements set forth and cross referenced in this subpart. Insurance companies should also refer to Subpart E of Part 1010 of this chapter for special information sharing procedures to deter money laundering and terrorist activity contained in that subpart which apply to insurance companies.

§ 1025.520 Special information sharing procedures to deter money laundering and terrorist activity for insurance companies.

(a) Refer to § 1010.520 of this chapter.

(b) [Reserved]

§ 1025.530 [Reserved]

§ 1025.540 Voluntary information sharing among financial institutions.

(a) Refer to § 1010.540 of this chapter.

(b) [Reserved]

Subpart F—Special Standards of Diligence; Prohibitions; and Special Measures for Insurance Companies

§ 1025.600 [Reserved]

§ 1025.610 [Reserved]

§ 1025.620 [Reserved]

§ 1025.630 [Reserved]

§ 1025.640 [Reserved]

§ 1025.670 [Reserved]

PART 1026—RULES FOR FUTURES COMMISSION MERCHANTS AND INTRODUCING BROKERS IN COMMODITIES

Subpart A—Definitions

Sec.

1026.100 Definitions.

Subpart B—Programs

1026.200 General.

1026.210 Anti-money laundering program requirements for futures commission merchants and introducing brokers in commodities.

1026.220 Customer identification program requirements for futures commission merchants and introducing brokers.

Subpart C—Reports Required To Be Made by Futures Commission Merchants and Introducing Brokers in Commodities

1026.300 General.

1026.310 Reports of transactions in currency.

1026.315 Exemptions.

1026.320 Reports by futures commission merchants and introducing brokers in commodities of suspicious transactions.

Subpart D—Records Required To Be Maintained by Futures Commission Merchants and Introducing Brokers in Commodities

1026.400 General.

1026.410 Recordkeeping.

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

1026.500 General.

1026.520 Special information sharing procedures to deter money laundering and terrorist activity for futures commission merchants and introducing brokers in commodities.

1026.530 [Reserved]

1026.540 Voluntary information sharing among financial institutions.

Subpart F—Special Standards of Diligence; Prohibitions, and Special Measures for Futures Commission Merchants and Introducing Brokers in Commodities

1026.600 General.

1026.610 Due diligence programs for correspondent accounts for foreign financial institutions.

1026.620 Due diligence programs for private banking accounts.

1026.630 Prohibition on correspondent accounts for foreign shell banks; records concerning owners of foreign banks and agents for service of legal process.

1026.640 [Reserved]

1026.670 Summons or subpoena of foreign bank records; Termination of correspondent relationship.

Subpart A—Definitions

§ 1026.100 Definitions.

Refer to § 1010.100 of this chapter for general definitions not noted herein. To the extent there is a differing definition in § 1010.100 of this chapter, the definition in this Section is what applies to Part 1026. Unless otherwise indicated, for the purposes of this Part:

(a) *Account.* For purposes of § 1026.220:

(1) *Account* means a formal relationship with a futures commission merchant, including, but not limited to, those established to effect transactions in contracts of sale of a commodity for future delivery, options on any contract of sale of a commodity for future delivery, or options on a commodity.

(2) *Account* does not include:

(i) An account that the futures commission merchant acquires through any acquisition, merger, purchase of assets, or assumption of liabilities; or

(ii) An account opened for the purpose of participating in an employee benefit plan established under the Employee Retirement Income Security Act of 1974.

(b) *Commodity* means any good, article, service, right, or interest described in Section 1a(4) of the Commodity Exchange Act (7 U.S.C. 1a(4)).

(c) *Contract of sale* means any sale, agreement of sale or agreement to sell as described in Section 1a(7) of the Commodity Exchange Act (7 U.S.C. 1a(7)).

(d) For purposes of § 1026.220:

(1) *Customer* means:

(i) A person that opens a new account with a futures commission merchant; and

(ii) An individual who opens a new account with a futures commission merchant for:

(A) An individual who lacks legal capacity; or

(B) An entity that is not a legal person.

(2) *Customer* does not include:

(i) A financial institution regulated by a Federal functional regulator or a bank regulated by a state bank regulator;

(ii) A person described in § 1020.315(b)(2) through (4) of this chapter; or

(iii) A person that has an existing account, provided the futures commission merchant or introducing broker has a reasonable belief that it knows the true identity of the person.

(3) When an account is introduced to a futures commission merchant by an introducing broker, the person or individual opening the account shall be deemed to be a *customer* of both the futures commission merchant and the introducing broker for the purposes of this section.

(e) *Financial institution* is defined at 31 U.S.C. 5312(a)(2) and (c)(1).

(f) *Futures commission merchant* means any person registered or required to be registered as a futures commission merchant with the Commodity Futures Trading Commission (''CFTC'') under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*), except persons who register pursuant to Section 4f(a)(2) of the Commodity Exchange Act (7 U.S.C. 6f(a)(2)).

(g) *Introducing broker* means any person registered or required to be registered as an introducing broker with the CFTC under the Commodity Exchange Act (7 U.S.C. 1 *et seq.*), except persons who register pursuant to Section 4f(a)(2) of the Commodity Exchange Act (7 U.S.C. 6f(a)(2)).

(h) *Option* means an agreement, contract or transaction described in Section 1a(26) of the Commodity Exchange Act (7 U.S.C. 1a(26)).

Subpart B—Programs

§ 1026.200 General.

Futures commission merchants and introducing brokers in commodities are subject to the program requirements set forth and cross referenced in this subpart. Futures commission merchants and introducing brokers in commodities should also refer to Subpart B of Part 1010 of this chapter for program requirements contained in that subpart which apply to futures commission merchants and introducing brokers in commodities.

§ 1026.210 Anti-money laundering program requirements for futures commission merchants and introducing brokers in commodities.

A financial institution regulated by a self-regulatory organization shall be deemed to satisfy the requirements of 31 U.S.C. 5318(h)(1) if:

(a) The financial institution complies with the requirements of §§ 1010.610 and 1010.620 of this chapter and any applicable regulation of its Federal functional regulator governing the establishment and implementation of anti-money laundering programs; and

(b)(1) The financial institution implements and maintains an anti-money laundering program that complies with the rules, regulations, or requirements of its self-regulatory organization governing such programs; and

(2) The rules, regulations, or requirements of the self-regulatory organization have been approved, if required, by the appropriate Federal functional regulator.

§ 1026.220 Customer identification programs for futures commission merchants and introducing brokers.

(a) *Customer identification program: minimum requirements*—(1) *In general.* Each futures commission merchant and introducing broker must implement a written Customer Identification Program (CIP) appropriate for its size and business that, at a minimum, includes each of the requirements of paragraphs (a)(1) through (a)(5) of this section. The CIP must be a part of each futures commission merchant's and introducing broker's anti-money laundering compliance program required under 31 U.S.C. 5318(h).

(2) *Identity verification procedures.* The CIP must include risk-based procedures for verifying the identity of each customer to the extent reasonable and practicable. The procedures must enable each futures commission merchant and introducing broker to form a reasonable belief that it knows the true identity of each customer. The procedures must be based on the futures commission merchant's or introducing broker's assessment of the relevant risks, including those presented by the various types of accounts maintained, the various methods of opening accounts, the various types of identifying information available, and the futures commission merchant's or introducing broker's size, location and customer base. At a minimum, these procedures must contain the elements described in paragraph (a)(2) of this section.

(i)(A) *Customer information required.* The CIP must include procedures for opening an account that specify identifying information that will be obtained from each customer. Except as permitted by paragraph (a)(2)(i)(B) of this section, each futures commission merchant and introducing broker must obtain, at a minimum, the following information prior to opening an account:

(*1*) Name;

(*2*) Date of birth, for an individual;

(*3*) Address, which shall be:

(*i*) For an individual, a residential or business street address;

(*ii*) For an individual who does not have a residential or business street address, an Army Post Office (APO) or Fleet Post Office (FPO) box number, or the residential or business street address of a next of kin or another contact individual; or

(*iii*) For a person other than an individual (such as a corporation, partnership or trust), a principal place of business, local office or other physical location; and

(*4*) Identification number, which shall be:

(*i*) For a U.S. person, a taxpayer identification number; or

(*ii*) For a non-U.S. person, one or more of the following: a taxpayer identification number, a passport number and country of issuance, an alien identification card number, or the number and country of issuance of any other government-issued document evidencing nationality or residence and bearing a photograph or similar safeguard.

Note to Paragraph (a)(2)(i)(A)(*4*)(*ii*): When opening an account for a foreign business or enterprise that does not have an identification number, the futures commission merchant or introducing broker must request alternative government-issued documentation certifying the existence of the business or enterprise.

(B) *Exception for persons applying for a taxpayer identification number.* Instead of obtaining a taxpayer identification number from a customer prior to opening an account, the CIP may include procedures for opening an account for a customer that has applied for, but has not received, a taxpayer identification number. In this case, the CIP must include procedures to confirm that the application was filed before the customer opens the account and to obtain the taxpayer identification number within a reasonable period of time after the account is opened.

(ii) *Customer verification.* The CIP must contain procedures for verifying the identity of each customer, using information obtained in accordance with paragraph (a)(2)(i) of this section, within a reasonable time before or after the customer's account is opened. The procedures must describe when the futures commission merchant or introducing broker will use documents, non-documentary methods, or a combination of both methods, as described in this paragraph (a)(2)(ii).

(A) *Verification through documents.* For a futures commission merchant or introducing broker relying on documents, the CIP must contain procedures that set forth the documents the futures commission merchant or introducing broker will use. These documents may include:

(*1*) For an individual, an unexpired government-issued identification evidencing nationality or residence and bearing a photograph or similar safeguard, such as a driver's license or passport; and

(*2*) For a person other than an individual (such as a corporation, partnership or trust), documents showing the existence of the entity, such as certified articles of incorporation, a government-issued business license, a partnership agreement, or a trust instrument.

(B) *Verification through non-documentary methods.* For a futures commission merchant or introducing broker relying on non-documentary methods, the CIP must contain procedures that set forth the non-documentary methods the futures commission merchant or introducing broker will use.

(*1*) These methods may include contacting a customer; independently verifying the customer's identity through the comparison of information provided by the customer with information obtained from a consumer reporting agency, public database, or other source; checking references with other financial institutions; or obtaining a financial statement.

(*2*) The futures commission merchant's or introducing broker's non-documentary procedures must address situations where an individual is unable to present an unexpired government-

issued identification document that bears a photograph or similar safeguard; the futures commission merchant or introducing broker is not familiar with the documents presented; the account is opened without obtaining documents; the customer opens the account without appearing in person at the futures commission merchant or introducing broker; and where the futures commission merchant or introducing broker is otherwise presented with circumstances that increase the risk that the futures commission merchant or introducing broker will be unable to verify the true identity of a customer through documents.

(C) *Additional verification for certain customers.* The CIP must address situations where, based on the futures commission merchant's or introducing broker's risk assessment of a new account opened by a customer that is not an individual, the futures commission merchant or introducing broker will obtain information about individuals with authority or control over such account in order to verify the customer's identity. This verification method applies only when the futures commission merchant or introducing broker cannot verify the customer's true identity after using the verification methods described in paragraphs (a)(2)(ii)(A) and (B) of this section.

(iii) *Lack of verification.* The CIP must include procedures for responding to circumstances in which the futures commission merchant or introducing broker cannot form a reasonable belief that it knows the true identity of a customer. These procedures should describe:

(A) When an account should not be opened;

(B) The terms under which a customer may conduct transactions while the futures commission merchant or introducing broker attempts to verify the customer's identity;

(C) When an account should be closed after attempts to verify a customer's identity have failed; and

(D) When the futures commission merchant or introducing broker should file a Suspicious Activity Report in accordance with applicable law and regulation.

(3) *Recordkeeping.* The CIP must include procedures for making and maintaining a record of all information obtained under procedures implementing paragraph (a) of this section.

(i) *Required records.* At a minimum, the record must include:

(A) All identifying information about a customer obtained under paragraph (a)(2)(i) of this section;

(B) A description of any document that was relied on under paragraph (a)(2)(ii)(A) of this section noting the type of document, any identification number contained in the document, the place of issuance, and if any, the date of issuance and expiration date;

(C) A description of the methods and the results of any measures undertaken to verify the identity of a customer under paragraphs (a)(2)(ii)(B) and (C) of this section; and

(D) A description of the resolution of each substantive discrepancy discovered when verifying the identifying information obtained.

(ii) *Retention of records.* Each futures commission merchant and introducing broker must retain the records made under paragraph (a)(3)(i)(A) of this section for five years after the account is closed and the records made under paragraphs (a)(3)(i)(B), (C), and (D) of this section for five years after the record is made. In all other respects, the records must be maintained pursuant to the provisions of 17 CFR 1.31.

(4) *Comparison with government lists.* The CIP must include procedures for determining whether a customer appears on any list of known or suspected terrorists or terrorist organizations issued by any Federal government agency and designated as such by Treasury in consultation with the Federal functional regulators. The procedures must require the futures commission merchant or introducing broker to make such a determination within a reasonable period of time after the account is opened, or earlier if required by another Federal law or regulation or Federal directive issued in connection with the applicable list. The procedures also must require the futures commission merchant or introducing broker to follow all Federal directives issued in connection with such lists.

(5)(i) *Customer notice.* The CIP must include procedures for providing customers with adequate notice that the futures commission merchant or introducing broker is requesting information to verify their identities.

(ii) *Adequate notice.* Notice is adequate if the futures commission merchant or introducing broker generally describes the identification requirements of this section and provides such notice in a manner reasonably designed to ensure that a customer is able to view the notice, or is otherwise given notice, before opening an account. For example, depending upon the manner in which the account is opened, a futures commission merchant or introducing broker may post a notice in the lobby or on its Web site, include the notice on its account applications or use any other form of written or oral notice.

(iii) *Sample notice.* If appropriate, a futures commission merchant or introducing broker may use the following sample language to provide notice to its customers:

Important Information About Procedures for Opening a New Account

To help the government fight the funding of terrorism and money laundering activities, Federal law requires all financial institutions to obtain, verify, and record information that identifies each person who opens an account.

What this means for you: When you open an account, we will ask for your name, address, date of birth and other information that will allow us to identify you. We may also ask to see your driver's license or other identifying documents.

(6) *Reliance on another financial institution.* The CIP may include procedures specifying when the futures commission merchant or introducing broker will rely on the performance by another financial institution (including an affiliate) of any procedures of its CIP, with respect to any customer of the futures commission merchant or introducing broker that is opening an account, or has established an account or similar business relationship with the other financial institution to provide or engage in services, dealings, or other financial transactions, provided that:

(i) Such reliance is reasonable under the circumstances;

(ii) The other financial institution is subject to a rule implementing 31 U.S.C. 5318(h), and is regulated by a Federal functional regulator; and

(iii) The other financial institution enters into a contract requiring it to certify annually to the futures commission merchant or introducing broker that it has implemented its anti-money laundering program, and that it will perform (or its agent will perform) specified requirements of the futures commission merchant's or introducing broker's CIP.

(b) *Exemptions.* The CFTC, with the concurrence of the Secretary, may by order or regulation exempt any futures commission merchant or introducing broker that registers with the CFTC or any type of account from the requirements of this section. In issuing such exemptions, the CFTC and the Secretary shall consider whether the exemption is consistent with the purposes of the Bank Secrecy Act, and in the public interest, and may consider other necessary and appropriate factors.

(c) *Other requirements unaffected.* Nothing in this section relieves a futures commission merchant or introducing broker of its obligation to comply with any other provision of this chapter,

including provisions concerning information that must be obtained, verified, or maintained in connection with any account or transaction.

Subpart C—Reports Required To Be Made by Futures Commission Merchants and Introducing Brokers in Commodities

§ 1026.300 General.

Futures commission merchants and introducing brokers in commodities are subject to the reporting requirements set forth and cross referenced in this subpart. Futures commission merchants and introducing brokers in commodities should also refer to Subpart C of Part 1010 of this chapter for reporting requirements contained in that subpart which apply to futures commission merchants and introducing brokers in commodities.

§ 1026.310 Reports of transactions in currency.

The reports of transactions in currency requirements for futures commission merchants and introducing brokers in commodities are located in subpart C of Part 1010 of this chapter and this subpart.

§ 1026.315 Exemptions.

Refer to § 1010.315 of this chapter for exemptions from the obligation to file reports of transactions in currency for futures commission merchants and introducing brokers in commodities.

§ 1026.320 Reports by futures commission merchants and introducing brokers in commodities of suspicious transactions.

(a) *General*—(1) Every futures commission merchant (''FCM'') and introducing broker in commodities (''IB–C'') within the United States shall file with FinCEN, to the extent and in the manner required by this section, a report of any suspicious transaction relevant to a possible violation of law or regulation. An FCM or IB–C may also file with FinCEN a report of any suspicious transaction that it believes is relevant to the possible violation of any law or regulation but whose reporting is not required by this section. Filing a report of a suspicious transaction does not relieve an FCM or IB–C from the responsibility of complying with any other reporting requirements imposed by the CFTC or any registered futures association or registered entity as those terms are defined in the Commodity Exchange Act (''CEA''), 7 U.S.C. 21 and 7 U.S.C. 1a(29).

(2) A transaction requires reporting under the terms of this section if it is conducted or attempted by, at, or through an FCM or IB–C, it involves or aggregates funds or other assets of at least $5,000, and the FCM or IB–C knows, suspects, or has reason to suspect that the transaction (or a pattern of transactions of which the transaction is a part):

(i) Involves funds derived from illegal activity or is intended or conducted in order to hide or disguise funds or assets derived from illegal activity (including, without limitation, the ownership, nature, source, location, or control of such funds or assets) as part of a plan to violate or evade any federal law or regulation or to avoid any transaction reporting requirement under federal law or regulation;

(ii) Is designed, whether through structuring or other means, to evade any requirements of this chapter or of any other regulations promulgated under the Bank Secrecy Act;

(iii) Has no business or apparent lawful purpose or is not the sort in which the particular customer would normally be expected to engage, and the FCM or IB–C knows of no reasonable explanation for the transaction after examining the available facts, including the background and possible purpose of the transaction; or

(iv) Involves use of the FCM or IB–C to facilitate criminal activity.

(3) The obligation to identify and properly and timely to report a suspicious transaction rests with each FCM and IB–C involved in the transaction, provided that no more than one report is required to be filed by any of the FCMs or IB–Cs involved in a particular transaction, so long as the report filed contains all relevant facts.

(b) *Filing procedures*—(1) *What to file.* A suspicious transaction shall be reported by completing a Suspicious Activity Report by Securities and Futures Industries (''SAR–SF''), and collecting and maintaining supporting documentation as required by paragraph (d) of this section.

(2) *Where to file.* The SAR–SF shall be filed with FinCEN in a central location, to be determined by FinCEN, as indicated in the instructions to the SAR–SF.

(3) *When to file.* A SAR–SF shall be filed no later than 30 calendar days after the date of the initial detection by the reporting FCM or IB–C of facts that may constitute a basis for filing a SAR–SF under this section. If no suspect is identified on the date of such initial detection, an FCM or IB–C may delay filing a SAR–SF for an additional 30 calendar days to identify a suspect, but in no case shall reporting be delayed more than 60 calendar days after the date of such initial detection. In situations involving violations that require immediate attention, such as terrorist financing or ongoing money laundering schemes, the FCM or IB–C shall immediately notify by telephone an appropriate law enforcement authority in addition to filing timely a SAR–SF. FCMs and IB–Cs wishing voluntarily to report suspicious transactions that may relate to terrorist activity may call FinCEN's Financial Institutions Hotline at 1–866–556–3974 in addition to filing timely a SAR–SF if required by this section. The FCM or IB–C may also, but is not required to, contact the CFTC to report in such situations.

(c) *Exceptions*—(1) An FCM or IB–C is not required to file a SAR–SF to report—

(i) A robbery or burglary committed or attempted of the FCM or IB–C that is reported to appropriate law enforcement authorities;

(ii) A violation otherwise required to be reported under the CEA (7 U.S.C. 1 *et seq.*), the regulations of the CFTC (17 CFR chapter I), or the rules of any registered futures association or registered entity as those terms are defined in the CEA, 7 U.S.C. 21 and 7 U.S.C. 1a(29), by the FCM or IB–C or any of its officers, directors, employees, or associated persons, other than a violation of 17 CFR 42.2, as long as such violation is appropriately reported to the CFTC or a registered futures association or registered entity.

(2) An FCM or IB–C may be required to demonstrate that it has relied on an exception in paragraph (c)(1) of this section, and must maintain records of its determinations to do so for the period specified in paragraph (d) of this section. To the extent that a Form 8–R, 8–T, U–5, or any other similar form concerning the transaction is filed consistent with CFTC, registered futures association, or registered entity rules, a copy of that form will be a sufficient record for the purposes of this paragraph (c)(2).

(d) *Retention of records.* An FCM or IB–C shall maintain a copy of any SAR–SF filed and the original or business record equivalent of any supporting documentation for a period of five years from the date of filing the SAR–SF. Supporting documentation shall be identified as such and maintained by the FCM or IB–C, and shall be deemed to have been filed with the SAR–SF. An FCM or IB–C shall make all supporting documentation available to FinCEN, the CFTC, or any other appropriate law enforcement agency or regulatory agency, and, for purposes of paragraph (g) of this section, to any registered futures association, registered entity, or self-regulatory organization (''SRO'') (as

defined in section 3(a)(26) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(26)), upon request.

(e) *Confidentiality of reports.* No financial institution, and no director, officer, employee, or agent of any financial institution, who reports a suspicious transaction under this chapter, may notify any person involved in the transaction that the transaction has been reported, except to the extent permitted by paragraph (a)(3) of this section. Thus, any person subpoenaed or otherwise requested to disclose a SAR–SF or the information contained in a SAR–SF, except where such disclosure is requested by FinCEN, the CFTC, another appropriate law enforcement or regulatory agency, or for purposes of paragraph (g) of this section, a registered futures association, registered entity, or SRO shall decline to produce the SAR–SF or to provide any information that would disclose that a SAR–SF has been prepared or filed, citing this paragraph and 31 U.S.C. 5318(g)(2), and shall notify FinCEN of any such request and its response thereto.

(f) *Limitation of liability.* An FCM or IB–C, and any director, officer, employee, or agent of such FCM or IB–C, that makes a report of any possible violation of law or regulation pursuant to this section or any other authority (or voluntarily) shall not be liable to any person under any law or regulation of the United States (or otherwise to the extent also provided in 31 U.S.C. 5318(g)(3), including in any arbitration or reparations proceeding) for any disclosure contained in, or for failure to disclose the fact of, such report.

(g) *Examination and enforcement.* Compliance with this section shall be examined by the Department of the Treasury, through FinCEN or its delegates, under the terms of the Bank Secrecy Act. Reports filed under this section or § 1023.320 (including any supporting documentation), and documentation demonstrating reliance on an exception under paragraph (c) of this section or § 1023.320 of this chapter, shall be made available, upon request, to the CFTC, Securities and Exchange Commission, and any registered futures association, registered entity, or SRO, examining an FCM, IB–C, or broker or dealer in securities for compliance with the requirements of this section or § 1023.320 of this chapter. Failure to satisfy the requirements of this section may constitute a violation of the reporting rules of the BSA or of this chapter.

(h) *Applicability date.* This section applies to transactions occurring after May 18, 2004.

Subpart D—Records Required To Be Maintained by Futures Commission Merchants and Introducing Brokers in Commodities

§ 1026.400 General.

Futures commission merchants and introducing brokers in commodities are subject to the recordkeeping requirements set forth and cross referenced in this subpart. Futures commission merchants and introducing brokers in commodities should also refer to Subpart D of Part 1010 of this chapter for recordkeeping requirements contained in that subpart which apply to futures commission merchants and introducing brokers in commodities.

§ 1026.410 Recordkeeping.

Refer to § 1010.410 of this chapter.

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

§ 1026.500 General.

Futures commission merchants and introducing brokers in commodities are subject to the special information sharing procedures to deter money laundering and terrorist activity requirements set forth and cross referenced in this subpart. Futures commission merchants and introducing brokers in commodities should also refer to Subpart E of Part 1010 of this chapter for special information sharing procedures to deter money laundering and terrorist activity contained in that subpart which apply to futures commission merchants and introducing brokers in commodities.

§ 1026.520 Special information sharing procedures to deter money laundering and terrorist activity for futures commission merchants and introducing brokers in commodities.

(a) Refer to § 1010.520 of this chapter.
(b) [Reserved]

§ 1026.530 [Reserved]

§ 1026.540 Voluntary information sharing among financial institutions.

(a) Refer to § 1010.540 of this chapter.
(b) [Reserved]

Subpart F—Special Standards of Diligence; Prohibitions; and Special Measures for Futures Commission Merchants and Introducing Brokers in Commodities

§ 1026.600 General.

Futures commission merchants and introducing brokers in commodities are subject to the special standards of diligence; prohibitions; and special measures requirements set forth and cross referenced in this subpart. Futures commission merchants and introducing brokers in commodities should also refer to Subpart F of Part 1010 for special standards of diligence; prohibitions; and special measures contained in that subpart which apply to futures commission merchants and introducing brokers in commodities.

§ 1026.610 Due diligence programs for correspondent accounts for foreign financial institutions.

(a) Refer to § 1010.610 of this chapter.
(b) [Reserved]

§ 1026.620 Due diligence programs for private banking accounts.

(a) Refer to § 1010.620 of this chapter.
(b) [Reserved]

§ 1026.630 Prohibition on correspondent accounts for foreign shell banks; records concerning owners of foreign banks and agents for service of legal process.

(a) Refer to § 1010.630 of this chapter.
(b) [Reserved]

§ 1026.640 [Reserved]

§ 1026.670 Summons or subpoena of foreign bank records; Termination of correspondent relationship.

(a) Refer to § 1010.670 of this chapter.
(b) [Reserved]

PART 1027—RULES FOR DEALERS IN PRECIOUS METALS, PRECIOUS STONES, OR JEWELS

Subpart A—Definitions

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1027.100 Definitions.

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1027.200 General.
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Subpart C—Reports Required To Be Made by Dealers in Precious Metals, Precious Stones, or Jewels

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1027.330 Reports relating to currency in excess of $10,000 received in a trade or business.

Subpart D—Records Required To Be Maintained by Dealers in Precious Metals, Precious Stones, or Jewels

1027.400 General.
1027.410 Recordkeeping.

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

1027.500 General.
1027.520 Special information sharing procedures to deter money laundering and terrorist activity for dealers in

precious metals, precious stones, or jewels.
1027.530 [Reserved]
1027.540 Voluntary information sharing among financial institutions.

Subpart F—Special Standards of Diligence; Prohibitions, and Special Measures for Dealers in Precious Metals, Precious Stones, or Jewels

1027.600 [Reserved]
1027.610 [Reserved]
1027.620 [Reserved]
1027.630 [Reserved]
1027.640 [Reserved]
1027.670 [Reserved]

Subpart A—Definitions

§ 1027.100 Definitions.

Refer to § 1010.100 for general definitions not noted herein. To the extent there is a differing definition in § 1010.100 of this chapter, the definition in this Section is what applies to Part 1027. Unless otherwise indicated, for purposes of this Part:

(a) *Covered goods* means:

(1) Jewels (as defined in paragraph (c) of this section);

(2) Precious metals (as defined in paragraph (d) of this section);

(3) Precious stones (as defined in paragraph (e) of this section); and

(4) Finished goods (including, but not limited to, jewelry, numismatic items, and antiques), that derive 50 percent or more of their value from jewels, precious metals, or precious stones contained in or attached to such finished goods;

(b) *Dealer.* (1) Except as provided in paragraphs (b)(2) and (b)(3) of this section, the term ''dealer'' means a person engaged within the United States as a business in the purchase and sale of covered goods and who, during the prior calendar or tax year:

(i) Purchased more than $50,000 in covered goods; and

(ii) Received more than $50,000 in gross proceeds from the sale of covered goods.

(2) For purposes of this section, the term ''dealer'' does not include:

(i) A retailer (as defined in paragraph (f) of this section), unless the retailer, during the prior calendar or tax year, purchased more than $50,000 in covered goods from persons other than dealers or other retailers (such as members of the general public or foreign sources of supply); or

(ii) A person licensed or authorized under the laws of any State (or political subdivision thereof) to conduct business as a pawnbroker, but only to the extent such person is engaged in pawn transactions (including the sale of pawn loan collateral).

(3) For purposes of paragraph (b) of this section, the terms ''purchase'' and ''sale'' do not include a retail transaction in which a retailer or a dealer accepts from a customer covered goods, the value of which the retailer or dealer credits to the account of the customer, and the retailer or dealer does not provide funds to the customer in exchange for such covered goods.

(4) For purposes of paragraph (b) of this section and § 1027.210(a), the terms ''purchase'' and ''sale'' do not include the purchase of jewels, precious metals, or precious stones that are incorporated into machinery or equipment to be used for industrial purposes, and the purchase and sale of such machinery or equipment.

(5) For purposes of applying the $50,000 thresholds in paragraphs (b)(1) and (b)(2)(i) of this section to finished goods defined in paragraph (a)(4) of this section, only the value of jewels, precious metals, or precious stones contained in, or attached to, such goods shall be taken into account.

(c) *Jewel* means an organic substance with gem quality market-recognized beauty, rarity, and value, and includes pearl, amber, and coral.

(d) *Precious metal* means:

(1) Gold, iridium, osmium, palladium, platinum, rhodium, ruthenium, or silver, having a level of purity of 500 or more parts per thousand; and

(2) An alloy containing 500 or more parts per thousand, in the aggregate, of two or more of the metals listed in paragraph (d)(1) of this section.

(e) *Precious stone* means a substance with gem quality market-recognized beauty, rarity, and value, and includes diamond, corundum (including rubies and sapphires), beryl (including emeralds and aquamarines), chrysoberyl, spinel, topaz, zircon, tourmaline, garnet, crystalline and cryptocrystalline quartz, olivine peridot, tanzanite, jadeite jade, nephrite jade, spodumene, feldspar, turquoise, lapis lazuli, and opal.

(f) *Retailer* means a person engaged within the United States in the business of sales primarily to the public of covered goods.

Subpart B—Programs

§ 1027.200 General.

Dealers in precious metals, precious stones, or jewels are subject to the program requirements set forth and cross referenced in this subpart. Dealers in precious metals, precious stones, or jewels should also refer to Subpart B of Part 1010 of this chapter for program requirements contained in that subpart which apply to dealers in precious metals, precious stones, or jewels.

§ 1027.210 Anti-money laundering programs for dealers in precious metals, precious stones, or jewels.

(a) *Anti-money laundering program requirement.* (1) Each dealer shall develop and implement a written anti-money laundering program reasonably designed to prevent the dealer from being used to facilitate money laundering and the financing of terrorist activities through the purchase and sale of covered goods. The program must be approved by senior management. A dealer shall make its anti-money laundering program available to the Department of Treasury through FinCEN or its designee upon request.

(2) To the extent that a retailer's purchases from persons other than dealers and other retailers exceeds the $50,000 threshold contained in § 1027.100(b)(2)(i), the anti-money laundering compliance program required of the retailer under this paragraph need only address such purchases.

(b) *Minimum requirements.* At a minimum, the anti-money laundering program shall:

(1) Incorporate policies, procedures, and internal controls based upon the dealer's assessment of the money laundering and terrorist financing risks associated with its line(s) of business. Policies, procedures, and internal controls developed and implemented by a dealer under this section shall include provisions for complying with the applicable requirements of the Bank Secrecy Act (31 U.S.C. 5311 *et seq.*), and this chapter.

(i) For purposes of making the risk assessment required by paragraph (b)(1) of this section, a dealer shall take into account all relevant factors including, but not limited to:

(A) The type(s) of products the dealer buys and sells, as well as the nature of the dealer's customers, suppliers, distribution channels, and geographic locations;

(B) The extent to which the dealer engages in transactions other than with established customers or sources of supply, or other dealers subject to this rule; and

(C) Whether the dealer engages in transactions for which payment or account reconciliation is routed to or from accounts located in jurisdictions that have been identified by the Department of State as a sponsor of international terrorism under 22 U.S.C. 2371; designated as non-cooperative with international anti-money laundering principles or procedures by an intergovernmental group or organization of which the United States is a member and with which

designation the United States representative or organization concurs; or designated by the Secretary of the Treasury pursuant to 31 U.S.C. 5318A as warranting special measures due to money laundering concerns.

(ii) A dealer's program shall incorporate policies, procedures, and internal controls to assist the dealer in identifying transactions that may involve use of the dealer to facilitate money laundering or terrorist financing, including provisions for making reasonable inquiries to determine whether a transaction involves money laundering or terrorist financing, and for refusing to consummate, withdrawing from, or terminating such transactions. Factors that may indicate a transaction is designed to involve use of the dealer to facilitate money laundering or terrorist financing include, but are not limited to:

(A) Unusual payment methods, such as the use of large amounts of cash, multiple or sequentially numbered money orders, traveler's checks, or cashier's checks, or payment from third parties;

(B) Unwillingness by a customer or supplier to provide complete or accurate contact information, financial references, or business affiliations;

(C) Attempts by a customer or supplier to maintain an unusual degree of secrecy with respect to the transaction, such as a request that normal business records not be kept;

(D) Purchases or sales that are unusual for the particular customer or supplier, or type of customer or supplier; and

(E) Purchases or sales that are not in conformity with standard industry practice.

(2) Designate a compliance officer who will be responsible for ensuring that:

(i) The anti-money laundering program is implemented effectively;

(ii) The anti-money laundering program is updated as necessary to reflect changes in the risk assessment, requirements of this chapter, and further guidance issued by the Department of the Treasury; and

(iii) Appropriate personnel are trained in accordance with paragraph (b)(3) of this section.

(3) Provide for on-going education and training of appropriate persons concerning their responsibilities under the program.

(4) Provide for independent testing to monitor and maintain an adequate program. The scope and frequency of the testing shall be commensurate with the risk assessment conducted by the dealer in accordance with paragraph (b)(1) of this section. Such testing may be conducted by an officer or employee of the dealer, so long as the tester is not the person designated in paragraph (b)(2) of this section or a person involved in the operation of the program.

(c) *Implementation date.* A dealer must develop and implement an anti-money laundering program that complies with the requirements of this section on or before the later of January 1, 2006, or six months after the date a dealer becomes subject to the requirements of this section.

Subpart C—Reports Required To Be Made by Dealers in Precious Metals, Precious Stones, or Jewels

§ 1027.300 General.

Dealers in precious metals, precious stones, or jewels are subject to the reporting requirements set forth and cross referenced in this subpart. Dealers in precious metals, precious stones, or jewels should also refer to Subpart C of Part 1010 of this chapter for reporting requirements contained in that subpart which apply to dealers in precious metals, precious stones, or jewels.

§ 1027.310 [Reserved]

§ 1027.315 [Reserved]

§ 1027.320 [Reserved]

§ 1027.330 Reports relating to currency in excess of $10,000 received in a trade or business.

Refer to § 1010.330 of this chapter for rules regarding the filing of reports relating to currency in excess of $10,000 received by dealers in precious metals, precious stones, or jewels.

Subpart D—Records Required To Be Maintained by Dealers in Precious Metals, Precious Stones, or Jewels

§ 1027.400 General.

Dealers in precious metals, precious stones, or jewels are subject to the recordkeeping requirements set forth and cross referenced in this subpart. Dealers in precious metals, precious stones, or jewels should also refer to Subpart D of Part 1010 of this chapter for recordkeeping requirements contained in that subpart which apply to dealers in precious metals, precious stones, or jewels.

§ 1027.410 Recordkeeping.

Refer to § 1010.410 of this chapter.

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

§ 1027.500 General.

Dealers in precious metals, precious stones, or jewels are subject to the special information sharing procedures to deter money laundering and terrorist activity requirements set forth and cross referenced in this subpart. Dealers in precious metals, precious stones, or jewels should also refer to Subpart E of Part 1010 of this chapter for special information sharing procedures to deter money laundering and terrorist activity contained in that subpart which apply to dealers in precious metals, precious stones, or jewels.

§ 1027.520 Special information sharing procedures to deter money laundering and terrorist activity for dealers in precious metals, precious stones, or jewels.

(a) Refer to § 1010.520 of this chapter.

(b) [Reserved]

§ 1027.530 [Reserved]

§ 1027.540 Voluntary information sharing among financial institutions.

(a) Refer to § 1010.540 of this chapter.

(b) [Reserved]

Subpart F—Special Standards of Diligence; Prohibitions; and Special Measures for Dealers in Precious Metals, Precious Stones, or Jewels

§ 1027.600 [Reserved]

§ 1027.610 [Reserved]

§ 1027.620 [Reserved]

§ 1027.630 [Reserved]

§ 1027.640 [Reserved]

§ 1027.670 [Reserved]

PART 1028—RULES FOR OPERATORS OF CREDIT CARD SYSTEMS

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1028.100 Definitions.

Subpart B—Programs

1028.200 General.
1028.210 Anti-money laundering programs for operators of credit card systems.

Subpart C—Reports Required To Be Made by Operators of Credit Card Systems

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1028.310 [Reserved]
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1028.330 Reports relating to currency in excess of $10,000 received in a trade or business.

Subpart D—Records Required To Be Maintained by Operators of Credit Card Systems

1028.400 General.
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Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

1028.500 General.
1028.520 Special information sharing procedures to deter money laundering and terrorist activity for operators of credit card systems.
1028.530 [Reserved]
1028.540 Voluntary information sharing among financial institutions.

Subpart F—Special Standards of Diligence; Prohibitions, and Special Measures for Operators of Credit Card Systems

1028.600 [Reserved]
1028.610 [Reserved]
1028.620 [Reserved]
1028.630 [Reserved]
1028.640 [Reserved]
1028.670 [Reserved]

Subpart A—Definitions

§ 1028.100 Definitions.

Refer to § 1010.100 of this chapter for general definitions not noted herein. To the extent there is a differing definition in § 1010.100 of this chapter, the definition in this Section is what applies to Part 1028. Unless otherwise indicated, for purposes of this Part:

(a) *Acquiring institution* means a person authorized by the operator of a credit card system to contract, directly or indirectly, with merchants or other persons to process transactions, including cash advances, involving the operator's credit card.

(b) *Credit card* has the same meaning as in 15 U.S.C. 1602(k). It includes charge cards as defined in 12 CFR 226.2(15).

(c) *Foreign bank* means any organization that is organized under the laws of a foreign country; engages in the business of banking; is recognized as a bank by the bank supervisory or monetary authority of the country of its organization or the country of its principal banking operations; and receives deposits in the regular course of its business. For purposes of this definition:

(1) The term foreign bank includes a branch of a foreign bank in a territory of the United States, Puerto Rico, Guam, American Samoa, or the U.S. Virgin Islands.

(2) The term foreign bank does not include:

(i) A U.S. agency or branch of a foreign bank; and

(ii) An insured bank organized under the laws of a territory of the United States, Puerto Rico, Guam, American Samoa, or the U.S. Virgin Islands.

(d) *Issuing institution* means a person authorized by the operator of a credit card system to issue the operator's credit card.

(e) *Operator of a credit card system* means any person doing business in the United States that operates a system for clearing and settling transactions in which the operator's credit card, whether acting as a credit or debit card, is used to purchase goods or services or to obtain a cash advance. To fall within this definition, the operator must also have authorized another person (whether located in the United States or not) to be an issuing or acquiring institution for the operator's credit card.

(f) Operator's credit card means a credit card capable of being used in the United States that:

(1) Has been issued by an issuing institution; and

(2) Can be used in the operator's credit card system.

Subpart B—Programs

§ 1028.200 General.

Operators of credit card systems are subject to the program requirements set forth and cross referenced in this subpart. Operators of credit card systems should also refer to Subpart B of Part 1010 for program requirements contained in that subpart which apply to operators of credit card systems.

§ 1028.210 Anti-money laundering programs for operators of credit card systems.

(a) *Anti-money laundering program requirement.* Effective July 24, 2002, each operator of a credit card system shall develop and implement a written anti-money laundering program reasonably designed to prevent the operator of a credit card system from being used to facilitate money laundering and the financing of terrorist activities. The program must be approved by senior management. Operators of credit card systems must make their anti-money laundering programs available to the Department of the Treasury or the appropriate Federal regulator for review.

(b) *Minimum requirements.* At a minimum, the program must:

(1) Incorporate policies, procedures, and internal controls designed to ensure the following:

(i) That the operator does not authorize, or maintain authorization for, any person to serve as an issuing or acquiring institution without the operator taking appropriate steps, based upon the operator's money laundering or terrorist financing risk assessment, to guard against that person issuing the operator's credit card or acquiring merchants who accept the operator's credit card in circumstances that facilitate money laundering or the financing of terrorist activities;

(ii) For purposes of making the risk assessment required by paragraph (b)(1)(i) of this section, the following persons are presumed to pose a heightened risk of money laundering or terrorist financing when evaluating whether and under what circumstances to authorize, or to maintain authorization for, any such person to serve as an issuing or acquiring institution:

(A) A foreign shell bank that is not a regulated affiliate, as those terms are defined in § 1010.605(g) and (n);

(B) A person appearing on the Specially Designated Nationals List issued by Treasury's Office of Foreign Assets Control;

(C) A person located in, or operating under a license issued by, a jurisdiction whose government has been identified by the Department of State as a sponsor of international terrorism under 22 U.S.C. 2371;

(D) A foreign bank operating under an offshore banking license, other than a branch of a foreign bank if such foreign bank has been found by the Board of Governors of the Federal Reserve System under the Bank Holding Company Act (12 U.S.C. 1841, *et seq.*) or the International Banking Act (12 U.S.C. 3101, *et seq.*) to be subject to comprehensive supervision or regulation on a consolidated basis by the relevant supervisors in that jurisdiction;

(E) A person located in, or operating under a license issued by, a jurisdiction that has been designated as noncooperative with international anti-money laundering principles or procedures by an intergovernmental group or organization of which the United States is a member, with which designation the United States representative to the group or organization concurs; and

(F) A person located in, or operating under a license issued by, a jurisdiction that has been designated by the Secretary of the Treasury pursuant to 31 U.S.C. 5318A as warranting special measures due to money laundering concerns;

(iii) That the operator is in compliance with all applicable provisions of subchapter II of chapter 53 of title 31, United States Code and this chapter;

(2) Designate a compliance officer who will be responsible for assuring that:

(i) The anti-money laundering program is implemented effectively;

(ii) The anti-money laundering program is updated as necessary to reflect changes in risk factors or the risk assessment, current requirements of this chapter, and further guidance issued by the Department of the Treasury; and

(iii) Appropriate personnel are trained in accordance with paragraph (b)(3) of this section;

(3) Provide for education and training of appropriate personnel concerning their responsibilities under the program; and

(4) Provide for an independent audit to monitor and maintain an adequate program. The scope and frequency of the audit shall be commensurate with the risks posed by the persons authorized to issue or accept the operator's credit card. Such audit may be conducted by an officer or employee of the operator, so long as the reviewer is not the person designated in paragraph (b)(2) of this section or a person involved in the operation of the program.

Subpart C—Reports Required To Be Made by Operators of Credit Card Systems

§ 1028.300 General.

Operators of credit card systems are subject to the reporting requirements set forth and cross referenced in this subpart. Operators of credit card systems should also refer to Subpart C of Part 1010 of this chapter for reporting requirements contained in that subpart which apply to operators of credit card systems.

§ 1028.310 [Reserved]

§ 1028.315 [Reserved]

§ 1028.320 [Reserved]

§ 1028.330 Reports relating to currency in excess of $10,000 received in a trade or business.

Refer to § 1010.330 of this chapter for rules regarding the filing of reports relating to currency in excess of $10,000 received by operators of credit card systems.

Subpart D—Records Required To Be Maintained by Operators of Credit Card Systems

§ 1028.400 General.

Operators of credit card systems are subject to the recordkeeping requirements set forth and cross referenced in this subpart. Operators of credit card systems should also refer to Subpart D of Part 1010 of this chapter for recordkeeping requirements contained in that subpart which apply to operators of credit card systems.

§ 1028.410 Recordkeeping.

Refer to § 1010.410 of this chapter.

Subpart E—Special Information Sharing Procedures To Deter Money Laundering and Terrorist Activity

§ 1028.500 General.

Operators of credit card systems are subject to the special information sharing procedures to deter money laundering and terrorist activity requirements set forth and cross referenced in this subpart. Operators of credit card systems should also refer to Subpart E of Part 1010 of this chapter for special information sharing procedures to deter money laundering and terrorist activity contained in that subpart which apply to operators of credit card systems.

§ 1028.520 Special information sharing procedures to deter money laundering and terrorist activity for operators of credit card systems.

(a) Refer to § 1010.520 of this chapter.

(b) [Reserved]

§ 1028.530 [Reserved]

§ 1028.540 Voluntary information sharing among financial institutions.

(a) Refer to § 1010.540 of this chapter.

(b) [Reserved]

Subpart F—Special Standards of Diligence; Prohibitions; and Special Measures for Operators of Credit Card Systems

§ 1028.600 [Reserved]

§ 1028.610 [Reserved]

§ 1028.620 [Reserved]

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§ 1028.640 [Reserved]

§ 1028.670 [Reserved]

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Dated: October 22, 2008.

James H. Freis, Jr.,

Director, Financial Crimes Enforcement Network.

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Proposed Modification of the Asheville, NC, Class C Airspace Area; Public Meeting; comments due by 11-14-08; published 9-12-08 [FR E8-21216]

TRANSPORTATION DEPARTMENT

Federal Railroad Administration

Miscellaneous Amendments to Accident/Incident Reporting Requirements; comments due by 11-10-08; published 9-9-08 [FR E8-20706]

TRANSPORTATION DEPARTMENT

National Highway Traffic Safety Administration

Federal Motor Vehicle Safety Standards:

Occupant Crash Protection; comments due by 11-12-08; published 9-12-08 [FR E8-21026]

Schedule of Fees Authorized (by 49 U.S.C. 30141); comments due by 11-10-08; published 9-24-08 [FR E8-22334]

TRANSPORTATION DEPARTMENT

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials:

Risk-Based Adjustment of Transportation Security Plan Requirements; comments due by 11-10-08; published 9-9-08 [FR E8-20856]

Pipeline Safety:

Control Room Management/ Human Factors; comments due by 11-12-08; published 9-12-08 [FR E8-20701]

TREASURY DEPARTMENT

Internal Revenue Service

Amendments to New Markets Tax Credit Regulations; comments due by 11-10-08; published 8-11-08 [FR E8-18442]

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

H.R. 6197/P.L. 110–448

To designate the facility of the United States Postal Service located at 7095 Highway 57 in Counce, Tennessee, as the "Pickwick Post Office Building". (Oct. 22, 2008; 122 Stat. 5013)

Last List October 23, 2008

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