Federal Register

4–04–05 Monday
Vol. 70 No. 63 Apr. 4, 2005

Pages 16921–17196

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9:00 a.m.–Noon

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Conference Room, Suite 700
800 North Capitol Street
Washington, DC 20002

RESERVATIONS: (202) 741–6008

Printed on recycled paper.

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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.

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

7 CFR Part 624

Emergency Watershed Protection Program

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Final rule.

SUMMARY: The United States Department of Agriculture (USDA) Natural Resources Conservation Service (NRCS) is issuing a final rule for the Emergency Watershed Protection (EWP) Program to improve the effectiveness of its response to natural disasters. This final rule establishes the process by which NRCS will administer the EWP Program, responds to comments on the proposed rule received from the public during the 60-day comment period, and incorporates modifications and clarifications to improve implementation of the program.

DATES: *Effective Date:* May 4, 2005.

ADDRESSES: This final rule may be accessed via the Internet. Users can access the Natural Resources Conservation Service (NRCS) homepage at *http://www.nrcs.usda.gov/programs/ewp/.* Select the EWP rule link listed on the EWP program page.

FOR FURTHER INFORMATION CONTACT: Victor Cole, (202) 690–0793, fax (202) 720–4265, *victor.cole@usda.gov,* Financial Assistance Programs Division, Natural Resources Conservation Service, P.O. Box 2890, Washington, DC 20013–2890 or for information regarding EWP floodplain easements, contact Leslie Deavers (202) 720–1062, fax (202) 720–6697, *leslie.deavers@usda.gov,* Easement Programs Division, Natural Resources Conservation Service, P.O. Box 2890, Washington, DC 20013–2890. For information regarding administration of the EWP program by the United States Department of Agriculture Forest Service, contact Meredith Webster, (202) 205–0804, fax (202) 205–1096, mmwebster@fs.fed.us, USDA Forest Service, 201 14th Street SW., 3 South Yates Building, Mail Stop 1121, Washington, DC 20024

SUPPLEMENTARY INFORMATION:

Background

The Secretary of Agriculture cooperates with other Federal, State, and local agencies in the recovery from natural disasters such as hurricanes, tornadoes, fires, drought, and floods through implementation of the EWP Program (authorized by Section 216 of the Flood Control Act of 1950, Public Law 81–516, 33 U.S.C. 701b–1; and Section 403 of the Agricultural Credit Act of 1978, Public Law 95–334, as amended by Section 382, of the Federal Agriculture Improvement and Reform Act of 1996, Public Law 104–127, 16 U.S.C. 2203). EWP, through local sponsors, provides emergency measures for run-off retardation and erosion control to areas where a sudden impairment of a watershed threatens life or property. The Secretary of Agriculture has delegated the administration of EWP to the Chief of NRCS on state, tribal, and private lands, and Chief of USDA Forest Service (FS) on National Forest System lands, including any other lands that are administered under a formal agreement with the FS. The FS administers the EWP Program in accordance with Forest Service Manuals 1950 and 3540, and the Forest Service Handbook 1909.15. This rule only provides direction to the NRCS on administering the EWP Program.

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this final rule is a ''significant action'' for the purposes of Executive Order 12866. Pursuant to Section 6(a)(3) of Executive Order 12866, NRCS has conducted an economic analysis of the potential impacts associated with this final rule as compared to the existing program. The economic analysis concluded that changes to the program implemented by this rule may save up to $1.4 million each year. These changes include: Setting EWP priorities, pre-disaster readiness, limiting repairs to 2 times in 10 years, and discontinuing the practice of providing EWP funds on Federal lands. However, some of this expected reduction may be offset by increased cost-share for limited resource counties and the use of EWP in the repair of conservation practices on agricultural lands. A copy of this cost-benefit analysis is available upon request from the address listed above.

Regulatory Flexibility Act

The Regulatory Flexibility Act is not applicable to this rule because neither the Secretary of Agriculture nor NRCS are required by 5 U.S.C 553 or any other law to publish a notice of proposed rulemaking for the subject matter of this rule.

Environmental Evaluation

A Programmatic Environmental Impact Statement (PEIS) and Record of Decision (ROD) were prepared as a part of this rulemaking. NRCS considered both the comments received on the draft PEIS and the proposed rule in formulation of the final regulation. Copies of the final PEIS and ROD may be obtained from the Financial Assistance Programs Division, Natural Resources Conservation Service, USDA, P.O. Box 2890, Washington, DC 20013–2890. The final PEIS and ROD may be accessed via the Internet. Users can access the NRCS homepage at *http://www.nrcs.usda.gov/programs/ewp/.* Select the PEIS link listed on the EWP program page.

Paperwork Reduction Act

This final rule will not alter the collection of information previously approved by the Office of Management and Budget and assigned number 0578–0030.

Government Paperwork Elimination Act

NRCS is committed to compliance with the Government Paperwork Elimination Act, which requires Government agencies, in general, to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. To better commodate public access, NRCS is proposing to develop an online application and information system for public use.

Executive Order 13132

This final rule has been reviewed in accordance with requirements of Executive Order 13132, Federalism. NRCS has determined that the rule conforms to the Federalism principles set forth in the Executive Order; would not impose any compliance cost on the States; and would not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities on the various levels of government.

Executive Order 12998

This final rule has been reviewed in accordance with Executive Order 12998. The provisions of this rule are not retroactive. Furthermore, the provisions of this final rule pre-empt State and local laws to the extent that such laws are inconsistent with this final rule. Before an action may be brought in a Federal court of competent jurisdiction, the administrative appeal rights afforded persons at 7 CFR parts 614 and 11 must be exhausted. For EWP recovery measures, an individual landowner is not an EWP participant nor is the legal substantive status of land affected by an NRCS decision regarding the eligibility of a measure for EWP assistance. Therefore, an individual landowner is not entitled to appeal an EWP recovery measure determination under 7 CFR parts 614 and 11.

Executive Order 13175

NRCS has taken measures to ensure tribal officials are aware of the EWP Program and are provided opportunities to receive assistance in compliance with the Executive Order. NRCS established field offices within some reservations and tribal liaison staff to promote outreach and coordination with tribal officials. The result of this effort has been increased participation in the EWP Program by tribes. Additionally, NRCS has included a waiver provision in this regulation which complies with the flexibility requirement of the Executive Order.

Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)

This regulation is not a major rule under 5 U.S.C. 801 *et. seq*. the Small Business Regulatory Enforcement Fairness Act:

(a) This regulation would not produce an annual economic effect of $100 million. The changes to the program are expected to yield cost savings of up to $1.4 million per year.

(b) This regulation would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) This regulation would not have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act of 1995

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, NRCS assessed the effects of this final rule on State, local, and tribal governments, and the public. This action does not compel the expenditure of $100 million or more by any State, local, or tribal government, or the private sector; therefore, a statement under Section 202 of the Unfunded Mandates Reform Act of 1995 is not required.

Overview

The EWP Program helps remove threats to life and property that remain in the nation's watersheds in the aftermath of natural disasters including, but is not limited to, floods, fires, windstorms, ice storms, hurricanes, typhoons, tornadoes, earthquakes, volcanic actions, slides, and drought. The EWP Program is administered by NRCS, on state, tribal, and private lands by providing technical and financial assistance to local sponsoring authorities to preserve life and property threatened by disaster for runoff retardation and soil-erosion prevention. Funding is typically provided through Congressional emergency supplemental appropriations. Threats that the EWP Program addresses are termed watershed impairments. These include, but are not limited to, debris-clogged stream channels, undermined and unstable streambanks, jeopardized water control structures and public infrastructure, wind-borne debris removal, and damaged upland sites stripped of protective vegetation by fire or drought. If these watershed impairments are not addressed, they would pose a serious threat of injury, loss of life, or devastating property damage should a subsequent event occur.

On November 19, 2003 (**Federal Register** Vol. 68, No. 223 pages 65202–65210) NRCS initiated rulemaking by publishing a proposed rule with request for comments to modify the existing regulation at 7 CFR part 624 to make programmatic changes that allow the repair of enduring conservation practices, limit repeated site repairs, allow additional easement purchases, address environmental justice issues, and limit treatments on federal lands. In this rulemaking, NRCS has incorporated changes in program administration and in project execution dealing with traditional watershed impairments. This final rule expands the program by providing for removal of sediment in the floodplain and repair of damaged structural conservation practices to the list of watershed impairments for which EWP Program funds may be used. Additionally, the regulatory changes include: Allowing for up to 90 percent cost-share for limited resource areas; limit repair to twice in a ten year period; eliminate the single beneficiary requirement; purchase of easements on non-agricultural lands; establish one easement category; and funding projects on Federal lands only when such funding is not an inappropriate funding augmentation of the land management agency appropriations.

Program delivery improvements contained in this final rule are designed to enable NRCS field and state office personnel to provide EWP assistance more effectively and efficiently. NRCS believes that these improvements will more fully, equitably, and consistently meet the needs of people requiring emergency assistance. Program improvements are designed to address environmental, economic, and social concerns and values.

The changes adopted in this final rule were identified, discussed, and refined in an ongoing comprehensive program review that NRCS initiated and then issued in the proposed rule. The process included extensive opportunities for public participation and identified substantive ways to improve the environmental, economic, social, and technical soundness of program activities.

In response to the proposed rulemaking, seven separate responses from the public containing about 25 specific comments were received during the 60-day comment period: 1 response from an individual, 2 from conservation districts and related groups, and 4 from State agencies.

Additional responses were received from a Federal agency and NRCS employees; their comments are not included in the following analysis of public comments. These responses were treated as inter and intra-agency comments and considered in the drafting of the final rule along with the public comments where appropriate.

All comments received are available for review in Room 6019, South Agriculture Building, 14th and

Independence Ave., SW., Washington, DC, during regular business hours (8 a.m. to 5 p.m.) Monday through Friday.

Analysis of Public Comment

Overall, the comments received were favorable and supported the proposed changes to the EWP Program. Some commentors offered suggestions for improving or clarifying specific sections of the proposed rule which resulted in the agency making changes to the proposed rule as identified in the section-by-section discussion of comments.

The comments focused on a wide variety of issues in the proposed rule. Editorial and other language clarification changes were suggested; these comments are not included in the following analysis but all were considered and many of the minor technical changes were included in the final rule. For the sections not listed in this preamble, the agency has adopted the language described in the proposed rule with the exception of non-substantive editorial and other language clarifications.

Several comments were related to funding and suggested that the EWP Program should be funded as a line item in NRCS' fiscal year appropriations since there is sometimes a significant delay from the date of the natural disaster until funding is provided. Funding for the EWP Program is typically provided through emergency supplemental appropriations and it would require Congressional action to include EWP funding as a line item.

Section-By-Section Discussion of Comments Received on the Proposed Rule Provisions

Section 624.4 (b) Exigency. Several comments were received supporting the clarification of the term ''exigency'' and elimination of the term ''non-exigency''.

NRCS acknowledges this support and consequently is adopting the proposed language without changes. The changes were proposed because the agency had previously encountered various cases where the term ''exigency'' was applied too liberally and implemented for purposes for which it was not intended. Interpretations of the terms ''exigency'' and ''non-exigency'' varied widely within NRCS. NRCS's intent when establishing these two categories (exigency and non-exigency) in the previous rulemaking (46 FR 65677, Nov. 17, 1981) was to allow NRCS to respond quickly to only those situations that needed immediate attention.

In addition, the previous regulation tied cost-sharing to this designation, although NRCS has not applied the higher cost-sharing rate, originally set for exigencies, for the past 11 years. Instead, NRCS has applied a single cost-share rate of 75 percent to exigent situations. However, NRCS recognizes there may be unique situations that require a waiver from this cost-sharing rate. The agency added *Section 624.11 Waivers* which allows the NRCS Deputy Chief for Programs to waive any provision of these regulations to the extent allowed by law. An example may include allowing up to 100 percent cost-sharing for a limited resource area.

Based upon past experience, NRCS reconsidered the 5-day exigency time frame and has lengthened the time frame to accomplish exigency measures from 5 days to 10 days. This additional time will aid sponsors in their effort to secure their cost-share. Additionally, many EWP exigency situations involve permitting or other legal requirements resulting in additional time. The additional five days should provide time for the sponsors to secure necessary ''emergency'' permits and for NRCS and sponsors to comply with any applicable Federal law or regulation.

Section 624.6(b)(2)(i). Two comments were received that express support for limiting of repair of the same site to only twice within a ten year period in order to avoid repetitive Federal funding, which could in turn perpetuate activities that are not best suited for the areas prone to impacts from natural disasters. Two comments also expressed concern regarding whether the limitation was applicable to the removal of debris within the same site. Consequently, NRCS has modified the language to reflect that the limitation refers to structural measures only. NRCS recognizes that in most areas of the country there is no practical means to effectively prevent debris from entering and accumulating in the watershed as a result of repetitive natural disasters. Therefore, NRCS does not intend to limit the number of times debris can be removed within the same location due to a natural or constructed (*e.g.*, road crossing) restriction within a waterway. Rather, NRCS would limit repairs under EWP to twice within a 10-year period for the same cause (*i.e.*, flooding) at the same site for structural measures. If structural measures have been installed/repaired or protected twice with EWP assistance and less than 10 years has elapsed between the disaster that triggered the first repair and the disaster triggering a third repair, the only option available under EWP would be to place a floodplain easement on the damaged site.

For example, if a home was protected from destruction twice using EWP assistance for two separate events, regardless of the structural measure used to protect the home or the location along the waterway of the protection efforts, EWP funds would not be available for a third protection effort of the home within the 10-year period for the same cause. For repairs of dikes, levees, berms, and similar structures, because these structures can run contiguously for miles, a specific location on a structure is considered one EWP site to determine whether future impacts to this site on the structure are eligible for EWP funds. Thus, repairs can be made repetitively so long as the same location is not repetitively repaired more than twice within 10 years.

Section 624.6(b)(2)(iv). Two comments were received that supported the language change to clarify that NRCS can only provide EWP assistance on Federal lands in situations where safeguards are followed to avoid inappropriate augmentation of appropriations, therefore, NRCS is adopting the proposal without changes. One comment recommended that exigency situations should be funded on Federal lands.

NRCS and the FS have been delegated the authority to administer the EWP program. NRCS administers the program on state, tribal, and private lands while the FS administers the program on National Forest System lands, including lands under an official management agreement with the FS. NRCS is the lead USDA agency, responsible for developing EWP regulations and policy for both agencies and through a 1998 Memorandum of Understanding with the FS, NRCS also manages the funding for both agencies. However, recent Congressional appropriations have designated the funding for NRCS, which does not authorize NRCS to transfer funding to the FS for EWP measures on lands it manages. The existing language of 7 CFR 624.4 language was changed to reflect that NRCS will transfer funding to the FS only when it is appropriate *e.g.*, when the EWP funding is provided to the Secretary of Agriculture with discretion to provide the funding to both agencies. For Federal lands, it is the Federal land management department or agency that is responsible for securing funding to undertake emergency repair activities within lands under its control.

In response to the commentor that recommended that exigency situations should be funded on Federal lands, the FS is responsible for determining whether exigency situations exist on

lands it manages in accordance with regulations and policy established by NRCS. Funding EWP activities on Federal lands other than those under FS management may be an inappropriate augmentation of another Federal agency's budget. If USDA is Congressionally authorized, funding EWP activities on Federal lands may be appropriate. NRCS has adopted, without changes, the proposal defined in section 624.6(b)(2)(iv) which limits the use of EWP funding on Federal lands except when authorized by Congress or adequate safeguards are followed.

Section 624.6(b)(3). Several comments were received that supported including eligibility for structural, enduring, and long-life conservation practices. Additionally, several comments expressed concern that the program should not overlap with Emergency Conservation Program (ECP) administered by the Farm Service Agency (FSA).

As stated in the preamble of the proposed rule, NRCS does not intend to overlap the EWP program with ECP. EWP assistance would only be applicable when the emergency measures are not eligible for assistance under ECP. EWP differs significantly from ECP because a sponsor is required for EWP recovery work; EWP recovery assistance does not provide financial assistance directly to individuals but rather to eligible sponsors.

NRCS can provide EWP assistance toward upgrading damaged or undersized practices for structural, enduring, and long-life conservation practices when technology advances or construction techniques warrant. Such modifications will be cost shared in accordance with Section 624.7. All structural, enduring, and long-life conservation practices for which the sponsor is required to obtain a permit issued by a Federal, State, or local entity shall be designed and installed to meet the permit requirements or NRCS standards, whichever is greater. If a structure has to be upgraded to meet federal permitting or other requirements, such modifications will be cost shared in accordance with Section 624.7 NRCS has adopted the proposal for structural, enduring, and long-life conservation practices and has modified the language in the final rule to clarify that EWP assistance is not available when ECP is applicable.

Section 624.6(c). Several comments were received that supported expansion of eligible work to include assistance for areas impacted that are beyond the immediate area of the waterway.

NRCS acknowledges this support and recognizes that agricultural productivity, public health and safety, and the environment are often threatened in the aftermath of disasters that occur outside the immediate limits of a waterway. Therefore, NRCS has expanded the EWP Program assistance described in the proposed rule and adopted here in the final rule to include all recovery measures within watersheds (*see* Section 624.6 (c) Eligible practices) on all state, tribal, and private lands otherwise meeting the EWP eligibility requirements. NRCS may provide EWP assistance for the removal of sediment and other debris from agricultural land (croplands, orchards, vineyards, and pastures) and windblown debris. This provision of the proposed regulation also provides for EWP assistance for drought recovery activities.

The expansion of eligible recovery measures is primarily associated with deposits of large quantities of sediments and other debris on floodplains usually occur from major flooding, and tornadoes and hurricanes. The sediments are usually coarse and infertile, and frequently destroy or smother plants and impair normal agricultural use. This is a normal occurrence in the dynamics of floodplain systems, but it can jeopardize the productivity of agricultural lands and adversely affect structures and property within urban areas. As set forth in the final rule, NRCS will now consider alternative practices to address the type of damage such as:

- Removing and disposing the sediment and other debris
- Incorporating the sediment into the underlying soil
- Offering to purchase a floodplain easement (see Section 624.10)

Whether these sites qualify for EWP assistance and what the most effective alternative treatment is for eligible sites depends upon many factors: size of the particles, depth of material deposited, lateral extent of the sediment and debris, soil type of the underlying material, and land use and value of the land. Floodplain easements (see Section 624.10) may be used if there is too much debris to incorporate or haul off-site, or otherwise disposed.

Most debris that is deposited on upland areas is carried from winds of hurricanes or tornadoes. Such debris may cover portions of several watersheds and normally consists of downed trees, utility poles, and fence posts; livestock and poultry carcasses; or building materials, such as insulation, shingles, metal roofing, metal siding, and similar non-biodegradable materials. Similarly, ice storms may result in debris deposition and cause the death of livestock and poultry. Debris removal will typically be associated with the removal of debris upstream of bridges and culverts, or in the upland portion of a watershed where debris would readily be moved through runoff and deposited during a subsequent storm event in a waterway which could cause blockages in the waterway, flooding homes and other structures.

The practice components adopted to address upland debris deposition may include, but are not limited to:

- Creating access when needed to move trucks and heavy equipment to a debris site
- Using chain saws, other power tools, winches, and other machinery and heavy equipment to gather and process the debris for onsite disposal or removal
- Disposing of debris in accordance with local rules and regulations on-site by burial, chipping, or burning
- Loading on trucks for removal and disposal off-site in approved sites or landfills, based upon the composition of the material
- Obtaining special technical assistance and personnel to handle hazardous materials such as asbestos, petroleum products, propane, or other compressed gas containers, or other potentially hazardous or toxic compounds or materials
- Grading, shaping, and revegetating, by seeding or planting, any portion of the area affected by the debris removal operation

Section 624.6(c) Eligible practices. Comments were received regarding drought emergencies suggesting the allowance of permanent drought measures such as drilling water wells, and also requested a timeframe for how long hay or water should be provided during a drought emergency.

Under the EWP Program drought recovery practices are generally temporary in nature and are intended to reduce the consequences of a drought. The EWP program provides for the repair or restoration to pre-disaster conditions. Drilling wells for livestock watering would be considered a ''betterment'' above that which existed prior to the drought and as such not eligible for EWP assistance. Additionally, the FSA may provide funding to drill wells for livestock watering under ECP during drought conditions. EWP assistance typically includes soil erosion prevention measures, prescribed grazing, or reseeding, which allows rangeland to recover more rapidly. As set forth in the proposed rule, NRCS believes that EWP assistance should not be used during

drought situations to install permanent practices or structures, including water wells, irrigation systems, or purchase of portable equipment (*i.e.*, water pumps) and has maintained this limitation in the final rule. NRCS has removed the provision in section 624.6(c)(4) of the proposed rule that allowed for providing temporary water for livestock and purchasing and transporting hay. The proposal to provide temporary water would be duplicative of eligible measures under the ECP administered by FSA. The proposal to purchase and transport hay was also eliminated since this activity may not achieve the results necessary for runoff retardation and soil erosion prevention since livestock would still be allowed to graze within the drought-impacted watershed area. Additionally, EWP practices during drought situations should not be conducted at the expense of another natural resource, such as pumping or releasing water from a water body to an extent that is environmentally detrimental.

Section 624.6(e) Implementation. Two comments were received that recommended NRCS consider the ''buy out'' of structures, primarily houses, rather than repairing the waterway to protect the houses. NRCS believes there is sufficient flexibility in this regulation to purchase and remove houses or other structures in cases where the removal meets the eligibility requirements of EWP, it is the least costly alternative, and the buy out is voluntary, and does not involve a leasee or rentor. Consequently, the proposed language has been adopted without change in the final rule.

Section 624.7 Cost share assistance. One comment recommended authorizing 100 percent for exigency situations since sponsors may not be able to secure funding within time frame required to complete exigency EWP measures.

NRCS has adopted in the final rule *Section 624.11 Waivers* which allows the NRCS Deputy Chief for Programs to waive any provision of these regulations to the extent allowed by law when the agency makes a written determination that such waiver is in the best interest of the Federal government. An example may include allowing up to 100 percent cost-sharing for a sponsor when the sponsor demonstrates they have insufficient resources or finances to contribute the 25 percent cost-share in an exigency situation. All exigency situations do not warrant 100 percent Federal cost-share. However, through the waiver provision of the final rule, the agency recognizes that there may be situations were 100 percent cost-share is warranted.

Section 624.7(b) (c). Several comments supported the definition set forth in the proposed rule at Section 624.4(e) and cost-share rate for limited resource areas. One commenter requested clarification as to whether all of the criteria must be met.

The definition of a limited-resource area is a county where average housing values are less than 75 percent of the State average, per capita income is less than 75 percent of the national per capita income, and unemployment during the preceding 3 years is at least twice the U.S. average. To respond to the comments and, to clarify NRCS' intent, the definition set forth in the proposed rule is being modified such that all three criteria have to be met to qualify for the 90 percent cost-share. NRCS would use the most recent U.S. census and unemployment data to make this determination. NRCS is not adopting the provision in the proposed rule which provided the NRCS State Conservationist with the authority to document the limited-resource status of an area within a non-limited resource county by applying National census data for the three factors mentioned above and approving the 90 percent cost-share rate for that area. After further review, NRCS recognizes that making this determination within a non-limited-resource county may be difficult since specific U.S. census and unemployment data may not be available. In situations where the NRCS State Conservationist believes the 90 percent cost-share is warranted, a waiver can be requested in accordance with Section 624.11 Waivers which allows the NRCS Deputy Chief for Programs to waive any provision of these regulations to the extent allowed by law when the agency makes a written determination that such waiver is in the best interest of the Federal government.

Section 624.8 Assistance. NRCS did not receive any comments on this provision and is adopting the change in the proposed rule which eliminated Section 624.8 Environment in the previous rulemaking (46 FR 65677, Nov. 17, 1981) since the information is duplicative of other USDA and NRCS regulations and policy (see 7 CFR part 1b; 7 CFR part 650; NRCS General Manual Title 190, Part 410; and NRCS National Environmental Compliance Handbook). In the proposed rule, NRCS did not identify the regulations and policies and has done so here to ensure that the public is aware of USDA and NRCS' environmental compliance regulations and policies that are applicable for the EWP Program.

Section 624.8(c)(3) Funding Priorities. One comment requested that floodplain easement acquisition should be included in the list of EWP priorities.

Funding for floodplain easement acquisition has been managed separately from EWP funding for recovery measures. This is due to Congressional language as part of the EWP funding appropriation which has designated the amount of funding that could be used to purchase floodplain easements. When NRCS receives funding for acquisition of floodplain easements, NRCS State Conservationist will establish ranking or priority watersheds to acquire floodplain easements. This proposed provision is adopted in the final rule with clarification that the funding priorities apply to EWP recovery measures.

Section 624.9 Time limits. One comment recommended extending the length of time by which recovery work must be completed beyond 220 days due to the length of time necessary in some cases for sponsors to obtain permits.

NRCS believes that in most cases emergency recovery measures should be completed within the 220-day time frame. However, *Section 624.11 Waivers* provides authority for the NRCS Deputy Chief for Programs to waive any provision of these regulations to the extent allowed by law which could include situations where permitting, endangered and threatened species compliance, cultural resources, or other legal requirements result in additional time to complete recovery work funded under the EWP Program. Accordingly, this proposed provision is adopted in the final rule without change.

Section 624.10 Floodplain easement. One comment requested that floodplain easements should focus on wetland and wildlife habitat restoration.

Under the floodplain easement option, a landowner offers to sell to NRCS a permanent easement that provides NRCS with the full rights to restore and enhance the floodplain's functions and values which include consideration of wetland and wildlife habitat restoration. The program is not a substitute for the Wetlands Reserve Program, also administered by NRCS, since many other floodplain restoration factors must be considered, and may be the focus, when restoring floodplain functions within a site. Floodplain easements restore, protect, maintain, and enhance the functions of wetlands and riparian areas; conserve natural values including fish and wildlife habitat, water quality, flood water retention, ground water recharge, and open space; and safeguard lives and

property from floods, drought, and the products of erosion. The agency has adopted the proposed provision in the final rule without change.

Section 624.10(b)(2)(ii). Comments were received that supported the acquisition of non-agricultural lands when purchasing floodplain easements.

Under the proposed rule, NRCS expanded the potential acquisition of floodplain easements to include non-agricultural lands. Structures within the floodplain easement may be demolished or relocated outside the 100-year floodplain, whichever costs less. This element of the proposed rule would tend to increase program costs in the short-term, but reduce costs to the Federal government in the long-term, as people and structures in non-agricultural areas are relocated out of the floodplain. In addition, as more acreage is returned to open space, the floodplain would function in a more natural state with increased long-term public benefits. The agency has adopted the proposed provision in the final rule without change.

Section 624.10(b)(4). Section 624.10(b)(4) sets forth the compensation that NRCS will pay a landowner for the purchase of a floodplain easement. The floodplain easement program is the successor program to the Emergency Wetlands Reserve Program (EWRP) that NRCS administered with EWP funds to address the 1993 and 1995 Midwest Flood events. As a component of the Wetlands Reserve Program, landowners received agricultural value for an EWRP easement. In the proposed rule, NRCS indicated that it would pay a landowner for a floodplain easement the lesser of the three following values as an easement payment: (1) A geographic rate established by the NRCS State conservationist, if one has been established; (2) A value based on a market appraisal analysis for agricultural uses or assessment for agricultural land; or (3) the landowner's offer, if one has been made.

NRCS is making a few adjustments to the compensation section of the final rule in response to recent changes made to the Department of Transportation's regulations to implement the Uniform Relocation Assistance and Real Property Acquisition for Federal and Federally Assisted Programs, 49 CFR Part 24, 7 CFR Part 21. In particular, NRCS relied upon an exemption for voluntary transactions in the former Department of Transportation regulations for its valuation methodology under the floodplain easement component of EWP. The Department of Transportation published its new regulations on January 4, 2005 (70 FR 590). The new Department of Transportation regulations have removed the voluntary transaction exemption, and therefore, NRCS modified the final rule to reflect that NRCS will follow applicable regulation and other law in its determination of easement compensation.

Section 624.10(c). Although no comments were received on this section, NRCS changed the language in this final regulation to accurately identify its policy related to easement modifications and terminations. The agency does not have the authority for either action. NRCS does have the authority under (7 U.S.C. 428a), in limited situations, to accept land exchanges.

Section 624.11 Waivers. Although no public comments were received on this section, NRCS is clarifying in the final rule that the NRCS Deputy Chief for Programs has the authority to waive any provision of these regulations to the extent allowed by law when the agency makes a written determination that such waiver is in the best interest of the Federal government. NRCS clarified that the determination must be in writing and in the best interest of the Federal government. NRCS will, upon request, make waivers available to the public in accordance with the Freedom of Information Act and 16 U.S.C. 3844(b).

List of Subjects in 7 CFR Part 624

Disaster assistance, Floodplain easement, Flooding, Imminent threat, Natural disaster, Watershed impairment.

■ Accordingly, for the reasons stated in the preamble, Part 624 of Title 7 of the Code of Federal Regulations is revised to read as follows:

PART 624—EMERGENCY WATERSHED PROTECTION

Sec.

624.1 Purpose.
624.2 Objective.
624.3 Scope.
624.4 Definitions.
624.5 Coordination.
624.6 Program administration.
624.7 Cost-sharing.
624.8 Assistance.
624.9 Time limits.
624.10 Floodplain easements.
624.11 Waivers.

Authority: Sec. 216, P.L. 81–516, 33 U.S.C. 70lb–1; Sec. 403, P.L. 95–334, as amended, 16 U.S.C. 2203; 5 U.S.C. 301.

§ 624.1 Purpose.

The Natural Resources Conservation Service (NRCS) and United States Forest Service (FS) are responsible for administering the Emergency Watershed Protection (EWP) Program. This part sets forth the requirements and procedures for Federal assistance, administered by NRCS, under Section 216, Public Law 81–516, 33 U.S.C. 701b–1; and Section 403 of the Agricultural Credit Act of 1978, Public Law 95–334, as amended by Section 382, of the Federal Agriculture Improvement and Reform Act of 1996, Public Law 104–127, 16 U.S.C. 2203. The Secretary of Agriculture has delegated the administration of the EWP Program to the Chief of NRCS on state, tribal, and private lands, and Chief of FS on National Forest Systems lands, including any other lands that are administered under a formal agreement with the FS. The FS administers the EWP Program in accordance with the Forest Service Manuals 1950 and 3540, and the Forest Service Handbook 1909.15

§ 624.2 Objective.

The objective of the EWP Program is to assist sponsors, landowners, and operators in implementing emergency recovery measures for runoff retardation and erosion prevention to relieve imminent hazards to life and property created by a natural disaster that causes a sudden impairment of a watershed.

§ 624.3 Scope.

EWP Program technical and financial assistance may be made available to a qualified sponsor, or landowners when a floodplain easement is the selected alternative by the Secretary of Agriculture, upon a qualified sponsor or landowner's request when a Federal emergency is declared by the President or when a local emergency is declared by the NRCS State Conservationist. The EWP Program is designed for emergency recovery work, including the purchase of floodplain easements. Emergency watershed protection is authorized in the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

§ 624.4 Definitions.

(a) *Defensibility* means the extent to which an action is:

(1) More beneficial than adverse in the extent and intensity of its environmental and economic effects;

(2) In compliance with Federal, State, and local laws;

(3) Acceptable to affected individuals and communities;

(4) Effective in restoring or protecting the natural resources;

(5) Complete with all necessary components included; and

(6) Efficient in achieving the desired outcome.

(b) *Exigency* means those situations that demand immediate action to avoid potential loss of life or property, including situations where a second event may occur shortly thereafter that could compound the impairment, cause new damages or the potential loss of life if action to remedy the situation is not taken immediately.

(c) *Floodplain easement* means a reserved interest easement, which is an interest in land, defined and delineated in a deed whereby the landowner conveys all rights and interest in the property to the grantee, but the landowner retains those rights, title, and interest in the property which are specifically reserved to the landowner in the easement deed.

(d) *Imminent threat* means a substantial natural occurrence that could cause significant damage to property or threaten human life in the near future.

(e)(1) *Limited resource area* is defined as a county where:

(i) Housing values are less than 75 percent of the State housing value average; and

(ii) Per capita income is 75 percent or less than the National per capita income; and

(iii) Unemployment is at least twice the U.S. average over the past 3 years based upon the annual unemployment figures.

(2) NRCS will use the most recent National census information available when determining paragraphs (e)(1)(i) and (ii) of this section.

(f) *Natural occurrence* includes, but is not limited to, floods, fires, windstorms, ice storms, hurricanes, typhoons, tornadoes, earthquakes, volcanic actions, slides, and drought.

(g) *Project sponsor* means a State government or a State agency or a legal subdivision thereof, local unit of government, or any Native American tribe or tribal organization as defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b), with a legal interest in or responsibility for the values threatened by a watershed emergency; is capable of obtaining necessary land rights; and is capable of carrying out any operation and maintenance responsibilities that may be required.

(h) *Watershed emergency* means adverse impacts to resources exist when a natural occurrence causes a sudden impairment of a watershed and creates an imminent threat to life or property.

(i) *Watershed impairment* means the situation that exists when the ability of a watershed to carry out its natural functions is reduced to the point where an imminent threat to health, life, or property is created. This impairment can also include sediment and debris deposition in floodplains and upland portions of the watershed.

§ 624.5 Coordination.

(a) If the President declares an area to be a major disaster area, NRCS will provide assistance which will be coordinated with the Federal Emergency Management Agency (FEMA) or its designee. FEMA is the lead federal agency for Presidentially-declared natural disasters.

(b) When an NRCS State Conservationist determines that a watershed impairment exists, but the President does not declare an area to be a major disaster area, FEMA does not coordinate assistance. In this situation, NRCS will assume the lead, provide assistance, and coordinate work with the appropriate State office of emergency preparedness and other Federal, tribal, or local agencies involved with emergency activities, as appropriate.

(c) In the case where the watershed impairment exists solely on FS System lands, the FS will determine the existence of the impairment, assume the lead, provide assistance and coordinate work with the appropriate State office of emergency preparedness and other Federal, tribal, or local agencies involved with emergency activities, as appropriate.

§ 624.6 Program administration.

(a) *Sponsors.* (1) When the State Conservationist declares that a watershed impairment exists, NRCS may, upon request, make assistance available to a sponsor which must be a State or political subdivision thereof, qualified Indian tribe or tribal organization, or unit of local government. Private entities or individuals may receive assistance only through the sponsorship of a governmental entity.

(2) Sponsors must:

(i) Contribute their share of the project costs, as determined by NRCS, by providing funds or certain services necessary to undertake the activity. Contributions that may be applied towards the sponsor's applicable cost-share of construction costs include:

(A) Cash;

(B) In-kind services such as labor, equipment, design, surveys, contract administration and construction inspection, and other services as determined by the State Conservationist; or

(C) A combination of cash and in-kind services;

(ii) Obtain any necessary real property rights, water rights, and regulatory permits; and

(iii) Agree to provide for any required operation and maintenance of the completed emergency measures.

(b) *Eligibility.* NRCS will provide assistance based upon the NRCS State Conservationist's determination that the current condition of the land or watershed impairment poses a threat to health, life, or property. This assistance includes EWP practices associated with the removal of public health and safety threats, and restoration of the natural environment after disasters, including acquisition of floodplain easements.

(1) Priority EWP assistance is available to alleviate exigency situations. NRCS may approve assistance for temporary correction practices to relieve an exigency situation until a more acceptable solution can be designed and implemented.

(2) *Limitations.* (i) In cases where the same type of natural event occurs within a 10-year period and a structural measure has been installed or repaired twice within that period using EWP assistance, then EWP assistance is limited to those sites eligible for the purchase of a floodplain easement as described in § 624.10 of this part.

(ii) EWP assistance will not be used to perform operation or maintenance, such as the periodic work that is necessary to maintain the efficiency and effectiveness of a measure to perform as originally designed and installed.

(iii) EWP assistance will not be used to repair, rebuild, or maintain private or public transportation facilities, public utilities, or similar facilities.

(iv) EWP assistance, funded by NRCS, will not be provided on any Federal lands if such assistance is found to augment the appropriations of other Federal agencies.

(v) EWP assistance is not available for repair or rehabilitation of nonstructural management practices, such as conservation tillage and other similar practices.

(3) *Repair of structural, enduring, and long-life conservation practices.* (i) Sponsors may receive EWP assistance for structural, enduring, and long-life conservation practices including, but not limited to, grassed waterways, terraces, embankment ponds, diversions, and water conservation systems, except where the recovery measures are eligible for assistance under the Emergency Conservation Program administered by the Farm Service Agency.

(ii) EWP assistance may be available for the repair of certain structural

practices (*i.e.*, dams and channels) originally constructed under Public Law 83–566; Public Law 78–534; Subtitle H of Title XV of the Agriculture and Food Act of 1981 (16 U.S.C. 3451 *et seq.*, commonly known as the Resource Conservation and Development Program); and the Pilot Watershed Program of the Department of Agriculture Appropriation Act of 1954 (Pub. L. 83–156; 67 Stat. 214). EWP assistance may not be used to perform operation and maintenance activities specified in the agreement for the covered structure project entered into with the eligible local organization responsible for the works of improvement.

(iii) NRCS may authorize EWP assistance for modifying damaged practices when technology advances or construction techniques warrant modifications, including when modifications are the result of federal permitting or other requirements necessary to implement the recovery measure, and will be cost-shared as described in § 624.7.

(iv) EWP assistance is only available when public or private landowners, land managers, land users, or others document they have exhausted or have insufficient funding or other resources available to provide adequate relief from applicable hazards.

(4) Increased level of protection. In cases other than those described in paragraph (b)(3)(iii) of this section, if the sponsor desires to increase the level of protection that would be provided by the EWP practice, the sponsor will be responsible for paying 100 percent of the costs of the upgrade or additional work.

(c) *Eligible practices*. NRCS will only provide assistance for measures that:

(1) Provide protection from additional flooding or soil erosion; and,

(2) Reduce threats to life or property from a watershed impairment, including sediment and debris removal in floodplains and uplands; and

(3) Restore the hydraulic capacity to the natural environment to the maximum extent practical; and

(4) Are economically and environmentally defensible and technically sound.

(d) *Documentation*. NRCS will document the economic rationale of proposed practices in appropriate detail before the allocation of emergency funding, including projects under consideration for floodplain easements in § 624.10. Generally, the expected value of the property restored should exceed the cost of emergency measures, including taking into consideration environmental benefits. Documentation will include, but is not limited to:

(1) Number of locations and extent of damage, including environmental and cultural resources at risk, because of the watershed impairment;

(2) Estimated damages to the values at risk if the threat is imminent but not yet realized;

(3) Events that must occur for any imminent threat to be realized and the estimated probability of their occurrence both individually and collectively;

(4) Estimates of the nature, extent, and costs of the emergency practices to be constructed to recover from an actual threat or relieve an imminent threat;

(5) Thorough description of the beneficial and adverse effects on environmental resources, including fish and wildlife habitat;

(6) Description of water quality and water conservation impacts, as appropriate;

(7) Analysis of effects on downstream water rights; and

(8) Other information deemed appropriate by NRCS to describe adequately the environmental impacts to comply with the National Environmental Policy Act, Endangered Species Act, National Historic Preservation Act, and related requirements.

(e) *Implementation*. When planning emergency recovery practices, NRCS will emphasize measures that are the most economical and are to be accomplished by using the least damaging practical construction techniques and equipment that retain as much of the existing characteristics of the landscape and habitat as possible. Construction of emergency practices may include, but are not limited to, timing of the construction to avoid impacting fish spawning, clearing of right-of-ways, reshaping spoil, debris removal, use of bioengineering techniques, and revegetation of disturbed areas. Mitigation actions needed to offset potential adverse impacts of the EWP Program practices should be planned for installation before, or concurrent with, the installation of the EWP Program practices. In rare occurrences where mitigation cannot be installed concurrently, plans will require mitigation be accomplished as soon as practical.

(f) NRCS may determine that a measure is not eligible for assistance for any reason, including economic and environmental factors or technical feasibility.

§ 624.7 Cost-sharing.

(a) Except as provided in paragraph (b) of this section, the Federal contribution toward the implementation of emergency measures may not exceed 75 percent of the construction cost of such emergency measures, including work done to offset or mitigate adverse impacts as a result of the emergency measures.

(b) If NRCS determines that an area qualifies as a limited resource area, the Federal contribution toward the implementation of emergency measures may not exceed 90 percent of the construction cost of such emergency measures.

§ 624.8 Assistance.

(a) Sponsors must submit a formal request to the State Conservationist for assistance within 60 days of the natural disaster occurrence, or 60 days from the date when access to the sites becomes available. Requests must include a statement that the sponsors understand their responsibilities and are willing to pay its cost-shared percentage as well as information pertaining to the natural disaster, including the nature, location, and scope of the problems and the assistance needed.

(b) On receipt of a formal request for EWP assistance, the State Conservationist or designee shall immediately investigate the emergency situation to determine whether EWP is applicable and to prepare an initial cost estimation for submission to the NRCS Chief or designee. The cost estimation will be submitted no later than 60 days from receipt of the formal request from the sponsor. The State Conservationist will take into account the funding priorities identified in paragraph (c) (3) of this section. The State Conservationist will forward the damage survey report, which provides the information pertaining to proposed EWP practice(s) and indicates the amount of funds necessary to undertake the Federal portion, to the NRCS Chief or designee. This information will be submitted no later that 60 days from receipt of the formal request from the sponsor, or no later than 60 days from the date funding is made available to the State Conservationist, whichever is later. NRCS may not commit funds until notified by the Chief, or designee, of the availability of funds.

(c) Before the release of financial assistance, NRCS will enter into a Cooperative Agreement with a sponsor that specifies the responsibilities of the sponsor under this part, including any required operation and maintenance responsibilities. NRCS will not provide funding for activities undertaken by a

sponsor prior to the signing of the agreement between NRCS and the sponsor.

(1) NRCS will only provide funding for work that is necessary to reduce applicable threats.

(2) Efforts must be made to avoid or minimize adverse environmental impacts associated with the implementation of emergency measures, to the extent practicable, giving special attention to protecting cultural resources and fish and wildlife habitat.

(3) Funding priorities for recovery measures. NRCS will provide EWP assistance based on the following criteria, which are ranked in the order of importance:

(i) Exigency situations;

(ii) Sites where there is a serious, but not immediate threat to human life;

(iii) Sites where buildings, utilities, or other important infrastructure components are threatened;

(iv) When reviewing paragraphs (c)(3)(i) through (iii) of this section, NRCS will take into account the following resources as they may affect the priority, including, but not limited to:

(A) Sites inhabited by federally listed threatened and endangered species or containing federally designated critical habitat where the species or the critical habitat could be jeopardized, destroyed, or adversely modified without the EWP practice;

(B) Sites that contain or are in the proximity to cultural sites listed on the National Register of Historic Places where the listed resource would be jeopardized if the EWP practice were not installed;

(C) Sites where prime farmland supporting high value crops is threatened;

(D) Sites containing wetlands that would be damaged or destroyed without the EWP practice;

(E) Sites that have a major effect on water quality; and

(F) Sites containing unique habitat, including but not limited to, areas inhabited by State-listed threatened and endangered species, fish and wildlife management areas, or State-identified sensitive habitats; and

(v) Other funding priorities established by the Chief of NRCS.

§ 624.9 Time limits.

Funds must be obligated by the State Conservationist and construction completed within 220 calendar days after the date funds are committed to the State Conservationist, except for exigency situations in which case the construction must be completed within 10 days after the date the funds are committed.

§ 624.10 Floodplain easements.

(a) *General*. NRCS may purchase floodplain easements as an emergency measure. NRCS will only purchase easements from landowners on a voluntary basis.

(b) *Floodplain easements*. (1) Floodplain easements established under this part will be:

(i) Held by the United States, through the Secretary of Agriculture;

(ii) Administered by NRCS or its designee; and

(iii) Perpetual in duration;

(2) *Eligible land*. NRCS may determine land is eligible under this section if:

(i) The floodplain lands were damaged by flooding at least once within the previous calendar year or have been subject to flood damage at least twice within the previous 10 years; or

(ii) Other lands within the floodplain would contribute to the restoration of the flood storage and flow, erosion control, or that would improve the practical management of the easement; or

(iii) Lands would be inundated or adversely impacted as a result of a dam breach.

(3) *Ineligible land*. NRCS may determine that land is ineligible under this section if:

(i) Implementation of restoration practices would be futile due to ''on-site'' or ''off-site'' conditions;

(ii) The land is subject to an existing easement or deed restriction that provides sufficient protection or restoration, as determined by the Chief of NRCS, of the floodplain's functions and values; or

(iii) The purchase of an easement would not meet the purposes of this part.

(4) *Compensation for easements*. NRCS will determine easement compensation in accordance with applicable regulation and other law.

(5) NRCS will not acquire any easement unless the landowner accepts the amount of the easement payment that is offered by NRCS. NRCS reserves the right not to purchase an easement if the easement compensation for a particular easement would be too expensive, as determined by NRCS.

(6) NRCS may provide up to 100 percent of the restoration and enhancement costs of the easement. NRCS may enter into an agreement with the landowner or another third party to ensure that identified practices are implemented. NRCS, the landowner, or other designee may implement identified practices. Restoration and enhancement efforts may include both structural and non-structural practices. An easement acquired under this part shall provide NRCS with the full authority to restore, protect, manage, maintain, and enhance the functions and values of the floodplain.

(7) The landowner must:

(i) Comply with the terms of the easement;

(ii) Comply with all terms and conditions of any associated agreement; and

(iii) Convey title to the easement that is acceptable to NRCS and warrant that the easement is superior to the rights of all others, except for exceptions to the title that are deemed acceptable by NRCS.

(8) Structures, including buildings, within the floodplain easement may be demolished and removed, or relocated outside the 100-year floodplain or dam breach inundation area.

(c) Easements acquired under this part may not be modified or terminated. However, in limited situations, as determined by the Chief of NRCS and when in the best interest of the Government, land exchanges may be authorized pursuant to (7 U.S.C. 428a) and other applicable authorities.

(d) *Enforcement*. (1) In the event of a violation of an easement, the violator will be given reasonable notice and an opportunity to correct the violation within 30 days of the date of the notice, or such additional time as NRCS may allow.

(2) NRCS reserves the right to enter upon the easement area at any time to remedy deficiencies or easement violations. Such entry may be made at the discretion of NRCS when such actions are deemed necessary to protect important floodplain functions and values or other rights of the United States under the easement. The landowner will be liable for any costs incurred by the United States as a result of the landowner's negligence or failure to comply with easement or agreement obligations.

(3) In addition to any and all legal and equitable remedies as may be available to the United States under applicable law, NRCS may withhold any easement and cost-share payments owing to landowners at any time there is a material breach of the easement covenants or any associated agreements. Such withheld funds may be used to offset costs incurred by the United States, in any remedial actions, or retained as damages pursuant to court order or settlement agreement.

(4) NRCS will be entitled to recover any and all administrative and legal costs, including attorney's fees or

expenses, associated with any enforcement or remedial action.

(5) On the violation of the terms or conditions of the easement or related agreement, the easement shall remain in force, and NRCS may require the landowner to refund all or part of any payments received by the landowner under this Part, together with interest thereon as determined appropriate by NRCS.

(6) All the general penal statutes relating to crimes and offenses against the United States shall apply in the administration of floodplain easements acquired under this part.

§ 624.11 Waivers.

To the extent allowed by law, the NRCS Deputy Chief for Programs may waive any provision of these regulations when the agency makes a written determination that such waiver is in the best interest of the Federal government.

Signed in Washington, DC, on March 21, 2005.

Bruce I. Knight,

Chief, Natural Resources Conservation Service.

[FR Doc. 05–6098 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–16–U

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1738

RIN 0572–AB81

Rural Broadband Access Loans and Loan Guarantees

AGENCY: Rural Utilities Service, USDA.

ACTION: Direct final rule.

SUMMARY: The Rural Utilities Service (RUS), an agency delivering the U.S. Department of Agriculture's Rural Development Utilities Programs, is amending its regulations to revise the definition for ''eligible rural community'' as it relates to the rural access broadband loans and loan guarantees program.

DATES: This rule will become effective May 19, 2005, unless we receive written adverse comments or a written notice of intent to submit adverse comments on or before May 4, 2005. If we receive such comments or notice, we will publish a timely document in the **Federal Register** withdrawing the rule. Comments received will be considered under the proposed rule published in this edition of the **Federal Register** in the proposed rule section. A second public comment period will not be held. Written comments must be received by RUS or carry a postmark or equivalent no later than May 4, 2005.

ADDRESSES: Submit adverse comments or notice of intent to submit adverse comments by any of the following methods:

- Federal eRulemaking Portal: Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.
- Agency Web Site: *http://www.usda.gov/rus/index2/Comments.htm*. Follow the instructions for submitting comments.
- E-mail: *RUSComments@usda.gov*. Include in the subject line of the message ''Broadband Loans and Loan Guarantees''.
- Mail: Addressed to Richard Annan, Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., STOP 1522, Washington, DC 20250–1522.
- Hand Delivery/Courier: Addressed to Richard Annan, Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 5168 South Building, Washington, DC 20250–1522.

Instructions: All submissions received must include that agency name and the subject heading ''Broadband Loans and Loan Guarantees''. All comments received must identify the name of the individual (and the name of the entity, if applicable) who is submitting the comment. All comments received will be posted without change to *http://www.usda.gov/rus/index2/Comments.htm*, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Jonathan Claffey, Acting Assistant Administrator, Telecommunications Program, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., STOP 1590, Room 4056, Washington, DC 20250–1590. Telephone number (202) 720–9554, Facsimile (202) 720–0810.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This proposed rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. RUS has determined that this rule meets the applicable standards provided in section 3 of that Executive Order. In addition, all State and local laws and regulations that are in conflict with this rule will be preempted. No retroactive effect will be given to the rule and, in accordance with section 212(e) of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6912(e)), administrative appeal procedures must be exhausted before an action against the Department or its agencies may be initiated.

Regulatory Flexibility Act Certification

RUS certifies that this rule will not have significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The RUS broadband program provides loans to borrowers at interest rates and terms that are more favorable than those generally available from the private sector. RUS borrowers, as a result of obtaining Federal financing, receive economic benefits that exceed any direct cost associated with complying with RUS regulations and requirements.

Information Collection and Recordkeeping Requirements

The reporting and recordkeeping requirements contained in the rule has been approved by the Office of Management and Budget (OMB) under OMB Control Number 0572–0130, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

Catalog of Federal Domestic Assistance

The program described by this rule is listed in the Catalog of Federal Domestic Assistance Programs under No. 10.851, Rural Telephone Loans and Loan Guarantees; No. 10.852, Rural Telephone Bank Loans; and No. 10.857, Rural Broadband Access Loans and Loan Guarantees. This catalog is available on a subscription basis from the Superintendent of Documents, the United States Government Printing Office, Washington, DC 20402. Telephone: (202) 512–1800.

Executive Order 12372

This rule is excluded from the scope of Executive Order 12372, Intergovernmental Consultation, which may require consultation with State and local officials. See the final rule related notice entitled ''Department Programs and Activities Excluded from Executive Order 12372,'' (50 FR 47034).

Executive Order 13132, Federalism

The policies contained in this rule do not have any substantial direct effect on 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. Nor does this rule impose substantial direct compliance costs on State and local governments. Therefore, consultation with States is not required.

Unfunded Mandates

This rule contains no Federal mandates (under the regulatory provision of Title II of the Unfunded Mandate Reform Act of 1995) for State, local, and tribal governments or the private sector. Thus, this rule is not subject to the requirements of sections 202 and 205 of the Unfunded Mandate Reform Act of 1995.

National Environmental Policy Act Certification

The Administrator of RUS has determined that this proposed rule will not significantly affect the quality of the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Therefore, this action does not require an environmental impact statement or assessment.

Background

The Rural Utilities Service (RUS) published in the **Federal Register** on January 30, 2003, at 68 FR 4684, a final rule amending its regulations in order to establish the Rural Broadband Access Loan and Loan Guarantee Program as authorized by the Farm Security and Rural Investment Act of 2002 (Pub. L. 101–171) (2002 Act). Section 6103 of the Farm Security and Rural Investment Act of 2002 amended the Rural Electrification Act of 1936, as amended (RE Act), to add Title VI, Rural Broadband Access, to provide loans and loan guarantees to fund the cost of construction, improvement, or acquisition of facilities and equipment for the provision of broadband service in eligible rural communities.

This rule amends § 1738.2, Definitions, to conform the rule to substantive changes in authority. The definition for ''eligible rural community'' in section 601(b)(2) of the Rural Electrification Act of 1936 (7 U.S.C. 950bb(b)(2)) was amended on January 23, 2004, by section 772 of Public Law 108–199, of the Consolidated Appropriations Act, 2004 to eliminate the requirement that a community exist outside a standard metropolitan statistical area. This rule incorporates the language of the revised statute and explains RUS' interpretation of the language.

List of Subjects in 7 CFR Part 1738

Broadband, Loan programs—communications, Rural areas, Telephone, Telecommunications.

■ For reasons set for in the preamble, chapter XVII of title 7 of the Code of Federal Regulations is amended to read as follows:

PART 1738—RURAL BROADBAND ACCESS LOANS AND LOAN GUARANTEES

■ 1. The authority citation for part 1738 continues to read as follows:

Authority: Public Law 107–171, 7 U.S.C. 901 *et seq.*

■ 2. Amend § 1738.2 to revise the definition to ''Eligible rural community'' to read as follows:

§ 1738.2 Definitions.

* * * * *

Eligible rural community is defined in the RE Act as any area of the United States that is not contained in an incorporated city or town with a population in excess of 20,000 inhabitants. For purposes of this part, RUS interprets:

(1) ''United States'' to include its territories and insular possessions (including the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau);

(2) ''Area'' to mean any identifiable place that has no more than 20,000 inhabitants based on the most recent available information of the Bureau of the Census; and

(3) ''An incorporated city or town with a population in excess of 20,000 inhabitants'' to mean any incorporated city or town with a population in excess of 20,000 inhabitants based on the most recent available information of the Bureau of the Census.

* * * * *

Dated: March 28, 2005.

Curtis M. Anderson,

Acting Administrator, Rural Utilities Service.

[FR Doc. 05–6537 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2004–17896; Airspace Docket No. 04–AGL–13]

Modification of Class D Airspace; Grissom ARB, IN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class D airspace at Grissom ARB, IN, where Instrument Flight Rules Category E circling procedures are being used. This action increases the current area of the Class D airspace.

EFFECTIVE DATE: 0901 UTC, July 7, 2005.

FOR FURTHER INFORMATION CONTACT: J. Mark Reeves, FAA, Terminal Operations, Central Service Office, Operations Branch, AGL–530, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7477.

SUPPLEMENTARY INFORMATION:

History

On Thursday, September 23, 2004, the FAA proposed to amend 14 CFR part 71 to modify the Class D airspace area at Grissom, ARB, IN. The proposal was to increase the existing radius of the Class D airspace area to allow for IFR Category E circling procedures.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal. One comment was received and reviewed prior to taking any final action this matter. It stated objection and provided other comments on the proposal. The comment expressed concern that the proposed expansion of the Class D airspace area would create a burden on the flying public. There were also comments pertaining to the belief that there is a lack of funding for training flights, and other operational concerns that would render the expansion as proposed unnecessary.

In response to the comment received, and taking into consideration the concerns of the commenter, discussions were held between the FAA and the military to see if a modification could be made to the proposed expansion. The military, in a letter, explained the need for the expansion as proposed due to training and proficiency needs. They do have the budget to support this, and their simulators are not set up to accomplish this. Except for a 1.1-mile

increase to the existing Class D airspace radius, the Class D airspace area would remain unchanged.

The Rule

This amendment to 14 CFR part 71 modifies the Class D airspace area at Grissom ARB, IN. The area will be depicted on appropriate aeronautical charts.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this, proposed regulation—(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 will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 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 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 the Federal Aviation Administration Order 7400.9M, Airspace Designations and Reporting Points, dated August 30, 2004, and effective September 16, 2004, is amended as follows:

* * * * *

Paragraph 5000 Class D airspace.

AGL IN D Grissom ARB, IN [Revised]

(Lat. 40° 38′53″ N., long. 86° 09′08″ W.)

That airspace extending upward from the surface to and including 3,300 feet MSL within a 5.6-mile radius of Grissom ARB. This Class D airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Des Plaines, Illinois on March 11, 2005.

Nancy B. Kort,

Area Director, Central Terminal Operations.

[FR Doc. 05–6655 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2003–19237; Airspace Docket No. 04–AGL–19]

Establishment of Class E Airspace; Tracy, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Tracy, MN. Standard Instrument Approach Procedures have been developed for Tracy Municipal Airport, Tracy, MN. Controlled airspace extending upward from 700 feet or more above the surface of the earth is needed to contain aircraft executing these approaches. This action establishes an area of controlled airspace for Tracy Municipal Airport.

EFFECTIVE DATE: 0901 UTC, July 7, 2005.

FOR FURTHER INFORMATION CONTACT: J. Mark Reeves, FAA, Terminal Operations, Central Service Office, Operations Branch, AGL–530, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7477.

SUPPLEMENTARY INFORMATION:

History

On Friday, December 10, 2004, the FAA proposed to amend 14 CFR part 71 to establish Class E airspace at Tracy, MN. The proposal was to establish controlled airspace extending upward from 700 feet or more above the surface of the earth to contain Instrument Flight Rules operations in controlled airspace during portions of the terminal operation and while transiting between the enroute and terminal environments.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9M dated August 30, 2004, and effective September 16, 2004, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

The amendment to 14 CFR part 71 establishes Class E airspace at Tracy, MN, to accommodate aircraft executing instrument flight procedures into and out of Tracy Municipal Airport. The area will be depicted on appropriate aeronautical charts.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(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 will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 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 part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 95665, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9M, Airspace Designations and Reporting Points, dated August 30, 2004, and

effective September 16, 2004, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 Feet or more above the surface of the earth.

AGL MN E5 Tracy, MN [New]

Tracy Municipal Airport, MN
(Lat. 44°14′57″ N., long. 95°36′26″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Tracy Municipal Airport.

* * * * *

Issued in Des Plaines, Illinois, on March 11, 2005.

Nancy B. Kort,

Area Director, Central Terminal Operations.

[FR Doc. 05–6654 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 558

New Animal Drugs; Limitations of Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the limitations to conditions of use for products approved under 22 new animal drug applications (NADAs) and 5 abbreviated new animal drug applications (ANADAs). In error, a label statement warning against the use of these products in calves to be processed for veal was not codified at the time supplemental NADAs or ANADAs were approved. FDA is also amending the animal drug regulations to reflect the approved preslaughter withdrawal periods and milk withholding period in cattle following use of penicillin G procaine aqueous suspension. This action is being taken to improve the accuracy of the animal drug regulations.

DATES: This rule is effective April 4, 2005.

FOR FURTHER INFORMATION CONTACT: Jeffrey Punderson, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4109, e-mail: *jpunders@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Over the past decade, FDA's Center for Veterinary Medicine (CVM) asked sponsors of certain products approved for use in cattle to place this warning on their labels: ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' This was done to reduce the frequency of unsafe residues of animal drugs in veal. While many sponsors complied and filed applications to change their labels, CVM did not always codify this limitation to approved conditions of use when the supplemental application was approved. At this time, FDA is amending the animal drug regulations to reflect the limitations to conditions of use for the following products:

Application No.	21 CFR Section	Trade Name
NADA 011–060	520.1660c	TERRAMYCIN Scour Tablets
NADA 012–350	558.55	AMPROVINE 25%; AMPROL 25%
NADA 012–350	520.100c	CORID 1.25% Crumbles
NADA 012–965	522.2640a	TYLAN Injection 50 mg; TYLAN Injection 200 mg
NADA 013–149	520.100a	CORID 9.6% Solution
NADA 030–434	520.540a	AZIUM Powder
NADA 030–435	520.540b	AZIUM Boluses 10 mg
NADA 031–715	520.2220b	ALBON; AGRIBON Boluses–2.5, -5.0, and -15.0
NADA 033–127	520.2200a	PRINZONE, PYRADAN, and VETISULID Boluses
NADA 033–165	520.100b	CORID 20% Soluble Powder
NADA 033–373	520.2200b	PRINZONE, PYRADAN, and VETISULID Powder
NADA 033–318	522.2200	PRINZONE, PYRADAN, and VETISULID Injection
NADA 041–245	522.2220	AGRIBON Injection 40%; ALBON
NADA 065–010	522.1696b	AGRICILLIN Pen Aqueous; AQUA-CILLIN; Penicillin G Co-op
NADA 065–110	522.1696b	PRO-PEN G in Aqueous Suspension
NADA 065–140	520.2345d	TET-SOL 10 and TET-SOL 324
NADA 065–269	520.2345d	POLYOTIC Soluble Powder
NADA 065–441	520.2345d	POLYOTIC Soluble Powder Concentrate
NADA 065–493	522.1696b	Penicillin G Procaine Aqueous Suspension
NADA 065–496	520.2345d	Tetracycline Soluble Powder

Application No.	21 CFR Section	Trade Name
NADA 093–107	520.2220b	ALBON S.R.
NADA 138–955	522.2640a	Tylosin Injection
NADA 141–002	520.1660c	OXY 500 and 1000 Calf Boluses
ANADA 200–038	522.2220	DI-METHOX Injection 40%; Sulfadimethoxine Injection 40%
ANADA 200–049	520.2345d	TETRA-BAC 324 Soluble Powder; Tetracycline Hydrochloride Soluble Powder–324.
ANADA 200–136	520.2345d	Tetracycline HCL Powder; Tetracycline Hydrochloride Soluble Powder–324.
ANADA 200–177	522.2220	Sulfadimethoxine Injection 40%
ANADA 200–234	520.2345d	TETRASOL Soluble Powder

Accordingly, the agency is amending the regulations in 21 CFR 520.100a, 520.100b, 520.100c, 520.540a, 520.540b, 520.1660c, 520.2200a, 520.2200b, 520.2220b, 520.2345d, 522.1696b, 522.2200, 522.2220, 522.2640a, and 558.55.

In addition, FDA has found that the animal drug regulations do not reflect the approved preslaughter withdrawal period for cattle, sheep, and swine for PRO–PEN G in Aqueous Suspension sponsored by Phoenix Scientific, Inc., approved under NADA 065–110. FDA has also found that the animal drug regulations do not reflect the approved milk withholding period for Penicillin G Procaine Aqueous Suspension sponsored by G.C. Hanford Manufacturing Co. (NADA 065–493) and AGRICILLIN Pen Aqueous, AQUA–CILLIN, and Penicillin G Co-op sponsored by Norbrook Laboratories Ltd. (NADA 065–010). At this time, the regulations are being amended in 21 CFR 522.1696b to correct these errors.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Parts 520 and 522

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520, 522, and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.100a [Amended]

■ 2. Section 520.100a is amended in paragraphs (d)(2)(i)(*b*) and (d)(2)(ii)(*b*) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.100b [Amended]

■ 3. Section 520.100b is amended in paragraphs (d)(1)(ii) and (d)(2)(ii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.100c [Amended]

■ 4. Section 520.100c is amended in paragraphs (d)(1)(ii) and (d)(2)(ii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.540a [Amended]

■ 5. Section 520.540a is amended in paragraph (c)(4) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.540b [Amended]

■ 6. Section 520.540b is amended in paragraph (a)(3)(vi) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.1660c [Amended]

■ 7. Section 520.1660c is amended in paragraph (d)(3) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.2200a [Amended]

■ 8. Section 520.2200a is amended in paragraph (e)(3) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.2200b [Amended]

■ 9. Section 520.2200b is amended in paragraph (e)(1)(iii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.2220b [Amended]

■ 10. Section 520.2220b is amended in paragraph (d)(1)(iii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 520.2345d [Amended]

■ 11. Section 520.2345d is amended in paragraph (d)(1)(iii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 12. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 13. Section 522.1696b is amended by revising paragraph (d)(2)(iii) to read as follows:

§ 522.1696b Penicillin G procaine aqueous suspension.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations*. Not for use in horses intended for food. Milk that has been taken during treatment and for 48 hours after the last treatment must not be used for food.

(A) For Nos. 053501 and 061623: Do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle. Discontinue treatment for the following number of days before slaughter: Nonruminating cattle (calves)—7; all other cattle—4; sheep—8; and swine—6.

(B) For Nos. 010515, 055529, and 059130: Treatment should not exceed 4 consecutive days. Discontinue treatment for the following number of days before slaughter: Cattle—10; sheep—9; and swine—7. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

§ 522.2200 [Amended]

■ 14. Section 522.2200 is amended in paragraph (e)(3) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 522.2220 [Amended]

■ 15. Section 522.2220 is amended in paragraph (a)(3)(iii)(*c*) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

§ 522.2640a [Amended]

■ 16. Section 522.2640a is amended in paragraph (e)(1)(iii) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 17. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.55 [Amended]

■ 18. Section 558.55 is amended in paragraphs (d)(1)(i)(*b*) and (d)(1)(ii)(*b*) by adding ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.'' at the end of the paragraph.

Dated: March 25, 2005.

Daniel G. McChesney,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

[FR Doc. 05–6518 Filed 4–1–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–262F]

Schedules of Controlled Substances: Placement of Zopiclone Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance, zopiclone, including its salts, isomers and salts of isomers into Schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, dispensing, importation and exportation of zopiclone and products containing zopiclone.

DATES: *Effective Date:* April 4, 2005.

FOR FURTHER INFORMATION CONTACT: Christine Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, (202) 307–7183.

SUPPLEMENTARY INFORMATION: Zopiclone is a central nervous system depressant drug. On December 15, 2004, the Food and Drug Administration (FDA) approved (S)-zopiclone (or eszopiclone), the active (S) isomer of zopiclone, for marketing under the trade name Lunesta TM. Eszopiclone will be marketed as a prescription drug product for the treatment of insomnia.

On January 18, 2005, the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a letter recommending that zopiclone and its isomers be placed into Schedule IV of the CSA (21 U.S.C. 801 *et seq.*). Enclosed with the January 18, 2005, letter was a document prepared by the FDA entitled, ''Basis for the Recommendation for Control of Zopiclone and its Optical Isomers in Schedule IV of the Controlled Substances Act (CSA).'' The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

The correspondence from the Acting Assistant Secretary for Health to DEA dated January 18, 2005, confirmed that FDA approved the New Drug Application (NDA) for eszopiclone and issued an approval letter to the NDA sponsor on December 15, 2004. After a review of the available data, including the DHHS recommendation, the Deputy Administrator of the DEA, in a February 14, 2005, **Federal Register** notice of proposed rulemaking (70 FR 7449), proposed placement of zopiclone into Schedule IV of the CSA. The proposed rule provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing to be received by the DEA on or before March 16, 2005.

Comments Received

DEA received one comment in response to this notice of proposed rulemaking. The commenter stated that the current federal regulations governing the process of drug control and approval are excessive and are interfering with the practice of medicine.

DEA disagrees. The Controlled Substances Act contains specific mandates pertaining to the scheduling of controlled substances. DEA has followed all of those mandates regarding the scheduling of zopiclone, including receiving from the Secretary of DHHS a scientific and medical evaluation, and recommendation, regarding control (21 U.S.C. 811(b)); considering the factors enumerated in 21 U.S.C. 811(c); determining, based on the above, appropriate scheduling for zopiclone (21 U.S.C. 812(b)); and conducting a formal rulemaking to schedule zopiclone (21 U.S.C. 811(a)). In no way does this scheduling action interfere with the practice of medicine.

Scheduling of Zopiclone

Relying on the scientific and medical evaluation and the recommendation of the Acting Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, and after a review of the comments received in

response to the Notice of Proposed Rulemaking, the Deputy Administrator of DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Zopiclone has a low potential for abuse relative to the drugs or other substances in Schedule III;

(2) Zopiclone has a currently accepted medical use in treatment in the United States; and

(3) Abuse of zopiclone may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III. (21 U.S.C. 812(b)(4)).

Based on these findings, the Deputy Administrator of DEA concludes that zopiclone, including its salts, isomers, and salts of isomers, warrants control in Schedule IV of the CSA.

In order to make zopiclone pharmaceutical products available for medical use as soon as possible, the Schedule IV controls of zopiclone will be effective April 4, 2005. In the event that the regulations impose special hardships on the registrants, the DEA will entertain any justified request for an extension of time to comply with the Schedule IV regulations regarding zopiclone. The applicable regulations are as follows:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with zopiclone, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with zopiclone, must be registered to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before April 4, 2005, and may continue their activities until DEA has approved or denied that application.

Security. Zopiclone is subject to Schedule III-V security requirements and must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77 of Title 21 of the Code of Federal Regulations after April 4, 2005.

Labeling and Packaging. All labels and labeling for commercial containers of zopiclone shall comply with requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

Inventory. Every registrant required to keep records and who possesses any quantity of zopiclone must keep an inventory of all stocks of zopiclone on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations after April 4, 2005. Every registrant who desires registration in Schedule IV for zopiclone is required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants must keep records pursuant to §§ 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations after April 4, 2005.

Prescriptions. All prescriptions for zopiclone or prescriptions for products containing zopiclone are to be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.21–1306.27. All prescriptions for zopiclone or products containing zopiclone issued after April 4, 2005, if authorized for refilling, shall, as of that date, be limited to five refills and shall not be refilled after October 3, 2005.

Importation and Exportation. All importation and exportation of zopiclone must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations after April 4, 2005.

Criminal Liability. Any activity with zopiclone not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful on or after April 4, 2005.

Regulatory Certifications

Administrative Procedure Act

The Administrative Procedure Act permits an agency to make a rule effective upon the date of publication where the agency finds good cause exists and publishes its findings with the rule (5 U.S.C. 553(d)(3)). As noted previously, on December 15, 2004, the Food and Drug Administration (FDA) approved (S)-zopiclone (or eszopiclone), the active (S) isomer of zopiclone, for marketing under the trade name Lunesta™. Further, on January 18, 2005, the Acting Assistant Secretary for Health, Department of Health and Human Services, sent the Deputy Administrator of DEA a letter recommending that zopiclone and its isomers be placed into Schedule IV of the Controlled Substances Act. Since this is a new drug not previously available in the United States, in order to prevent harm to the public health and safety by delaying the availability of this new drug, the Drug Enforcement Administration finds good cause exists to make this Final Rule effective immediately upon publication.

Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Eszopiclone products will be prescription drugs used for the treatment of insomnia. Handlers of eszopiclone also handle other controlled substances used to treat insomnia which are already subject to the regulatory requirements of the CSA.

Eszopiclone is a new drug in the United States; recent approval of the product and its labeling by the FDA will allow it to be marketed once it is placed into Schedule IV of the CSA. This final rule will allow these entities to have access to a new pharmaceutical product.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking 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 rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $115,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement

Fairness Act of 1996. This rule 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.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

■ Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES [AMENDED]

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

■ 2. Section 1308.14 is amended by adding a new paragraph (c)(51) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(51) Zopiclone—2784

* * * * *

Dated: March 30, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–6703 Filed 3–31–05; 12:24 pm]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 10

[Public Notice 5036]

RIN 1400–AC09

Removal of Regulations on Employee Responsibilities and Conduct

AGENCY: State Department and United States Agency for International Development.

ACTION: Direct final rule.

SUMMARY: The Department of State and the United States Agency for International Development (USAID) are removing regulations on employee responsibilities and conduct (22 CFR part 10). Most of these regulations have been superseded or otherwise made unnecessary by Office of Government Ethics or Office of Personnel Management regulations of executive branch-wide applicability. Certain sections of the regulations are based on Foreign Service Act provisions that have been repealed. Some provisions have continuing application and are published, as modified, in the Foreign Affairs Manual and other provisions simply reference other statutory or regulatory provisions. The Department of State and USAID are using direct final rulemaking for this action because it is expected that there will be no significant adverse comment on the rule.

DATES: This direct final rule is effective on June 3, 2005, without further notice, unless the Department of State and USAID receive adverse comment by May 4, 2005. If adverse comment is received, then the Department of State and USAID will publish a timely withdrawal of the direct final rule in the **Federal Register**.

ADDRESSES: You may submit comments, identified by any of the following methods:

- E-mail: *eirinbergjl@state.gov*. You must include the RIN in the subject line of your message.
- Mail (paper, disk, or CD–ROM submissions): Julia L. Eirinberg, Attorney-Adviser, Department of State, Office of the Assistant Legal Adviser for Employment Law, 2201 C Street NW, Suite 5425, Washington, DC 20520.
- Fax: 202–647–6794.

Persons with access to the internet may also view this notice and provide comments by going to the regulations.gov Web site at: *http://www.regulations.gov/index.cfm*.

FOR FURTHER INFORMATION CONTACT: Julia L. Eirinberg, Attorney-Adviser, Department of State, Office of the Assistant Legal Adviser for Employment Law, 2201 C Street NW., Suite 5425, Washington DC 20520; e-mail address: *eirinbergjl@state.gov*.

SUPPLEMENTARY INFORMATION: The Department of State and USAID are removing part 10, ''Employee Responsibilities and Conduct,'' from 22 CFR as a result of developments in the executive branch ethics program and in other areas of law that have occurred since the promulgation of part 10 on May 2, 1978. While the regulations in 22 CFR part 10 also applied to the International Communication Agency (ICA), that agency no longer exists and its functions have been assumed by the Department of State.

Pursuant to the Ethics in Government Act of 1978 (5 U.S.C. App.), as amended, the U.S. Office of Government Ethics (OGE) now provides overall direction and leadership in relation to the executive branch ethics program. In 1989, E.O. 12674 (as modified by E.O. 12731) directed OGE to establish ''a single, comprehensive, and clear set of executive-branch standards of conduct'' and ''a system of nonpublic (confidential) financial disclosure.'' On August 7, 1992, OGE published the Standards of Ethical Conduct for Employees of the Executive Branch (Standards), now codified at 5 CFR part 2635. On April 7, 1992, OGE modified its existing financial disclosure regulation, at 5 CFR part 2634, to incorporate a revised system of confidential financial disclosure reporting.

Part 10 of 22 CFR was published in 1978 largely on the basis of a model standards of conduct regulation at old 5 CFR part 735 that had been promulgated by the Office of Personnel Management (OPM) pursuant to Executive Order 11222. The new OGE Standards became effective February 3, 1993. The Standards superseded individual executive agency conduct provisions—like those in 22 CFR part 10—that had been issued on the basis of the model OPM regulation, and superseded much of the model regulation itself. (As discussed below in relation to section 10.735–205 of part 10, certain agency conduct provisions were ''grandfathered'' or preserved for a few years after the February 3, 1993, effective date.) Provisions in the OGE regulation at 5 CFR part 2634 concerning the revised system of confidential financial disclosure became effective on October 5, 1992, and superseded those portions of individual executive agency regulations pertaining to confidential reporting that had been issued on the basis of the model OPM regulation. Taken together and as discussed more fully below, 5 CFR part 2635 and 5 CFR part 2634 superseded subpart C, subpart D, and much of subparts A and B of part 10. As also discussed below, the remaining sections of subparts A and B have been superseded or supplanted by other OGE regulations, are obsolete, or are unnecessary.

In subpart A of part 10, the statement of purpose in section 10.735–101 has been superseded by corollary sections in 5 CFR part 2635 and 5 CFR part 2634

and by language in section 101 of E.O. 12674 emphasizing the importance of ethical conduct. The definitions in section 10.735–102 have been superseded by definitions in the OGE regulations or are relevant only in relation to restrictions in volume 3 of the Foreign Affairs Manual and will, in any event, be rendered unnecessary when the rest of part 10 is removed from the CFR. Section 10.735–104 states that part 10 applies to all employees on detail to the Department. This section was important when each agency had its own conduct regulation, but is no longer necessary to the extent that the same basic standards, financial disclosure requirements, and conflict of interest statutes (and implementing regulations) now apply to all executive branch employees. Section 10.735–105 states that a violation of part 10 may be cause for appropriate disciplinary action. This section has been superseded by provisions in the Standards and the financial disclosure regulation, at sections 2635.106 and 2634.701, and by provisions in volume 3 of the Foreign Affairs Manual.

Section 10.735–103 of subpart A requires that the Secretary of State and Administrator of USAID each designate a ''Counselor'' to provide advice on employee conduct and to coordinate counseling services provided by designated ''Deputy Counselors.'' This section has been supplanted by procedural and staffing changes made by the Department and USAID consistent with the OGE regulation at 5 CFR part 2638. Part 2638 requires the Secretary and Administrator to each name a ''Designated Agency Ethics Official'' (DAEO) who, assisted by one or more ''Deputy Ethics Officials'' and other staff, is responsible for counseling and training and for other aspects of the ethics programs at the respective agencies.

In subpart B of part 10, section 10.735–201 sets forth general principles of conduct from Executive Order 11222. Executive Order 11222 was revoked in 1989 by Executive Order 12674. Similar principles now appear in Executive Order 12674 and are restated in the Standards, at section 2635.101. Section 10.735–201 also highlights provisions in part 10 having some application to a U.S. citizen employee's family. The highlighted provisions have been superseded by the Standards, are now implemented in 22 CFR part 3 (in relation to gifts from foreign governments), or are published, as modified, in volume 3 of the Foreign Affairs Manual (in relation to employees and family members abroad). The application of provisions to family members accompanying employees overseas is treated specifically in the Foreign Affairs Manual because of privileges and immunities attributed to family members by virtue of the official status of employees under international law. In addition, certain provisions in the Standards may affect an employee by virtue of the actions or interests of a family member. See, *e.g.*, 5 CFR 2635.203 (providing that an employee accepts a gift indirectly if it is given with the employee's knowledge and acquiescence to his or her parent, sibling, spouse, child, or dependent relative because of that person's relationship to the employee).

The first paragraphs of section 10.735–202 of part 10 prohibit an employee from accepting gifts from outside sources in certain circumstances, *e.g.*, from persons doing or seeking to do business with his or her agency, but provide for several exceptions. These provisions were superseded by subpart B of the Standards. In addition, section 10.735–202 prohibits an employee from giving a gift to an official superior and from accepting a gift from an employee receiving less pay. These prohibitions derive from 5 U.S.C. 7351 and are now implemented in subpart C of the Standards.

In addition, section 10.735–202 affirms that an employee may accept travel and subsistence expenses in connection with permissible outside activities notwithstanding the gifts prohibitions in part 10, but prohibits ''excessive'' benefits. The acceptance of gifts, compensation, or travel expenses in connection with outside activities is now addressed in the Standards, in subparts B and H. See also 5 CFR 2636.303 (defining ''outside earned income'' in relation to the outside compensation restrictions imposed on certain high-level ''noncareer'' employees by section 102 of E.O. 12674 and by title V of 5 U.S.C. App., as implemented by OGE in section 2635.804 of the Standards and in 5 CFR part 2636). Section 10.735–202 also cites a 1967 Comptroller General opinion, Decision B–128527. The appropriations law principles addressed in this decision are addressed in numerous subsequent legal opinions and are reflected in volume 2 of the Foreign Affairs Manual and in other regulations.

Section 10.735–203 of part 10 briefly summarizes the Foreign Gifts and Decorations Act, at 5 U.S.C. 7342, and references the Department's implementing regulation at 22 CFR part 3. The Foreign Gifts and Decorations Act is summarized in the OGE Standards, e.g., in section 2635.204. Other laws and regulations of significance to the ethics program are similarly summarized or referenced in subparts A through H of the Standards. Separately, subpart I of the Standards lists these significant laws and regulations (including 5 U.S.C. 7342), as well as other laws that establish standards to which an employee's conduct must conform. The subpart I compilation has replaced the listing in section 10.735–216 of part 10. (Even to the extent that a summary or reference in part 10 is not included in the Standards or some other regulation relating to the ethics program, the Department has determined that a summary or reference does not warrant further publication in part 10 absent some additional justification.)

Section 10.735–204 of part 10 prohibits an employee from engaging in an outside activity that conflicts with the employee's official duties and summarizes the Emoluments Clause of the U.S. Constitution and a conflict of interest statute, 18 U.S.C. 209, pertaining to the acceptance of compensation for services to the Government. These provisions have been superseded by the general provisions in subpart H of the Standards pertaining to conflicting outside activities, including the brief summaries in subpart H of the Emoluments Clause and various conflict of interest statutes.

Section 10.735–204 specifically addresses teaching, speaking, and writing pursued as an outside activity. It restricts the use of Government information in connection with the preparation of a person for an examination of the Civil Service Commission (now OPM) or Board of Examiners for the Foreign Service, prohibits certain Presidential appointees from accepting compensation for teaching, speaking, or writing about certain subject matter, and alerts employees to the existence of clearance procedures. The compensation restriction has been superseded by section 2635.807 of the Standards. See also section 102 of E.O. 12674 and title V of 5 U.S.C. App. (imposing ''outside earned income'' restrictions on certain high-level ''noncareer'' employees, as implemented in section 2635.804 of the Standards and in 5 CFR part 2636). The restriction pertaining to the use of Government information remains in the residual OPM regulation at 5 CFR part 735. As discussed above, the mere reference in part 10 to the teaching, speaking, and writing clearance procedures, now in volume 3 of the Foreign Affairs Manual, is unnecessary.

Section 10.735–204 also affirms that an employee may serve a foreign government or international organization of states if serving on behalf of the United States, and that the section does not preclude participation in the activities of political parties or participation in (or awards from) private organizations. While these affirmations remain generally correct, other statutes and regulations address, for example, the detail or transfer of employees to international organizations or to foreign governments. See e.g., 5 U.S.C. 3343; 5 U.S.C. 3581–84; 5 CFR 352.301 *et seq.*; 22 U.S.C. 2387; 22 U.S.C. 2388. The general permissibility of domestic political activity is implicit in the references, at section 2635.801 and 2635.902 of the Standards, to the ''Hatch Act'' restrictions. See also 5 CFR 2635.204 (providing that an employee may accept certain gifts in connection with active participation in political management or political campaigns). It is also apparent from subpart H of the Standards that participation in outside organizations is generally permissible, subject to certain restrictions. The acceptance of awards from private organizations is specifically addressed in section 2635.204 of the Standards.

Section 10.735–211 of part 10 requires that an employee make clear that his or her participation in a private organization, in his or her personal capacity, should not be construed as an official endorsement of the organization's viewpoints, but provides that an employee may make use of his or her title for purposes of identification when participating in certain organizations (e.g., civic organizations) and that an employee is generally free to refer to his or her connection with the agency when participating in an employee organization. This portion of section 10.735–211 has been superseded by section 2635.702 of the Standards.

Section 10.735–211 specifically addresses employee participation, in a personal capacity, in private organizations concerned with foreign policy. Unless approved by specified officials at the Department or USAID, an employee ''may not serve as advisor, officer, director, teacher, sponsor, committee chairman, or in any other official capacity or permit the employee's name to be used on a letterhead, in a publication, in an announcement or news story, or at a public meeting * * *'' and ''senior officers'' are limited to mere membership. These limitations have been superseded by the more general outside activities provisions in subpart H of the Standards and by the restriction at 5 CFR 2635.702 pertaining to the use of official title. Moreover, an employee's participation in an outside organization must be consistent with certain conflict of interest statutes and with the impartiality standard as implemented in 5 CFR 2635.502.

Section 10.735–211 affirms that an employee is free to join or not join an employee organization, and that an employee may participate in professional organizations not concerned with foreign policy subject to limitations. While these affirmations remain generally correct, they do not warrant continued publication and must be read, in any event, in the context of restrictions in the Standards (especially in subpart H) and certain conflict of interest statutes or regulations.

Section 10.735–211 briefly summarizes the ''Hatch Act'' restrictions and highlights several political activities that are permissible. It also briefly summarizes laws prohibiting disloyalty and striking. As discussed above, the restrictions on employee participation in political activities are referenced in more than one section of the Standards. Moreover, all of these laws are listed in subpart I of the Standards.

Section 10.735–211 also states that a U.S. citizen employee shall not engage in any form of political activity in any foreign country. This prohibition, as modified, is in volume 3 of the Foreign Affairs Manual. Section 10.735–206 lists several other restrictions or obligations that apply to U.S. citizen employees abroad, their family members, and non-U.S. citizen employees abroad. These restrictions and obligations derive from provisions in the Vienna Convention on Diplomatic Relations (23 U.S.T. 3227) and the Convention on Consular Relations (21 U.S.T. 77). They are published, as modified, in volume 3 of the Foreign Affairs Manual. This portion of volume 3 of the Foreign Affairs Manual also contains the substance of the requirement in section 10.735–215(b) requiring that an employee abroad obey the laws of the country in which the employee is present.

Section 10.735–205 contains a summary of an exception to certain conflict of interest statutes, 18 U.S.C. 203 and 205, and identifies ''the head of the employee's division'' as the appointing official authorized by the statutes to approve use of the exception. The statutes themselves are summarized in section 2635.801 (including general references to the exceptions) and in subpart I of the Standards. The statutes do not require that the identity of the appointing official be published in the CFR or elsewhere. Moreover, it is expected that the DAEOs and ethics staff will counsel employees concerning the identity of the ''appointing official'' who must approve use of the exception.

Section 10–735.205 mainly concerns 18 U.S.C. 208. All executive branch employees are prohibited by 18 U.S.C. 208 from participating in an official capacity in particular matters in which they, or certain persons or entities with whom they have specified relationships, have a financial interest. When part 10 was published in 1978, individual agencies were authorized by 18 U.S.C. 208 to adopt agency-specific regulations exempting financial interests from the applicability of the statutory prohibition. Section 10.735–205 lists the interests deemed by the Department under 18 U.S.C. 208(b) to be too ''remote'' or ''inconsequential'' to affect the integrity of an employee's services to the Government. The Ethics Reform Act of 1989 (Public Law No. 101–194), as amended, eliminated the authority of individual agencies to adopt waivers pursuant to 18 U.S.C. 208(b) and established OGE's authority to issue executive branch-wide exemptions. The initial OGE exemptions, now codified in subpart B of 5 CFR part 2640, became effective on August 28, 1995 and January 17, 1997. As of January 17, 1997, all of the agency-specific exemptions as in effect prior to November 30, 1989—including those in section 10.735–205 of part 10—were superseded.

Primarily in contemplation of conflicts arising under 18 U.S.C. 208, section 10.735–205 prohibits an employee from having a financial interest that conflicts or appears to conflict substantially with the employee's official duties. Section 10.735–205 also prohibits an employee from engaging in a financial transaction based on information obtained through Government employment. These provisions were superseded by sections 2635.403 and 2635.703 of the Standards.

Section 10.735–217 specifies a procedure by which an employee may request an advance written determination from the Under Secretary for Management at the Department or from the Administrator of USAID that the prohibitions of 18 U.S.C. 208 do not apply. These procedures have been supplanted by the procedures developed by the DAEOs and ethics staff to provide oral and written advice concerning matter relating to any of the Federal ethics laws and regulations, including the issuance of individual waivers as authorized by 18 U.S.C. 208.

Section 10.735–207 of part 10 prohibits the use of Government property for other than officially approved activities. This prohibition has been superseded by section

2635.704 of the Standards. As contemplated by the OGE regulation, various Foreign Affairs Manual provisions and other Department issuances define ''authorized purposes.'' In addition, the General Services Administration has promulgated various regulations concerning the use of Government property generally. Section 10.735–209 of part 10 requires an employee to pay all just financial obligations, especially taxes. This section has been superseded by section 2635.809 of the Standards. Section 10.735–208 of part 10 prohibits an employee from using nonpublic Government information to further a private interest (subject to an exception concerning the preparation of persons for certain examinations). This section has been superseded by section 2635.703 of the Standards (and, as discussed above, by 5 CFR 735.202 insofar as section 10.735–209 references an exception relating to the preparation of persons for certain examinations).

Section 10.735–210 of part 10 prohibits an employee from engaging in any gambling activity while on Government property or while on duty for the Government. Section 10.735–215(a) prohibits an employee from engaging in conduct prejudicial to the Government. These provisions remain implemented in sections 735.201 and 735.203, respectively, of the OPM regulation at 5 CFR part 735.

Section 10.735–212 of part 10 generally prohibits an employee of the Foreign Service from wearing any uniform except as may be authorized by law or as a military commander may require civilians to wear in a theatre of military operations, but indicates that certain attire should not be considered a uniform for purposes of this prohibition and refers to an appropriations restriction applicable to the then ICA pertaining to the purchase of uniforms. The statute underlying the prohibition, 22 U.S.C. 803, has been repealed by the Foreign Service Act of 1980 and, as discussed above, the ICA no longer exists. Moreover, members of the Foreign Service do not wear uniforms.

Section 10.735–213 concerns making recommendations in an official or personal capacity and references a statute, 22 U.S.C. 806, that prohibited an employee from recommending another person for employment by the country to which the employee is accredited or assigned. Section 806 has been repealed, and the limitations prescribed in section 10.735–213 concerning recommendations made in a personal capacity have been superseded by those in section 2635.702 of the Standards. To the extent that section 2635.702 is construed to apply to recommendations offered in an official capacity, it supersedes section 10.735–213 in that regard as well. The provision in section 10.735–213 pertaining to the recommendation of firms in connection with USAID programs is addressed in regulations pertaining to Government procurement and is, therefore, no longer necessary.

Section 10.735–214 contains a number of limitations on employees' transmission of communications and gifts. Paragraph (a) refers to limitations on correspondence regarding the affairs of foreign governments, which is derived from a statutory provision (former 22 U.S.C. 806(a)), which has been repealed.

Paragraph (b) provides that an employee must not act as agent for transmitting communications from persons or organizations in foreign countries to the President or other governmental officials, except that a chief of mission may do so when he or she determines it to be clearly in the public interest. This provision was derived from the restriction on transmitting gifts, and was intended as a practical limitation on employees serving as a conduit for transmitting communications from foreign persons or organizations. While this limitation still serves a valid purpose, it is reflected in other authorities and does not warrant the continued publication of 22 CFR part 10.

Paragraph (c) provides that an employee shall not act as agent for the transmission of gifts from persons or organizations in foreign countries to the President or other officials; however, principal officers may accept and forward to the Office of Protocol gifts made to the United States, or to any political division thereof, by the government to which they are accredited. This is largely a restatement of former 22 U.S.C. 804, which has been repealed. It also was intended as a practical limitation on employees serving as a conduit for transmitting gifts from foreign persons or organizations. The rules governing acceptance of gifts from foreign governments or international organizations are set out in the Foreign Gifts and Decorations Act and 22 CFR part 3. While the limitations on transmission of gifts also encompasses foreign individuals or organizations not affiliated with a foreign government or international organization, these limitations, as modified, are properly reflected in 2 FAM 344 and do not warrant the continued publication of this section of 22 CFR part 10.

Subpart C of part 10 concerns ''special Government employees.'' As defined in 18 U.S.C. 202, a special Government employee (SGE) is an officer or employee who is retained, designated, appointed, or employed by the Government to perform temporary duties, with or without compensation, for not more than 130 days during any period of 365 consecutive days. (The full statutory definition of SGE also encompasses employees serving in specified Government positions without regard to the number of days of expected service. In addition, particular statutes may specifically designate individuals occupying certain positions as SGEs.) Subpart C states generally that an SGE is subject to the conflict of interest statutes and to the U.S. Constitution as it pertains to gifts from foreign governments, referencing a discussion of the conflict of interest statutes in the now defunct Federal Personnel Manual and the regulations at 22 CFR part 3 implementing the Foreign Gifts and Decorations Act. In addition, subpart C contains standards deriving from E.O. 11222 that are specific to SGEs.

The definition of ''employee'' in section 2635.102 of the Standards encompasses SGEs. Therefore, the restrictions and obligations set forth (or summarized) in the Standards apply equally to SGEs and other employees unless a particular provision specifies (or explains) that SGEs are treated differently or are exempted altogether. For example, the compensation restriction in section 2635.807 of the Standards, relating to teaching, speaking, and writing, applies differently to SGEs (and, in fact, applies still differently to SGEs serving for 60 or fewer days). And, the summaries of 18 U.S.C. 209 in subparts B and H of the Standards make clear that the statute does not apply to SGEs at all.

Subpart D of part 10 concerns the system of confidential financial disclosure developed under authority of Executive Order 11222. Under authority conferred by Executive Order 12674 (and pursuant to authority in the Ethics in Government Act of 1978, as amended), OGE has established a revised system of confidential disclosure. As noted above, the revised system, published in 5 CFR part 2634, superseded subpart D of part 10 on October 5, 1992. Section 10.735–411 of subpart D concerns disqualification and other remedies available to address conflicts of interest. These matters are now addressed in various sections of 5 CFR parts 2634, 2635, and 2640.

Regulatory Findings

Administrative Procedure Act

In accordance with provisions of the Administrative Procedure Act governing rules promulgated by Federal agencies that affect the public (5 U.S.C. 552), the Department is publishing this direct final rule and inviting public comment.

Regulatory Flexibility Act

The Department of State, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100 million 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 import markets.

Executive Order 12866

The Department of State does not consider this rule to be a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review. In addition, the Department is exempt from Executive Order 12866 except to the extent that it is promulgating regulations in conjunction with a domestic agency that are significant regulatory actions. The Department has nevertheless reviewed the regulation to ensure its consistency with the regulatory philosophy and principles set forth in that Executive Order.

Executive Order 13132

This regulation 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. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement.

Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. chapter 35.

List of Subjects in 22 CFR Part 10

Conflict of interest, Government employees.

■ Accordingly, under the authority of the Ethics in Government Act of 1978 (5 U.S.C. App.); Executive Order 12674, as modified by Executive Order 12731; 5 CFR Part 2634 and 5 CFR Part 2635, the Department of State and the United States Agency for International Development are amending 22 CFR chapter 1 by removing part 10.

Dated: January 19, 2005.

Grant S. Green Jr.,

Under Secretary of State for Management, Department of State.

Dated: March 11, 2005.

Steven Wisecarver,

Acting Assistant Administrator for Management, U.S. Agency for International Development.

[FR Doc. 05–6383 Filed 4–1–05; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 936

[Docket No. OK–031–FOR]

Oklahoma Abandoned Mine Land Reclamation Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving an amendment to the Oklahoma abandoned mine land reclamation plan (Oklahoma plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Oklahoma proposed revisions to its plan concerning project ranking and selection procedures, the State Reclamation Committee, and the public participation policies. Oklahoma intends to improve operational efficiency.

EFFECTIVE DATE: April 4, 2005.

FOR FURTHER INFORMATION CONTACT: Michael C. Wolfrom, Director, Tulsa Field Office. Telephone: (918) 581–6430. E-mail address: *mwolfrom@osmre.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on the Oklahoma Plan
II. Submission of the Amendment
III. OSM's Findings
IV. Summary and Disposition of Comments
V. OSM's Decision
VI. Procedural Determinations

I. Background on the Oklahoma Plan

The Abandoned Mine Land Reclamation (AMLR) Program was established by Title IV of the Act (30 U.S.C. 1201 *et seq.*) in response to concerns over extensive environmental damage caused by past coal mining activities. The program is funded by a reclamation fee collected on each ton of coal that is produced. The money collected is used to finance the reclamation of abandoned coal mines and for other authorized activities. Section 405 of the Act allows States and Indian Tribes to assume exclusive responsibility for reclamation activity within the State or on Indian lands if they develop and submit to the Secretary of the Interior for approval, a program (often referred to as a plan) for the reclamation of abandoned coal mines. On the basis of these criteria, the Secretary of the Interior approved the Oklahoma plan on January 21, 1982. You can find background information on the Oklahoma plan, including the Secretary's findings, the disposition of comments, and the approval of the plan in the January 21, 1982, **Federal Register** (47 FR 2989). You can find later actions concerning the Oklahoma plan and amendments to the plan at 30 CFR 936.25.

II. Submission of the Amendment

By letter dated November 1, 2004 (Administrative Record No. OK–994), Oklahoma sent us a proposed amendment to its plan under SMCRA (30 U.S.C. 1201 *et seq.*). Oklahoma sent the amendment at its own initiative.

We announced receipt of the proposed amendment in the December 29, 2004, **Federal Register** (69 FR 77965). In the same document, we opened the public comment period and provided an opportunity for a public hearing on the adequacy of the proposed amendment. We did not hold a public hearing or meeting because no one

requested one. The public comment period ended on January 28, 2005. We did not receive any public comments.

During our review of the amendment, we identified areas that could benefit from improved clarity and completeness. These areas concerned the State Reclamation Committee and the public participation policies. We notified Oklahoma of these areas by e-mail on January 18, 2005 (Administrative Record No. OK–994.03), and provided the State with suggestions for improving their clarity and completeness.

By letter dated January 24, 2005 (Administrative Record No. OK–994.04), Oklahoma sent us additional explanatory information and revisions to its plan amendment. Because the additional information merely clarified certain provisions of Oklahoma's proposed amendment, we did not reopen the public comment period.

III. OSM's Findings

Following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 884.14 and 884.15. We are approving the amendment.

A. Section 884.13(c)2—Project Ranking and Selection Procedure

1. Site Selection

Under the section titled, ''Site Selection,'' Oklahoma proposed to revise the introductory paragraph by eliminating the four annual public regional meetings. Oklahoma also proposed to change where it will annually publish a public notice as part of the abandoned mine land (AML) project selection process. Currently, the notices are being published in the 16 counties with abandoned coal mine problem regions. Oklahoma proposed to publish the notices, which include the address of the Oklahoma Conservation Commission (OCC), in cities/towns within the abandoned coal mine region in eastern Oklahoma. These notices retain the public's ability to contact the OCC if a member of the public believes he or she has an AML site that poses a dangerous health and/or safety problem.

The Federal regulation at 30 CFR 884.13(c)(7) requires public participation and involvement in the State's reclamation program. Because Oklahoma will continue to annually publish public notices as part of the AML project selection process and will continue to allow the public the opportunity to be involved in this process by being able to contact the OCC if they believe they have an AML site that poses a dangerous health and/or safety problem, we find that Oklahoma's proposed changes meet the requirement of the above Federal regulation. Therefore, we are approving the above changes.

2. Table 3 Project Ranking and Selection Procedure

a. Under the heading, ''General Public,'' Oklahoma proposed to remove the provision that allowed the general public to attend regional meetings to voice concerns regarding abandoned mine land and water that pose a threat to health and/or safety. Oklahoma is retaining the provision that allows the general public to send concerns in writing to the OCC.

The Federal regulation at 30 CFR 884.13(c)(7) requires public participation and involvement in the State's reclamation program. Because Oklahoma will continue to allow the public the opportunity to be involved in the site selection process by being able to contact the OCC if they believe they have an AML site that poses a dangerous health and/or safety problem, we find that Oklahoma's proposed change meets the requirement of the above Federal regulation. Therefore, we are approving the above change.

b. Under the heading ''State Reclamation Committee,'' Oklahoma proposed to make editorial changes to one of its purposes to read as follows:

> Review reclamation projects submitted by the OCC and make suggestions concerning these projects. After projects have been selected for reclamation, OCC will prepare and submit project applications to OSM.

Because these changes are editorial in nature and do not alter the original meaning of the previous language, we are approving the changes.

B. Section 884.13(c)3 Coordination of Reclamation Work Between the State, the Soil Conservation Service [Currently the Natural Resources Conservation Service] and Other Reclamation Agencies

1. State Reclamation Committee

The State Reclamation Committee is composed of members from various agencies and organizations. Oklahoma proposed to revise the list of agencies and organizations from which this committee's membership comes by deleting or adding agencies and organizations. Oklahoma originally proposed to revise this list by removing the following agencies or organizations from the list: Oklahoma Association of Conservation Districts, Oklahoma Biological Survey, Oklahoma Department of Agriculture's Forestry Division, Oklahoma Department of Environmental Quality, Oklahoma Geological Survey, Oklahoma Wildlife Conservation Commission, Oklahoma Wildlife Federation, U.S. Department of Agriculture's Natural Resources Conservation Service, U.S. Department of the Interior's Bureau of Land Management, and U.S. Geological Survey. After considering the suggestions to the amendment that we sent to the State via e-mail on January 18, 2005 (Administrative Record No. OK–994.03), Oklahoma decided to retain the Oklahoma Biological Survey's membership on the committee. Also, Oklahoma proposed to add the following agency and organization to the list: U.S. Department of the Interior's Fish and Wildlife Service and the Applicable Tribal Entity.

The Federal regulation at 30 CFR 884.13(c) requires a State reclamation plan to include a description of the policies and procedures to be followed by the designated agency in conducting the reclamation program. As stated in Oklahoma's AML plan, the purpose of the State Reclamation Committee is to: (1) Review the reclamation projects submitted by the OCC and to provide comments concerning the projects, (2) coordinate the reclamation activities taking place in the State, and (3) serve in an advisory capacity providing informational and educational services. With these specific purposes, the State Reclamation Committee, as revised, is integrated in the policies and procedures necessary to conduct the reclamation program and has a vital role in implementing the policies and procedures that are used in conducting the State's reclamation program. Therefore, we find that Oklahoma's proposed changes meet the requirement of the Federal regulation at 30 CFR 884.13(c), and we are approving them.

2. Purpose of the State Reclamation Committee

a. Currently, the OCC and the Natural Resources Conservation Service can submit reclamation projects to the State Reclamation Committee for review. Oklahoma proposed to revise item number 1 of the purpose of the State Reclamation Committee by removing the Natural Resources Conservation Service as a submitter of reclamation projects. Oklahoma also proposed to revise item number 1 by requiring the State Reclamation Committee to provide comments to the OCC concerning the reclamation projects.

The Federal regulation at 30 CFR 884.13(c)(3) requires each State reclamation plan to include a description of the policies and procedures to be followed by the

designated agency in conducting the reclamation program, including the coordination of reclamation work among the State reclamation program, the Rural Abandoned Mine Program (RAMP) administered by the U.S. Department of Agriculture's Natural Resources Conservation Service (formerly the Soil Conservation Service), the reclamation programs of any Indian tribes located within the State, and OSM's reclamation program.

Oklahoma has set forth a description of the policies/procedures to be followed in conducting its reclamation program and has decided to change a portion of the policies/procedures by removing the Natural Resources Conservation Service as a submitter of reclamation projects and by revising one of the purposes of the State Reclamation Committee. Because Oklahoma has policies/procedures for conducting the State's reclamation program that include coordination with the entities listed at 30 CFR 884.13(c)(3), as applicable, and has chosen to change them as they relate to the purpose of the State Reclamation Committee as proposed in item number 1, we find that the State's proposed revisions meet the requirements of the Federal regulation at 30 CFR 884.13(c)(3). Therefore, we are approving the above changes.

b. Currently, item number 2 of the purpose of the State Reclamation Committee requires the committee to coordinate reclamation activities taking place in the State with RAMP activities and the State and Federal AML Programs to avoid duplication of effort.

Oklahoma proposed to remove the requirement to coordinate reclamation activities taking place in the State with RAMP activities and the Federal AML Program and proposed to retain the coordination of reclamation activities taking place in the State with the State AML Program.

The Federal regulation at 30 CFR 884.13(c)(3) requires a description of the policies/procedures to be followed by the State in conducting the reclamation program including the coordination of reclamation work among the State reclamation program, the RAMP administered by the U.S. Department of Agriculture's Natural Resources Conservation Service (formerly the Soil Conservation Service), the reclamation programs of any Indian tribes located within the State, and OSM's reclamation program.

As allowed by section 401(c)(2) of SMCRA, moneys in the Abandoned Mine Reclamation Fund may be transferred on an annual basis to the Secretary of Agriculture for use under section 406 of SMCRA titled, ''Reclamation of Rural Lands.'' Section 406 of SMCRA establishes the RAMP. Congress has not appropriated funds to the Secretary of Agriculture for the RAMP since 1995. Without these appropriations, the Natural Resources Conservation Service cannot conduct the RAMP in Oklahoma or any other State. Because the RAMP does not exist in Oklahoma, the language in Oklahoma's AMLR program requiring coordination of reclamation with RAMP activities is unnecessary. Therefore, we are approving the removal of this language from Oklahoma's AMLR program. However, if Congress appropriates funds for the RAMP and the Natural Resources Conservation Service conducts such a program in Oklahoma, it will then become necessary for Oklahoma to amend its program to include coordination of reclamation activities with RAMP activities. Also, we are approving the removal of the requirement to coordinate with the Federal AML Program. This requirement, found in Section 884.13(c)(2) of the Oklahoma plan, is a duplication of one currently contained in ''Table 3 Project Ranking and Selection Procedure'' where the OCC prepares and submits reclamation project applications to OSM.

C. Section 884.13(c)7 Public Participation Policies

Oklahoma originally proposed to revise the introductory paragraph by deleting language stating that public participation will be incorporated in the project selection and the annual grant application process and by adding language stating that public participation will be incorporated by utilizing public notices in several newspapers in the AML areas. After considering the suggestions to the amendment that we sent to the State via e-mail on January 18, 2005 (Administrative Record No. OK–994.03), Oklahoma decided to retain the language stating that public participation will be incorporated in the project selection and the annual grant application process. The revised introductory paragraph will read as follows:

> Public participation in this program will be encouraged throughout the period in which the State Reclamation Plan is being developed and/or amended. Public participation will also be incorporated in the project selection and the annual grant application process by utilizing public notices in several newspapers in the AML areas.

Also, in paragraph (1) titled, ''Public participation in the development and/or amendment of the State Reclamation Plan,'' the current language under this title reads as follows:

> At least 15 days before the submission of the State Reclamation Plan to the OSM, the Oklahoma Conservation Commission will begin public meetings which will be convenient in time and location to the impacted population. Issues raised in the public meetings will be addressed by the OCC and documentation of any action taken to resolve each issue will be made by the OCC.

Oklahoma proposed to revise the first sentence in the above language by inserting the words, ''or amendment to the State Reclamation Plan,'' after the words, ''State Reclamation Plan.'' The revised language reads as follows:

> At least 15 days before the submission of the State Reclamation Plan or amendment to the State Reclamation Plan to the OSM, the Oklahoma Conservation Commission will begin public meetings which will be convenient in time and location to the impacted population. Issues raised in the public meetings will be addressed by the OCC and documentation of any action taken to resolve each issue will be made by the OCC.

In paragraph (2) titled, ''Public participation in the annual grant application process, Oklahoma proposed to remove the current language and replace it with the following language:

> Before the OCC submits the annual grant application, a public notice is printed in one of the major newspapers requesting input on the grant application. The public notice gives the purpose of the grant, where it can be reviewed, where written comments may be sent, and the comment deadline date.

Finally, Oklahoma proposed to add a new paragraph (3) titled, ''Public participation in the project selection and submission process.'' This new section provides the general public an opportunity to identify AML projects for possible reclamation and requires publication of a public notice in the local newspaper requesting comments on any proposed project before the OCC submits the project to OSM. The public notice also requests suggestions for other possible reclamation of surface coal mine strip pits, underground coal mine open shafts or mine portals, and any other hazards associated with past coal mining that pose a threat to the health and safety of the general public. The public notice provides the contact person and address at the OCC. In addition, public notices that seek public input on possible hazardous AML sites will be printed annually in the Tulsa, Muskogee, McAlester, Claremore, Sallisaw, Poteau, and Vinita newspapers.

The Federal regulation at 30 CFR 884.13(c)(7) requires each proposed State reclamation plan to include a description of the policies and procedures to be followed by the designated agency in conducting the reclamation program including public participation in the State reclamation program. Because Oklahoma's State reclamation plan includes provisions for public participation in the State reclamation program, it meets the requirement of the above Federal regulation and we are, therefore, approving the above revisions.

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment, but did not receive any.

Federal Agency Comments

On November 18, 2004, under 30 CFR 884.14(a)(2) and 884.15(a), we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Oklahoma plan (Administrative Record No. OK–994.01). No comments were received.

V. OSM's Decision

Based on the above findings, we approve the amendment Oklahoma sent us on November 1, 2004, and as revised on January 24, 2005.

To implement this decision, we are amending the Federal regulations at 30 CFR part 936, which codify decisions concerning the Oklahoma plan. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately. Section 405 of SMCRA requires that the State's plan demonstrate that the State has the capability of carrying out the provisions of the Act and meeting its purposes. Making this rule effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

IV. Procedural Determinations

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulations.

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State and Tribal abandoned mine land reclamation plans and plan amendments because each program is drafted and promulgated by a specific State or Tribe, not by OSM. Decisions on proposed abandoned mine land reclamation plans and plan amendments submitted by a State or Tribe are based solely on a determination of whether the submittal meets the requirements to Title IV of SMCRA (30 U.S.C. 1231–1243) and 30 CFR part 884 of the Federal regulations.

Executive Order 13132—Federalism

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of abandoned mine reclamation programs. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 405(d) of SMCRA requires State abandoned mine land reclamation programs to be in compliance with the procedures, guidelines, and requirements established under SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. This determination is based on the fact that the Oklahoma plan does not provide for reclamation and restoration of land and water resources adversely affected by past coal mining on Indian lands. Therefore, the Oklahoma plan has no effect on Federally-recognized Indian tribes.

Executive Order 13211—Regulations That Significantly Affect The Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because agency decisions on proposed State and Tribal abandoned mine land reclamation plans and plan amendments are categorically excluded from compliance with the National Environmental Policy Act (42 U.S.C. 4332) by the Manual of the Department of the Interior (516 DM 6, appendix 8, paragraph 8.4B(29)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of $100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete

with foreign-based enterprises. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulations did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 936

Intergovernmental relations, Surface mining, Underground mining.

Dated: February 14, 2005.

Ervin J. Barchenger,

Acting Regional Director, Mid-Continent Regional Coordinating Center.

■ For the reasons set out in the preamble, 30 CFR part 936 is amended as set forth below:

PART 936—OKLAHOMA

■ 1. The authority citation for part 936 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 936.25 is amended in the table by adding a new entry in chronological order by ''Date of Final Publication'' to read as follows:

§ 936.25 Approval of Oklahoma abandoned mine land reclamation plan amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
*	*	* * * * *
11/01/2004	4/4/05	Oklahoma Plan §§ 884.13(c)2—Project Ranking and Selection; (c)3—Coordination with Other Entities; and (c)7—Public Participation.

[FR Doc. 05–6600 Filed 4–1–05; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 950

[WY–032–FOR]

Wyoming Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving, with one exception, a proposed amendment to the Wyoming regulatory program (the ''Wyoming program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Wyoming proposed to remove rules pertaining to soft rock surface mining and to revise and add rules about highwalls and coal exploration. Wyoming intended to revise or revised its program to be consistent with the corresponding Federal regulations, provide additional safeguards, clarify ambiguities, and to enhance and diversify reclamation.

DATES: *Effective Date:* April 4, 2005.

FOR FURTHER INFORMATION CONTACT: James F. Fulton, Chief, Denver Field Division, telephone: (303) 844–1400, extension 1424; Internet address: *jfulton@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Wyoming Program
II. Submission of the Proposed Amendment
III. Office of Surface Mining's (OSM's) Findings
IV. Summary and Disposition of Comments
V. OSM's Decision
VI. Procedural Determinations

I. Background on the Wyoming Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * * and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Wyoming program on November 26, 1980. You can find background information on the Wyoming program, including the Secretary's findings, the disposition of comments, and conditions of approval in the November 26, 1980, **Federal Register** (45 FR 78637). You can also find later actions concerning Wyoming's program and program amendments at 30 CFR 950.10, 950.12, 950.15, 950.16, and 950.20.

II. Submission of the Proposed Amendment

By letter dated May 21, 2004, Wyoming sent us an amendment to its program (Rule Package 1R, Administrative Record number WY–37–1) under SMCRA (30 U.S.C. 1201 *et seq.*). Wyoming sent the amendment in response to a February 21, 1990, letter (Administrative Record number WY–37–7) that we sent to the State under 30 CFR 732.17(c), and in response to the required program amendments at 30 CFR 950.16(a), (w), and (ll), and to include the changes made at its own initiative.

Changes Wyoming proposed to make in its Coal Rules included: (1) Chapter 1, section 2(l), revising the definition of ''coal exploration;'' (2) Chapter 1, section 2(ce), removing the definition of ''soft rock surface mining;'' (3) Chapter 4, section 2(b)(iv)(A), adding provisions for small depressions; (4) Chapter 4, section 2(b)(ix), (ix)(A), (B), and (C), removing soft rock surface mining provisions for backfilling and grading; (5) Chapter 4, section 2(b)(ix)(D), retaining and revising a soft rock mining provision for highwall retention; (6) Chapter 10, sections 1 and 1(b)(iii), revising requirements for coal exploration of 250 tons or less; (7) Chapter 10, sections 2(b), (b)(i), (ii), (iii), (iv), (v), (vi), (vii), (viii), (ix), (x), (xi), and (xii), adding and revising application requirements for coal exploration of more than 250 tons or in areas designated unsuitable for mining; (8) Chapter 10, section 3(b), revising

provisions of application approval for exploration of more than 250 tons or in areas designated unsuitable for mining; (9) Chapter 10, section 4(e), revising performance standards for protecting certain critical, crucial and important habitats during exploration; and (10) Chapter 10, sections 8, 8(a), (b), (b)(i), (ii), (ii)(A), (ii)(B), (ii)(C), (iii), and (iv), adding rules pertaining to commercial use and sale of coal extracted during exploration.

We announced receipt of the proposed amendment in the August 17, 2004, **Federal Register** (69 FR 51026). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the amendment's adequacy (Administrative Record number WY–37–10). We did not hold a public hearing or meeting because nobody requested either one. The public comment period ended on September 15, 2004. We received comments from two Federal agencies.

During our review of the amendment, we identified concerns about Wyoming's proposed highwall retention rule at Chapter 4, section 2(b)(ix)(D). We notified the State of our concerns by letter dated August 11, 2004 (Administrative Record Number WY–37–11).

Wyoming responded in a letter dated August 30, 2004, by sending us a Coal Rule Package 1–T (Administrative Record Number WY–37–12). In that package, Wyoming proposed additional revisions to the highwall retention rule at Chapter 4, section 2(b)(ix)(D). It also noted, however, that the proposed change to the highwall retention rule included in Coal Rule Package 1–T must be reviewed further in the State's internal rulemaking process, which it expected to take several months. In light of Wyoming's ongoing rulemaking, we will defer making a final decision on Chapter 4, section 2(b)(ix) until that process is completed and we know the final wording of that proposed rule.

III. OSM's Findings

Following are our findings concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment, with one exception as noted above and discussed below.

A. Minor Revisions to Wyoming's Rules

Wyoming proposed minor recodification changes to the following previously-approved rules as shown:

Chapter 10, sections 2(b)(iii), (iv), (v), (vii), (vi), and (viii), application requirements for exploration of more than 250 tons or in an area designated unsuitable for mining, recodified as 2(b)(vi), (vii), (viii), (x), (xi), and (xii), respectively (Federal counterparts at 30 CFR 772(b)(6), (7), (8), (8)(i), (8)(ii), (8)(iii), (9), (11), (12), and (13), respectively).

Because these changes are minor, we find that they will not make Wyoming's rules less effective than the corresponding Federal regulations and can be approved.

B. Revisions to Wyoming's Rules That Have the Same Meaning as the Corresponding Provisions of the Federal Regulations

Wyoming proposed revisions to the following rules containing language that is the same as or similar to the corresponding sections of the Federal regulations. In some cases, the State also proposed to recodify the revised rules as shown below:

1. Chapter 1, section 2(l), revising the definition of ''coal exploration'' (30 CFR 701.5);
2. Chapter 4, section 2(b)(iv)(A), adding a new provision for the use of small depressions in reclamation (30 CFR 816.102(h));
3. Chapter 10, sections 1 and 1(b)(iii), revising general requirements for coal exploration of 250 tons or less (30 CFR 772.11, 11(b), and 11(b)(3));
4. Chapter 10, sections 2(b), (b)(i), (ii), and (iii), (b)(iv), and (b)(v), revising and adding general requirements for coal exploration of more than 250 tons or in an area designated as unsuitable for mining, including recodification (30 CFR 772.12(b), (b)(1), (2), (3), (4) and (5));
5. Chapter 10, section 2(b)(ix), description of measures to be used so exploration of more than 250 tons or in areas designated unsuitable for mining complies with exploration performance standards at Chapter 10, section 4, including recodification (30 CFR 772.12(b)(10));
6. Chapter 10, section 3(b), provision for administrative and judicial review for anyone adversely affected by decisions on coal exploration applications (30 CFR 772.12(e)(2); required amendment at 30 CFR 950.16(a));
7. Chapter 10, section 8, adding a new heading for the section addressing commercial use or sale of coal extracted under a coal exploration license (30 CFR 772.14);
8. Chapter 10, section 8(b), adding a new provision for written approval to not require a mining permit for coal exploration where sale or commercial use of extracted coal is for coal testing purposes only, with an added requirement for an application to demonstrate the need for coal testing and the purpose for coal extraction during exploration (30 CFR 772.14(b));
9. Chapter 10, section 8(b)(i), adding a new requirement for the testing firm name and coal testing locations for coal extracted during exploration (30 CFR 772.14(b)(1));
10. Chapter 10, section 8(b)(ii), adding a new requirement for a statement from the end user or agent or broker if coal extracted during exploration is sold or commercially used, with a requirement for the statement to include other information described in following subsections (30 CFR 772.14(b)(2));
11. Chapter 10, section 8(b)(ii)(A), adding a new requirement for the statement to include the reason for the test, including why the coal is so different from the user's coal as to require testing (30 CFR 772.14(b)(2)(i));
12. Chapter 10, section 8(b)(ii)(B), adding a new requirement for the statement to show the amount of coal needed for testing and why a lesser amount is insufficient (30 CFR 772.14(b)(2)(ii));
13. Chapter 10, section 8(b)(ii)(C), adding a new requirement for a description of the test to be conducted (30 CFR 772.14(b)(2)(iii));
14. Chapter 10, section 8(b)(iii), adding a new requirement for evidence of sufficient coal reserves to show that coal to be removed during exploration is not the total reserve but a sample (30 CFR 772.14(b)(3)); and
15. Chapter 10, section 8(b)(iv), adding a new requirement for an explanation as to why other means of exploration are not adequate to determine coal quality and/or mining feasibility (30 CFR 772.14(b)(4).

Because these proposed rules contain language that is the same as or similar to the corresponding Federal regulations, we find that they are no less effective than the corresponding Federal regulations and can be approved.

C. Revisions to Wyoming's Rules That Are Not the Same as the Corresponding Provisions of the Federal Regulations

1. Information Required in Applications for Exploration About Historic or Archeological Resources

Wyoming proposed to add a sentence to the end of recodified section 2(b)(vii) in Chapter 10 of its Coal Rules describing requirements for applications for coal exploration involving more than 250 tons or in areas designated unsuitable for mining. Wyoming's proposed change responds to the amendment required at 30 CFR 950.16(w). The new sentence would expand exploration application

requirements to ''* * * include any other information which the Administrator may require regarding known or possible historic or archeological resources.'' With the exception of the word ''possible,'' Wyoming's proposed change is substantively identical to the counterpart Federal regulation at 30 CFR 772.12(b)(8)(iv), which requires a description of ''[a]ny other information which the regulatory authority may require regarding known or *unknown* historic or archeological resources' (emphasis added for comparison). Wyoming did not explain its use of the word ''possible'' in contrast to the term ''unknown'' used in the Federal regulation.

Neither Black's Law Dictionary nor the regulations at 36 CFR part 800 *et seq.* define the adjectives ''possible'' or ''unknown.'' Webster's Ninth New Collegiate Dictionary defines the adjective ''unknown'' as—

> [n]ot known or not well-known; also: having an unknown value.

On the other hand, Webster's defines the adjective ''possible'' as—

> 1 a: being within the limits of ability, capacity, or realization b: being what may be done or may occur according to nature, custom, or manners 2 a : being something that may or may not occur b : being something that may or may not be true or actual 3 : having an indicated potential.

In its explanation of synonyms for ''possible,'' Webster's adds that—

> POSSIBLE implies that a thing may certainly exist or occur given the proper conditions * * *.

In the preamble to the final rule **Federal Register** publishing the regulations at 30 CFR 772.12 (52 FR 4244; February 10, 1987) we said ''[s]everal commenters stated that they do not believe that OSMRE has any authority to require information on unknown archeological sites.'' In response, we acknowledged that ''[s]ection 772.12(b) does not require submission of information on unknown archeological sites.'' We continued by saying—

> [r]ather, OSMRE is making explicit that the regulatory authority has the discretion to require such information, should the regulatory authority need the information to make informed decisions in the public interest concerning important historic properties that may be disturbed by coal exploration activities. The basis for such authority is the same as for requiring information on historic resources in the permitting process, discussed in the preceding portion of this preamble (*Id.*, at 4256).

In the preamble's discussion of our authority to require information on historic and archeological resources in the permitting process, as referenced in the quotation above, we said—

> [c]onsideration of the effects of surface coal mining operations extends both to know[n] [sic] resources and to situations where a well reasoned conclusion has been reached that there may be resources which are likely to be impacted, as well as to properties listed on, and those eligible for listing on, the National Register of Historic Properties.

The foregoing explanation reveals consistency between use of the terms ''unknown'' and ''possible'' in the Federal regulation and proposed State rule, respectively. The preamble's explanation of the Federal regulation characterizes ''unknown'' resources as ''situations where a well reasoned conclusion has been reached that there may be resources which are likely to be impacted * * *.'' Wyoming's use of the term ''possible'' is not inconsistent with the Federal regulation's corresponding use of the term ''unknown'' in view of Webster's definition of ''possible'' as ''being what may be done or may occur according to nature, custom, or manners'' and its explanation that ''possible'' ''* * * implies a thing may certainly exist or occur given the proper conditions.''

As we explained in the 1987 final rule (*Id.*) , the Federal regulation does not require operators to submit information about ''unknown'' resources but gives regulatory authorities the discretion to require such information if they need it. In effect, Wyoming's proposed rule gives it the authority to require additional information about historic and archeological resources if needed and the discretion to require it for known resources and ''possible'' others that might exist but are not definitely known to exist. As such, we find the State's proposed rule at Chapter 10, recodified section 2(b)(vii) is not inconsistent with, and is no less effective than, the counterpart Federal regulation and can be approved. We also are removing the required amendment at 30 CFR 950.16(w).

2. Restrictions on Disturbing Certain Critical, Crucial, and Important Habitats During Exploration

Wyoming's proposed rule at Chapter 10, section 4(e) of its coal rules would prohibit disturbing critical habitat for listed threatened and endangered species during exploration. It also would prohibit disturbing crucial or important wildlife habitat during exploration without written evidence of consultation with the Wyoming Game and Fish Department, including any resulting recommendations. The counterpart Federal regulation at 30 CFR 815.15(a) prohibits disturbing unique or unusually high value habitats for fish, wildlife, and other related environmental values and critical habitats for threatened and endangered species during exploration. The State rule pertains to *listed* threatened and endangered species; the counterpart Federal regulation refers only to threatened and endangered species.

Wyoming defines the terms ''crucial habitat'' and ''important habitat'' in its rules. We approved Wyoming's definitions of those two terms in the August 6, 1996, **Federal Register** for amendment WY–022–FOR (61 FR 40735). In that approval, we noted that Wyoming's definition of ''important habitat'' coincides with ''habitats of unusually high value for fish [and] wildlife'' as described further in 30 CFR 780.16(a)(2)(ii) (*Id.*, at 40737). It also is consistent with the wording of the counterpart Federal regulation at 30 CFR 815.15(a) for the rule being revised at section 4(e) of Chapter 10 of the State's rules. In the 1996 approval (*Id.*), we found Wyoming's definitions of ''important habitat'' and ''crucial habitat'' were not inconsistent with the surface mining permit application regulations at 30 CFR 780.16(a) and (b) and the performance standards at 816.97(f). There are no counterpart provisions in the Federal regulations for the term ''crucial habitat.''

In the same August 6, 1996, **Federal Register** (*Id.*), we required Wyoming to revise section 4(e) of Chapter 10. The required amendment is found at 30 CFR 950.16(ll). As proposed then in amendment WY–022–FOR, section 4(e) would have allowed coal exploration operations to disturb important habitat after consultation with the Wyoming Game and Fish Department while prohibiting disturbance to critical and crucial habitat. Because ''important habitat'' in Wyoming's rules is analogous to ''habitats of unique or unusually high value for fish [and] wildlife'' as used in the Federal regulations and because the Federal regulations prohibit disturbance of unusually high value habitats, we found Wyoming's proposed rule was less effective than the counterpart Federal regulation because it allowed coal exploration to disturb important habitat based on consultation with the Wyoming Game and Fish Department.

In a letter dated April 8, 1997 (Administrative Record number WY–37–13), Wyoming noted its ongoing efforts to reword section 4(e) of Chapter 10 to comply with the required amendment. The State asked us for

guidance and flexibility in interpreting the prohibition on disturbance required at 30 CFR 815.15(a). We responded to Wyoming's request for guidance in a letter dated September 7, 2000 (Administrative Record number WY–37–14) after discussing the issue with the State on a number of occasions. In that letter, we acknowledged the Federal regulation's prohibition of exploration disturbance on habitats of unique or unusually high value for fish, wildlife, and related environmental values, and by analogy, on important habitats in Wyoming. However, we suggested the following alternative:

> For coal exploration on ''important habitat'' or ''crucial habitat'' the State may wish to consider a proposed amendment that requires the same consultation process with State and Federal agencies responsible for fish and wildlife as those required by permanent regulatory program surface coal mining activities and reclamation plans (30 CFR 780.16, 816.97 and the State counterparts). We would consider this alternative to be consistent with and no less effective in meeting the intent of SMCRA.

As proposed, Wyoming's exploration performance standard at section 4(e) of Chapter 10 responds to the required amendment as follows:

> Critical habitats of listed threatened or endangered species identified pursuant to the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*) shall not be disturbed during coal exploration. Crucial or important habitat for wildlife shall not be disturbed during coal exploration unless written evidence of consultation with the Wyoming Game and Fish Department and any resulting recommendations are submitted to the Administrator as part of either a coal exploration license or notice of intent to explore application.

Wyoming explained in its amendment how its proposed rule addresses the approval criterion we established in the September 7, 2000, letter. The State explained that—

> * * * as is currently required prior to approving any coal permit, the Wyoming Game and Fish Department reviews the permit application and their recommendations for minimizing the impacts to wildlife and their habitats are considered and integrated into the Mine and Reclamation Plan of that permit. A similar process would be necessary as part of any [Land Quality Division] approval of a Notice of Intent to Explore or a Coal Exploration License. Therefore, this proposed rule amendment is maintaining the current requirement that important habitat can only be disturbed after consultation with the Wyoming Game and Fish Department, but is extending this flexibility to crucial habitats which had previously been off limits to coal exploration.

We reviewed Wyoming's surface coal mining provisions for consultation on fish and wildlife issues in context of the criterion established in our September 7, 2000, letter. The State's approved counterparts to the Federal regulations for permit application requirements and consultation at 30 CFR 780.16(a) and (a)(1) are found at Chapter 2, sections 2(a)(vi)(C)(III), (G), (G)(I), (II), and (III). Its approved counterparts to the Federal regulations for permit application requirements at 30 CFR 780.16(a)(2)(i) and (ii) and 780.16(b) are found at Chapter 2, sections 2(b)(vi), (vi)(B) and (vi)(C). Chapter 4, section 2(r) of Wyoming's rules includes the State's previously-approved counterparts to the Federal performance standards for surface coal mining at 30 CFR 816.97(a) and (b).

Chapter 10 of Wyoming's exploration rules includes requirements pertaining to endangered and threatened species as well. Section 2(b)(v) of Wyoming's coal exploration rules is the State's previously-approved counterpart to the Federal regulation at 30 CFR 772.12(b)(9). The State's rule requires applications for exploration of more than 250 tons or in areas designated as unsuitable to include a description of any endangered or threatened species listed under the Endangered Species Act that are in the proposed exploration area. Further, section 2(b)(vi) requires a map showing the areas of land to be disturbed by proposed exploration and reclamation, including the location of critical habitats of any endangered or threatened species listed pursuant to the Endangered Species Act. Its Federal counterpart is found at 30 CFR 772.12(b)(12).

Proposed section 4(e) does not repeat the various fish and wildlife consultation provisions that appear throughout the State's regulations for surface coal mining. However, it requires written evidence of consultation with the Wyoming Department of Game and Fish and the results of that consultation to be submitted to the State as a prerequisite to disturbing important or crucial habitat during coal exploration. Wyoming's explanation for proposed section 4(e) said it would require a process similar to that for mine permit applications. Such a process would require the Game and Fish Department's review of applications for exploration that would disturb important or crucial habitat, consider its recommendations for minimizing impacts to wildlife and their habitats, and integrate its recommendations into any approval of a Notice of Intent to Explore or a Coal Exploration License. Those procedures are not explicit in Wyoming's proposed wording of section 4(e). We interpret proposed section 4(e) as requiring persons who explore for coal in crucial and important habitats to submit to the Land Quality Division the recommendations that resulted from their consultation with the Wyoming Department of Game and Fish *and* to fully comply with those recommendations. We interpret and therefore accept Wyoming's explanation as a commitment to providing the described level of protection for important and crucial habitat during exploration, and will verify its implementation during our oversight of the State's regulatory program.

Though proposed section 4(e) also does not explicitly require consultation with the U.S. Department of the Interior, Fish and Wildlife Service (U.S. Fish and Wildlife Service or the Service), it prohibits disturbing critical habitat for listed threatened and endangered species. Moreover, section 2(b)(v) of the State's exploration rules requires a description of any listed endangered or threatened species in the proposed exploration area, and section 2(b)(vi) requires a map showing areas to be disturbed by exploration and reclamation, including the location of critical habitats of any listed endangered or threatened species. We recognized in our August 6, 1996, approval of amendment WY–022–FOR (*Id.*, at 40741) that the Service is responsible for listing, recovery, administration, and prohibitions associated with threatened and endangered species designated under the Endangered Species Act. As such, the Service is the primary repository of information compiled for threatened and endangered species and their critical habitats under the Endangered Species Act. Our experience shows that the Service either disseminates such information directly to State regulatory authorities upon request or indirectly through States' wildlife / fish and game agencies. We interpret the proposed wording of Wyoming's section 4(e), as well as sections 2(b)(v) and (b)(vi) of its Chapter 10 exploration rules, to imply direct or indirect consultation with the Service as a result of requiring information pertaining to listed threatened and endangered species and critical habitats.

Wyoming applied proposed section 4(e)'s prohibition of disturbance to critical habitats to such habitats of threatened and endangered species listed under the Endangered Species Act. The State explained in its amendment that it added the word ''listed'' to the rule ''* * * in order to add specificity and to be consistent with the language in the rest of the chapter * * *.'' The distinction is that such a

prohibition would not apply to species that are proposed for listing but are not yet listed. As Wyoming noted, proposed section 4(e) is consistent with the previously-approved wording of sections 2(b)(v) and 2(b)(vi) of Chapter 10, described above, which pertain to threatened and endangered species and critical habitats, respectively, listed under the Endangered Species Act. Section 4(a)(1) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) requires the Secretary of the Interior to determine if species within his or her program responsibilities are threatened or endangered based on certain factors, and section 4(c) requires the publication of a list of such species. Also, section 4(a)(3) of the Endangered Species Act requires the Secretary to designate critical habitat of species concurrently when determining the same species to be threatened or endangered. The Endangered Species Act's requirement to designate critical habitats applies only to those species determined to be threatened and endangered (*i.e.*, *listed* species), not to species only proposed for listing. Wyoming's qualification of its proposed rule's prohibition on disturbing critical habitats of listed threatened and endangered species is not inconsistent with that limitation of the Endangered Species Act. The State's proposed addition of the ''listed'' qualifier also is not inconsistent with the counterpart Federal regulation at 30 CFR 815.15(a), which similarly prohibits exploration operations from disturbing critical habitats of threatened or endangered species ''identified pursuant to the Endangered Species Act * * *.''

Based on the foregoing discussions, we find Wyoming's proposed Chapter 10, section 4(e) to be in accordance with SMCRA and consistent with the Federal regulations. We also find it satisfies the required amendment at 30 CFR 950.16(ll). Accordingly, we approve proposed section 4(e) and remove the required amendment.

3. Requirement To Obtain a Permit To Conduct Surface Coal Mining Operations If Coal Extracted During Exploration Will Be Commercially Used or Sold

Our 30 CFR part 732 (Part 732) letter dated September 21, 1990, notified Wyoming of the need to change its rules in response to changes in the Federal regulations for coal exploration. Item F–4 of that letter addressed 30 CFR 772.14(a). We said —

[t]his Federal rule has been expanded to apply to both commercial use and sale of coal. Thus, except as provided under 30 CFR 772.14(b) and 700.11(a)(5), any person who intends to commercially use or sell coal extracted under an exploration permit must first obtain a surface coal mining and reclamation operations permit. Since Wyoming's rules restrict commercial sale but not commercial use, the program will need to be revised to include commercial use restrictions no less effective than those of the Federal rule.

Wyoming proposes a number of changes in response to our letter. First, it proposes to revise its definition of ''coal exploration'' at Chapter 1, section 2(l) of its rules by removing the sentence that reads ''[i]f this activity results in the extraction of coal, the coal shall not be offered for commercial sale (except for test burns) * * *.'' That change makes Wyoming's proposed definition substantively identical to the Federal definition at 30 CFR 701.5, and is included in our finding at Part III.B of this final rule.

The State also proposes to add new rules at section 8 of Chapter 10 for coal exploration. Proposed section 8(a) would require any person who intends to commercially use or sell coal extracted during coal exploration operations under an exploration license to first obtain a permit to conduct surface coal mining operations, except as provided under proposed section (8)(b). Wyoming's proposed rule contains the required restrictions on commercial use and sale of coal as described in our Part 732 letter and contained in the Federal regulation. Referenced, proposed section 8(b) provides that, with the Administrator's prior written permission, no permit to mine is required for the sale or commercial use of coal extracted during exploration if such sale or use is for coal testing purposes only. It also describes the application that must be filed with, and approved by, the Administrator as a basis for waiving the permit requirement. Referenced, proposed section 8(b) is Wyoming's counterpart to 30 CFR 772.14(b) and is substantively identical to that Federal regulation. We included it in our finding at Part III.B of this final rule.

As proposed, section 8(a) is similar to counterpart 30 CFR 772.14(a) with one significant difference. The Wyoming rule provides one exception to the requirement to obtain a mine permit if coal extracted during exploration is to be commercially used or sold; the Federal regulation provides two exceptions. The exception provided in Wyoming's rules is referenced section 8(b), described above, and is the same as the first exception provided by the Federal regulation at referenced 30 CFR 772.14(b). The second exception provided by the Federal regulation is referenced 30 CFR 700.11(a)(5), which has no counterpart in Wyoming's proposed rule. Under that regulation, Chapter VII of Title 30 does not apply to exploration on lands subject to the requirements of 43 CFR parts 3480—3487. Those referenced regulations govern operations for the exploration, development, and production of Federal coal under Federal coal leases, licenses, and permits. As authorized by 43 CFR 3480.0–6(b), the U.S. Department of the Interior, Bureau of Land Management (BLM) issues exploration licenses for unleased Federal coal and supervises exploration operations for Federal coal.

Wyoming noted in its amendment that it is required by State statute to oversee coal exploration on all lands within Wyoming regardless of the ownership of the coal. The State referred to three sections of the Wyoming Environmental Quality Act to support its position that its rule must apply to all lands within the State's borders. Section 35–11–404(a) addresses closure of all drill holes ''on all lands within the State of Wyoming * * *.'' Section 35–11–404(j) requires notice to be filed with the Administrator before drilling ''on lands within the state of Wyoming * * *.'' Third, section 35–11–414(a) requires anyone who wants to ''engage in mineral exploration * * *'' to apply to the Administrator for a special license.

We find Wyoming's proposed section 8(a) of Chapter 10 to be no less effective than counterpart 30 CFR 772.14(a) based on restricting the commercial sale and use of coal extracted during exploration as required by item F–4 in the September 21, 1990, Part 732 letter, and can be approved. We also recognize that proposed section 8(a) reflects Wyoming's assertion of jurisdiction over all coal exploration on lands within the State's borders. Including exploration for Federal coal within the scope of Wyoming's proposed rule does not make it less effective than the Federal regulations because the State's rule applies as needed to exploration for non-Federal coal and the commercial use and sale of that coal. Though we recognize Wyoming asserts jurisdiction over all exploration within the State, we make no determination on that point and expect Wyoming and persons seeking permits to explore for Federal coal to abide by the regulations at 43 CFR part 3480 *et seq.*

D. Revisions to Wyoming's Rules With No Corresponding Federal Regulations

1. Definition of ''Soft Rock Surface Mining''

Wyoming explained that the definition of ''soft rock surface mining'' was to have been deleted from its coal rules when the State separated its coal and noncoal rules in 1994. That is a reference to OSM's approval of amendment WY–016–FOR in the March 30, 1994, **Federal Register** (59 FR 14750). The State noted that, though the definition of ''soft rock surface mining'' includes coal mining, it ''* * * should not have been incorporated into the Coal-Only set of rules * * *.'' Wyoming added that, ''* * * because the Coal rules pertain only to coal mining, there is no reason to maintain a definition that also lists other minerals.''

In the March 30, 1994, **Federal Register** approving amendment WY–016–FOR, (*id.*), OSM recognized that Wyoming submitted that amendment ''* * * as part of a State effort to eliminate the confusion that was inherent in regulatory rules that applied to two separate and distinct programs, i.e. the regulation of coal and noncoal mining operations.'' OSM further noted that ''[t]he proposed reorganized rule package is intended to facilitate a better understanding of and increased compliance with Wyoming's statutes and rules, and with SMCRA.''

Wyoming's removal of the definition at Chapter 1, section 2(ce) further clarifies that its coal rules pertain only to coal mining. We find the proposed change does not make the State's coal rules less effective than the Federal regulations and, therefore, we can approve it.

2. Backfilling and Grading Requirements for Soft Rock Surface Mining, Including Highwall Retention

Wyoming explained that it proposed to remove sections 2(b)(ix), 2(b)(ix)(A), (B), (C), and (D) from Chapter 4 of its coal rules because section 2(b)(ix) was inadvertently ''* * * carried over when the coal and noncoal rules were divided into separate rules.'' The State added that, ''[w]hen the rules were separated in 1994, the rules pertaining to soft rock mining should not have been incorporated into the Coal-Only set of rules.'' Amendment WY–016–FOR, which we approved in the March 30, 1994, **Federal Register** (59 FR 14750), separated most of the State's coal and noncoal regulations by removing most ''soft rock surface mining'' provisions from the State's coal rules. The rules cited above survived that separation, and Wyoming now proposes to correct that oversight by removing them in amendment WY–032–FOR. Also, the State explained that the ''* * * language [of section 2(b)(ix)(A)] was redundant to other sections of the Coal rules.''

In a letter dated December 20, 1993 (Administrative Record number WY–20–26), responding to our concerns for amendment WY–016–FOR, the State agreed to delete section 2(b)(ix) of Chapter 4 to remove language pertaining to ''bluffs,'' which we considered a form of retained highwalls. Because section 2(b)(ix) is only the heading ''Soft rock surface mining,'' Wyoming's reference to it can be interpreted to include subsections A, B, C, and D as well, though subsection D specifically addresses highwall retention, not bluffs. We referred to Wyoming's removal of section 2(b)(ix) in our approval of amendment WY–016–FOR when its subsections included provisions for bluff retention as a form of highwall retention that we never approved (*Id.*, at 14751).

Sections 2(b)(ix), 2(b)(ix)(A), (B), and (C) included backfilling and grading performance standards for ''soft rock surface mining'' operations that do, or do not, plan to leave permanent impoundments and for those that wish to construct terraces or benches. Similar provisions appear in Wyoming's rules at Chapter 8, sections 4(a)(v), (vi), and (vii) for special bituminous surface coal mines and in the permit application requirements at Chapter 2, sections 2(b)(i)(D)(IV) and 2(b)(iv)(B). There are no direct counterpart provisions in the Federal regulations though 30 CFR 816.102 includes similar provisions concerning general backfilling and grading and 30 CFR 816.49(10) addresses underwater highwalls in permanent impoundments. Removal of these provisions, given Wyoming's assertion that they only pertain to noncoal mining, does not make the State's rules less effective than the Federal regulations. Accordingly, we can approve Wyoming's removal of sections 2(b)(ix), 2(b)(ix)(A), 2(b)(ix)(B), and 2(b)(ix)(C) from Chapter 4 of its coal rules.

Though Wyoming noted that its highwall retention rule at Chapter 4, section 2(b)(ix)(D) is among those pertaining to ''soft rock surface mining'' that should be removed to complete its separation of coal and noncoal rules, instead it proposed to partly delete that rule and partly revise it. Wyoming explained that it wants to ''* * * make a clear statement that [it] supports the retention of highwalls to enhance and diversify reclamation as allowed by the current coal program.'' The rule currently reads—

> [h]ighwall retention may be considered on a case-by-case basis for enhanced wildlife habitat. The Wyoming Game and Fish Department shall be consulted by the applicant for need and design of the land form. Any approval under this paragraph shall be based on a demonstration of safety, stability, environmental protection, and equal or better land use considerations.

Wyoming's proposed rule would read—

> [h]ighwall retention may be considered on a case-by-case basis to enhance wildlife habitat as replacement for natural features that were eliminated by mining.

In the amendment's statement of reasons, Wyoming recognized the differences between its proposed rule, the Federal regulations, and the highwall retention provision we approved as part of the New Mexico regulatory program. It also said a future State rule amendment package would address those differences.

Section 515(b)(3) of SMCRA and 30 CFR 816.102(a)(2) require highwalls to be eliminated to achieve approximate original contour (AOC), with an exception for previously mined areas. As Wyoming noted in its amendment, however, we previously approved a highwall retention provision in New Mexico's rules (45 FR 86458; December 31, 1980). The approved New Mexico provision is an alternative approach to restoring mined land to its approximate original contour, in contrast to a provision that would allow a variance from AOC. It also imposes specific criteria for retained highwalls. Those criteria address: The static safety factor; overall highwall safety; backfilling to cover coal seams; allowable length of retained highwalls; the need to replace pre-existing cliff-type habitat and contouring the ends of highwalls; and a requirement for State approval to retain highwalls. By requiring an operator to demonstrate that retained highwalls will meet all six criteria of New Mexico's rule, thereby showing they closely resemble premining features, we concluded that—

> [s]uch retention in these instances actually reflects the intent of ''approximate original contour'' since these features were part of the natural pre-mined landscape. In all other cases, the highwall must be eliminated according to 30 CFR 816.102 (*id.*, at 86464).

Based on the criteria New Mexico imposed for retained highwalls, as conditioned in the approval, we found the State's ''* * * alternative to be in accordance with the provisions of SMCRA and consistent with the regulations in 30 CFR Chapter VII.''

In our disapproval of the rule Wyoming proposed in 1988 to allow highwall retention by recreating ''bluffs'' (54 FR 52958; December 26, 1989), we asserted that—

> [w]here the two requirements [achieving AOC and eliminating highwalls] are in conflict, *i.e.*, where the premining topography includes sheer cliffs or bluffs, as is common in New Mexico's San Juan Basin, the Secretary previously determined that highwalls could be retained only to the extent that they closely resemble premining features in both form and function * * * (Finding 4(b), 45 FR 86464, December 31, 1980).

Our review of Wyoming's proposed section 2(b)(ix)(D) finds that it is not specific enough with respect to the criteria retained highwalls must meet as an alternative approach to achieving AOC. As proposed, the rule would provide for highwall retention on a case-by-case basis to enhance wildlife habitat as replacement for natural features that were eliminated by mining. In comparison with the New Mexico provision that Wyoming refers to in its amendment, the proposed rule addresses one criterion for allowing highwall retention: Retained highwalls would replace pre-existing natural features. However, the proposed rule does not address other criteria that would require retained highwalls to closely resemble premining features in form and function.

To approve Wyoming's proposed alternative approach to achieving AOC by retaining highwalls, we must find that the proposed rule is in accordance with the provisions of SMCRA and consistent with the requirements of the Federal regulations at Chapter VII of the Title 30 regulations, as required by the reference at 30 CFR 732.17(h)(10) to 732.15. As defined at 30 CFR 730.5, ''consistent with'' and ''in accordance with'' mean, respectively:

> (a) With regard to [SMCRA], the State laws and regulations are no less stringent than, meet the minimum requirements of and include all applicable provisions of [SMCRA].
>
> (b) With regard to the Secretary's regulations, the State laws and regulations are no less effective than the Secretary's regulations in meeting the requirements of [SMCRA].

Absent more specific criteria for retained highwalls to meet, Wyoming's proposed rule does not impose requirements similar to those of 30 CFR 816.102 for ensuring the safety and effectiveness of reclamation in achieving AOC. As such, it is not in accordance with the requirements of SMCRA and is not consistent with the Federal regulations.

In a letter dated August 11, 2004, we notified Wyoming of our concern with the proposed highwall retention rule at section 2(b)(ix)(D) of Chapter 4 (Administrative Record number WY–37–11). As noted above, Wyoming's amendment recognized the differences between the proposed rule, the Federal regulations, and New Mexico's approved highwall retention regulation. It also said the State would submit another amendment to continue addressing those differences. Given those statements, we said in our August 11, 2004, letter that we were uncertain how to proceed with the amended highwall retention rule and are unlikely to approve it as proposed. We suggested that Wyoming provide a letter with specific rule language that would further explain how the State will further consider highwall retention, including provisions similar to those we approved for New Mexico. We added that we could defer a decision on the proposed highwall retention rule in amendment WY–032-FOR instead of disapproving it if the letter described Wyoming's future rulemaking and a timetable for submitting another amendment.

Wyoming responded to our August 22, 2004, letter, by submitting Coal Rule Package 1-T, dated August 30, 2004 (Administrative Record number WY–37–12). That submittal patterns additional proposed changes after provisions we approved as part of the New Mexico and Utah regulatory programs. However, the transmittal letter says several months might pass before the State's internal rulemaking can proceed to the next step, ''* * * which is to require a hearing before the Environmental Quality Council (EQC) * * *'' on changes proposed in Coal Rule Package 1(T). Because the EQC has yet to make the final determination of how Wyoming's rule will be worded, at this time we cannot consider the State's August 30, 2004, submittal to be the final version of the proposed revision to the highwall retention rule. We therefore defer making a decision on proposed Chapter 4, section 2(b)(ix)(D) until the State completes its internal rulemaking.

IV. Summary and Disposition of Comments

A. Public Comments

We asked for public comments on the amendment (Administrative Record number WY–37–10), but did not receive any.

B. Federal Agency Comments

Under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Wyoming program (Administrative Record number WY–37–06).

1. U.S. Department of Labor, Mine Safety and Health Administration Comments

The U.S. Department of Labor, Mine Safety and Health Administration (MSHA), responded to our request for comments in a letter dated July 15, 2004 (Administrative Record number WY–37–09). MSHA stated that it did not find anything in the proposed amendment that would conflict with its regulations or policies.

2. U.S. Department of the Interior, Fish and Wildlife Service Comments

We also received comments from the U.S. Fish and Wildlife Service (Service) in a letter dated July 15, 2004 (Administrative Record number WY–37–08). The Service found the proposed changes ''increased clarity of some sections of the program direction.''

The Service also expressed concern that the proposed amendment might lead to increased use of undesirable grading and contouring of disturbed areas and a decreased use of highwall retention around permanent ponds. More specifically, the Service commented that—

> * * * it is unclear why soft rock surface mining; terraces or benches; sloping, grading or contouring or proposed pit areas for permanent water impoundments; and highwall retention are being dropped from the program direction.

The Service's comment refers to Wyoming's proposed removal of the rules at Chapter 4, section 2(b)(ix), (ix)(A), (B), (C), and (D). Regarding the proposed removal of section 2(b)(ix)(A) and (B), the Service commented that eliminating those provisions—

> [w]ill lead to an increase in the use of terraces and benches to recontour disturbed areas. The Service strongly recommends, to the greatest extent possible, that all mining reclamation reestablish areas to the original contour.

As we explained in our finding at Part III.D.2 of this final rule, Wyoming explained that it proposed to remove sections 2(b)(ix), 2(b)(ix)(A), (B), (C), and (D) from Chapter 4 of its coal rules because those rules were inadvertently ''carried over when the coal and noncoal rules were divided into separate rules * * *.'' We previously approved Wyoming's separation of most

of its coal and noncoal rules on March 30, 1994, in amendment WY–016–FOR (59 FR 14750). The rules cited in the Service's comment survived that separation, and Wyoming now proposes to remove them in amendment WY–032–FOR. Wyoming also explained that the provisions of section 2(b)(ix)(A) were repeated elsewhere in the coal rules and asserted that 2(b)(ix), (ix)(A), (B), (C), and (D) do not belong in its coal-only rules.

In our approval of amendment WY–016–FOR, we recognized the State's effort to eliminate the confusion inherent to rules that applied to two separate and distinct programs (coal and noncoal mining). We further noted that separating the coal and noncoal rules is ''* * * intended to facilitate a better understanding of and increased compliance with Wyoming's statutes and rules, and with SMCRA.''

We also believe the Service's comment misinterprets section 2(b)(ix)(B). This rule allows use of terraces or benches ''* * * *only* when it can be shown to the Administrator's satisfaction that other methods of contouring will not provide the required result * * *'' (emphasis added). As written, it provides a limited exception to the requirement to backfill and grade to approximate original contour (''the required result''). By removing this rule, Wyoming will reduce those circumstances under which terraces and benches can be used in final reclamation.

Similar reasoning applies to the Service's comment concerning section 2(b)(ix)(C). General performance standards for sloping, grading, and contouring to blend in with the topography (*i.e.*, AOC) and to control erosion similar to those imposed by this rule appear in other sections of Chapter 4 of Wyoming's coal rules. The remaining part of the rule provides for certain circumstances in which partial pitwalls may be left intact above water along the shoreline of permanent impoundments. This provision actually conflicts with the Federal regulation at 30 CFR 816.49(10). That regulation requires the vertical portion of any remaining highwall ''* * * to be located far enough below the low-water line along the full extent of the highwall to provide adequate safety and access for the proposed water users * * *'' at temporary and permanent impoundments. By removing section 2(b)(ix)(C), Wyoming will reduce the circumstances under which highwalls may be left intact where they were not part of the premining landscape and also eliminate a conflict with Federal provisions for reclaiming to AOC.

Conversely, the Service expressed concern in another comment that Wyoming's proposed removal of section 2(b)(ix)(D) would lead to a decrease in highwall retention around permanent ponds. It stated that retained highwalls are ''* * * highly beneficial to wildlife, especially raptors, by providing nesting structure.'' Wyoming explained that it proposes to remove section 2(b)(ix)(D) along with other rules that pertain to ''soft rock surface mining'' in an effort to separate its coal rules from its noncoal rules. Further, while we agree in principle with the Service about highwalls' potential benefit, we cannot waive the requirement of SMCRA and the Federal regulations to reclaim mined lands to AOC on that basis. We are unlikely to approve the proposed revision as written because it provides an exemption from reclaiming mined lands to AOC that is not in accordance with section 515(b)(3) of SMCRA and consistent with 30 CFR 816.102(a)(1) and (2). The only exceptions to the AOC requirement are cases involving steep slopes or previously mined areas, and Wyoming's proposed rule does not fit either situation.

On the other hand, Wyoming is considering further revisions to proposed section 2(b)(ix)(D) in an effort to develop an alternative approach to achieving AOC that would allow highwall retention in certain cases. As we discussed in our finding at Part III.D.2 of this final rule, the State submitted Coal Rule Package 1–T in response to our August 11, 2004, concern letter. That package proposed to further revise section 2(b)(ix)(D) to include provisions similar to those we approved as part of the New Mexico and Utah regulatory programs for retaining highwalls where similar features existed in the pre-mine landscape and where the retained highwalls were very similar to the pre-existing features in form and function. We recognize Wyoming's review process is ongoing for this proposed rule and defer our decision on it until we know the final form it will take.

The Service also expressed concern that Wyoming's proposed change to section 4(e) of Chapter 10 would lessen protection of crucial wildlife habitats during coal exploration. It added that the State should also promote the protection of ''other important habitats'' during coal exploration. The proposed rule would prohibit disturbing crucial and important habitat during coal exploration ''* * * unless written evidence of consultation with the Wyoming Game and Fish Department and any resulting recommendations are submitted to the Administrator as part of either a coal exploration license or notice of intent to explore application.'' In part III.C.2 of this final rule, we described an alternative we suggested Wyoming consider in response to the State's request for guidance and flexibility in interpreting the prohibition on disturbance required at 30 CFR 815.15(a). Specifically, we suggested that Wyoming consider requiring the same consultation process with State and Federal agencies for coal exploration on important or crucial habitat that it requires of surface coal mining activities and reclamation plans. We agreed that we would consider such an alternative to be consistent with and no less effective in meeting the intent of SMCRA. Our finding at Part III.C.2 of this final rule describes how we interpret Wyoming's proposed rule and additional explanation as a commitment to providing the same level of protection for important or crucial habitat during exploration as its rules require for surface coal mining and reclamation operations. As we stated in our finding, we will verify Wyoming's consultation during our oversight of its regulatory program.

3. Environmental Protection Agency (EPA) Concurrence and Comments

Under 30 CFR 732.17(h)(11)(i) and (ii), we are required to get concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*).

None of the revisions that Wyoming proposed to make in this amendment pertains to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment. Nevertheless, under 30 CFR 732.17(h)(11)(i), we requested EPA's comments on the amendment in a letter dated May 27, 2004 (Administrative Record number WY–37–05). EPA did not respond to our request.

C. State Historic Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. In a letter dated May 27, 2004, we requested comments from the SHPO and ACHP on Wyoming's amendment (Administrative Record numbers WY–37–03 and WY–37–04, respectively), but neither responded to our request.

V. OSM's Decision

Based on the above findings, we approve Wyoming's May 21, 2004, amendment with one exception as noted below.

We defer making a decision on proposed section 2(b)(ix)(D), highwall retention, as discussed in finding number III.D.2.

We approve, as discussed in: finding III.A, Chapter 10, sections 2(b)(vi), (vii), (x), and (xi), application requirements for exploration of more than 250 tons or in an area designated unsuitable for mining; finding III.B., Chapter 1, section 2(l), revising the definition of ''coal exploration;'' Chapter 4, section 2(b)(iv)(A), using small depressions; Chapter 10, sections 1 and 1(b)(iii), general requirements for coal exploration of 250 tons or less, including recodification; Chapter 10, sections 2(b), (b)(i), (ii), and (iii), (b)(iv), (vi), and (v), general requirements for coal exploration of more than 250 tons or in an area designated as unsuitable for mining, including recodification; Chapter 10, section 2(b)(ix), measures used so exploration of more than 250 tons or in areas designated unsuitable for mining complies with exploration performance standards, including recodification; Chapter 10, section 3(b), administrative and judicial review for anyone adversely affected by decisions on coal exploration applications; Chapter 10, section 8, section heading for commercial use or sale of coal extracted under a coal exploration license; Chapter 10, section 8(b), written approval to not require a mining permit for coal exploration where commercial use or sale of coal is for testing only and demonstrating the need for coal testing and the purpose for coal extraction; Chapter 10, section 8(b)(i), requirement for the testing firm name and coal testing locations; Chapter 10, section 8(b)(ii), requirement for a statement from the end user or agent or broker if coal extracted during exploration is sold or commercially used and for other information; Chapter 10, section 8(b)(ii)(A), requirement for the statement to include the reason for coal testing; Chapter 10, section 8(b)(ii)(B), requirement for the statement to show the amount of coal needed for testing and why a lesser amount is insufficient; Chapter 10, section 8(b)(ii)(C), requirement for a description of the test to be conducted; Chapter 10, section 8(b)(iii), requirement for evidence of sufficient coal reserves; Chapter 10, section 8(b)(iv), requirement for explanation why other means of exploration are not adequate to determine coal quality and/or mining feasibility; in finding III.C.1, Chapter 10, section 2(b)(vii), provision authorizing the State to require exploration applications to include information regarding known or possible historic or archeological resources; in finding III.C.2, Chapter 10, section 4(e), prohibiting disturbance of critical habitat during exploration, and disturbance of important or crucial habitat during exploration without written evidence of consultation with the Wyoming Game and Fish Department; in finding III.C.3, Chapter 10, Section 8(a), requiring a permit to conduct surface coal mining operations if coal extracted during construction will be commercially used or sold, with one exception; in finding III.D.1, Chapter 1, section 2(ce), removal of the definition of ''soft rock surface mining;'' and in finding III.D.2, Chapter 4, sections 2(b)(ix), (ix)(A), (B), and (C), removing backfilling and grading requirements for soft rock surface mining.

To implement this decision, we are amending the Federal regulations at 30 CFR part 950, which codify decisions concerning the Wyoming program. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately. Section 503(a) of SMCRA requires that the State's program demonstrates that the State has the capability of carrying out the provisions of the Act and meeting its purposes. Making this regulation effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

Effect of OSM's Decision

Section 503 of SMCRA provides that a State may not exercise jurisdiction under SMCRA unless the State program is approved by the Secretary. Similarly, 30 CFR 732.17(a) requires that any change of an approved State program be submitted to us for review as a program amendment. The Federal regulations at 30 CFR 732.17(g) prohibit any changes to approved State programs that we do not approve. In the oversight of the Wyoming program, we will recognize only the statutes, regulations and other materials we have approved, together with any consistent implementing policies, directives and other materials. We will require the State to enforce only approved provisions.

VI. Procedural Determinations

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based in part on the analysis performed for the counterpart Federal regulations. Some of the State provisions addressed in this final rule have no counterpart Federal regulations. In those instances, we have determined that there are no takings implications because we are approving the State's removal of those provisions, which then no longer apply to the regulated industry. In one instance, we are deferring our decision on a State rule that has no Federal counterpart. There are no takings implications in that instance either because 30 CFR 731.17(g) prevents State laws and regulations from taking effect without our approval; therefore, the provision has no effect on the regulated industry.

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rule does not have federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be ''in accordance with'' the requirements of SMCRA, and section 503(a)(7) requires

that State programs contain rules and regulations ''consistent with'' regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on federally-recognized Indian Tribes and have determined that the rule does not have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes. The rule does not involve or affect Indian Tribes in any way.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that the provisions in this rule based on counterpart Federal regulations will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) This determination is based on the economic analysis performed for the counterpart Federal regulations for which a certification was made that those regulations would not have a significant economic effect on a substantial number of small entities. The Department of the Interior also certifies that the provisions in this rule that are not based on counterpart Federal regulations will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This determination is based on the fact that the State is removing all those provisions but one. Because the removed provisions no longer apply to the regulated industry, they have no effect. The remaining provision does not impose significant economic impacts on a substantial number of small entities because we are deferring our decision in that instance, and 30 CFR 731.17(g) prevents State laws and regulations from taking effect without our approval.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: a. does not have an annual effect on the economy of $100 million; b. will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and c. does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

This determination is based upon the fact that some of the State provisions are based on counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule. For all but one of those State provisions that are not based on counterpart Federal regulations, the ''non-major'' determination is based on the fact that the State is removing them, so they no longer apply to the regulated industry. For the one remaining State provision without a Federal counterpart, this determination is based on the fact that we are deferring a decision on that provision, and 30 CFR 731.17(g) prevents State laws and regulations from taking effect without our approval.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. This determination is based on the fact that part of the State submittal is based on counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate. For all but one of those State provisions that are not based on counterpart Federal regulations, this determination is based on the fact that the State is removing them, so they no longer apply to the regulated industry. For the one remaining State provision without a Federal counterpart, this determination is based on the fact that we are deferring a decision on that provision, and 30 CFR 731.17(g) prevents State laws and regulations from taking effect without our approval.

List of Subjects in 30 CFR Part 950

Intergovernmental relations, Surface mining, Underground mining.

Dated: February 25, 2005.

Allen D. Klein,

Regional Director, Western Regional Coordinating Center.

■ For the reasons set out in the preamble, 30 CFR part 950 is amended as set forth below:

PART 950—WYOMING

■ 1. The authority citation for part 950 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 950.15 is amended in the table by adding a new entry in chronological order by date of final publication to read as follows:

§ 950.15 Approval of Wyoming regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation description
* * *	*	* * *
May 21, 2004	April 4, 2005	Coal Rules: Chapter 1, sections 2(l) and (ce); chapter 4, sections 2(b)(iv)(A), (b)(ix), (b)(ix)(A), (B), and (C); Chapter 10, sections 1, 1(b)(iii), 2(b), (b)(i), (ii), (iii), (iv), (v), (vi), (vii), (viii), (ix), (x), (xi), and (xii), 3(b), 4(e), 8, 8(a), 8(b), (b)(i), (ii), (ii)(A), (ii)(B), (ii)(C), (iii), and (iv).

§ 950.16 [Amended]

■ 3. Section 950.16 is amended by removing and reserving paragraphs (a), (w), and (ll).

[FR Doc. 05–6602 Filed 4–1–05; 8:45 am]

BILLING CODE 4310–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R03–OAR–2005–PA–0002; FRL–7894–5]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; VOC and NO_X RACT Determinations for Three Individual Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Commonwealth of Pennsylvania's State Implementation Plan (SIP). The revisions were submitted by the Pennsylvania Department of Environmental Protection (PADEP) to establish and require reasonably available control technology (RACT) for three major sources of volatile organic compounds (VOC) and nitrogen oxides (NO_X). These sources are located in Pennsylvania. EPA is approving these revisions to establish RACT requirements in the SIP in accordance with the Clean Air Act (CAA).

DATES: This rule is effective on June 3, 2005, without further notice, unless EPA receives adverse written comment by May 4, 2005. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID Number R03–OAR–2005–PA–0002 by one of the following methods:

A. Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. Agency Web site: *http://www.docket.epa.gov/rmepub/* RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

C. E-mail: *morris.makeba@epa.gov.*

D. Mail: R03–OAR–2005–PA–0002, Makeba Morris, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

E. Hand Delivery: At the previously listed EPA Region III address. 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 RME ID No. R03–OAR–2005–PA–0002. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.docket.epa.gov/rmepub/,* 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 RME, regulations.gov or e-mail. The EPA RME and the Federal regulations.gov Web sites are 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 RME or 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.

Docket: All documents in the electronic docket are listed in the RME index at *http://www.docket.epa.gov/rmepub/.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Amy Caprio, (215) 814–2156, or by e-mail at *caprio.amy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to sections 182(b)(2) and 182(f) of the CAA, the Commonwealth of Pennsylvania (the Commonwealth or Pennsylvania) is required to establish and implement RACT for all major VOC and NO_X sources. The major source size is determined by its location, the classification of that area and whether it is located in the ozone transport region (OTR). Under section 184 of the CAA, RACT as specified in sections 182(b)(2) and 182(f) applies throughout the OTR. The entire Commonwealth is located within the OTR. Therefore, RACT is applicable statewide in Pennsylvania.

State implementation plan revisions imposing RACT for three classes of VOC sources are required under section 182(b)(2). The categories are:

(1) All sources covered by a Control Technique Guideline (CTG) document issued between November 15, 1990 and the date of attainment;

(2) All sources covered by a CTG issued prior to November 15, 1990; and

(3) All major non-CTG sources.

The Pennsylvania SIP already has approved RACT regulations and requirements for all sources and source categories covered by the CTGs. The Pennsylvania SIP also has approved regulations to require major sources of NO_X and additional major sources of VOC emissions (not covered by a CTG) to implement RACT. These regulations are commonly termed the ''generic RACT regulations''. A generic RACT regulation is one that does not, itself, specifically define RACT for a source or source categories but instead establishes procedures for imposing case-by-case RACT determinations. The Commonwealth's SIP-approved generic RACT regulations consist of the procedures PADEP uses to establish and impose RACT for subject sources of VOC and NO_X. Pursuant to the SIP-approved generic RACT rules, PADEP imposes RACT on each subject source in an enforceable document, usually a Plan Approval (PA) or Operating Permit (OP). The Commonwealth then submits these PAs and OPs to EPA for approval as source-specific SIP revisions.

It must be noted that the Commonwealth has adopted and is implementing additional ''post RACT requirements'' to reduce seasonal NO_X emissions in the form of a NO_X cap and trade regulation, 25 Pa Code Chapters 121 and 123, based upon a model rule developed by the States in the OTR. That regulation was approved as SIP revision on June 6, 2000 (65 FR 35842). Pennsylvania has also adopted 25 Pa Code Chapter 145 to satisfy Phase I of the NO_X SIP call. That regulation was approved as a SIP revision on August 21, 2001 (66 FR 43795). Federal approval of a source-specific RACT determination for a major source of NO_X in no way relieves that source from any applicable requirements found in 25 PA Code Chapters 121, 123 and 145.

On August 30, 2004, PADEP submitted revisions to the Pennsylvania SIP which establish and impose RACT for three sources of VOC and NO_X. The Commonwealth's submittals consist of PAs and OPs which impose VOC and NO_X RACT requirements for each source.

II. Summary of the SIP Revisions

Copies of the actual PAs and OPs imposing RACT and PADEP's evaluation memorandum are included in the electronic and hard copy docket for this final rule. As previously stated, all documents in the electronic docket are listed in the RME index at *http://www.docket.epa.gov/rmepub/*. Publicly available docket materials are available either electronically in RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105. The table below identifies the sources and the individual PAs and OPs which are the subject of this rulemaking.

PENNSYLVANIA—VOC AND NO_X RACT DETERMINATIONS FOR INDIVIDUAL SOURCES

Source	County	Plan approval (PA #) operating permit (OP #)	Source type	''Major source'' pollutant
Waste Management Disposal Services of Pennsylvania, Inc. (Pottstown Landfill).	Berks	OP–46–0033	Turbines; Enclosed Flares	NO_X and VOC.
Waste Management Disposal Services of PA, Inc.	York	67–02047	Internal Combustion Engines; Enclosed Ground Flares.	NO_X and VOC.
Armstrong World Industries, Inc	Lancaster	36–2001	Space Heaters; Dryers; Surface Coatings.	NO_X and VOC.

EPA is approving these RACT SIP submittals because PADEP established and imposed these RACT requirements in accordance with the criteria set forth in its SIP-approved generic RACT regulations applicable to these sources. The Commonwealth has also imposed record-keeping, monitoring, and testing requirements on these sources sufficient to determine compliance with the applicable RACT determinations.

III. Final Action

EPA is approving the revisions to the Pennsylvania SIP submitted by PADEP to establish and require VOC and NO_X RACT for three major sources. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comment. However, in the ''Proposed Rules'' section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective on June 3, 2005, without further notice unless EPA receives adverse comment by May 4, 2005. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Statutory and Executive Order Reviews

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves State law as meeting Federal requirements and imposes no additional requirements beyond those imposed by State law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this

rule approves pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have federalism implications because it does 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 Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

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. Section 804 exempts from section 801 the following types of rules: (1) Rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability establishing source-specific requirements for three named sources.

C. Petitions for Judicial Review

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 June 3, 2005. Filing a petition for reconsideration by the Administrator of this final rule approving source-specific RACT requirements for three sources in the Commonwealth of Pennsylvania does not affect the finality of this rule 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, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: March 23, 2005.

Donald S. Welsh,

Regional Administrator, Region III.

■ 40 CFR part 52 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 NN—Pennsylvania

■ 2. In Section 52.2020, the table in paragraph (d)(1) is amended by revising the entry for Waste Management Disposal Services of Pennsylvania, Inc. (Pottstown Landfill) and by adding the entries for Waste Management Disposal Services of PA, Inc. and Armstrong World Industries, Inc. at the end of the table to read as follows:

§ 52.2020 Identification of plan.

* * * * *

(d) * * *

(1) * * *

Name of source	Permit number	County	State effective date	EPA approval date	Additional explanation/ § 52.2063 citation
* *	*	*	*	*	*
Waste Management Disposal Services of Pennsylvania, Inc. (Pottstown Landfill).	OP–46–0033	Berks	3/20/99	4/4/05 [Insert page number where the document begins].	52.2020(d)(1)(a)
* *	*	*	*	*	*
Waste Management Disposal Services of PA, Inc.	67–02047	York	4/20/99	4/4/05 [Insert page number where the document begins].	52.2020(d)(1)(a)
Armstrong World Industries, Inc	36–2001	Lancaster	7/3/99	4/4/05 [Insert page number where the document begins].	52.2020(d)(1)(a)

* * * * *

[FR Doc. 05–6498 Filed 4–1–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[RME Docket Number; R03–OAR–2005–DC–0001, R03–OAR–2005–MD–0001, R03–OAR–2005–PA–0010; FRL–7894–4]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia, Maryland, Virginia and Pennsylvania; Revised Carbon Monoxide Maintenance Plans for Washington Metropolitan, Baltimore and Philadelphia Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action approving State Implementation Plan (SIP) revisions submitted by the District of Columbia, the State of Maryland, the Commonwealth of Virginia, and the Commonwealth of Pennsylvania that provide revised carbon monoxide (CO) maintenance plans and transportation conformity budgets for the Washington Metropolitan area, the Baltimore area, and the Philadelphia area. These plans provide for continued maintenance of the National Ambient Air Quality Standard (NAAQS) for CO. For the Washington Metropolitan area, the District of Columbia formally submitted its maintenance plan revision on March 9, 2004; the Maryland Department of the Environment formally submitted its revision on March 3, 2004, and the Commonwealth of Virginia submitted its revision on March 22, 2004. The Maryland Department of the Environment formally submitted its revision for the Baltimore area on July 15, 2004, previously having submitted a parallel processing request of the same name on December 18, 2003. The Pennsylvania Department of Environmental Protection formally submitted its revision for the Philadelphia area on September 3, 2004. In this action, EPA is approving the revised maintenance plans and revised transportation conformity budgets for each respective CO maintenance area. This action is being taken under section 110 of the Clean Air Act (CAA).

DATES: This rule is effective on June 3, 2005 without further notice, unless EPA receives adverse written comment by May 4, 2005. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID Number R03–OAR–2005–DC–0001 for the Washington Metropolitan area plan, R03–OAR–2005–MD–0001 for the Baltimore area plan, and/or R03–OAR–2005–PA–0010 for the Philadelphia area plan by one of the following methods:

A. Federal eRulemaking Portal: *http://www.regulations.gov.**COM028* Follow the on-line instructions for submitting comments.

B. Agency Web site: *http://www.docket.epa.gov/rmepub/* RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

C. E-mail: *morris.makeba@epa.gov.*

D. Mail: R03–OAR–2005–DC–0001, R03–OAR–2005–MD–0001, and/or R03–OAR–2005–PA–0010 Makeba Morris, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

E. Hand Delivery: At the previously-listed EPA Region III address. 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 RME ID No. R03–OAR–2005–DC–0001, R03–OAR–2005–MD–0001, and/or R03–OAR–2005–PA–0010. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.docket.epa.gov/rmepub/,* 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 RME, regulations.gov or e-mail. The EPA RME and the Federal regulations.gov Web sites are 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 RME or 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.

Docket: All documents in the electronic docket are listed in the RME index at *http://www.docket.epa.gov/rmepub/.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of material to be incorporated by reference are available at the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 1301 Constitution Avenue, NW, Room B108, Washington, DC 20460. Copies of the respective State submittals are available at: District of Columbia Department of Public Health, Air Quality Division, 51 N Street, NE., Washington, DC 20002; Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230; Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105; Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219; Department of Public Health, Air Management Services, 321 University Avenue, Philadelphia, Pennsylvania 19104.

FOR FURTHER INFORMATION CONTACT: Catherine L. Magliocchetti, (215) 814–2174, or by e-mail at *magliocchetti.catherine@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to EPA. This supplementary information is organized as follows.

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I. EPA Analysis of the Washington Metropolitan Carbon Monoxide Maintenance/Attainment Area Using Limited Maintenance Area Criteria

A. Statutory Requirements and Previous Redesignation of the Area to Attainment

The Federal Clean Air Act, 42 U.S.C. 7401 *et seq.*, as amended by the Clean Air Act Amendments of 1990 (CAAA), requires all areas of the nation to attain and maintain compliance with the national ambient air quality standards (NAAQS), including the 8-hour carbon monoxide (CO) standard.

In accordance with CAAA section 175A(a), the District of Columbia, the State of Maryland and the Commonwealth of Virginia submitted a CO maintenance plan for the Washington Metropolitan area in 1995, covering the period 1996–2007. EPA approved that maintenance plan, effective March 16, 1996 (61 FR 2931, 1/30/96). In accordance with section 175A(b), the region is required to submit a revised maintenance plan within eight years of its redesignation as an attainment area. The revised maintenance plan must provide for maintenance of the carbon monoxide standard for an additional ten years. This maintenance plan is submitted to fulfill that requirement, and provides for continued attainment of the CO standard in the Washington Metropolitan attainment area through March 16, 2016. Emissions projections to the year 2016, from this maintenance plan, are consistent with ambient CO levels below the NAAQS.

The maintenance plan approved in 1996 established a motor vehicle emissions budget of 1671.5 tons per day (tpd) of CO, apportioned among the three jurisdiction as follows: 369.3tpd for the District of Columbia, 1045.2 tpd for Maryland and 257.0 tpd for Virginia. The revised maintenance plan does not change the CO emissions budget for conformity purposes, as is discussed below.

B. Maintenance Plan Review—Subsequent Maintenance Plan Revisions

The Clean Air Act requires the State to submit a revision of the SIP 8 years after the original redesignation request is approved to provide for maintenance of the NAAQS for an additional 10 years following the first 10-year period [see section 175A(b)].

In addition, the maintenance plan shall contain such contingency measures as the Administrator deems necessary to ensure prompt correction of any violation of the NAAQS [see section 175A(d)]. Failure to maintain the NAAQS and triggering of the contingency plan will not necessitate a revision of the SIP unless required by the Administrator, as stated in section 175A(d). Under the limited maintenance plan option, the following criteria must be met by the state:

i. *Attainment Inventory*—EPA guidance recommends that the CO attainment inventory be based upon actual ''typical CO season day'' emissions for the attainment year. This generally corresponds to one of the periodic inventories required for nonattainment areas.

The maintenance plan for the first 10-year maintenance period contained a base-year inventory of 1990. The anticipated change in emissions levels from the attainment year was used to estimate the future air quality levels. The analysis for the Washington Metropolitan area in this second 10-year maintenance plan documents a revised base-year inventory. Use of a revised 1990 base-year inventory for this purpose is acceptable, since the area was monitoring attainment during this time period. The base-year inventory is based upon actual ''typical CO season days.'' As part of the revised maintenance plan, the revised base-year emissions inventory will be updated and approved as part of this rulemaking for maintenance plan purposes.

Conformity budgets will remain at the original level, as discussed below, and per the request of each jurisdiction.

ii. *Maintenance Demonstration*—This maintenance demonstration for CO calculates future emissions of the pollutant out to the year 2016, and projects that the level of emissions will not exceed the level emitted in the attainment inventory. Since the Washington DC–MD–VA CO nonattainment area was classified as a moderate CO area, with a design value less than 12.7 ppm, the areas were not required to do further modeling to demonstrate attainment of the CO standard. The use of 2016 as the projected year allows ample time for EPA to process the request. The maintenance plan assumed the following emission control programs, which are or will be permanent and enforceable measures: Enhanced Vehicle Emissions I/M programs in each jurisdiction, Reformulated Gasoline (on-road), Federal Tailpipe Standards and Regulations (including on-road and off-road sources and small engines), and reductions in stationary sources from implementation of BACT (Best Available Control Technology), and other combustion improvements.

iii. *Monitoring Network*—The monitoring data is quality assured in accordance with 40 CFR 58, and EPA has repeatedly verified the integrity of the Washington DC–MD–VA area's air monitoring network. In addition, EPA approved the site selection of each CO monitor, and EPA agrees that the air monitoring network serves as a reliable indicator of ambient concentrations of air pollutants.

iv. *Verification of Continued Attainment*—CO inventories will be included as part of the Consolidated Emission Reporting Rule (CERR) during the maintenance period to ensure that the Washington Metropolitan attainment area remains in compliance with the CO NAAQS. The Metropolitan Washington region has remained in attainment for the federal 8-hour standard for carbon monoxide since its redesignation in 1996. Monitor data for the nonattainment area continue to show downward trends in the ambient levels of CO. Current and projected inventories also remain below the attainment inventory.

v. *Contingency Plan*—Each of the three jurisdictions continues to designate the oxygenated fuel program as a contingency measure for the region's maintenance plan. The states propose to re-implement the oxygenated fuels program if a monitor in the network were to detect two exceedances in one calendar year. Implementation of an oxygenated fuels program would increase the percentage oxygenate requirement to 2.7% from the 2.0%

currently mandated under the region's reformulated gasoline program.

C. Impact of This Revised Maintenance Plan on Conformity and the Mobile Emissions Budget

Under 40 CFR Parts 51 and 93, as part of the SIP process, the three jurisdictions, in consultation with the Transportation Planning Board, establish a mobile source emissions budget, under the interagency consultation process, to be used for transportation conformity purposes. The motor vehicle emissions budget establishes a cap on emissions, which cannot be exceeded by predicted highway and transit vehicle emissions.

Since mobile source estimates were updated during the development of this SIP revision, using updated planning assumptions and the MOBILE6 model, a revised estimate of the 1990 attainment year inventory has been calculated. This revised estimate of 2589.5 tpd for the area is higher than the estimate of 1671.5 tpd included in the 1995 plan as the attainment year inventory. Despite the revised inventory, the emissions budget will remain at 1671.5 tpd (which is equal to 90% of the 1990 attainment year inventory, as projected in the 1995 plan). The CO budget for the Washington DC–MD–VA maintenance area is ascribed as follows: 369.3 tpd for the District of Columbia, 1045.1 tpd for the Maryland area, and 257.0 tpd for the Virginia area, totaling 1671.5 tpd for the entire maintenance area, which remains acceptable to EPA.

D. Special Section Addressing Virginia Law

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) ''privilege'' for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information (1) that are generated or developed before the commencement of a voluntary environmental assessment; (2) that are prepared independently of the assessment process; (3) that demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) that are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information ''required by law,'' including documents and information ''required by Federal law to maintain program delegation, authorization or approval,'' since Virginia must ''enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts * * *.'' The opinion concludes that ''[r]egarding section 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval.''

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that ''[t]o the extent consistent with requirements imposed by Federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.'' Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the Clean Air Act, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the Clean Air Act is likewise unaffected by this, or any, state audit privilege or immunity law.

II. EPA Analysis of the Baltimore Carbon Monoxide Maintenance/Attainment Area Using Limited Maintenance Area Criteria

A. Statutory Requirements and Previous Redesignation of the Area to Attainment

The Federal Clean Air Act, 42 U.S.C. 7401 *et seq.*, as amended by the Clean Air Act Amendments of 1990 (CAAA), requires all areas of the nation to attain and maintain compliance with the national ambient air quality standards (NAAQS), including the 8-hour carbon monoxide (CO) standard.

In accordance with CAAA section 175A(a), the State of Maryland submitted a CO maintenance plan for the Baltimore area in 1995, covering the period 1995–2007. EPA approved that maintenance plan effective December 15, 1995 (60 FR 55325, 10/31/95). In accordance with section 175A(b), the region is required to submit a revised maintenance plan within eight years of its redesignation as an attainment area. This maintenance plan is submitted to fulfill that requirement, and provides for continued attainment of the CO standard in the Baltimore attainment area through 2015. Emissions projections to the year 2015, from this maintenance plan, are consistent with ambient CO levels below the NAAQS.

The maintenance plan that became effective in 1996 established a motor vehicle emissions budget of 1689.8 tons per day of CO. The revised maintenance plan does not change the CO emissions budget for conformity purposes, as is discussed below.

B. Maintenance Plan Review—Subsequent Maintenance Plan Revisions

The Clean Air Act requires the State to submit a revision of the SIP 8 years after the original redesignation request is approved to provide for maintenance of the NAAQS for an additional 10 years following the first 10-year period [see section 175A(b)].

In addition, the maintenance plan shall contain such contingency measures as the Administrator deems necessary to ensure prompt correction of any violation of the NAAQS [see section 175A(d)]. Failure to maintain the NAAQS and triggering of the contingency plan will not necessitate a revision of the SIP unless required by

the Administrator, as stated in section 175A(d). Under the limited maintenance plan option, the following criteria must be met by the state:

i. *Attainment Inventory*—EPA guidance recommends that the CO attainment inventory be based upon actual ''typical CO season day'' emissions for the attainment year. This generally corresponds to one of the periodic inventories required for nonattainment areas. The maintenance plan for the first 10-year maintenance period contained a base-year inventory of 1990. The anticipated change in emissions levels from the attainment year was used to estimate the future air quality levels. Maryland's analysis for Baltimore in this second 10-year maintenance plan documents a revised base-year inventory. Maryland's use of a revised 1990 base-year inventory for this purpose is acceptable, since the area was monitoring attainment during this time period. Maryland's base-year inventory for Baltimore is based upon actual ''typical CO season days.'' As part of the revised maintenance plan, the revised base-year emissions inventory will be updated and approved as part of this rulemaking for maintenance plan purposes.

ii. *Maintenance Demonstration*—Maryland's maintenance demonstration for the Baltimore area for CO calculates future emissions of the pollutant out to the year 2015, and projects that the level of emissions will not exceed the level emitted in the attainment inventory. Since the Baltimore CO nonattainment area was classified as a moderate CO area, with a design value less than 12.7 ppm, the state was not required to do further modeling to demonstrate attainment of the CO standard. Maryland's use of 2015 as the projected year allows ample time for EPA to process the request. Maryland's maintenance plan for Baltimore assumed the following emission control programs, which are or will be permanent and enforceable measures: FMVCP (Federal Motor Vehicle Control Program), the 1992 Reid Vapor Pressure Programs, Tier I and Tier II controls, Evaporative Emission Control Program, Federal Reformulated Gasoline Program Phase I and Phase II, Enhanced Inspection and Maintenance, Low Emission Vehicles, and On-Board Controls.

iii. *Monitoring Network*—The monitoring data is quality assured in accordance with 40 CFR 58, and EPA has repeatedly verified the integrity of Maryland's air monitoring network. In addition, EPA approved the site selection of each CO monitor, and EPA agrees that the air monitoring network serves as a reliable indicator of ambient concentrations of air pollutants.

iv. *Verification of Continued Attainment*—Maryland will periodically conduct a comprehensive review of the factors that were used to develop the attainment inventory and project the CO emissions levels for 2015. If there are significant differences between the actual and projected growth, then Maryland has committed to creating updated emissions inventories to compare with the projections.

v. *Contingency Plan*—Through COMAR 03.03.06, Maryland adopted the oxygenated fuel program as a contingency measure. If a monitor in the Central Business District experiences a violation of the CO standard—two exceedances of the standard within one year, then the oxygenated fuel program will automatically resume the following CO season.

C. Impact of This Revised Maintenance Plan on Conformity and the Mobile Emissions Budget

Under 40 CFR Parts 51 and 93, as part of the SIP process, Maryland establishes an emissions budget, under the interagency consultation process, to be used for transportation conformity purposes. The motor vehicle emissions budget establishes a cap on emissions, which cannot be exceeded by predicted highway and transit vehicle emissions.

Since mobile source estimates were updated during the development of this SIP revision, using updated planning assumptions and the MOBILE6 model, Maryland now estimates that 2452.1 tons of CO per day were emitted in 1990 from on-road mobile sources, when the original attainment budget was established. This differs with the redesignation request and maintenance plan submitted in 1995, which estimated 1789.80 tons of CO per day, and which led to setting the conformity budget at 1689.9 tons per day (the base year emissions level minus a cushion of 100 tons per day.) For conformity purposes, Maryland has stated in this revised maintenance plan that it will retain the mobile budget of 1689.8 tons per day of CO, which remains acceptable to EPA.

III. EPA Analysis of the Philadelphia Carbon Monoxide Maintenance/Attainment Area Using Limited Maintenance Plan Criteria

A. Statutory Requirements and Previous Redesignation of the Area to Attainment

The Federal Clean Air Act, 42 U.S.C. 7401 et seq., as amended by the Clean Air Act Amendments of 1990 (CAAA), requires all areas of the nation to attain and maintain compliance with the national ambient air quality standards (NAAQS), including the 8-hour carbon monoxide (CO) standard.

In accordance with CAAA section 175A(a), the Commonwealth of Pennsylvania submitted a CO maintenance plan in 1995, covering the period 1997–2007. EPA approved this maintenance plan effective March 15, 1996 (61 FR 2926, 1/30/96). In accordance with section 175A(b), the region is required to submit a revised maintenance plan within eight years of its redesignation as an attainment area. The revised maintenance plan must provide for maintenance of the carbon monoxide standard for an additional ten years. This maintenance plan is submitted to fulfill that requirement, and provides for continued attainment of the CO standard in the Philadelphia attainment area through 2017. Emissions projections to the year 2017, from this maintenance plan, are consistent with ambient CO levels below the NAAQS.

The maintenance plan that became effective in 1996 established a motor vehicle emissions budget of 334.33 tons per day of CO, which is revised in this action as discussed below.

B. Maintenance Plan Review—Subsequent Maintenance Plan Revisions

The Clean Air Act requires the State to submit a revision of the SIP 8 years after the original redesignation request is approved to provide for maintenance of the NAAQS for an additional 10 years following the first 10-year period [see section 175(b)].

In addition, the maintenance plan shall contain such contingency measures as the Administrator deems necessary to ensure prompt correction of any violation of the NAAQS [see section 175A(d)]. Failure to maintain the NAAQS and triggering of the contingency plan will not necessitate a revision of the SIP unless required by the Administrator, as stated in section 175A(d). Under the limited maintenance plan option, the following criteria must be met by the state:

i. *Attainment Inventory*—EPA guidance recommends that the CO attainment inventory be based upon actual ''typical CO season day'' emissions for the attainment year. This generally corresponds to one of the periodic inventories required for nonattainment areas. The maintenance plan for the first 10-year maintenance period contained a base-year inventory of 1990. The anticipated change in emissions levels from the attainment year was used to estimate the future air quality levels. Pennsylvania's analysis

in this second 10-year maintenance plan documents a base-year inventory of 2002. The 2002 emission inventory was selected because it is current and representative of the emissions in Philadelphia County during the period air quality data has shown maintenance of the CO NAAQS. The inventory contains emission estimates of point, area, highway and nonroad sources of CO in Philadelphia County for the year, and for a typical CO season workday. The CO season is defined as the months of December, January and February. The 2002 inventory will be used to project point and area emissions to future years.

As part of the revised maintenance plan, the revised attainment year emissions inventory will be updated and approved as part of this rulemaking for maintenance plan purposes. Conformity budgets will be amended, as discussed below.

ii. *Maintenance Demonstration*—Pennsylvania's maintenance demonstration for CO calculates future emissions of the pollutant out to the year 2017, and projects that the level of emissions will not exceed the level emitted in the attainment inventory. Since the Philadelphia CO nonattainment area was classified as a moderate CO area, with a design value less than 12.7 ppm, the Commonwealth was not required to do further modeling to demonstrate attainment of the CO standard. Philadelphia's use of 2017 as the projected year allows ample time for EPA to process the request.

Pennsylvania's maintenance plan assumed the following emission control programs, which are or will be permanent and enforceable measures: FMVCP (Federal Motor Vehicle Control Program), reformulated gasoline, and the state inspection and maintenance (I/M) program. The impact of these programs provides for emission to remain well below those that brought about the attainment of the NAAQS for the area.

iii. *Monitoring Network*—The monitoring data is quality assured in accordance with 40 CFR 58, and EPA has repeatedly verified the integrity of the Philadelphia area's air monitoring network. In addition, EPA approved the site selection of each CO monitor, and EPA agrees that the air monitoring network serves as a reliable indicator of ambient concentrations of air pollutants.

iv. *Verification of Continued Attainment*—Pennsylvania will continue to operate an air quality monitoring network, and the Department has committed to investigate should ambient levels of CO rise and threaten to exceed the NAAQS.

v. *Contingency Plan*—The Commonwealth has revised its existing oxygenated fuel program rule, at Chapter 126.1 of Title 25 of the Pennsylvania Code, to permit the use of oxygenated fuel as a contingency measure in the Philadelphia region, if required. If triggered, implementation would commence at the beginning of the following control season. The trigger for such a measure would be a measured violation of the NAAQS for CO.

C. Impact of This Revised Maintenance Plan on Conformity and the Mobile Emissions Budget

Under 40 CFR Parts 51 and 93, as part of the SIP process, Pennsylvania establishes an emissions budget, under the interagency consultation process, to be used for transportation conformity purposes. The motor vehicle emissions budget establishes a cap on emissions, which cannot be exceeded by predicted highway and transit vehicle emissions.

As part of the SIP revision, Pennsylvania has submitted new transportation conformity budgets that will supercede the previous allowances. Highway CO emissions will now be capped for conformity purposes as follows: 331.25 tpd in 2007, 278.23 tpd in 2013, and 260.97 tpd in 2017.

IV. Final Action

In this action, EPA is approving the revised CO maintenance plans for the Washington Metropolitan area, submitted by District of Columbia on March 9, 2004; the Maryland Department of the Environment on March 3, 2004, and the Commonwealth of Virginia on March 22, 2004; for the Baltimore area, submitted by the Maryland Department of the Environment on July 15, 2004, previously having submitted a parallel processing request of the same name on December 18, 2003; and for the Philadelphia area, submitted by the Pennsylvania Department of Environmental Protection on September 3, 2004. We are also approving the revised transportation conformity motor vehicle emission budgets for CO for each respective area.

EPA is publishing this rule without prior proposal because we view this as a noncontroversial amendment and we anticipate no adverse comments. However, in the ''Proposed Rules'' section of today's **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are filed. This rule will be effective June 3, 2005 without further notice unless the Agency receives adverse comments by May 4, 2005. If the EPA receives adverse comments, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

V. Statutory and Executive Order Reviews

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does 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 Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

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 rule 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**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

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 June 3, 2005. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule 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 approving State Implementation Plan (SIP) revisions to the carbon monoxide (CO) maintenance plans and transportation conformity budgets for the Washington Metropolitan area, the Baltimore area, and the Philadelphia area, 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, Intergovernmental relations.

Dated: March 18, 2005.

Donald S. Welsh,

Regional Administrator, Region III.

■ 40 CFR part 52 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 J—District of Columbia

■ 2. In section 52.470, the table in paragraph (e) is amended by revising the existing entry for Carbon Monoxide Maintenance Plan to read as follows:

§ 52.470 Identification of plan.

* * * * *

(e) * * *

Name of nonregulatory SIP revision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Additional explanation
*	*	*	*	*
Carbon Monoxide Maintenance Plan.	Washington, DC	10/12/95 3/9/04	1/30/96, 61 FR 2931 ..... [Insert Federal Register page number where the document begins and date].	52.515(c)(36) Revised Carbon Monoxide Maintenance Plan Base Year Emissions Inventory using MOBILE6.

Subpart V—Maryland

■ 3. In Section 52.1070, the table in paragraph (e) is amended by revising the two existing entries for Carbon Monoxide Maintenance Plan to read as follows:

§ 52.1070 Identification of plan.

* * * * *

(e) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
*	*	*	*	*
Carbon Monoxide Maintenance Plan.	City of Baltimore-Regional Planning District 118.	9/20/95 7/15/04	10/31/95, 60 FR 55321 ..... [Insert *Federal Register* publication date] [Insert page number where the document begins].	52.1100(c)(117) Revised Carbon Monoxide Maintenance Plan Base Year Emissions Inventory using MOBILE6.
Carbon Monoxide Maintenance Plan.	Montgomery County Election Districts 4, 7, and 13; Prince Georges County Election Districts 2, 6, 16, 17 and 18.	10/12/95 3/3/04	1/30/96, 61 FR 2931 ..... [Insert *Federal Register* publication date] [Insert page number where the document begins].	52.1100(c)(118) Revised Carbon Monoxide Maintenance Plan Base Year Emissions Inventory using MOBILE6.
*	*	*	*	*

Subpart NN—Pennsylvania

■ 4. In Section 52.2020, the table in paragraph (e)(1) is amended by revising the existing entry for Carbon Monoxide Maintenance Plan (Philadelphia County) to read as follows:

§ 52.2020 Identification of plan.

* * * * *

(e) * * *

(1) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
*	*	*	*	*
Carbon Monoxide Maintenance Plan.	Philadelphia County	9/8/95, 10/30/95 9/3/04	1/30/96, 61 FR 2982 ..... [Insert *Federal Register* publication date] [Insert page number where the document begins].	52.2063(c)(105) Revised Carbon Monoxide Maintenance Plan Base Year Emissions Inventory using MOBILE6.
*	*	*	*	*

* * * * *

Subpart VV—Virginia

■ 5. In Section 52.2420, the table in paragraph (e) is amended by revising the existing entry for Carbon Monoxide Maintenance Plan to read as follows:

§ 52.2420 Identification of plan

* * * * *

(e) * * *

Name of non-regulatory SIP revision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Additional explanation
*	*	*	*	*
Carbon Monoxide Maintenance Plan.	Arlington County and Alexandria City.	10/4/95 3/22/04	1/30/96, 61 FR 2931 ..... [Insert *Federal Register* publication date] [Insert page number where the document begins].	52.2465(c)(107) Revised Carbon Monoxide Maintenance Plan Base Year Emissions Inventory using MOBILE6.
*	*	*	*	*

[FR Doc. 05–6503 Filed 4–1–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket No. FEMA–7873]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date.

EFFECTIVE DATES: The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

ADDRESSES: If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

FOR FURTHER INFORMATION CONTACT: Michael M. Grimm, Mitigation Division, 500 C Street, SW., Room 412, Washington, DC 20472, (202) 646–2878.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 *et seq.*; unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59 *et seq.* Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than a year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives a 6-month, 90-day, and 30-day notification letter addressed to the Chief Executive Officer that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications have been made, this final rule may take effect within less than 30 days.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless they take remedial action.

Regulatory Classification

This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Paperwork Reduction Act

This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, October 26, 1987, 3 CFR, 1987 Comp.; p. 252.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, October 25, 1991, 56 FR 55195, 3 CFR, 1991 Comp.; p. 309.

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

■ Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain federal assistance no longer available in special flood hazard areas
Region V				
Ohio: Lake County, Unincorporated Areas.	390771	October 22, 1975, Emerg; January 2, 1981, Reg; April 5, 2005, Susp.	Apr. 5, 2005	Apr. 5, 2005.
Perry, Village of, Lake County	390320	June 11, 1975, Emerg; December 15, 1978, Reg; April 5, 2005, Susp.	.....do	Do.
Region IX				
California: West Covina, City of, Los Angeles County.	060666	December 9, 1982, Emerg; September 7, 1984, Reg; April 5, 2005, Susp.	Dec. 2, 2004	Do.

* -do- = Ditto.
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: March 24, 2005.

David I. Maurstad,

Acting Mitigation Division Director, Emergency Preparedness and Response Directorate.

[FR Doc. 05–6542 Filed 4–1–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 219

[Docket No. 2001–11213, Notice No. 5]

RIN 2130–AA81

Alcohol and Drug Testing: Change of Corporate Name, Address, and Telephone Numbers of Post-Accident Toxicological Testing Laboratory

AGENCY: Federal Railroad Administration (FRA), DOT.

ACTION: Final rule; technical amendment.

SUMMARY: FRA is amending its alcohol and drug rule to reflect changes to the corporate name, address, and telephone numbers of the laboratory designated to conduct post-accident toxicological testing.

DATES: Effective April 4, 2005.

FOR FURTHER INFORMATION CONTACT: Lamar Allen, Alcohol and Drug Program Manager, Office of Safety Enforcement, Mail Stop 25, Federal Railroad Administration, 1120 Vermont Avenue, NW., Washington, DC 20005, (202) 493–6313); or Kathy Schnakenberg, FRA Alcohol/Drug Program Specialist, (816) 561–2714.

SUPPLEMENTARY INFORMATION: FRA is amending appendix B to part 219 to reflect changes to the corporate name, address, and telephone numbers of the laboratory designated to conduct post-accident toxicological testing. In 1995, FRA awarded a contract to Northwest Toxicology, Inc. to conduct post-accident toxicological testing. The laboratory has since changed its corporate name twice; in 1998, when Northwest Toxicology, Inc. changed its corporate name to NWT Inc.; and in 2003, when LabOne acquired a division of NWT Inc. and changed the laboratory's name to Northwest Toxicology, a LabOne Company. FRA has modified its post-accident testing contract to recognize the laboratory's name change. Northwest Toxicology, a LabOne Company, recently moved to a new location. For mailing purposes, railroads should ship post-accident toxicological testing specimens to the following address and use the telephone numbers below: Northwest Toxicology/LabOne, Hayes Building, Suite #C, 2282 South Presidents Drive, West Valley City, UT 84120, Telephone: (800) 322–3361 or (801) 293–2300 (Day), (801) 244–5599 (Night/Weekend).

List of Subjects in 49 CFR Part 219

Alcohol abuse, Drug abuse, Drug testing, Penalties, Railroad safety, Safety, Transportation.

The Final Rule

■ In consideration of the foregoing, FRA amends chapter II, subtitle B of title 49, Code of Federal Regulations as follows:

PART 219—[AMENDED]

■ 1. The authority citation for part 219 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20140, 21301, 21304, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.49(m).

■ 2. Appendix B to part 219 is revised to read as follows:

Appendix B to Part 219—Designation of Laboratory for Post-Accident Toxicological Testing

The following laboratory is currently designated to conduct post-accident toxicological analysis under subpart C of this part: Northwest Toxicology/LabOne, Hayes Building, Suite #C, 2282 South Presidents Drive, West Valley City, UT 84120, Telephone: (800) 322–3361 or (801) 293–2300 (Day), (801) 244–5599 (Night/Weekend).

Issued in Washington, DC, on March 29, 2005.

Robert D. Jamison,

Acting Administrator, Federal Railroad Administrator.

[FR Doc. 05–6653 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–06–P

Proposed Rules

Federal Register
Vol. 70, No. 63
Monday, April 4, 2005

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

Rural Utilities Service

7 CFR Part 1738

RIN 0572–AB81

Rural Broadband Access Loans and Loan Guarantees

AGENCY: Rural Utilities Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Rural Utilities Service (RUS), an agency delivering the U. S. Department of Agriculture's Rural Development Utilities Programs, is amending its regulations to revise the definition for ''eligible rural community'' as it relates to the rural access broadband loans and loan guarantees program.

In the final rule section of this **Federal Register**, RUS is publishing this action as a direct final rule without prior proposal because RUS views this as a non-controversial action and anticipates no adverse comments. If no adverse comments are received in response to the direct final rule, no further action will be taken on this proposed rule and the action will become effective at the time specified in the direct final rule. If RUS receives adverse comments, a timely document will be published withdrawing the direct final rule and all public comments received will be addressed in a subsequent final rule based on this action.

DATES: Comments on this proposed action must be received by RUS via facsimile transmission or carry a postmark or equivalent no later than May 4, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- Federal eRulemaking Portal: Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.
- Agency Web Site: *http://www.usda.gov/rus/index2/Comments.htm*. Follow the instructions for submitting comments.
- E-mail: *RUSComments@usda.gov*. Include in the subject line of the message ''Broadband Loans and Loan Guarantees''.
- Mail: Addressed to Richard Annan, Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., STOP 1522, Washington, DC 20250–1522.
- Hand Delivery/Courier: Addressed to Richard Annan, Director, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 5168 South Building, Washington, DC 20250–1522.

Instructions: All submissions received must include that agency name and the subject heading ''Broadband Loans and Loan Guarantees''. All comments received must identify the name of the individual (and the name of the entity, if applicable) who is submitting the comment. All comments received will be posted without change to *http://www.usda.gov/rus/index2/Comments.htm*, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Jonathan Claffey, Acting Assistant Administrator, Telecommunications Program, Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Avenue, SW., STOP 1590, Room 4056, Washington, DC 20250–1590. Telephone number (202) 720–9554, Facsimile (202) 720–0810.

SUPPLEMENTARY INFORMATION: See the supplementary information provided in the direct final rule located in the Rules and Regulations direct final rule section of this **Federal Register** for the applicable supplementary information on this action.

Dated: March 28, 2005.

Curtis M. Anderson,

Acting Administrator, Rural Utilities Service.

[FR Doc. 05–6538 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–15–P

FEDERAL ELECTION COMMISSION

11 CFR Parts 100, 110 and 114

[Notice 2005–10]

Internet Communications

AGENCY: Federal Election Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Election Commission requests comments on proposed changes to its rules that would include paid advertisements on the Internet in the definition of ''public communication.'' These changes to the Commission's rules would implement the recent decision of the U.S. District Court for the District of Columbia in *Shays* v. *Federal Election Commission*, which held that the current definition of ''public communication'' impermissibly excludes all Internet communications. Comment is also sought on the related definition of ''generic campaign activity'' and on proposed changes to the disclaimer regulations. Additionally, comment is sought on proposed new exceptions to the definitions of ''contribution'' and ''expenditure'' for certain Internet activities and communications that would qualify as individual volunteer activity or that would qualify for the ''press exemption.'' These proposals are intended to ensure that political committees properly finance and disclose their Internet communications, without impeding individual citizens from using the Internet to speak freely regarding candidates and elections. The Commission has made no final decision on the issues raised in this rulemaking. Further information appears in the supplementary information that follows.

DATES: Comments must be received on or before June 3, 2005. The Commission will hold a hearing on the proposed rules on June 28–29, 2005 at 9:30 a.m. Anyone wishing to testify at the hearing must file written comments by the due date and must include a request to testify in the written comments.

ADDRESSES: All comments must be in writing, must be addressed to Mr. Brad C. Deutsch, Assistant General Counsel, and must be submitted in either electronic, facsimile, or hard copy form. Commenters are strongly encouraged to submit comments electronically to ensure timely receipt and consideration. Electronic comments must be sent to either *internet@fec.gov* or submitted through the Federal eRegulations Portal at *http://www.regulations.gov*. Any commenters who submit electronic comments and wish to testify at the hearing on this rulemaking must also send a copy of their comments to *internettestify@fec.gov*. If the electronic

comments include an attachment, the attachment must be in the Adobe Acrobat (.pdf) or Microsoft Word (.doc) format. Faxed comments must be sent to (202) 219–3923, with hard copy follow-up. Hard copy comments and hard copy follow-up of faxed comments must be sent to the Federal Election Commission, 999 E Street, NW., Washington, DC 20463. All comments must include the full name and postal service address of the commenter or they will not be considered. The Commission will post comments on its Web site after the comment period ends. The hearing will be held in the Commission's ninth floor meeting room, 999 E Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Brad C. Deutsch, Assistant General Counsel, Ms. Amy L. Rothstein, Mr. Richard T. Ewell, or Ms. Esa L. Sferra, Attorneys, 999 E Street, NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Bipartisan Campaign Reform Act of 2002, Pub. L. 107–155, 116 Stat. 81 (March 27, 2002) (''BCRA''), amended the Federal Election Campaign Act of 1971, as amended, 2 U.S.C. 431 *et seq.* (the ''Act''), in many respects. Four of these amendments are germane to this rulemaking.

First, section 441i(b) of BCRA requires state, district, and local political party committees to use only Federal funds [1] for certain types of ''Federal election activity,'' including for any ''*public communication* that refers to a clearly identified candidate for Federal office * * * and that promotes or supports a candidate for that office, or attacks or opposes a candidate for that office[.]'' [2] 2 U.S.C. 431(20)(A)(iii) (emphasis added). BCRA defines a ''public communication'' as ''a communication by means of any broadcast, cable, or satellite communication, newspaper, magazine, outdoor advertising facility, mass mailing, or telephone bank to the general public, *or any other form of general public political advertising.*'' 2 U.S.C. 431(22) (emphasis added).

Second, section 441i(b) of BCRA also restricts the funds that state, district, and local political party committees may use for certain ''generic campaign activity.'' 2 U.S.C. 431(20)(A)(ii); 11 CFR 100.24(2)(ii). BCRA defines ''generic campaign activity'' as ''campaign activity that promotes a political party and does not promote a [Federal] candidate or non-Federal candidate.'' 2 U.S.C. 431(21). ''Generic campaign activity'' by state, district, and local party committees conducted in connection with an election in which a candidate for Federal office appears on the ballot (regardless of whether a candidate for state or local office also appears on the ballot) must be paid for either entirely with Federal funds or with an allocated mix of Federal funds and Levin funds.[3] *See* 2 U.S.C. 441i(b)(2)(A); 11 CFR 300.32(b)(1)(ii), 300.32(c) and 300.33.

Third, BCRA expressly repealed the Commission's then-existing rules on ''coordinated general public political communication'' at former 11 CFR 100.23, Public Law 107–155, sec. 214(b) (March 27, 2002), and instructed the Commission to promulgate new regulations on ''coordinated communications paid for by persons other than candidates, authorized committees of candidates, and party committees.'' Public Law 107–155, sec. 214(c) (March 27, 2002).

Fourth, Congress revised the ''disclaimer'' requirements in 2 U.S.C. 441d, by requiring a disclaimer when a ''disbursement'' (rather than an ''expenditure'') is made for certain communications.

The Commission promulgated regulations in 2002 to implement BCRA's provisions regarding (1) ''public communication,'' (2) ''generic campaign activity,'' (3) coordination with candidates and political parties, and (4) disclaimers. *See* Final Rules on Prohibited and Excessive Contributions; Non-Federal Funds or Soft Money, 67 FR 49,064 (July 29, 2002) (''Soft Money Final Rules''); Coordinated and Independent Expenditures, 68 FR 421 (Jan. 3, 2003); Disclaimers, Fraudulent Solicitation, Civil Penalties, and Personal Use of Campaign Funds, 67 FR 76,962 (Dec. 13, 2002).

In *Shays* v. *Federal Election Commission*, 337 F.Supp.2d 28 (D.D.C.) *appeal filed*, No. 04–5352 (DC Cir. Sept. 28, 2004) (''Shays''), the United States District Court for the District of Columbia overturned some of these regulations. First, the district court held that excluding all Internet communications from the Commission's rule defining ''public communication'' in 11 CFR 100.26 was inconsistent with Congress's use of the phrase ''or any other form of general public political advertising'' in BCRA's definition of ''public communication.'' [4] *Shays* at 69. The district court concluded that ''[w]hile all Internet communications do not fall within [the scope of 'any other form of general public political advertising'], some clearly do.'' *Id.* at 67. The court left it to the Commission to determine ''what constitutes 'general public political advertising' in the world of the Internet,'' and thus should be treated as a ''public communication''. *Id.* at 70.

Second, the district court found the Commission's rule defining the term ''generic campaign activity'' to be ''an impermissible construction of the Act,'' to the extent it incorporated the regulatory definition of ''public communication,'' which excludes all forms of Internet communications. *Id.* at 112. Although the court specifically approved the definition of ''generic campaign activity'' as a ''public communication,'' the *Shays* court found that the 2002 Notice of Proposed Rulemaking for ''generic campaign activity'' did not provide adequate notice to the public that the Commission might define ''generic campaign activity'' as a ''public communication'' in the final rules. *Id.* at 112; *see also Notice* of Proposed Rulemaking on Prohibited and Excessive Contributions; Non-Federal Funds or Soft Money, 67 FR 35,654, 35,675 (May 20, 2002).

[1] ''Federal funds'' are funds subject to the limitations, prohibitions, and reporting requirements of the Act. *See* 11 CFR 300.2(g). ''Non-Federal funds'' are funds not subject to the limitations and prohibitions of the Act. *See* 11 CFR 300.2(k).

[2] There are four types of ''Federal election activity'': Type 1—Voter registration activity during the period that begins on the date that is 120 days before a regularly scheduled Federal election is held and ends on the date of the election; Type 2—Voter identification, get-out-the-vote activity, or generic campaign activity conducted in connection with an election in which a candidate for Federal office appears on the ballot; Type 3—A public communication that promotes, supports, attacks or opposes a clearly identified candidate for Federal office; and Type 4—Services provided during any month by an employee of a state, district, or local committee of a political party who spends more than 25 percent of that individual's compensated time during that month on activities in connection with a Federal election. *See* 2 U.S.C. 431(20) and 11 CFR 100.24.

[3] Levin funds are a type of non-Federal funds created by BCRA that may be raised and spent by state, district, and local party committees and organizations to pay for the allocable portion of Types 1 and 2 Federal election activity. *See* 2 U.S.C. 441i(b)(2)(A) and (B); 11 CFR 300.2(i), 300.32(b). These funds may include donations from some sources ordinarily prohibited by Federal law (*e.g.*, corporations, labor organizations and Federal contractors) to the extent permitted by state law, but are limited to $10,000 per calendar year from any source or to the limits set by State law—whichever limit is lower. *See* 11 CFR 300.31.

[4] The court found that this rule did not satisfy step one of the test set out by the Supreme Court in *Chevron, U.S.A., Inc.* v. *National Res. Def. Council,* 467 U.S. 837 (1984) (''*Chevron*''). The *Shays* court stated that, in the alternative, the regulatory definition of ''public communication'' as applied to the ''content prong'' of the coordinated communication regulations in 11 CFR 109.21(c) is inconsistent with the Act and, therefore, provides an independent basis for invalidation under step two of the *Chevron* test. *See Shays* at 70–71.

Third, the district court invalidated the ''content prong'' of the Commission's coordinated communications rule at 11 CFR 109.21(c), which incorporates the definition of ''public communication'' at 11 CFR 100.26. The *Shays* court found that expenditures for communications that have been coordinated with a candidate, a candidate's authorized committee, or a political party committee have value for, and therefore are in-kind contributions to, that candidate or committee, regardless of the content, timing, or geographic reach of the communications. *Shays* at 63–64. Accordingly, the court held that certain regulatory exclusions contained in the ''content prong'' ''undercut [the Act's] statutory purpose of regulating campaign finance and preventing circumvention of the campaign finance rules.'' *Id.* at 63.

The district court remanded each of these rules to the Commission for further action consistent with its opinion. Accordingly, the Commission is issuing this Notice of Proposed Rulemaking (''NPRM''), which addresses several topics. First, the proposed rules in 11 CFR 100.26 would identify the types of Internet communications that are forms of ''general public political advertising'' and that therefore would qualify as public communications. Specifically, the Commission proposes to retain a general exclusion of Internet communications from the definition of ''public communication,'' except for those advertisements where another person or entity has been paid to carry the advertisement on its Web site, because these communications would constitute ''general public political advertising.'' This proposed change addresses the *Shays* court's concern about the wholesale exclusion of all Internet communications from the definition of ''public communication.'' Because only Internet communications that constitute ''general public political advertising,'' as defined by the regulation, would be included in the proposed definition of ''public communication'' in section 100.26, the Commission anticipates that the proposed definition would have an extremely limited impact, if any, on the use of the Internet by individuals as a means of communicating their political views, obtaining information regarding candidates and elections, and participating in political campaigns.

Second, this NPRM republishes and invites comment on the current definition of ''generic campaign activity'' in section 100.25, which includes the term ''public communication.'' The Commission notes that any changes to the underlying definition of ''public communication'' pertaining to the Internet would automatically apply to ''generic campaign activity.''

Third, the Commission proposes to modify somewhat its rules at 11 CFR 110.11(a) as to which Internet communications require disclaimers. Political committee Web sites would continue to need disclaimers. Individuals and entities other than political committees, however, would need to place disclaimers only on paid Internet advertisements (*i.e.*, Internet communications that constitute ''general public political advertising'' under the proposed definition of ''public communication'') if the advertisements either solicit contributions or expressly advocate the election or defeat of a clearly identified candidate for Federal office. The Commission also proposes to clarify the current requirement that disclaimers be included in ''unsolicited electronic mail of more than 500 substantially similar communications'' by defining ''unsolicited'' as ''those e-mails that are sent to electronic mail addresses purchased from a third party.'' The goal of this proposed change would be to continue to require disclaimers on political ''spam,'' without interfering with individuals who participate in large on-line communities.

In addition, the Commission is proposing to add new rules specifically excepting certain volunteer activity on the Internet from the definitions of ''contribution'' and ''expenditure,'' and by clarifying that the rules in section 114.9 regarding the use of corporate or labor organization facilities apply to the use of computers, software, and other Internet equipment and services. Lastly, the proposed rules seek to establish an Internet exception from the definitions of ''contribution'' and ''expenditure'' for certain media activity.

The Commission has announced plans to initiate a separate rulemaking on certain non-Internet aspects of the coordinated communication rules at 11 CFR 109.21(c) in the coming months. For purposes of this rulemaking, the coordinated communication rules are referenced only to provide notice that the proposed changes to the definition of ''public communication'' in 11 CFR 100.26 would have an impact on the scope of the coordinated communication rules.

II. 11 CFR 100.26—Definition of ''Public Communication''

BCRA defines a ''public communication'' as ''a communication by means of any broadcast, cable, or satellite communication, newspaper, magazine, outdoor advertising facility, mass mailing or telephone bank to the general public, or any other form of general public political advertising.'' 2 U.S.C. 431(22). The Commission's current rules at 11 CFR 100.26 track the statutory definition, except that the definition in the rules explicitly excludes all communications over the Internet.

As a consequence, Internet communications are excluded from other rules governing the funding of a ''public communication.'' For example, State, district, and local political party committees and organizations must use only Federal funds for any ''public communication'' that promotes, supports, attacks or opposes (''PASOs'') a Federal candidate. *See* 2 U.S.C. 431(20)(A)(iii) and 441i(b); 11 CFR 100.24(b)(3) and (c)(1), 300.32(a)(1) and (2). In addition, these party committees must use all Federal funds or an allocable mix of Federal funds and Levin funds for any ''public communication'' that constitutes ''generic campaign activity'' in connection with an election in which a candidate for Federal office appears on the ballot. *See* 11 CFR 100.25; 11 CFR 300.33(a)(2).

The term ''public communication'' is also used to determine whether a disclaimer is needed on certain communications under 11 CFR 110.11. Moreover, the ''public communication'' definition is one key element in determining what qualifies as a coordinated communication under 11 CFR 109.21 and a party coordinated communication under 11 CFR 109.37. ''Public communication'' may also be used to determine whether a person is an agent of a candidate for State or local office in 11 CFR 300.2(b)(4), and whether certain expenses must be allocated between Federal and non-Federal accounts by separate segregated funds (''SSFs'') and nonconnected committees under 11 CFR 106.6(b) and (f).

In light of the *Shays* decision, the Commission is reconsidering which Internet communications would qualify as ''general public political advertising,'' and thus would be a ''public communication.'' The Commission's proposed rule attempts to strike a balance between provisions of the Act that regulate ''general public political advertising'' and significant public policy considerations that encourage the Internet as a forum for free or low-cost speech and open information exchange.

A. The Internet and the 2004 Elections

The Internet has unique characteristics that distinguish it from traditional media.[5] Unlike traditional media, ''the Internet can hardly be considered a 'scarce' expressive commodity. It provides relatively unlimited, low-cost capacity for communication of all kinds.'' *Reno* v. *ACLU*, 521 U.S. 844, 870 (1997) (''*Reno*''). Additionally, because an Internet communication is not limited in format and is not necessarily limited in duration, unlike television and radio programming, the Internet provides a means to communicate with a large and geographically widespread audience, often at little cost.[6]

The Internet also differs from traditional media because individuals must generally be proactive in order to access information over the Internet, unlike users of traditional media. The Supreme Court has found that communications over the Internet are not as ''invasive'' as communications through traditional media. *Reno* at 870. In further contrast to passive, one-way traditional media, the Internet can provide interactive, real-time, two-way communications.

The Internet's accessibility, low-cost, and interactive features make it a popular choice for sending and receiving information. In 2004, an estimated 201 million people in the United States used the Internet.[7] At the end of 2004, an estimated 63 percent of the adult American population, and 81 percent of American teenagers, used the Internet; on average, some 70 million American adults logged onto the Internet daily.[8]

A growing segment of the American population uses the Internet as a supplement to, or as a replacement for, more traditional sources of information and entertainment, such as newspapers, magazines, television, and radio. In mid-2004, 92 million Americans reported obtaining news from the Internet.[9]

As the public has turned increasingly to the Internet for information and entertainment, advertisers have embraced the Internet and its new marketing opportunities. Internet advertising revenue increased by 21 percent between 2002 and 2003 and reached $4.6 billion in the first six months of 2004.[10]

The 2004 election cycle marked a dramatic shift in the scope and manner in which citizens used Web sites, blogs,[11] listservs,[12] and other Internet communications to obtain information on a wide range of issues and candidates.[13] The number of Americans who used the Internet as a source of campaign news more than doubled between 2000 and 2004, from 30 million to 63 million.[14] An estimated 11 million people relied on politically oriented blogs as a primary source of information during the 2004 presidential campaign,[15] and a full 18 percent of all Americans cited the Internet as their leading source of news about the 2004 presidential election.[16]

B. Internet Communications—Proposed 11 CFR 100.26

Because the Internet is a unique form of communication, the Commission proposes to preserve the general exclusion of Internet communications from the definition of ''public communication'' in 11 CFR 100.26.

At the same time, however, the Commission recognizes that Internet communications may, in some circumstances, constitute ''general public political advertising'' within the definition of ''public communication'' in 11 CFR 100.26.

Accordingly, the Commission proposes to amend 11 CFR 100.26 to include ''general public political advertising'' in the form of paid Internet advertisements placed on another person's or entity's Web site. Such advertisements could take the form, for example, of streaming video that appears in banner advertisements[17] or ''pop-up'' advertisements.[18]

The Commission invites comment on whether announcements placed for a fee on another entity's Web site should be considered ''general public political advertising,'' and therefore, a ''public communication'' under 11 CFR 100.26. Is this approach consistent with BCRA's definition of ''public communication'' to include broadcast, cable or satellite communications, newspaper, magazines and outdoor advertising facilities, all of which typically charge fees to those who run political advertisements?

If a mode of communication does not cost any money, can it be ''general public political advertising'' and therefore a ''public communication'' within the meaning of the statute? For

[5] *See* Enrique Armijo, *Public Airwaves, Private Mergers: Analyzing the FCC's Faulty Justification for the 2003 Media Ownership Rule Change*, N.C. L. Rev. 1482, 1494 (May 2004) (discussing broadcast media and the Internet as ''imperfect substitutes''); *see also* Ryan Z. Watts, *Independent Expenditures on the Internet: Federal Election Law and Political Speech on the World Wide Web*, 8 CommLaw Conspectus 149, 160 (Winter 2000) (discussing *Reno* v. *ACLU*, 521 U.S. 844 (1997) and the Internet's differences from traditional media).

[6] *See* Edward L. Carter, Esq., *Outlaw Speech on the Internet: Examining the Link Between Unique Characteristics of Online Media and Criminal Libel Prosecutions*, 21 Santa Clara Computer & High Tech. L.J. 289, 316–17 (January 2005) (''Internet is unlike traditional print or broadcast media in that messages can have a long shelf life—an Internet message can circulate via e-mail or remain posted somewhere even long after the message's creator has tried to retract it.'').

[7] *See* Internet World Stats *available at http://www.internetworldstats.com/stats2.htm* (last visited 3/7/2005).

[8] *See* Pew Internet & American Life Project, Trends 2005, Chapter 4, Internet: The Mainstreaming of Online Life, p. 58 (2005) *available at http://www.pewinternet.org/pdfs/Internet_Status_2005.pdf* (last visited 3/7/2005).

[9] *See* Pew Internet & American Life Project and the University of Michigan School of Information, The Internet and the Democratic Debate, p. 2 (October 27, 2004) *available at http://www.pewinternet.org/pdfs/PIP_Political_Info_Report.pdf* (last visited 3/7/2005).

[10] See PriceWatherhouseCoopers and Interactive Advertising Bureau, IAB Internet Advertising Revenue Report (April 2004 and September 2004), available at http://www.iab.net/recources/ad_revenue.asp (last visited 3/7/2005).

[11] The word ''blog'' derives from the term ''Web log'' and is defined as ''a Web site that contains an online personal journal with reflections, comments and often hyperlinks provided by the writer.'' *http://www.merriam-webster.com* (last visited 3/7/2005). People who maintain blogs are known as ''bloggers.''

[12] A ''listserv'' is a software program that automatically sends electronic mail messages to multiple e-mail addresses on an electronic mailing list. See, *e.g., http://www.lsoft.com/products/listserv.asp* (last visited 3/7/2005). The term ''listserv'' is commonly used, however, to denote the electronic mailing list itself or the automated forwarding to all addresses on the mailing list of an e-mail sent only to the listserv's e-mail address.

[13] *See* Pew Internet & American Life Project, The Internet and Campaign 2004, *available at http://www.pewinternet.org/pdfs/PIP_2004_Campaign.pdf* (last visited 3/17/2005).

[14] *See* note 9, above, The Internet and Democratic Debate, p. 2. During the same time period, the number of people reporting television as their primary source of campaign information declined. *Id.*

[15] *See* Jessica Mintz, *When Bloggers Make News—As Their Count Increases, Web Diarists Are Asking: Just What Are the Rules?* Wall St. J., Jan. 21, 2005 at B1.

[16] *See* note 8, above, The Mainstreaming of Online Life, p. 2.

[17] ''Banner advertisements'' are advertisements on a Web page that convey messages in text, animated graphics, and sound. They traditionally appear in rectangular shape, but may take any shape. Typically, banner advertisements are linked to the advertiser's Web site, which enables a viewer to ''click through'' the advertisement to view the advertiser's Web site for further information on the product or service advertised. *See http://www.netlingo.com/lookup.cfm?term=ad+banner* (last visited 3/7/2005).

[18] ''Pop-up'' advertisements usually appear in a separate browser window from the one being viewed. The advertisements are superimposed over the window being viewed, and require the viewer to take some action, such as closing the window in which the pop-up advertisement appears, to continue viewing the underlying browser window. *See http://www.netlingo.com/lookup.cfm?term=pop%2Dup%20ad* (last visited 3/7/2005). Although pop-up advertisements technically are not part of the underlying Web site or account, the Commission seeks comment on whether they should be considered to be ''placed on'' the Web site for purposes of this rulemaking.

example, a person might appear in a public square and give a campaign speech before 500 or more people. If such a public speech does not cost any money to undertake, is it outside the scope of ''general public political advertising'' under the statute and therefore not a ''public communication''? Likewise, is such a public speech outside the scope of an ''expenditure'' or ''contribution'' under the statute? Also, should ''general public political advertising'' include Internet advertisements where the advertising space is provided in exchange for something of value other than a monetary payment, for example through an exchange of comparable advertising? Although the Commission's proposed rule would exclude Internet activity that is not placed for a fee, should the Commission amend its regulation to explicitly state that it is not including ''bloggers'' in the definition of ''public communication''?

The Act and Commission regulations recognize that corporations and labor organizations can communicate with their restricted class, but not with the general public, on ''any subject,'' and that membership organizations may similarly communicate with their members. *See* 2 U.S.C. 431(9)(B)(iii) and 441b(b)(2)(A); 11 CFR 100.134(a) and 114.3(c)(3); *see also* AO 1997–16. Should the Commission consider excluding from the definition of ''general public political advertising'' paid advertisements appearing on corporate and labor organization Web sites if access to those sites is restricted to the restricted class of a corporation or labor organization, or to only the members of a membership organization?

C. Effect of Proposed Definition of ''Public Communication'' on Federal Election Activity by State, District, and Local Party Committees Under 11 CFR 100.24(b) and (c)

BCRA defines ''Federal election activity'' to include ''a public communication that refers to a clearly identified candidate for Federal office * * * and that promotes or supports a candidate for that office, or attacks or opposes a candidate for that office[.]'' 2 U.S.C. 431(20)(A)(iii); *see also* 11 CFR 100.24(b)(3). State, district, and local political party committees and organizations, State and local officeholders and candidates, and their agents, are prohibited from using non-Federal funds to pay for this type of Federal election activity. *See* 2 U.S.C. 441i(b) and (f); 11 CFR 100.24(b)(3) and (c)(1), 300.32(a)(1) and (2), and 300.71.

The Commission notes that the original definition of ''public communication'' in 11 CFR 100.26 was promulgated to permit state, district, and local committees to make references to their Federal candidates on the committees' official Web sites without automatically federalizing the year-round costs of maintaining such a site. It should be noted that this effect of the Internet exclusion was not rejected by the *Shays* court. The proposed rule would continue to allow this exclusion for these Web sites, while requiring that state, district, and local party committees use exclusively Federal dollars to place advertisements that PASO a Federal candidate on another individual's or entity's Web site. State, district, and local committee Web sites would still have to maintain disclaimers as required under 11 CFR 110.11(a)(1). The Commission invites comment on this approach and on whether the Commission should consider further changing its definition of ''public communication.''

The Commission also seeks comment on the consequences of alternative approaches. For example, if a mere PASO reference to a Federal candidate on a State, district, or local committee's Web site were to constitute a public communication, does that require that the entire Web site be paid for with hard dollars? If not, the Commission seeks comment on how to allocate that portion of the Web site that must be paid for with hard dollars—for example, based on the time and space of the Web site that contains PASO communications as compared to the site overall, or should another allocation method be required? In addition, what costs should be included in the allocation calculations—all of the costs associated with establishing and maintaining the Web site, or only the marginal costs of creating and maintaining the PASO communication, or some other formulation?

The Commission seeks comment on whether any payment by a State, district, or local party to an outside vendor for content that PASOs a Federal candidate that is exclusively placed on the party's Web site should constitute ''general public political advertising'' and be deemed a ''public communication,'' thus requiring regulation under 2 U.S.C. 441i(b)(1).

III. 11 CFR 100.25—Definition of ''Generic Campaign Activity''

''Federal election activity'' includes ''generic campaign activity'' conducted in connection with an election in which a candidate for Federal office appears on the ballot. 2 U.S.C. 431(20)(A) and 11 CFR 100.24. BCRA defines ''generic campaign activity'' to mean ''campaign activity that promotes a political party and does not promote a candidate or non-Federal candidate.'' 2 U.S.C. 431(21). The Commission's regulations construe this statutory term to mean ''a *public communication* that promotes or opposes a political party and does not promote or oppose a clearly identified Federal candidate or a non-Federal candidate.'' 11 CFR 100.25 (emphasis added).

As noted above, the *Shays* court rejected the Commission's definition of ''generic campaign activity'' on two grounds: first, that it improperly excluded all Internet communications and, second, for lack of notice to the public that it would be limited to ''public communications'' as defined in 11 CFR 100.26. The Commission proposes to address the district court's first concern by revising the definition of ''public communication'' to remove the wholesale exclusion of all Internet communications and to replace it with a more limited exclusion, as explained above. The Commission is addressing the court's second concern by providing the public with notice and an opportunity to comment at this time on whether the Commission should continue to define the term ''generic campaign activity'' as ''a public communication,'' which, as proposed, would include some types of Internet advertisements. Given that *Shays* specifically approved the existing definition of ''generic campaign activity,'' except for the exclusion of Internet communications and the notice issue, the Commission is not proposing to revise the definition of ''generic campaign activity'' at this time. The Commission invites comments on this approach.

IV. 11 CFR 110.11—Communications; Advertising; Disclaimers (2 U.S.C. 441d)

With its relatively low cost, wide availability, and ease of access, the Internet is used by millions of individuals daily to share information and air their views on a variety of subjects. The Commission recognizes that significant policy reasons support the continued exclusion of most Internet communications from the disclaimer requirements.

As the Commission has stated previously, the Internet ''is a medium that allows almost limitless, inexpensive communication across the broadest possible cross-section of the American population. Unlike media such as television and radio, where the constraints of the medium make access financially prohibitive for the general population, the Internet is by definition

a bastion of free political speech, where any individual has access to almost limitless political expression with minimal cost.'' Soft Money Final Rules, 67 FR at 49,072. To this extent, the Internet can be the modern equivalent of a soapbox in a public square. *See Reno,* 521 U.S. at 870 (''Through the use of chat rooms, any person with a phone line can become a town crier with a voice that resonates farther than it could from any soapbox. Through the use of Web pages, mail exploders, and newsgroups, the same individual can become a pamphleteer.'')

The Commission notes that with respect to most Internet Web sites and blogs, the burden of complying with a disclaimer requirement, and the resources needed for the Commission to monitor such a requirement, could outweigh the value of disclosure. This is particularly true given that the identity of the sponsor of an Internet communication is often already apparent from the face of the communication. The Commission seeks comment on these policy rationales and alternative approaches to the disclaimer requirement.

The Act and the Commission's rules require certain communications to include clear and conspicuous statements to the public regarding the sources of their funding. *See* 2 U.S.C. 441d; 11 CFR 110.11. This disclaimer notice must identify the payor and disclose either the name of the candidate's committee that authorized the communication or the fact that no candidate or candidate's committee authorized the communication. *See* 2 U.S.C. 441d(a); 11 CFR 110.11(b). If the disclaimer notice states that the communication was not authorized by a candidate or candidate's committee, the notice must disclose the payor's full name and street address, telephone number, or World Wide Web address. *See* 2 U.S.C. 441d(a)(3); 11 CFR 110.11(b)(3). Political committees must include a disclaimer on any ''public communication'' for which they make disbursements. *See* 11 CFR 110.11(a)(1). For all other persons, a disclaimer is required for any ''public communication'' that expressly advocates the election or defeat of a clearly identified candidate for Federal office or that solicits contributions. *See* 11 CFR 110.11(a)(2) and (3).[19] The Commission notes that the lack of an affirmative disclaimer requirement for most Internet activities does not alleviate a duty to comply with 2 U.S.C. 441h prohibitions against fraudulent misrepresentation. The Commission originally promulgated these regulations to focus on what is commonly referred to as ''spam'' e-mail.

A. Scope of Disclaimer Requirements—Proposed 11 CFR 110.11(a)

In the existing disclaimer regulations in section 110.11(a), the term ''public communication'' differs slightly from the term ''public communication'' as defined in 11 CFR 100.26. Specifically, ''public communication'' as defined in current 11 CFR 100.26 expressly excludes Internet communications, whereas ''public communication'' as defined in the current disclaimer regulations includes ''unsolicited electronic mail of more than 500 substantially similar communications and Internet Web sites of political committees available to the general public.'' 11 CFR 110.11(a). Thus, political committees must include disclaimers on their Web sites available to the general public, and in unsolicited e-mail of more than 500 substantially similar communications. Other persons must also provide disclaimers in unsolicited e-mail of more than 500 substantially similar communications that expressly advocate the election or defeat of a clearly identified Federal candidate or solicit a contribution.

The Commission is concerned that the current regulation emphasizes the number of e-mail communications sent, rather than focusing on whether an expenditure was made that would justify governmental regulation. The Commission notes that the statute generally seems to be predicated on an ''expenditure'' or ''disbursement'' being made. The Commission is not interested in requiring disclaimers on the personal communications of private citizens. The Commission is concerned that the lack of definition for the term ''unsolicited,'' could have the effect of discouraging individuals from engaging in discussion and advocacy that is core political speech protected by the First Amendment and that is virtually cost-free.

Therefore, the Commission is proposing to change the disclaimer requirement in 11 CFR 110.11(a) to focus on those e-mail communications for which the e-mail addresses of the recipients were acquired through a commercial transaction. Such a disclaimer requirement is intended to strike a balance between the disclosure purposes of the Act and regulation of expenditures, and the protection of individual free speech and robust communication. The Commission seeks comment on this approach. Should the Commission continue to include a 500-e-mail threshold? Given the ease of sending large numbers of e-mail, would a larger numerical threshold be appropriate? The Commission also seeks comment on whether a minimum cost should be included in this disclaimer requirement, such as the $250 threshold contained in the statute for independent expenditures. *See* 2 U.S.C. 434(c)(1). Should a dollar threshold be included in concert with or in lieu of the 500-piece requirement? Is there a more appropriate definition of ''unsolicited'' e-mail in this context? Should ''unsolicited'' e-mail include e-mail where the recipients'' e-mail addresses were acquired from a third party in a non-cash transaction, either through an e-mail list ''swap,'' or other multi-party transactions where list of e-mail addresses is acquired at no cost? The Commission, alternatively, seeks comments on whether the disclaimer requirement for e-mail should be removed entirely from the regulation.

The proposed revisions to the disclaimer provisions in 11 CFR 110.11(a) would still require disclaimers for any ''public communication'' as defined at 11 CFR 100.26 made by a political committee, and for any ''public communication'' by any person that expressly advocates the election or defeat of a clearly identified Federal candidate or that solicits a contribution. *See* 11 CFR 110.11(a). The proposed definition of ''public communication'' in section 100.26 would have the effect of expanding the scope of the disclaimer requirements in section 110.11 to any advertisement placed for a fee on another party's Web site that expressly advocates the election or defeat of a clearly identified Federal candidate or solicits a contribution. In addition, political committees would continue to be required to post disclaimers on their Web sites provided that they are ''available to the general public.''

The Commission seeks comments on these proposed revisions to 11 CFR 110.11(a).

B. Bloggers Paid by Candidates

News reports indicate that in the 2004 elections some individual bloggers received significant fees from the campaign committees of at least one presidential candidate and one Senate candidate to promote the candidates' campaigns on their blogs.[20] For example, the operator of the ninth most ''linked'' blog on the Internet, which

[19] Electioneering communications also require a disclaimer. *See* 11 CFR 110.11(a)(4).

[20] *See, e.g.,* William M. Bulkely and James Bandler, *Dean Campaign Made Payments to Two Bloggers*, Wall St. J., Jan. 14, 2005 at B2; Charles Babington and Brian Faler, *A Committee Post and a Pledge Drive—-Bloggers on the Payroll*, Wash. Post, Dec. 17, 2004, at A16.

received as many as one million visits daily, reportedly received $12,000 over a four-month period from one presidential candidate.[21] The news reports further indicate that not all of the bloggers disclosed the payments to the blogs' readers.

The Commission notes that its current rules require a political committee to disclose this type of disbursement on its publicly available reports filed with the Commission. The Commission does not therefore propose to change the disclaimer regulation in 11 CFR 110.11(a) to require bloggers to disclose payments from a candidate, a campaign, or a political committee. The Commission seeks comment on this approach. Could or should bloggers be required to disclose such payments? Could or should a blogger be required to disclose payments only if the blogger expressly advocates the election or defeat of a clearly identified candidate or solicits a contribution? Would a payment by a political committee to a blogger for promotional content on the blog constitute ''general public political advertising'' within the meaning of section 100.26?

V. 11 CFR 109.21 and 109.37—Coordinated Communications

A. Content Standards for Coordinated Communications—11 CFR 109.21(c)

Payments for certain communications that are coordinated with a candidate, a candidate's authorized committee, a political party committee, or any of their agents, are treated as in-kind contributions to the candidate, the candidate's authorized committee, or the political party committee. *See* 2 U.S.C. 441a(a)(7); 11 CFR 109.21. The Commission's regulations set out a three-pronged test for determining whether a communication has been ''coordinated.'' *See* 11 CFR 109.21. The three-pronged test looks, in part, at whether the communication satisfies the ''content prong'' of 11 CFR 109.21(c).[22] To satisfy the ''content prong'' of the coordinated communication test, a communication must: (1) Be an electioneering communication, as defined in 11 CFR 100.29; (2) be a public communication that disseminates, distributes, or republishes, in whole or in part, campaign materials prepared by a Federal candidate, the candidate's authorized committee, or their agents; (3) be a public communication that expressly advocates the election or defeat of a clearly identified candidate for Federal office; or (4) be a public communication that refers to a political party or a clearly identified candidate for Federal office, is publicly distributed or disseminated within 120 days of an election for Federal office, and is directed to voters within the jurisdiction of the clearly identified candidate or to voters in a jurisdiction in which one or more candidates of the political party appear on the ballot. *See* 11 CFR 109.21(c)(1)–(c)(4).

In *Shays*, the court struck down the ''content prong'' of the coordinated communication test. The Commission announced its intention to propose changes regarding the non-Internet aspects of the coordinated communication regulations in a separate rulemaking to take place later this year, with final rules pending the outcome of the Commission's appeal of certain aspects of the *Shays* decision.

Because of the pending appeal and the upcoming rulemaking on coordinated communications, the Commission is not proposing to revise 11 CFR 109.21 in this rulemaking. The Commission notes, however, that revising the definition of ''public communication'' to include certain Internet communications would render such Internet communications subject to the current coordinated communication provisions of section 109.21.[23] The Commission invites comments on this approach.

The Commission's rule would exempt from the coordinated communication rules advertisements that require payments to outside vendors to create, but that are placed only on the payor's own Web site. This could include a corporation or other prohibited source. The Commission seeks comment on whether this approach is appropriate, and on whether any other parts of the Commission's regulations, *e.g.* those provisions at 11 CFR 114.4 that deal with corporate and labor communications beyond the restricted class, can be interpreted to nonetheless place restrictions on such activity. The Commission's rule would also exempt from the coordinated communication rules advertisements that are placed on a prohibited source's Web site for free, even though a fee would normally be charged. Is this an appropriate course? Do any of the Commission's other rules already regulate this so that such activity would be prohibited?

B. Dissemination, Distribution, or Republication on the Internet—11 CFR 109.21

Under the current Commission regulations, a person makes a contribution by financing a public communication that disseminates, distributes, or republishes, in whole or in part, campaign materials prepared by a candidate, the candidate's authorized committee, or an agent of any of the foregoing,'' unless certain exceptions apply. 11 CFR 109.21(c)(2). A candidate's principal campaign committee need not report the dissemination, distribution, or republication of its campaign materials as an in-kind contribution, however, unless such activity is a ''coordinated communication'' under 11 CFR 109.21. *See* 11 CFR 109.23(a).

The Commission notes that the proposed changes to the definition of ''public communication'' would expand the reach of this regulation to individuals or entities that place announcements for a fee on another individual's or entity's Web site, when the advertisement content otherwise constitutes a republication regulated under 11 CFR. 109.21(d)(6).

The Commission notes that the proposed change to the definition of ''public communication'' would not affect content placed by an individual on his or her own Web site, blog, or e-mail. Because republishing campaign materials on one's own Web site, blog, or e-mail would not be a public communication, it would not be a contribution to the candidate under 11 CFR 109.21. The Commission notes that Senator Russ Feingold, one of BCRA's sponsors, stated recently that ''linking campaign Web sites, quoting from, or republishing campaign materials and even providing a link for donations to a candidate, if done without compensation, should not cause a blogger to be deemed to have made a contribution to a campaign or trigger reporting requirements.''[24] Should the Commission amend 11 CFR 109.21(c)(2) to exempt all dissemination, distribution, or republication of campaign materials on the Internet generally, or keep the reference in the regulation to ''public communication''?

[21] *See* William M. Bulkely and James Bandler, *Dean Campaign Made Payments to Two Bloggers*, Wall St. J., Jan. 14, 2005 at B2.

[22] The other two prongs of the coordinated communication test are (1) whether someone other than the candidate, the candidate's authorized committee, a political party committee, or any of their agents paid for the communication in question; and (2) whether the communication satisfies the ''conduct prong'' of 11 CFR 109.21(d).

[23] In addition to its use in connection with the ''content prong,'' the term ''public communication'' is used in connection with the ''conduct prong'' of the coordinated communication regulations involving the use of a ''common vendor.'' *See* 11 CFR 109.21(d)(4)(ii)(E) and (F).

[24] Senator Russ Feingold, ''Blogs Don't Need Big Government'' *available at http://mydd.com/story/2005/3/10/112323/534* (last visited 3/17/2005).

C. Political Party Coordinated Communications—11 CFR 109.37

The ''party coordinated communication'' rule at 11 CFR 109.37(a) sets out a three-pronged test for determining whether payments by a political party committee for communications are ''coordinated'' with a candidate for Federal office, a candidate's authorized committee, or an agent of either of the foregoing. This test parallels the three-pronged test in the ''coordinated communication'' regulations in 11 CFR 109.21. Therefore, as with the coordinated communication regulation, the proposed change to the definition of ''public communication'' in 11 CFR 100.26 would expand the scope of communications covered by the party coordinated communication regulation to include certain communications over the Internet. The Commission seeks comment on this result.

VI. Other Uses of the Term ''Public Communication'' in the Commission's Regulations

The term ''public communication'' is also used in 11 CFR 106.6 and 300.2. Thus, any changes to the definition of ''public communication'' or ''general public political advertising'' in proposed 11 CFR 100.26 to include certain Internet advertisements would affect the application of these two sections.

A. Allocation of Expenses Between Federal and Non-Federal Activities by Separate Segregated Funds and Nonconnected Political Committees—11 CFR 106.6

The Commission recently promulgated revisions to its rules on the allocation of certain expenses by SSFs and nonconnected committees. *See 11* CFR 106.6(b)(1), (b)(2), and (f) (2005); Final Rules on Political Committee Status, Definition of Contribution, and Allocation for Separate Segregated Funds and Nonconnected Committees, 69 FR 68,056 (Nov. 23, 2004). These revised regulations require SSFs and nonconnected committees to allocate between their Federal and non-Federal accounts the costs of certain public communications, such as those that refer to a political party and clearly identified Federal and non-Federal candidates. In addition, the new regulations set forth requirements as to which public communications these committees may pay for using non-Federal funds.

The effect of the proposed revisions to the definition of ''public communication'' in 11 CFR 100.26 would require SSFs and nonconnected committees to use Federal funds to pay for some public communications over the Internet. The Commission invites comment on this result.

B. Definition of ''Agent''—11 CFR 300.2

BCRA prohibits candidates for state and local offices, and their agents, from using non-Federal funds to pay for any ''public communication'' that PASOs a candidate for Federal office. *See* 2 U.S.C. 441i(f). Under the Commission's regulations, an ''agent'' includes any person who is authorized by a candidate for state or local office to ''spend funds for a public communication,'' as defined in 11 CFR 100.26. 11 CFR 300.2(b)(4). Thus, as a result of the proposed change to the definition of ''public communication,'' a person would be an agent of a state or local candidate if he or she is authorized by that non-Federal candidate to pay for any Internet communication that is a ''public communication'' under proposed 11 CFR 100.26. The Commission invites comments on this result and whether it should consider further changing its proposed definition of ''general public political advertising'' or ''public communication'' in 11 CFR 100.26 in light of this result.

VII. 11 CFR 100.73 and 100.132—Exception for News Story, Commentary, or Editorial by the Media

The Commission is also considering whether expressly to extend the protections of the exception for news stories, commentaries and editorials to media activities that occur on the Internet. In the Act, Congress exempted from the definition of ''expenditure'' ''any news story, commentary, or editorial distributed through the facilities of any broadcasting station, newspaper, magazine, or other periodical publication, unless such facilities are owned or controlled by any political party, political committee, or candidate.'' 2 U.S.C. 431(9)(B)(i). In enacting the statutory exemption for the media, Congress intended to assure ''the unfettered right of the newspapers, television networks, *and other media* to cover and comment on political campaigns.'' H.R. Rep. No. 93–1239, 93d Congress, 2d Session at 4 (1974) (emphasis added). The Commission has implemented this statutory exemption in its regulations. *See* 11 CFR 100.73 and 100.132.

Many aspects of the contemporary media did not exist, or were not as prevalent, when Congress enacted the statutory exemption in the Act in the 1970s. In the past, however, the Commission has made clear that the statutory exemption applies to new and emerging forms of mass media, even if they did not exist or were not widespread when Congress passed the Act. For example, recognizing that cable programming utilized the same aspects of speech and communication of ideas as broadcast stations, the Commission modified its regulations to make clear that the Act's statutory exemption applied to cable programming. The Commission noted that ''although the cable television industry was much less developed when Congress expressed this intent, it is reasonable to conclude that cable operators, programmers and producers, when operating in their capacity as news producers and distributors, would be precisely the type of 'other media' appropriately included within this exemption.'' Final Rules on Candidate Debates and News Stories, 61 FR 18,050 (Apr. 24, 1996). Accordingly, cable programming is included in the Commission's current regulations implementing the statutory exemption. See 11 CFR 100.73 and 100.132. *See also Turner Broadcasting System*, v. *FCC*, 512 U.S. 622 (1994); *Medlock* v. *Leathers*, 499 U.S. 439, 444 (1991) (stating that cable television provides news, information, and entertainment and is, in much of its operation, part of the press).

The Commission is now considering whether to amend its regulations to make clear that the statutory exemption also applies to media activities on the Internet. Specifically, the Commission is proposing to amend sections 100.73 and 100.132 of its regulations to indicate that any media activities that otherwise would be entitled to the statutory exemption are likewise exempt when they are transmitted over the Internet. In so doing, the Commission recognizes that media operations increasingly take place on the Internet. The proposed revision would allow for the application of the media exemption to all forms of media activities on the Internet, whether it be through a Web site, e-mail, or some other form of Internet communication.

The Commission seeks comment on the proposed revisions to its regulatory media exemption for news stories, commentaries, and editorials. The Commission also seeks comment on whether the proposed revisions are consistent with or required by the statutory language of the Act. The Commission further seeks comment on the appropriate breadth of the exemption to media activities over the Internet. Should the exemption be limited to entities who are media entities and who are covering or carrying a news story, commentary, or editorial? Should the exemption be

limited only to the Internet activities of media entities that also have off-line media operations? The Commission notes that the proposed regulation expressly rejects a policy that only a *bona fide* press entity with an off-line component is entitled to protection in their on-line news stories, commentaries, and editorials.

The proposed revision would extend the media exemption to media entities whose activities exist solely on-line, without a print or broadcast component, as well as to media entities who have a broadcast or print component as well as an on-line presence. For example, Salon.com, Slate.com, and Drudgereport.com do not publish off-line. Such on-line sites provide direct access to political news and events and offer commentary on current affairs. The Commission recognizes that on-line sites are as accessible as printed periodicals or news programs and therefore proposes to clarify that the media exemption extends to those entities who may solely have an on-line presence as well as to those entities who have an on-line component in addition to their broadcast or print activities. The Commission seeks comment on this approach. The Commission notes that it has applied the media exemption on a case-by-case basis in a wide variety of contexts. *See* AOs 2004–7, 2003–34, 2000–13, 1996–48, 1996–41, 1996–16, 1992–26, 1988–22, 1987–08, 1982–44, 1982–58, 1980–90, 1980–109, and 1978–76.

The Commission also seeks comment on whether bloggers, whether acting as individuals or through incorporated or unincorporated entities, are entitled to the statutory exemption. Can on-line blogs be treated as ''periodical publications'' within the meaning of the exemption? *See* 2 U.S.C. 431(9)(B)(i). If not, why not? Is the media exemption to be limited to traditional business models, meaning entities that finance operations with subscriptions or advertising revenue? The Commission also seeks comment on whether on-line forums qualify for the exemption.

The Commission further seeks comment on whether it makes any difference under the Act if a blogger receives compensation or any other form of payment from any candidate, political party, or political committee for his or her editorial content. Would any such payments mean that the blogger is ''controlled'' by a candidate or political party within the meaning of 2 U.S.C. 431(9)(B)(i), and therefore is not entitled to the exemption? The Commission has previously determined that ''commentary was intended to allow third persons access to the media to discuss issues.'' *See* AO 1982–44. Should bloggers' activity be considered commentary or editorializing, or news story activity?

Lastly, the Commission seeks comment on any other issue pertinent to the Commission's consideration of whether to extend the protections of this statutory exemption to media activities on the Internet.

VIII. Proposed 11 CFR 100.94 and 100.155—Exceptions to the Definitions of ''Contribution'' and ''Expenditure'' for Individual or Volunteer Activity on the Internet

Although the Internet is generally a free or low-cost medium for communication, the Act's definitions of ''contribution'' and ''expenditure'' are broad enough to apply to some Internet activity. For example, section 431(8) of the Act states that the term ''contribution'' includes ''any gift, subscription, loan, advance or deposit of money or anything of value made by any person for the purpose of influencing any election for Federal office.'' 2 U.S.C. 431(8)(A)(i). Similarly, section 431(9) of the Act states that the term ''expenditure'' includes ''any purchase, payment, distribution, loan, advance, deposit, gift of money or anything of value, made by any person for the purpose of influencing any election for Federal office.'' 2 U.S.C. 431(9)(A). These definitions have been incorporated into subparts B and D of 11 CFR part 100.

Similarly, the Act's definition of ''independent expenditure'' is broad enough to apply to some Internet activity. Section 431(17) of the Act states that ''the term 'independent expenditure' means an expenditure by a person expressly advocating the election or defeat of a clearly identified candidate which is made without cooperation or consultation with any candidate, or any authorized committee or agent of such candidate, and which is not made in concert with, or at the request or suggestion of, any candidate, or any authorized committee or agent of such candidate.'' 2 U.S.C. 431(17); *see also* 11 CFR 100.16.

However, the definition of ''contribution'' in the Act and Commission regulations does not include ''the value of services provided without compensation by any individual who volunteers on behalf of a candidate or political committee.'' 2 U.S.C. 431(8)(B)(i); 11 CFR 100.74. Furthermore, the definition of a ''contribution'' does not include:

> the use of real or personal property, including a church or community room used on a regular basis by members of a community for noncommercial purposes, * * * voluntarily provided by an individual to any candidate or any political committee of a political party in rendering voluntary personal services on the individual's residential premises or in the church or community room for candidate-related or political party-related activities * * *.

2 U.S.C. 431(8)(B)(ii). *See also* 11 CFR 100.75 and 100.76. The Commission's regulations contain a parallel exception to the definition of ''expenditure'':

> [n]o expenditure results where an individual, in the course of volunteering personal services on his or her residential premises to any candidate or political committee of a political party, provides the use of his or her real or personal property to such candidate for candidate-related activity or to such political committee of a political party for party-related activity.

11 CFR 100.135. *See also* 11 CFR 100.136.

The Commission is proposing new rules to address the treatment of uncompensated individual or volunteer campaign activity on the Internet. Specifically, the Commission proposes the addition of two new sections to 11 CFR part 100 to provide new exceptions from the definition of contribution'' and ''expenditure.'' Proposed 11 CFR 100.94 would create an exception to the definition of ''contribution'' for certain uncompensated individual or volunteer Internet activity, while proposed 11 CFR 100.155 would create a parallel exception to the definition of ''expenditure'' for the same activity.

Under proposed 11 CFR 100.94 and 100.155, an uncompensated individual acting independently or as a volunteer would not make a contribution or expenditure simply by using computer equipment and services to engage in Internet activities for the purpose of influencing an election for Federal office. The Commission notes that the proposed rule would only apply to computer and other facilities to which the individual would otherwise have access. The proposed rule would not permit the purchase of equipment by an individual or entity solely for the purposes of allowing another individual to participate in Internet activity. The Commission seeks comment on this approach.

In AO 1998–22, the Commission concluded that even if an individual acting independently incurs no additional costs in creating a Web site that contains express advocacy of a clearly identified candidate, at least some portion of the underlying costs of creating and maintaining that Web site is an expenditure under the Act and must be reported if it exceeds $250 in a calendar year. In contrast, in AO

1999–17, the Commission concluded that costs incurred by a campaign volunteer in preparing a Web site on behalf of a candidate on the volunteer's home computer are exempt from the definition of ''contribution'' under the volunteer exception contained in section 100.75 of the regulations (formerly section 100.7(b)(4)). The Commission stated that the volunteer exception applies to ''individuals known to the campaign who, with the campaign's permission (at some level) engage in volunteer activity.'' *Id.* The Commission also determined that the costs of e-mail messages sent by a campaign volunteer using his or her own computer equipment would be covered by the volunteer exception, and thus would not result in a contribution to the campaign. *Id.*

The proposed rules in new sections 100.94 and 100.155 would supersede AO 1998–22 to the extent that it treats an individual's independent use of computer equipment and services for Internet activity as an expenditure. The proposed rules would also extend beyond the specific guidance provided in AO 1999–17 to clarify that these exceptions would apply to an uncompensated individual acting independently or as a volunteer without regard to whether the individual or another person owns the computer being used or where the Internet activity is taking place. For example, the proposed rule would permit an individual or a volunteer to use computer equipment and services provided at a public facility, such as a library or school, or provided by a friend, without such Internet activity being a contribution or expenditure. The Commission, however, would continue to view the purchase of mailing lists (including e-mail lists) for the purposes of forwarding candidate and political committee communications as expenditures or contributions. The Commission seeks comment on this approach. If the computer equipment and service is provided by a corporation or labor organization, the rules at 11 CFR 114.9 would apply. The proposed rules would thereby avoid disparate treatment of individuals or volunteers who may not be able to afford the purchase or maintenance of their own computers or Web sites. The Commission invites comments on this approach. The Commission also seeks comments on whether this exception should be extended to volunteers who receive some form of payment or reimbursement from a candidate or a political committee, such as transportation, subsistence, or supplies. Additionally, the Commission seeks comments on whether the entirety of AOs 1998–22 and 1999–17, or any additional AOs, should be superseded or whether there is any aspect of those AOs that should remain valid.

Under the proposed rules, individuals acting independently or as volunteers would come within this exception when using any ''computer equipment and services'' to engage in ''Internet activities.'' Specific examples of ''computer equipment and services'' would be listed in paragraph (c) of each section and would include, but would not be limited to, computers, software, Internet domain names, and Internet Service Provider(''ISP'') services (*e.g.*, connecting to the Internet). ''Internet activities'' would be defined in paragraph (b) of each section to include, but not be limited to, creating and sending e-mail or producing and maintaining a Web site or a blog. Furthermore, because many individuals who use the Internet cannot, or do not, maintain their own Web sites, or simply wish to post a blog in a place where it is more likely to be seen by others, there are a number of blog ''hosts'' that provide space on a Web site for other individuals to post their own blogs or other commentary. Individuals acting independently or as volunteers posting blogs or other content on the Web sites of these hosts would be entitled to the exception just as if the content were posted on their own Web site. However, the exceptions would not apply to paid advertising or other payments for the use of another person's Web site, other than a nominal fee. *See* current 11 CFR 100.75 and 100.135 (a volunteer's payment of a nominal fee in the course of providing personal services does not constitute a contribution or expenditure).

Thus, an individual or volunteer producing or maintaining a Web site or blog, or conducting other grassroots campaign activity on the Internet, from that individual's own home or elsewhere, would not make a contribution or expenditure and would not incur any reporting responsibilities as the result of that activity. For example, if an individual downloaded materials from a candidate or party Web site, such as campaign packets, yard signs, and other items, the downloading of such items would not constitute republication of campaign materials. In addition, even when the Internet activity is made in cooperation, consultation, or concert with a candidate or a political party committee, no contribution or expenditure would result and neither the candidate nor the political party committee would incur any reporting responsibilities. Furthermore, if an individual forwarded an e-mail received from a political committee, the forwarding of that e-mail would not constitute republication of campaign materials or be an in-kind contribution. The Commission invites comments on this approach.

The Commission notes that existing Commission regulations regarding volunteer activity use the concept of volunteer in the context of an individual volunteering personal services to a candidate, political committee, or political party. The proposed regulations would apply regardless of whether the individual's activities were known to a candidate, political party, or political committee. The Commission seeks comment on whether it has authority to do this and whether the word ''individual'' or ''volunteer'' more accurately conveys the concept of when an individual, whether known or unbeknownst to the campaign, engages in Internet activity.

IX. 11 CFR 114.9—Use of Corporate or Labor Organization Facilities and Means of Transportation

The Commission's rules at 11 CFR 114.9 permit employees and stockholders of a corporation, as well as officials, members, and employees of a labor organization, to use corporate or labor organization ''facilities'' for individual volunteer activities in connection with a Federal election, so long as that use is ''occasional, isolated, or incidental.'' 11 CFR 114.9(a)(1) and (b)(1).[25] In order to clarify that corporate and labor organization ''facilities'' include computer equipment and Internet services that could be used to exchange e-mail, produce or maintain Web sites, or engage in other activities over the Internet, the Commission proposes to amend 11 CFR 114.9(a)(1) and (b)(1) to expressly include ''computers, software, and other Internet equipment and services,'' within the meaning of ''facilities.'' The Commission invites comments on this proposed revision.

In addition, the Commission notes that many corporations and labor

[25] The use of equipment or services is ''occasional, isolated, or incidental'' during the workday if it does not prevent the individual from carrying out her normal duties or interfere with the corporation or labor organization carrying out its normal activities. *See* 11 CFR 114.9(a)(1) (i) and (ii) and (b)(1) (i) and (ii) The Commission has established a safe harbor such that an individual's activity during or outside working hours is considered ''occasional, isolated, or incidental'' if it does not exceed one hour per week or four hours per month. 11 CFR 114.9(a)(1)(ii) and (b)(1)(iii). The examples of ''occasional, isolated, or incidental'' use are not exhaustive, and other uses may also qualify.

organizations now permit individuals to take laptops home and to use computers and other Internet services for non-work purposes. The Commission notes that a volunteer's use of a corporate or labor organization computer or Internet service for campaign activity over the Internet at home, or at locations outside of work, is still subject to the ''occasional, isolated, or incidental'' use restriction.

The Commission further notes that corporations and labor organizations are prohibited from ''[u]sing coercion, such as the threat of a detrimental job action, the threat of any other financial reprisal, or the threat of force, to urge any individual to make a *contribution* or engage in fundraising activities on behalf of a candidate or political committee.'' 11 CFR 114.2(f)(2)(iv) (emphasis added); *see also* 2 U.S.C. 441b(b)(3). Because the proposed revisions to 11 CFR 114.9(a) and (b) would expressly except the occasional, isolated, or incidental use of corporate or labor organization computers, software, and other Internet equipment and services from the definition of ''contribution,'' the Commission seeks comment on whether additional rules are necessary to ensure that corporations and labor organizations do not ''coerce'' their employees or others into engaging in Internet activities on behalf of a candidate or political committee. Should such an exemption be avoided in that it could lead to inherently coercive situations? Should it be premised on the corporation or labor organization not directing the individual to engage in activity on behalf of a certain candidate or political committee?

Certification of No Effect Pursuant to 5 U.S.C. 605(b) [Regulatory Flexibility Act]

The Commission certifies that the attached proposed rules, if promulgated, would not have a significant economic impact on a substantial number of small entities. The basis for this certification is that the individuals and not-for-profit entities affected by these proposed rules are not ''small entities'' under 5 U.S.C. 601. The definition of ''small entity'' does not include individuals, but classifies a not-for-profit enterprise as a ''small organization'' if it is independently owned and operated and not dominant in its field. 5 U.S.C. 601(4).

State, district, and local party committees affected by these proposed rules are not-for-profit committees that do not meet the definition of ''small organization.'' State political party committees are not independently owned and operated because they are not financed and controlled by a small identifiable group of individuals, and they are affiliated with the larger national political party organizations. In addition, the State political party committees representing the Democratic and Republican parties have a major controlling influence within the political arena of their State and are thus dominant in their field. District and local party committees are generally considered affiliated with the State committees and need not be considered separately.

Separate segregated funds affected by these proposed rules are not-for-profit political committees that do not meet the definition of ''small organization'' because they are financed by a combination of individual contributions and financial support for certain expenses from corporations, labor organizations, membership organizations, or trade associations, and therefore are not independently owned and operated.

Most other political committees affected by these rules are not-for-profit committees that do not meet the definition of ''small organization.'' Most political committees are not independently owned and operated because they are not financed by a small identifiable group of individuals. Most political committees rely on contributions from a large number of individuals to fund the committees operations and actives.

To the extent that any State party committees representing minor political parties or any other political committees might be considered ''small organizations,'' the number affected by this proposed rule is not substantial. Additionally, because the proposed rule preserves the Commission's general exclusion of Internet communications from the scope of regulation, any economic impact of complying with these rules will not be significant. Accordingly, to the extent that any other entities may fall within the definition of ''small entities,'' any economic impact of complying with these rules will not be significant.

List of Subjects

11 CFR Part 100

Elections.

11 CFR Part 110

Campaign funds, Political committees and parties.

11 CFR Part 114

Business and industry, Elections, Labor.

For the reasons set out in the preamble, the Federal Election Commission proposes to amend subchapter A of chapter 1 of title 11 of the *Code of Federal Regulations* as follows:

PART 100—SCOPE AND DEFINITIONS (2 U.S.C. 431)

1. The authority citation for part 100 would continue to read as follows:

Authority: 2 U.S.C. 431, 434, and 438(a)(8).

2. Section 100.25 would be republished to read as follows:

§ 100.25 Generic campaign activity (2 U.S.C. 431(21)).

Generic campaign activity means a public communication that promotes or opposes a political party and does not promote or oppose a clearly identified Federal candidate or a non-Federal candidate.

3. Section 100.26 would be revised to read as follows:

§ 100.26 Public communication (2 U.S.C. 431(22)).

Public communication means a communication by means of any broadcast, cable, or satellite communication, newspaper, magazine, outdoor advertising facility, mass mailing or telephone bank to the general public, or any other form of general public political advertising. The term *general public political advertising* shall not include communications over the Internet, except for announcements placed for a fee on another person's or entity's Web site.

4. In §100.73, the introductory text would be revised to read as follows:

§ 100.73 News story, commentary, or editorial by the media.

Any cost incurred in covering or carrying a news story, commentary, or editorial by any broadcasting station (including a cable television operator, programmer or producer), newspaper, magazine, or other periodical publication, whether the news story, commentary, or editorial appears in print or over the Internet, is not a contribution unless the facility is owned or controlled by any political party, political committee, or candidate, in which case the costs for a news story:

* * * * *

5. Section 100.94 would be added to subpart C of part 100 to read as follows:

§ 100.94 Uncompensated individual or volunteer activity that is not a contribution.

(a) *Contribution.* (1) No contribution results where an individual, acting independently or as a volunteer, without receiving compensation,

performs Internet activities using computer equipment and services that he or she personally owns for the purpose of influencing any Federal election, whether or not the individual's activities are known to or coordinated with any candidate, authorized committee or party committee.

(2) No contribution results where an individual, acting independently or as a volunteer, without receiving compensation, performs Internet activities using computer equipment and services available at any public facility for the purpose of influencing any Federal election, whether or not the individual's activities are known to or coordinated with any candidate, authorized committee or party committee. The term ''public facility'' within the meaning of this section shall include, but is not limited to, public libraries, public schools, community centers, and Internet cafes.

(3) No contribution results where an individual, acting independently or as a volunteer, without receiving compensation, performs Internet activities using computer equipment and services in his or her residential premises for the purpose of influencing any Federal election, whether or not the individual's activities are known to or coordinated with any candidate, authorized committee or party committee.

(b) *Internet activities.* ''Internet activities'' within the meaning of this section shall include, but are not limited to: e-mailing, including forwarding; linking, including providing a link or hyperlink to a candidate's, authorized committee's or party committee's Web site; distributing banner messages; blogging; and hosting an Internet site.

(c) *Computer equipment and services.* ''Computer equipment and services'' within the meaning of this section shall include, but are not limited to, computers, software, Internet domain names, and Internet Service Provider (ISP) services.

6. In §100.132, the introductory text would be revised to read as follows:

§ 100.132 News story, commentary, or editorial by the media.

Any cost incurred in covering or carrying a news story, commentary, or editorial by any broadcasting station (including a cable television operator, programmer or producer), newspaper, magazine, or other periodical publication, whether the news story, commentary, or editorial appears in print or over the Internet, is not an expenditure unless the facility is owned or controlled by any political party, political committee, or candidate, in which case the cost for a news story:

* * * * *

7. Section 100.155 would be added to subpart E of part 100 to read as follows:

§ 100.155 Uncompensated individual or volunteer activity that is not an expenditure.

(a) *Expenditure.* (1) No expenditure results where an individual, acting independently or as a volunteer, without receiving compensation, performs Internet activities using computer equipment and services that he or she personally owns for the purpose of influencing any Federal election, whether or not the individual's activities are known to or coordinated with any candidate, authorized committee or party committee.

(2) No expenditure results where an individual, acting independently or as a volunteer, without receiving compensation, performs Internet activities using computer equipment and services available at any public facility for the purpose of influencing any Federal election, whether or not the individual's activities are known to or coordinated with any candidate, authorized committee or party committee. The term ''public facility'' within the meaning of this section shall include, but is not limited to, public libraries, public schools, community centers, and Internet cafes.

(3) No expenditure results where an individual acting independently or as a volunteer, without receiving compensation, performs Internet activities using computer equipment and services in his or her residential premises for the purpose of influencing any Federal election, whether or not the individual's activities are known to or coordinated with any candidate, authorized committee or party committee.

(b) *Internet activities.* ''Internet activities'' within the meaning of this section shall include, but are not limited to: e-mailing, including forwarding; linking, including providing a link or hyperlink to a candidate's, authorized committee's or party committee's Web site; distributing banner messages; blogging; and hosting an Internet site.

(c) *Computer equipment and services.* ''Computer equipment and services'' within the meaning of this section shall include, but are not limited to, computers, software, Internet domain names, and Internet Service Provider (ISP) services.

PART 110—CONTRIBUTION AND EXPENDITURE LIMITATIONS AND PROHIBITIONS

8. The authority citation for part 110 would continue to read as follows:

Authority: 2 U.S.C. 431(8), 431(9), 432(c)(2), 437d, 438(a)(8), 441a, 441b, 441d, 441e, 441f, 441g, 441h, and 36 U.S.C. 510.

9. Section 110.11 would be amended by revising the introductory text in paragraph (a) to read as follows:

§ 110.11 Communications; advertising; disclaimers (2 U.S.C. 441d).

(a) *Scope.* Public communications are those defined by 11 CFR 100.26. For the purposes of this section, public communications will also include more than 500 unsolicited substantially similar electronic communications; Internet Web sites of political committees available to the general public; and electioneering communications as defined in 11 CFR 100.29. *Unsolicited e-mail* shall be defined as those e-mail that are sent to electronic mail addresses purchased from a third party. The following types of such communications must include disclaimers, as specified in this section:

* * * * *

PART 114—CORPORATE AND LABOR ORGANIZATION ACTIVITY

10. The authority citation for part 114 continues to read as follows:

Authority: 2 U.S.C. 431(8)(B), 431(9)(B), 432, 434, 437d(a)(8), and 441b.

11. In §114.9, the introductory text of paragraphs (a)(1) and (b)(1) would be revised to read as follows:

§ 114.9 Use of corporate or labor organization facilities and means of transportation.

(a) *Use of corporate facilities for individual volunteer activity by stockholders and employees.*

(1) Stockholders and employees of the corporation may, subject to the rules and practices of the corporation, make occasional, isolated, or incidental use of the facilities of a corporation for individual volunteer activities in connection with a Federal election and will be required to reimburse the corporation only to the extent that the overhead or operating costs of the corporation are increased. The facilities of a corporation within the meaning of this paragraph include computers, software, and other Internet equipment and services. As used in this paragraph, *occasional, isolated, or incidental* use generally means—

* * * * *

(b) *Use of labor organization facilities for individual volunteer activity by officials, members, and employees.*

(1) The officials, members, and employees of a labor organization may, subject to the rules and practices of the labor organization, make occasional, isolated, or incidental use of the facilities of a labor organization for individual volunteer activities in connection with a Federal election and will be required to reimburse the labor organization only to the extent that the overhead or operating costs of the organization are increased. The facilities of a labor organization within the meaning of this paragraph include computers, software, and other Internet equipment and services. As used in this paragraph, *occasional, isolated, or incidental use* generally means—

* * * * *

Dated: March 29, 2005.

Scott E. Thomas,

Chairman, Federal Election Commission.

[FR Doc. 05–6521 Filed 4–1–05; 8:45 am]

BILLING CODE 6715–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20799; Directorate Identifier 2004–NM–264–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 727 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Boeing Model 727 airplanes. This proposed AD would require determining whether any float switches are installed in the fuel tanks, and corrective actions if necessary. This proposed AD is prompted by reports of contamination of the fueling float switch by moisture or fuel, and chafing of the float switch wiring against the fuel tank conduit. We are proposing this AD to prevent such contamination and chafing, which could present an ignition source inside the fuel tank that could cause a fire or explosion.

DATES: We must receive comments on this proposed AD by May 19, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- *By fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2005–20799; the directorate identifier for this docket is 2004–NM–264–AD.

FOR FURTHER INFORMATION CONTACT: Sulmo Mariano, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6501; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2005–20799; Directorate Identifier 2004–NM–264–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov.*

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

Boeing has performed a quality analysis on float switches removed from Model 737–200 series airplanes. Investigation revealed cracked potting material, which permitted moisture and fuel to enter the switch cavity. Fuel and moisture contamination inside the float switch reed cavity could provide an electrical path between the switch and the airplane structure that could result in electrical arcing that could lead to a fuel tank explosion. Also, Boeing reported worn float switch wiring insulation in the center fuel tank due to chafing of the wires against the walls of the conduit housing the wires. Wire chafing against the conduit could present an ignition source inside the fuel tank that could cause a fire or explosion.

The float switch wiring installation is similar on Model 727 and 737–200 series airplanes. Therefore, the unsafe condition could exist on Model 727 airplanes equipped with the same float switch model found on the 737–200 series airplanes.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 727–28A0127, dated August 26, 2004. The service bulletin describes procedures for replacing Ametek Model F8300–146 float switches with new switches and installing a liner system inside the electrical cable conduit in the main and auxiliary fuel tanks.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or

develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between the Proposed AD and the Service Bulletin.''

Differences Between the Proposed AD and the Service Bulletin

The service bulletin affects Model 727 airplanes ''with active Boeing fueling float switch shutoff systems installed'' and requires replacing the float switches and installing a liner system. However, this proposed AD would apply to all Model 727 airplanes and would require first determining whether any fuel float switches are installed in the fuel tanks. For those airplanes with float switches, this proposed AD would then require identifying the float switches, replacing Ametek Model F8300–146 float switches with new switches, and installing the liner system. We have determined that the effectivity in the service bulletin may not encompass all possible scenarios involving the subject float switches. Because the auxiliary fuel tanks have been moved from airplane to airplane—via field approval or supplemental type certificate, the proposed applicability and requirements would ensure that all subject float switch designs are replaced.

These differences have been coordinated with Boeing and are intended to adequately address the unsafe condition.

Costs of Compliance

There are about 1,300 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 800 airplanes of U.S. registry.

The proposed inspections (for presence and model of float switch) would take about 1 work hour, at an average labor rate of $65 per hour. Based on these figures, the estimated cost of the proposed inspections for U.S. operators is $52,000, or $65 per airplane.

The following table provides the estimated costs for U.S. operators to replace the float switches, if necessary. We estimate that about 162 airplanes may require parts replacement.

ESTIMATED COSTS

Airplane	Airplane model	Number of auxiliary fuel tanks	Work hours	Average hourly labor rate	Parts	Cost per airplane
1	727–200	0	27	$65	$4,174	$5,929
2	727–200	1	9	65	1,542	2,127
3	727–200	2	14	65	3,108	4,018
4	727–200	3	18	65	4,626	5,796
5	727–200	4	23	65	6,168	7,663
6	727–100	2	14	65	3,079	3,989

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2005–20799; Directorate Identifier 2004–NM–264–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by May 19, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Boeing Model 727 airplanes, certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports of contamination of the fueling float switch by moisture or fuel, and chafing of the float switch wiring against the fuel tank conduit. We are issuing this AD to prevent such contamination and chafing, which could present an ignition source inside the fuel tank that could cause a fire or explosion.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection for Float Switches

(f) Within 48 months after the effective date of this AD, inspect the wing and auxiliary fuel tanks to determine if any float switches are present. Instead of an inspection of the fuel tanks, a review of airplane maintenance records is acceptable if the presence of any float switch can be conclusively determined from that review.

(1) If no float switches are present: No further work is required by this paragraph.

(2) If any float switch is present: Before further flight, inspect to identify the float switch models. Instead of an inspection of the fuel tanks, a review of airplane maintenance records is acceptable if the identity of the float switch can be conclusively determined from that review.

(i) If a float switch other than an Ametek Model F8300–146 float switch is installed: Before further flight, install a liner system inside the float switch electrical cable conduit in the fuel tanks by doing all applicable actions specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 727–28A0127, dated August 26, 2004.

(ii) If any Ametek Model F8300–146 float switch is installed: Before further flight, replace it with a new switch and install a liner system inside the float switch electrical cable conduit in the fuel tanks, by doing all applicable actions specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 727–28A0127, dated August 26, 2004.

Note 1: Boeing Alert Service Bulletin 727–28A0127 segregates the work into nine work packages for the six fuel tank configurations identified in the service bulletin. The work packages do not have to be completed sequentially. Each work package can be done independently or simultaneously. However, all work packages, as applicable for each fuel tank configuration, must be done to complete the requirements of this AD.

Parts Installation

(g) As of the effective date of this AD, no person may install an Ametek Model F8300–146 float switch in a fuel tank on any airplane.

Alternative Methods of Compliance (AMOCs)

(h) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on March 28, 2005.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6577 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20796; Directorate Identifier 2004–NM–160–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A300 B2 and A300 B4 Series Airplanes; Model A300 B4–600, B4–600R and F4–600R Series Airplanes, and Model A300 C4–605R Variant F Airplanes (Collectively Called A300–600); and Model A310 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all the Airbus models identified above. This proposed AD would require modifying the electrical power supply logic for the integral lighting of the standby horizon indicator in the cockpit; accomplishing repetitive operational tests of the integral lighting logic system, and corrective action if necessary. This proposed AD is prompted by a report of temporary loss of six cathode ray tube flight displays and the integral lighting of the standby horizon indicator in the cockpit during takeoff, due to failure of the normal electrical power circuit. We are proposing this AD to prevent loss of that integral lighting due to such failure, which could result in inability of the pilot to read the backup attitude information during takeoff, and possible deviation from the intended flight path.

DATES: We must receive comments on this proposed AD by May 4, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- *By fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2005–20796; the directorate identifier for this docket is 2004–NM–160–AD.

FOR FURTHER INFORMATION CONTACT: Tim Backman, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2797; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–20796; Directorate Identifier 2004–NM–160–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of our docket website, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov.*

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza

level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified us that an unsafe condition may exist on all Airbus Model A300 B2 and A300 B4 series airplanes; Model A300 B4–600, B4–600R and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called A300–600); and Model A310 series airplanes. The DGAC advises that, during takeoff on a Model A300 B2 series airplane, an operator reported the temporary loss of six cathode ray tube (CRT) flight displays and the integral lighting of the standby horizon indicator in the cockpit due to failure of the normal electrical power circuit. The temporary loss of the CRTs is still under investigation. Power for the integral lighting of the standby horizon indicator is supplied through the normal electrical power circuit. In the event of failure of the normal electrical power circuit, modifying the logic for the integral lighting of the standby horizon will allow automatic switching from the normal to the essential electrical power circuit. Loss of the integral lighting due to such failure could result in loss of the backup source of attitude data, consequent inability of the pilot to access attitude information during takeoff, and possible deviation from the intended flight path.

The integral lighting logic system on Model A300 B4 series airplanes; Model A300 B4–600, B4–600R and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes; and Model A310 series airplanes is identical to the integral lighting logic system on the affected Model A300 B2 series airplane. Therefore, those airplanes may be subject to the same unsafe condition identified on Model A300 B2 series airplanes.

Relevant Service Information

We have reviewed the following Airbus service bulletins:

REFERENCED SERVICE BULLETINS

For model—	Service bulletin/date—
A300 B2 and A300 B4 series airplanes	A300–31–0077, dated March 2, 2004 . A300–33–0126, dated April 5, 2004.
A300 B4–600, B4–600R and F4–600R series airplanes; A300 C4–605R Variant F airplanes.	A300–31–6105, Revision 02, dated May 27, 2003. A300–33–6049, Revision 01, dated May 28, 2004.
A310 series airplanes	A310–31–2120, Revision 01, dated May 27, 2003. A310–33–2047, dated April 5, 2004.

Service Bulletins A300–31–0077, A300–31–6105, and A310–31–2120 describe procedures for modifying the electrical power supply for the standby horizon indicator.

Service Bulletins A300–33–0126, A300–33–6049, and A310–33–2047 describe procedures for accomplishing repetitive operational tests (inspections) of the integral lighting logic system. The service bulletins also recommend sending an inspection report to Airbus.

Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition. The DGAC mandated the service information and issued French airworthiness directive F–2004–098, dated July 7, 2004, to ensure the continued airworthiness of these airplanes in France.

FAA's Determination and Requirements of the Proposed AD

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept us informed of the situation described above. We have examined the DGACs findings, evaluated all pertinent information, and determined that we need to issue an AD for products of this type design that are certificated for operation in the United States.

Therefore, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between the Proposed AD and Service Information.''

Differences Between the Proposed AD and Service Information

Service Bulletins A300–33–0126, A300–33–6049, and A310–33–2047 recommend sending an inspection report to Airbus, but this proposed AD does not contain that requirement.

Service Bulletins A300–33–0126, A300–33–6049, and A310–33–2047 do not specify repair procedures for failure of the operational test, but this proposed AD would require you to repair those conditions using a method that we or the DGAC (or its delegated agent) approve. In light of the type of repair that would be required to address the unsafe condition, and consistent with existing bilateral airworthiness agreements, we have determined that, for this proposed AD, a repair we or the DGAC approve would be acceptable for compliance with this proposed AD.

Costs of Compliance

This proposed AD would affect about 189 airplanes of U.S. registry.

It would take between approximately 10 and 36 work hours per airplane to accomplish the proposed modification (depending on the number of kits needed), at an average labor rate of $65 per work hour. Required parts would cost approximately between $310 and $4,880 per airplane. Based on these figures, the estimated cost of the proposed modification is between $960 and $7,220 per airplane.

It would take about 1 work hour per airplane to accomplish the proposed operational test, at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of the proposed test is $12,285, or $65 per airplane, per test cycle.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that

section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD will not have federalism implications under Executive Order 13132. This proposed AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA–2005–20796; Directorate Identifier 2004–NM–160–AD.

Comments Due Date

(a) The Federal Aviation Administration must receive comments on this AD action by May 4, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Airbus Model A300 B2 and A300 B4 series airplanes; Model A300 B4–600, A300 B4–600R, and A300 F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called A300–600); and Model A310 series airplanes; certificated in any category.

Unsafe Condition

(d) This AD was prompted by a report of temporary loss of six cathode ray tube flight displays and the integral lighting of the standby horizon indicator in the cockpit during takeoff, due to failure of the normal electrical power circuit. We are issuing this AD to prevent loss of that integral lighting due to such failure, which could result in inability of the pilot to read the backup attitude information during takeoff, and possible deviation from the intended flight path.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Required Service Information

(f) Unless otherwise specified in this AD, the term ''service bulletin,'' as used in this AD, means the Accomplishment Instructions of the applicable service bulletin identified in Table 1 of this AD. Service Bulletins A300–33–0126, A300–33–6049, and A310–33–2047 specify to submit certain information to the manufacturer, but this AD does not include that requirement.

TABLE 1.—SERVICE BULLETINS

For Airbus models—	Use Airbus service bulletin(s)—	Revision—	Dated—	And, for actions done before the effective date of this AD, credit is given for prior accomplishing of—
A300 B2 and A300 B4 series	A300–31–0077 (Airbus Modification 12513).	Original	March 2, 2004	N/A.
	A300–33–0126	Original	April 5, 2004	N/A.
A300 B4–600; A300 B4–600R and F4–600R series; and A300 C4–605R Variant F airplanes.	A300–31–6105 (Airbus Modifications 12513 and 12730).	02	May 27, 2003	None.
	A300–33–6049	01	May 28, 2004	Original, dated April 5, 2004.
A310 series	A310–31–2120 (Airbus Modification 12513).	01	May 27, 2003	Original, dated November 19, 2002.
	A310–33–2047	Original	April 5, 2004	N/A.

Modification

(g) For airplanes on which Airbus Modifications 12513 and 12730 have not been accomplished: Within 12 months after the effective date of this AD, modify the electrical power supply logic of the integral lighting for the standby horizon indicator in the cockpit in accordance with the service bulletin.

Repetitive Operational Tests

(h) For all airplanes: Within 600 flight hours after accomplishing the modification required by paragraph (g) of this AD, or within 600 flight hours after the effective date of this AD, whichever is later, accomplish the operational test of the integral lighting logic system in accordance with the service bulletin. Repeat the test thereafter at intervals not to exceed 600 flight hours.

Corrective Action

(i) If any operational test required by paragraph (h) of this AD fails: Before further flight, accomplish any applicable repair per a method approved by either the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate; or the Direction Générale de l'Aviation Civile (or its delegated agent).

Alternative Methods of Compliance (AMOCs)

(j) The Manager, International Branch, ANM–116, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Related Information

(k) French airworthiness directive F–2004–098, dated July 7, 2004, also addresses the subject of this AD.

Issued in Renton, Washington, on March 23, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6578 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20798; Directorate Identifier 2004–NM–257–AD]

RIN 2120–AA64

Airworthiness Directives; Learjet Model 23, 24, 25, 35, and 36 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede an existing airworthiness directive (AD) that applies to certain Learjet Model 23, 24, 25, 35, and 36 airplanes. The existing AD currently requires repetitive inspections to detect deterioration of both flappers of the tip tank in each wing of the airplane, and various follow-on actions. The existing AD also requires replacing the flappers with new flappers, and repetitively performing certain other follow-on actions. This proposed AD would require an inspection of the flappers and flapper assemblies of the tip tank in each wing or a review of the airplane maintenance records to determine the part numbers, and replacement of certain flappers or flapper assemblies if necessary, which would end the existing repetitive inspections. This proposed AD is prompted by the results of numerous continual inspections, and the approval of a new, improved flapper and flapper assembly. We are proposing this AD to prevent significant reduction in the lateral control of the airplane due to imbalance of the fuel loads in the wings of the airplane.

DATES: We must receive comments on this proposed AD by May 19, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC 20590.
- Fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Learjet, Inc., One Learjet Way, Wichita, Kansas 67209–2942.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2005–20798; the directorate identifier for this docket is 2004–NM–257–AD.

FOR FURTHER INFORMATION CONTACT: Jeffrey Janusz, Aerospace Engineer, Systems and Propulsion Branch, ACE–116W, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; telephone (316) 946–4148; fax (316) 946–4107.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–20798; Directorate Identifier 2004–NM–257–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of our docket Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov*.

Examining the Docket

You can examine the AD docket on the Internet at http://dms.dot.gov, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

On November 27, 1995, we issued AD 95–25–03, amendment 39–9447 (60 FR 63617, December 12, 1995), for certain Learjet Model 23, 24, 25, 35, and 36 airplanes. That AD requires repetitive inspections to detect deterioration of both flappers of the tip tank in each wing of the airplane, and various follow-on actions. That AD also requires replacing the flappers with new flappers, and repetitively performing certain other follow-on actions. That AD was prompted by reports of imbalance of the fuel loads in the wings of the airplane due to failed or cracked flappers. We issued that AD to prevent significant reduction in the lateral control of the airplane due to imbalance of the fuel loads in the wings of the airplane.

Actions Since Existing AD Was Issued

Since we issued AD 95–25–03, we have reviewed Learjet Service Bulletin 23/24/25–28–7, Revision 2, dated May 9, 2001 (for Model 23, 24, and 25 airplanes); and Learjet Service Bulletin 35/36–28–14, Revision 2, dated May 9, 2001 (for Model 35 and 36 airplanes). The service bulletins describe procedures for replacing flappers with new flappers or replacing the flapper assemblies with new or modified and reidentified assemblies, which eliminates the need for the repetitive inspections required by AD 95–25–03. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

The unsafe condition described previously is likely to exist or develop on other airplanes of the same type design that may be registered in the U.S. at some time in the future.

We can better ensure long-term continued operational safety by design changes to remove the source of the problem, rather than by repetitive inspections. Long-term inspections, as

required by AD 95–25–03, may not provide the degree of safety necessary for the transport airplane fleet. This determination, along with a better understanding of the human factors and other systems effects associated with numerous continual inspections, has led us to consider placing less emphasis on inspections and more emphasis on design improvements. The proposed replacement requirement is consistent with these conditions.

We are proposing to supersede AD 95–25–03. This proposed AD would retain the requirements of the existing AD. This proposed AD would also require accomplishing the actions specified in service bulletins described previously in this proposed AD, which would end the repetitive inspection requirements of the existing AD. This proposed AD would also require an inspection of the flappers and flapper assemblies of the tip tank in each wing, or a review of the airplane maintenance records, to determine the part numbers.

Change to Existing AD

This proposed AD would retain all requirements of AD 95–25–03. Since AD 95–25–03 was issued, the AD format has been revised, and certain paragraphs have been rearranged. As a result, the corresponding paragraph identifiers have changed in this proposed AD, as listed in the following table:

REVISED PARAGRAPH IDENTIFIERS

Requirements in AD 95–25–03	Corresponding requirement in this proposed AD
Paragraph (a)	Paragraph (f).
Paragraph (b)	Paragraph (g).
Paragraph (c)	Paragraph (h).
Paragraph (d)	Paragraph (i).

Costs of Compliance

There are about 1,459 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 882 airplanes of U.S. registry.

The actions that are required by AD 95–25–03 and retained in this proposed AD take about 16 work hours per airplane, at an average labor rate of $65 per work hour. Required parts cost about $708 per airplane. Based on these figures, the estimated cost of the currently required actions is $1,541,736, or $1,748 per airplane.

The new proposed actions would take about 2 work hours per airplane, at an average labor rate of $65 per work hour. Required parts would cost about $327 or $1,262 per airplane (depending on the kit installed). Based on these figures, the estimated cost of the new actions specified in this proposed AD for U.S. operators is $457 or $1,392, per airplane (depending on the kit installed).

Authority for this Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing amendment 39–9447 (60 FR 63617, December 12, 1995) and adding the following new airworthiness directive (AD):

Learjet: Docket No. FAA–2005–20798; Directorate Identifier 2004–NM–257–AD.

Comments Due Date

(a) The Federal Aviation Administration must receive comments on this AD action by May 19, 2005.

Affected ADs

(b) This AD supersedes AD 95–25–03, amendment 39–9447 (60 FR 63617, December 12, 1995).

Applicability

(c) This AD applies to the airplanes in Table 1 of this AD, certificated in any category.

TABLE 1.—APPLICABILITY

Learjet—	Serial Nos.
Model 23 airplanes	23–003 through 23–090 inclusive.
Model 24 airplanes	24–100 through 24–357 inclusive.
Model 25 airplanes	25–002 through 25–373 inclusive.
Model 35 airplanes	35–002 through 35–676 inclusive.
Model 36 airplanes	36–002 through 36–063 inclusive.

Unsafe Condition

(d) This AD was prompted by the results of numerous continual inspections, and the approval of a new, improved flapper and flapper assembly. We are issuing this AD to prevent significant reduction in the lateral control of the airplane due to imbalance of the fuel loads in the wings of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Requirements of AD 95–25–03

Repetitive Inspections, Related Investigative Actions, and Replacement

(f) Within 50 hours time-in-service after December 27, 1995 (the effective date of AD 95–25–03), or prior to the accumulation of 600 hours time-in-service since installation of the flapper valve, whichever occurs later: Perform an inspection to detect deterioration (such as cracks, cuts, breaks, splits, or warpage) of both flappers of the tip tank in each wing, in accordance with either Learjet Service Bulletin SB 23/24/25–28–2, dated

October 6, 1995 (for Model 23, 24, and 25 airplanes), or Learjet Service Bulletin SB 35/36–28–10, dated October 6, 1995 (for Model 35 and 36 airplanes); as applicable. Repeat this inspection thereafter at intervals not to exceed 600 hours time-in-service.

(1) If no deterioration of the flapper valve is detected, prior to further flight, inspect the flapper valve to ensure proper positioning, inspect the condition of the screws that retain the flapper valve to the plate assembly to ensure that the flapper valve is secure, inspect to ensure that the flapper valve completely covers the opening of the tube and is seated against the tube, and inspect the flapper valve to verify that it moves freely; and accomplish the follow-on corrective actions, if any discrepancy is found. These actions shall be accomplished in accordance with the applicable service bulletin.

(2) If any flapper valve is found to be deteriorated, prior to further flight, replace it with a new flapper valve in accordance with the applicable service bulletin.

(g) Except as provided in paragraph (h) of this AD, at the later of the times specified in paragraphs (g)(1) and (g)(2) of this AD: Replace both flappers of the tip tank in each wing with new flappers in accordance with either Learjet Service Bulletin SB 23/24/25–28–2, dated October 6, 1995 (for Model 23, 24, and 25 airplanes), or Learjet Service Bulletin SB 35/36–28–10, dated October 6, 1995 (for Model 35 and 36 airplanes); as applicable.

(1) Within 5 years since date of installation of the flapper valve, or prior to the accumulation of 2,400 total hours time-in-service on the flapper valve, whichever occurs earlier.

(2) Within 50 hours time-in-service after December 27, 1995.

(h) For airplanes on which the age and time-in-service of the flapper valve cannot be determined: Within 50 hours time-in-service after December 27, 1995, replace both flappers of the tip tank in each wing in accordance with either Learjet Service Bulletin SB 23/24/25–28–2, dated October 6, 1995 (for Model 23, 24, and 25 airplanes), or Learjet Service Bulletin SB 35/36–28–10, dated October 6, 1995 (for Model 35 and 36 airplanes); as applicable.

(i) Within 600 hours time-in-service following replacement of any flapper valve in accordance with the requirements of this AD, and thereafter at intervals not to exceed 600 hours time-in-service: Accomplish the requirements of paragraph (f) of this AD.

New Requirements

Inspection and Replacement

(j) Within 600 hours time-in-service since last replacement of any flapper valve in accordance with the requirements of this AD, or within 90 days after the effective date of this AD, whichever occurs later, inspect the flappers and flapper assemblies of the tip tank in each wing to determine their part numbers (P/N). The raised letter and numbers ''S–461'' on the convex side of the flappers can identify these parts. Instead of inspecting the flappers and flapper assemblies, a review of airplane maintenance records is acceptable if the P/N of the flappers and flapper assemblies can be conclusively determined from that review.

(1) If four flappers having P/N 2323006–802 and four flapper assemblies having P/N 2323006–801 are found installed, no further action is required by this paragraph, and the repetitive inspections required by paragraphs (f) and (i) of this AD can be stopped.

(2) If any flapper having P/N 2323006–5 or any flapper assembly having P/N 2323006–6 is found installed, within 600 hours time-in-service since last replacement of any flapper valve in accordance with the requirements of this AD, replace the flapper valve with a new flapper valve or replace the flapper assembly with new or modified and reidentified assembly, as applicable. The replacement must be done in accordance with the Accomplishment Instructions of Learjet Service Bulletin 23/24/25–28–7, Revision 2, dated May 9, 2001 (for Model 23, 24, and 25 airplanes); or Learjet Service Bulletin 35/36–28–14, Revision 2, dated May 9, 2001 (for Model 35 and 36 airplanes); as applicable. Accomplishment of the replacement ends the repetitive inspections required by paragraphs (f) and (i) of this AD.

Parts Installation

(k) As of the effective date of this AD, no person may install a flapper having P/N 2323006–5 or a flapper assembly having P/N 2323006–6, on any airplane.

Alternative Methods of Compliance (AMOCs)

(l)(1) The Manager, Wichita Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) AMOCs approved previously according to AD 95–25–03 are not approved as AMOCs with this AD.

Issued in Renton, Washington, on March 22, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6579 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20836; Directorate Identifier 2005–NM–028–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 727–200 and 727–200F Series Airplanes; 737–200, 737–200C, 737–300, and 737–400 Series Airplanes; 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747SR, and 747SP Series Airplanes; 757–200 and 757–200PF Series Airplanes; and 767–200 and 767–300 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing transport category airplanes. This proposed AD would require replacing any insulation blanket constructed of polyethyleneteraphthalate (PET) film, ORCON Orcofilm® AN–26 (hereafter ''AN–26'') with a new insulation blanket. This proposed AD is prompted by reports of in-flight and ground fires on certain airplanes manufactured with insulation blankets covered with AN–26, which may contribute to the spread of a fire when ignition occurs from sources such as electrical arcing or sparking. We are proposing this AD to ensure that insulation blankets constructed of AN–26 are removed from the fuselage. Such insulation blankets could propagate a fire that is the result of electrical arcing or sparking.

EFFECTIVE DATES: We must receive comments on this proposed AD by June 3, 2005.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building,

400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC. This docket number is FAA–2005–20836; the directorate identifier for this docket is 2005–NM–028–AD.

FOR FURTHER INFORMATION CONTACT: Sue Rosanske, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6448; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–20836; Directorate Identifier 2005–NM–028–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov.*

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Background

Based on research experiments and in-service experience in the mid-1990's, the FAA initiated an investigation into the adequacy of the existing Bunsen burner flammability criteria for thermal/acoustic insulation.

Thermal/acoustic insulation is usually constructed in the form of what is commonly referred to as a ''blanket.'' Insulation blankets are typically composed of:

1. A batting material generically referred to as fiberglass; and
2. A film covering to contain the batting and to resist moisture penetration.

Metallized polyethyleneteraphthalate (MPET) and AN–26 are specific manufacturers' examples of these film covering materials.

Our investigation included large-scale fire testing, as well as tests for ignitability; these tests covered a broad range of materials. By the late 1990's, we had concluded that the Bunsen burner test method required by the existing rules was not adequate. That is, the test method did not discriminate between materials with desirable and undesirable flammability characteristics under realistic in-service conditions. A new certification standard was therefore needed.

In order to develop a new standard, we had to quantify the potential hazard. This involved additional large scale fire testing and tests to correlate the large scale tests with a laboratory scale test method. A necessary element of any new certification test method is that it must screen out materials that would be considered unacceptable for future installation because those materials would create the potential hazard that the new test standard is intended to prevent. The new test standard was adopted into the regulations and includes changes to the operating rules for newly manufactured airplanes. (Reference ''Improved Flammability Standards for Thermal/Acoustic Insulation Materials Used in Transport Category Airplanes'' (68 FR 45046, July 31, 2003).) The operating rule changes become effective in September of this year.

In developing the new test standard, we also developed criteria by which materials already in service could be judged as safe to remain in service. This involved measuring their susceptibility to an ignition source (such as an electrical arc or sparks) and their tendency to propagate a fire once ignited.

Materials that are susceptible to ignition by electrical arc or sparks and that would propagate a fire are considered unsafe. Using these criteria, we have published airworthiness directives (AD) to address a particular material. The following ADs require removal of MPET:

- AD 2000–11–01, amendment 39–11749 (65 FR 34321, May 26, 2000), applicable to certain McDonnell Douglas Model DC–9–80 and MD–90–30 series airplanes, and Model MD–88 airplanes;
- AD 2000–11–02, amendment 39–11750 (65 FR 34341, May 26, 2000), applicable to certain McDonnell Douglas Model DC–10–10F, DC–10–15, DC–10–30, DC–10–30F, and DC–10–40 series airplanes, and Model MD–11 and –11F series airplanes; and
- AD 2003–08–10, amendment 39–13122 (68 FR 19326, April 21, 2003), applicable to certain Aerospatiale Model ATR42–500 series airplanes, and Model ATR72–102, –202, –212, and –212A series airplanes.

At that time, MPET was the only material identified that had demonstrated the propensity to propagate a fire from an ignition source such as electrical arcing and sparks. We indicated then that we would take the same action, should any other materials be identified.

Even though we did extensive testing on a variety of materials, we could not identify and test every material produced, as the permutations of material combinations were too extensive to accomplish such testing in a prudent time frame. As a result, we were not aware of AN–26 as a unique insulation material until a review of subsequent service data indicated that this material might not have adequate flammability resistance. We conducted a review of the service history and subjected AN–26 material to a variety of tests. In November 2003, we established that AN–26 could propagate a fire from an electrical arc. As part of our review, we also worked with industry to explore the potential ramifications of aging and contamination on material performance. Opinions differ on the significance of these effects. After careful consideration of this complex issue, we have concluded that the flammability characteristics of AN–26 are more a factor of fundamental material properties than a factor of aging or contamination.

Discussion

We have received reports of in-flight and ground fires on certain Boeing Model 737, 747, 757, and 767 series airplanes that were manufactured with insulation material covered with AN–26. Investigation has revealed that AN–26 covered insulation blankets may contribute to the propagation of a fire. The results of extensive flammability testing, conducted by the airplane manufacturer and the FAA, revealed that even though AN–26 met the certification standards in place at the time of original certification in 1981, this type of insulation material will propagate a fire when subjected to electrical arcing and sparks. The FAA used the insulation blankets' response to electrical arcing and spark testing as the basis for identifying the unsafe condition with MPET and has determined that these same safety criteria are applicable to AN–26. In addition, research data have shown that contamination, such as dust, lint, grease, corrosion-inhibiting compounds, etc., can increase susceptibility to ignition and flame propagation.

Insulation blankets constructed of AN–26 installed throughout the fuselage, if not corrected, could propagate a fire that is the result of electrical arcing or sparking.

We have determined that Boeing's preferred supplier of insulation blankets produced blankets constructed of AN–26 between July 1981 and December 1988. Therefore, it is likely that these blankets are installed on almost all Boeing airplanes produced during that period, as listed in the following table:

BOEING AIRPLANE MODELS PRODUCED BETWEEN JULY 1981 AND DECEMBER 1988

Model
727–200 and 727–200F series airplanes.
737–200, 737–200C, 737–300, and 737–400 series airplanes.
747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747SR, and 747SP series airplanes.
757–200 and 757–200PF series airplanes.
767–200 and 767–300 series airplanes.

Eleven Boeing Model 747–400 series airplanes were built in 1988 that are also likely to have AN–26 installed. However, the type certificate was not amended to include these airplanes until 1989. Therefore, these airplanes did not have an original Airworthiness Certificate or original Export Certificate of Airworthiness before January 1989.

The other affected airplanes were issued an original Airworthiness Certificate or original Export Certificate of Airworthiness between July 1981 and December 1988.

Unlike MPET, which is easily distinguishable from other types of insulation, AN–26 is similar in appearance to other types of insulation that are acceptable. At this time, there is no documented method for distinguishing between AN–26 and these other types of insulation.

Other Relevant Service Information

The FAA issued Flight Standards Information Bulletin for Airworthiness (FSAW) 00–09, ''Special Emphasis Inspection on Contamination of Thermal/Acoustic Insulation,'' effective September 28, 2000, to ensure that operators have procedures defined in their approved maintenance programs for the inspection for contamination and corrective action. The airplane manufacturer also has recently revised its service letters alerting operators to methods for preventing and removing contamination.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD to require removing all insulation blankets within the pressurized areas of the affected airplanes and installing a new insulation blanket meeting the requirements of Section 25.856(a) of Title 14 of the Code of Federal Regulations (CFR) (14 CFR 25.856(a)). The proposed AD would also allow operators to develop methods for distinguishing between insulation blankets constructed of AN–26 and other materials. If the FAA's Seattle Aircraft Certification Office (ACO) approves such a method, operators would not be required to remove blankets they determine are not constructed of AN–26.

As of the effective date of this AD, paragraph (h)(1) of this proposed AD would prohibit installation of AN–26 insulation blankets. 14 CFR 91.613(b)(1), 121.312(e)(1), 125.113(c)(1), and 135.170(c)(1) already prohibit installation of this type of insulation blanket after September 2, 2005. Some international civil aviation authorities have not adopted similar regulations. Therefore, this prohibition is included in this proposed AD to inform them of the need to prevent such installation.

As of six months after the effective date of this AD, paragraph (h)(2) of this proposed AD would also prohibit re-installation of any insulation blanket that has been removed for any reason unless the insulation blanket either has been determined not to be constructed of AN–26, or has been modified to comply with 14 CFR 25.856(a). For example, during normal maintenance, operators frequently remove insulation to perform inspections and other maintenance actions on systems and structure located behind the insulation blanket. Under this proposal, when insulation is removed for this or any other purpose, it must either be determined not to be constructed of AN–26, or replaced with insulation meeting 14 CFR 25.856(a). This paragraph would require operators to correct the identified unsafe condition when they have an opportunity to do so.

The airplane manufacturer has been developing a proposed alternative method of compliance (AMOC) that involves modification of existing AN–26 insulation blankets. This method of compliance may significantly reduce the number of required replacement blankets and labor costs. The manufacturer has indicated that the service information for this method will be available in April 2006. We anticipate that the manufacturer's approach is similar to AMOCs approved for ADs 2000–11–01 and 2000–11–02. The criteria that will be used to evaluate proposed modifications of existing AN–26 insulation blankets (in-place) can be obtained from the Manager, Seattle ACO, upon request.

Costs of Compliance

There are about 1,613 airplanes of the affected design in the worldwide fleet. The following table provides the estimated costs for U.S. operators to comply with the proposed replacement, if necessary. The average labor rate is $65 per hour.

ESTIMATED COSTS FOR REPLACEMENT

Model	Work hours	Parts per airplane	Number of U.S.-registered airplanes	U.S. fleet cost	Fleet cost per year over 6 years
727–200 series airplanes	4,623	$42,504	29	$9,946,971	$1,657,829
727–200F and 727–200 series airplanes that have been modified to a freighter configuration	1,618	31,878	41	5,618,968	936,495
737–200, 737-200C, 737–300, and 737–400 series airplanes	4,238	38,962	452	142,123,264	23,687,211
747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–300, 747–400, 747SR, and 747SP series airplanes	16,951	155,848	19	23,895,597	3,982,600
747–200F and 747–200B and 747–300 series airplanes that have been modified to a freighter configuration	5,933	116,886	16	8,040,496	1,340,083
757–200 series airplanes	6,445	59,258	116	55,469,228	9,244,871
757–200PF and 757–200 series airplanes that have been modified to a freighter configuration	2,256	44,443	15	2,866,245	477,708
767–200 and 767–300 series airplanes	9,246	85,008	114	78,203,772	13,033,962
767–200 and 767–300 series airplanes that have been modified to a freighter configuration	3,236	63,756	29	7,948,784	1,324,797

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation.'' To achieve that principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the Act.

The proposed AD would require operators of certain Boeing transport category airplanes, including about 20 small business operators, to retrofit their airplanes. We believe that this proposed AD would have a significant impact on a substantial number of small entities. Accordingly, an initial regulatory flexibility analysis, as required by the RFA, is included as part of the Initial Regulatory Analysis that is in the docket.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Would have a significant economic impact on a substantial number of small entities, and as a result, an initial regulatory flexibility analysis has been conducted.

See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2005–20836; Directorate Identifier 2005–NM–028–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by June 3, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing airplanes, certificated in any category, specified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Boeing airplanes listed in Table 1 of this AD, having an original Airworthiness Certificate or original Export Certificate of Airworthiness issued between July 1981 and December 1988 inclusive.

TABLE 1.—APPLICABILITY OF CERTAIN AIRPLANES

Model
727–200 and 727–200F series airplanes.
737–200, 737–200C, 737–300, and 737–400 series airplanes.

TABLE 1.—APPLICABILITY OF CERTAIN AIRPLANES—Continued

Model
747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747SR, and 747SP series airplanes.
757–200 and 757–200PF series airplanes.
767–200 and 767–300 series airplanes.

(2) Boeing Model 747–400 series airplanes, serial numbers 23719, 23720, 23814, 23816, 23817, 23818, 23819, 23820, 23999, 24061, and 24062.

Unsafe Condition

(d) This AD was prompted by reports of in-flight and ground fires on certain airplanes manufactured with insulation blankets covered with a specific polyethyleneteraphthalate (PET), ORCON Orcofilm® AN–26 (all variants, including AN–26, AN–26A, and AN–26B), hereafter referred to as ''AN–26'', which may contribute to the spread of a fire when ignition occurs from sources such as electrical arcing or sparking. We are issuing this AD to ensure that insulation blankets constructed of AN–26 are removed from the fuselage. Such insulation blankets could propagate a fire that is the result of electrical arcing or sparking.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Replacement

(f) Except as provided in paragraph (g) of this AD, within 72 months after the effective date of this AD, remove all insulation blankets from the pressurized areas of the fuselage and install a new insulation blanket using applicable maintenance manual procedures. The new insulation blankets must comply with 14 Code of Federal Regulations (CFR) 25.856(a). The areas where the affected insulation blankets are installed include, but are not limited to, the following areas:

(1) Crown area of the airplane;

(2) Areas behind flight deck panels and circuit breaker panels;

(3) Areas behind sidewalls, lavatories, closets, and galleys;

(4) Cargo compartment areas;

(5) Air ducting;

(6) Waste and water tubing; and

(7) Areas attached to the underside of floor panels.

Exception

(g) The actions described in paragraph (f) are not required for any insulation blanket that is determined not to be constructed of AN–26, using a method approved by the Manager, Seattle Aircraft Certification Office (ACO).

Note 1: Insulation material that is part-marked with a date of manufacture indicating that it was manufactured before July 1981 or after December 1988 is not constructed of AN–26.

Parts Installation

(h)(1) As of the effective date of this AD, no person may install any insulation blanket constructed of AN–26 on any airplane unless it has been modified to comply with 14 CFR 25.856(a), in accordance with a method approved by the Manager, Seattle ACO.

(2) As of six months after the effective date of this AD, if any insulation blanket is removed for any reason, it may not be re-installed unless:

(i) It has been determined not to be constructed of AN–26 using a method approved by the Manager, Seattle ACO; or

(ii) It has been modified to comply with 14 CFR 25.856(a), in accordance with a method approved by the Manager, Seattle ACO.

Alternative Methods of Compliance (AMOCs)

(i) The Manager, Seattle ACO, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Issued in Renton, Washington, on March 29, 2005.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–6674 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 256

[Docket No. OST–2005–20826]

RIN 2105–AD44

Display of Joint Operations in Carrier-Owned Computer Reservations Systems Regulations

AGENCY: Office of the Secretary, Department of Transportation.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department's rules currently prohibit each airline that owns, controls, or operates a computer reservations system (''CRS'' or ''system'') from denying system access to two or more carriers whose flights share a single designator code and discriminating against any carrier because the carrier uses the same designator code as another carrier. The Department recently determined that its comprehensive rules governing CRS operations should be terminated because they are no longer necessary. The Department is initiating this proceeding to consider whether it should also terminate the rules governing the treatment of code-sharing airlines by airlines that own, control, or operate a system.

DATES: Comments must be submitted on or before May 4, 2005. Reply comments must be submitted on or before May 19, 2005.

ADDRESSES: You may submit comments identified by DOT DMS Docket Number OST–2005–20826 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, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number or Regulatory Identification Number (RIN) for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to *http://dms.dot.gov.* including any personal information provided. Please see the Privacy Act heading under Regulatory Notices.

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Due to security procedures in effect since October 2001 on mail deliveries, mail received through the Postal Service may be subject to delays. Commenters should consider using an express mail firm to ensure the timely filing of any comments not submitted electronically or by hand. Late filed comments will be considered to the extent possible.

FOR FURTHER INFORMATION CONTACT: Thomas Ray, Office of the General Counsel, 400 Seventh St. SW., Washington, DC 20590, (202) 366–4731.

Electronic Access: You can view and download this document by going to the

website of the Department's Docket Management System (*http://dms.dot.gov/*). On that page, click on ''search.'' On the next page, type in the last five digits of the docket number shown on the first page of this document. Then click on ''search.'' An electronic copy of this document also may be downloaded by using a computer, modem, and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the Office of the Federal Register's home page at: *http://www.nara.gov/fedreg* and the Government Printing Office's database at: *http://www.access.gpo.gov/nara/index.html.*

SUPPLEMENTARY INFORMATION:

A. Introduction

We have had two sets of rules governing airline computer reservations systems (''CRSs'' or ''systems'') (although the systems now are also commonly called global distribution systems, or GDSs, we will refer to them as CRSs for purposes of this rulemaking). One set of rules, 14 CFR Part 255, established comprehensive requirements governing the systems' relationships with airlines and the systems' travel agency customers. These rules covered any system that was owned or marketed by an airline or airline affiliate. 14 CFR 255.2. The other set, 14 CFR Part 256, concerned the systems' treatment of airlines that share the same two-symbol designator code, the code used by the systems and other sources of airline information to identify the airline offering the seats being sold (the codes for America West and U.S. Airways, for example, are HP and US). This set of rules prohibits the airlines that own, control, or operate each system from denying access to the system to two or more airlines whose flights share a single designator code and from discriminating against any airline because that airline uses the same designator code as another airline.

The federal agency formerly responsible for the economic regulation of the airline industry, the Civil Aeronautics Board (''the Board''), adopted both the comprehensive rules (Part 255) and the rules governing the treatment of airlines that code-share (Part 256) in the same year, 1984, on the basis of a common economic and competitive analysis. 49 FR 12675 (March 30, 1984) (Part 256); 49 FR 32540 (August 15, 1984) (Part 255). The Board adopted the rules barring systems from discriminating against code-sharing airlines in an expedited proceeding to keep Apollo, the system then controlled by United, from carrying out its plan to deny access to any airline that used another airline's code.

Our comprehensive CRS rules included a sunset date to ensure that we would reexamine whether the rules remained necessary and were effective. 57 FR 43780, 43829–43830 (September 22, 1992). As a result of our most recent reexamination of those rules, completed in 2003, we determined that the CRS rules had become unnecessary. We allowed most of the rules to expire on January 31, 2004, their sunset date, and terminated the remaining rules on July 31, 2004. 69 FR 976, 977 (January 7, 2004).

The rules governing the systems' treatment of code-sharing airlines, Part 256, have not had a sunset date. However, because the Board adopted those rules and the comprehensive rules governing CRS operations, Part 255, on the basis of the same factual analysis and competitive rationale, our findings that industry changes have made the comprehensive rules unnecessary requires us to reexamine whether the rules on the treatment of code-sharing airlines are still necessary. After considering that question, we are proposing to terminate these rules as well.

We ask the parties to submit comments that thoroughly discuss the factual and policy issues raised by our proposal to eliminate the rules and to provide detailed information on the proposal and on the amount of its likely benefits and costs.

Comments will be due thirty days after publication of this notice, and reply comments will be due fifteen days thereafter. After considering the comments, we will issue a final rule.

B. Background

As we have explained in our other CRS rulemakings, the systems efficiently provide travel agents with comprehensive information and booking capabilities on airlines and other travel suppliers, such as hotel and rental car companies. *See, e.g.*, 67 FR 69366, 69370 (November 15, 2002). Each system provides information and booking capabilities on the airlines that ''participate'' in the system, that is, agree to make their services saleable through the system and to pay the fees required for participation. A CRS presents displays that integrate the services of all participating airlines. The displays show schedules and fares and whether specific flights and fares are available. A travel agent can compare the services offered by different airlines and determine which would best meet a customer's needs. The agent can reserve seats and issue tickets through the system. 67 FR 69370.

The basis for our past adoption of CRS regulations was the systems' important role in the distribution of airline tickets (and their ownership by airlines). Airlines obtained a large majority of their bookings from travel agents, and travel agents relied on a system to determine what services and fares were available for their customers and to make bookings. Each travel agency office typically relied entirely or almost entirely on one system to carry out these functions. If an airline did not participate in one of the systems, the travel agents using that system could not readily obtain information and make bookings on that airline, which would therefore lose a significant amount of business. As a result, almost every airline had to participate in each of the systems, so airlines had no bargaining leverage with the systems. 67 FR 69375–69382; 69 FR 980.

With one small exception, each of the systems operating in the United States was developed and owned by one airline, which had the ability and incentive to operate its system in ways that would prejudice airline competition. 67 FR 69367, 69375–69376.

Soon after the systems were first offered to travel agencies, the systems' impact on airline competition became a matter of concern. For example, an airline owning a system would bias the system's display of airline services so that flights operated by rival airlines were difficult to find, even when a competitor's flights met the travel agency customer's needs better than did the owner airline's flights. The Board therefore began a rulemaking to determine whether it should adopt regulations governing the systems' role in airline distribution. The Board first issued an advance notice of proposed rulemaking. 48 FR 41171 (September 14, 1983). After considering the comments responding to that notice, the Board decided that it should propose comprehensive rules governing CRS operations, and submitted a draft notice of proposed rulemaking to the Office of Management and Budget for review. While the Board's proposal was under review at OMB, several smaller airlines complained to the Board that Apollo, the system controlled by United, had announced that it would no longer display services operated by one airline under another airline's code. They alleged that Apollo's change in policy would substantially injure their marketing efforts. 49 FR 9430–9431.

As a result of the competitive harm that could result from Apollo's proposed policy change, the Board proposed and, after reviewing the comments, adopted as Part 256 the rules that prohibit airlines that own, control, or operate a system from discriminating against an airline because the airline offered its services under another airline's code. As noted, the Board relied on the industry and competitive analysis developed in its rulemaking on the comprehensive CRS regulations. 49 FR 9430; 49 FR 12675.

Soon after the Board proposed the rules governing the treatment of code-sharing airlines, the Board issued its notice of proposed rulemaking on the adoption of comprehensive CRS rules. 49 FR 11644 (March 27, 1984). The Board later adopted those proposed rules, with some revisions, as Part 255. Among other things, those rules barred systems from biasing their primary displays and from charging discriminatory booking fees. 49 FR 32540 (August 15, 1984).

The Board adopted both the comprehensive rules and the rules governing the treatment of code-sharing airlines under its authority under section 411 of the Federal Aviation Act, then 49 U.S.C. 1381, later recodified as 49 U.S.C. 41712, to prohibit unfair and deceptive practices and unfair methods of competition (we will refer to the section under its traditional name, section 411).

The Court of Appeals affirmed the Board's adoption of Parts 255 and 256. *United Air Lines* v. *CAB,* 766 F.2d 1107 (7th Cir. 1985).

C. Basis for Proposed Termination of Rules

The factual basis for our recent decision to terminate all of the comprehensive CRS rules suggests that we should also terminate the rule governing the treatment of code-sharing airlines. As noted above, we concluded that the on-going developments in airline distribution and the CRS business in recent years had substantially eroded the basis for CRS regulations and made the rules unnecessary. The two major developments were the increasing importance of the Internet in airline distribution and the divestiture by U.S. airlines of all CRS ownership interests.

The Internet's growing use by consumers and travel agents has created alternative channels for airline bookings and the dissemination of information on schedules and fares. Airlines have been encouraging many consumers to book their travel directly through an airline website rather than through a travel agent. 67 FR 69373–69374. Travel agents are increasingly checking Internet sites to see whether better fares and flights are available than those displayed in the system they use. 69 FR 980. Airlines also began offering special discounts, commonly known as webfares, to consumers who booked tickets through the airline's own website, and they have used their control over access to their webfares to obtain better terms for CRS participation. 67 FR 69373; 69 FR 979–980. Because these developments are establishing market discipline for the terms and quality of the systems' services offered airlines, we concluded that the comprehensive rules had become unnecessary. 69 FR 984.

Secondly, all of the U.S. airlines that held an ownership interest in a system have divested those interests. The Board had adopted the original rules because each significant system was then controlled by an airline, and the airline owner had the incentive and the ability to use its system to distort airline competition. 67 FR 69373. Now, in contrast, none of the systems is owned or controlled by any U.S. airline or airline affiliate, and only Amadeus has any airline owners. 69 FR 979. In our final decision in our reexamination of the comprehensive rules, we found that the systems should have no incentive to operate in ways designed to distort airline competition, because none of them are owned or controlled by U.S. airlines or airline affiliates. 69 FR 990–991. While Amadeus is owned in part by three European airlines, it also has substantial public ownership, its airline owners should have no motive to undermine airline competition within the United States, and its U.S. market share is less than ten percent. 69 FR 986. We recognized that a system might be willing to take steps to prejudice airline competition if compensated for doing so by an airline, for example, by selling display bias, but there is no certainty that such conduct will occur or, if it did, that it would substantially harm consumers. We accordingly concluded that the possibility of display bias did not warrant the continuation of industry-wide rules, especially in light of the systems' declining market power. 69 FR 994. While we could not predict precisely how systems will respond to the industry's deregulation, we expected that consumers and participants in the airline distribution business will benefit from the rules' termination. 69 FR 978. We stated, moreover, that we intend to monitor the effects of the CRS industry's deregulation and that we will take appropriate action if a system engages in conduct that would violate section 411. 69 FR 978, 986.

The rules on the treatment of code-sharing airlines, unlike the comprehensive rules, have never contained a sunset date that would cause us to reconsider whether the rules remained necessary. However, the findings on which we based our decision to terminate the comprehensive rules suggest that we should also terminate the Part 256 rules governing the systems' treatment of airlines that share codes. The Board adopted those rules largely to protect airline competition from potential efforts by the airlines that controlled the systems to create displays that discriminated against competing airlines that shared codes. As noted, the Board began the rulemaking due to United's plan to eliminate code-sharing airlines from Apollo's displays. The complete divestiture of their CRS ownership interests by the U.S. airlines that had controlled the systems has eliminated the primary basis for the Board's original adoption of these rules.

Furthermore, as we found in our reexamination of the comprehensive rules, because the Internet has created alternative sources of information and booking capabilities for airlines and travel agents, market forces are beginning to discipline the systems' prices and terms for airline participation. If an airline believes that a system's display of its services is unreasonable or unfair, the airline should have some ability at least to lower its level of participation. The airlines' ability to reject unacceptable terms for CRS participation should continue to grow. Furthermore, travel agencies have an interest in obtaining full, accurate, and useful information on airline services, and they have the ability to choose between systems. 69 FR 1005. These factors should encourage the systems to display information on airline services in a manner that will meet the needs of travel agents. Eliminating the rules may give a system additional flexibility to tailor its displays to meet travel agent and consumer demands and may result in more useful displays. We therefore have tentatively determined that the rules governing the systems' treatment of code-sharing airlines are no longer necessary and should be ended.

In addition, as noted above, these rules cover only airlines that own, control, or operate a system, not the systems themselves, and Amadeus' airline owners are therefore the only firms required to comply with the rules. Applying the rules only to Amadeus' owner airlines appears illogical and

potentially inequitable, when Amadeus has the smallest market share in the United States and has airline owners that should have little interest in distorting competition within this country.

We do not expect systems to adopt the practices now barred by Part 256, denials of system access to airlines that code-share and discrimination against such airlines. Code-sharing has become a widespread practice and, among other things, has formed the basis for the development of international alliances between U.S. and foreign airlines, such as the Star Alliance, oneworld, and SkyTeam. We have found that code-sharing can provide significant consumer benefits. 67 FR 69396–69397. As a result, we assume that travel agents will demand that systems provide displays that show airline services marketed under code-share arrangements. Systems may also choose to offer displays that limit the display of code-share services, as some have being doing. 69 FR 1005. Any decision by a system to change or limit the display of code-sharing services, however, should reflect the system's response to market demands, not a decision to distort airline competition by creating displays that discriminate against all code-share services. The systems' vigorous competition for travel agency customers should cause them to provide displays that satisfy travel agent preferences.

Regulatory Process Matters

Regulatory Assessment and Unfunded Mandates Reform Act Assessment

1. Unfunded Mandates Reform Act Assessment

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531–1538, requires Federal agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal or private mandate likely to result in the expenditures by State, local, or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually.

The proposed rule would not result in expenditures by the private sector or by State, local, or tribal governments because we propose to eliminate the rules. In addition, no such government operates a system or airline that is or has been subject to our regulations.

2. Regulatory Assessment

Executive Order 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993), defines a significant regulatory action as one that is likely to result in a rule that may have an annual effect on the economy of $100 million or more, or that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. Regulatory actions are also considered significant if they are likely to create a serious inconsistency or interfere with the actions taken or planned by another agency, if they establish novel policy issues, or if they materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of the recipients of such programs.

The Department's Regulatory Policies and Procedures (44 FR 11034, February 26, 1979) outline similar definitions and requirements with the goal of simplifying and improving the quality of the Department's regulatory process. They state that a rule will be significant if it is likely to generate much public interest.

This proposed regulation would be a significant regulatory action under the Executive Order, since CRS rules have long been a subject of public controversy. The Department's tentative assessment of the likely costs and benefits for this proposal is set forth below. This proposal has been reviewed by the Office of Management and Budget under the Executive Order.

This preliminary economic analysis seeks to assess the potential economic and competitive consequences of our proposed rules on computer reservations systems, airlines, and travel agencies and to evaluate the benefits to the industry and the traveling public. We tentatively find, as discussed below, that the elimination of the rules barring airline-owned systems from discriminating against airlines that code-share should not harm airlines, travel agencies, or consumers, or have a material effect on firms in the airline or airline distribution businesses or on consumers.

The Civil Aeronautics Board originally adopted the rules barring discrimination against airlines that shared the same code when each of the systems was owned by an airline and when each airline owner had the ability and the incentive to use its system to prejudice the competitive position of rival airlines. The systems' conduct at that time justified the Board's action. The Board proposed these rules as a result of United's plan to eliminate code-share services from the displays offered by Apollo, the system then owned by United, a plan that would harm several of United's competitors. Airlines then relied on travel agents for the large majority of their revenues, and travel agents relied on the systems to determine what airline services were available, to make bookings, and to issue tickets.

The industry conditions that caused the Board to adopt the rules barring discrimination against code-sharing airlines no longer exist. No system is currently owned by a U.S. airline or airline affiliate. No system should have an incentive to discriminate against code-share services in order to distort airline competition. The share of airline revenues produced by travel agents has been falling. Many travel agents now use multiple sources of information to investigate options for their customers and no longer rely almost entirely on one of the systems to determine what airline flights and fares are available. As a result, airlines have been obtaining some bargaining leverage against the systems, and a system's failure to display airline services in an unbiased manner will no longer deny travel agents the ability to electronically obtain complete information on airline service options. The systems' competition for travel agency customers will give the systems an incentive to provide displays that meet the travel agents' needs for more accurate, complete, and useful information. The airlines' growing bargaining leverage with the systems should encourage systems to provide access to their services on terms which are consistent with airline marketing strategies.

The rules barring discrimination against code-sharing airlines may limit the ability of Amadeus, the only system now subject to the rules, to respond to travel agency preferences to create displays less cluttered with code-shares, and may keep travel agents from obtaining displays that meet their needs. Even if the rules impose no burden on Amadeus, however, there is no apparent justification for maintaining them.

For the same reasons on which we based our decision to terminate the comprehensive rules, our elimination of the rules barring discrimination against airlines that share codes should have no significant economic impact on airlines, travel agencies, or consumers. First, because the existing rule covers only airlines that own, operate, or control a system, only the smallest of the four systems operating in the United States—Amadeus—is subject to the rule. Secondly, no system should have an incentive to distort competition in the U.S. airline industry, because no system is owned or controlled by a U.S. airline or airline affiliate. Amadeus' principal owners are three European airlines. In addition, public shareholders own a

substantial amount of Amadeus' stock, and Amadeus' management must operate the business for the benefit of all of its shareholders, not just its airline shareholders. Code-sharing is a much more widespread practice now than it was when the Board adopted these rules, and no system is likely to block the display of services operated under code-share arrangements. For these reasons, we do not expect Amadeus or any other system to begin discriminating against airlines that share codes.

We request interested persons to provide us with detailed information about the possible consequences of this proposal, including its benefits, costs, and economic and competitive impacts.

Initial Regulatory Flexibility Statement

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601 *et seq.*, was enacted by Congress to ensure that small entities are not unnecessarily and disproportionately burdened by government regulations. The act requires agencies to review proposed regulations that may have a significant economic impact on a substantial number of small entities. For purposes of this rule, small entities include smaller U.S. and foreign airlines and smaller travel agencies. This notice of proposed rulemaking sets forth the reasons for our rule proposal and its objectives and legal basis.

Our proposed termination of the existing rules would not have a significant economic impact on a substantial number of small business entities. The rules impose obligations only on airlines that own, control, or operate a system, and none of the airlines that now own, or have owned, a system has been a small entity. The rules may indirectly affect smaller airlines and travel agencies, which are small entities, because they may affect how code-share services are displayed in the systems used by travel agents. Eliminating the rules should have no significant impact on smaller airlines or travel agencies.

First, the rules currently govern only Amadeus, the system with the smallest market share in the United States, because the other three systems have no airline owners. Secondly, the rules prohibit a system from discriminating against code-share services offered by airlines. The Board adopted the rules because one of the airline-owned systems was then planning to stop displaying flights operated by any airline if they were sold under another airline's code, a change that would undermine the marketing efforts of a major competitor of the system's airline owner. 49 FR 9435. It seems unlikely that any system would adopt a similar policy on the display of code-share services, because all major U.S. and European airlines have code-share operations. Furthermore, travel agencies have a substantial degree of bargaining leverage with the systems, as shown by the record in our last reexamination of the comprehensive rules, 69 FR 981–983, which should cause the systems to offer displays that meet the needs of travel agents. Airlines are obtaining more bargaining power with the systems, which should also keep systems from offering displays that would significantly interfere with airline marketing programs. Because code-sharing is now a widespread practice, a system's refusal to display services operated under code-share arrangements would probably undermine that system's ability to obtain travel agency customers, and it would displease its major airline customers. Finally, the Internet has provided new sources of airline information for travel agents to use, so travel agents no longer rely so greatly on the systems for airline information. Furthermore, as discussed, there no longer appears to be any rationale for maintaining these rules.

The Regulatory Flexibility Act requires us to publish an initial regulatory flexibility analysis that considers such matters as the impact of a proposed rule on small entities if the rule would have ''a significant economic impact on a substantial number of small entities.'' 5 U.S.C. 605(b). For the reasons stated above, I certify that the elimination of our rule on the treatment of code-share operations which is proposed by this notice would not have a significant economic impact on a substantial number of small entities. No initial regulatory flexibility analysis is therefore required for this action.

Our proposed rule contains no direct reporting, record-keeping, or other compliance requirements that would affect small entities. There are no other federal rules that duplicate, overlap, or conflict with our proposed rules.

Interested persons may address our tentative conclusions under the Regulatory Flexibility Act in their comments submitted in response to this notice of proposed rulemaking.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, we want to assist small entities in understanding the proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult Thomas Ray at (202) 366–4731.

Paperwork Reduction Act

The proposed rule contains no collection-of-information requirements subject to the Paperwork Reduction Act, Pub. L. 96–511, 44 U.S.C. Chapter 35. *See* 57 FR at 43834.

Federalism Implications

Our proposal would have no 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. Therefore, in accordance with Executive Order 13132, dated August 4, 1999, we have determined that it does not present sufficient federalism implications to warrant consultations with State and local governments.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Government Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Heath Risks and Safety Risks. This rule does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Consultation and Coordination With Tribal Governments.

This proposed rule will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Therefore, it is exempt from the consultation requirements of Executive Order 13175. If tribal implications are identified during the comment period, we will undertake appropriate consultations with the affected Indian tribal officials.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that this is not classified as a ''significant energy action'' under that order because it is a ''significant regulatory action'' under Executive Order 12866 and it would not have a significant adverse effect on the supply, distribution, or use of energy.

Environment

The proposed rule would have no significant impact on the environment.

PART 256—[REMOVED AND RESERVED]

1. Accordingly the Department proposes to remove 14 CFR art 256 and reserve art 256.

Issued in Washington, DC, on March 27, 2005.

Norman Y. Mineta,

Secretary of Transportation.

[FR Doc. 05–6650 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2001N–0548] (formerly Docket No. 01N–0548)

Food Labeling; Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish; Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 3, 2005, the comment period for a proposed rule published in the **Federal Register** of March 20, 2002. In that document, FDA proposed to amend its voluntary nutrition labeling regulations by updating the names and nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States. Since publication of the proposed rule, the agency has received new data in comments that it intends to use to further update the nutrition labeling values. The agency also intends to use additional data from the U.S. Department of Agriculture (USDA) for certain nutrients in raw produce. Those data became available after the close of the comment period. FDA is reopening the comment period to allow all interested parties the opportunity to review its tentative nutrition labeling values based upon data FDA received within and after the comment period, and to comment on the additional nutrient data for some of the 20 most frequently consumed raw fruits, vegetables, and fish. FDA will evaluate any new data submissions during this reopened comment period and will consider use of those data in a final rule.

DATES: Submit written or electronic comments by June 3, 2005.

ADDRESSES: You may submit comments, identified by Docket No. 2001N–0548, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2001N–0548 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/hand delivery/courier [for paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number or regulatory information number for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the relevant docket number, 01N–0548, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary Brandt, Center for Food Safety and Applied Nutrition (HFS–840), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1788.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 20, 2002 (67 FR 12918) (the proposed rule), FDA proposed to amend its voluntary nutrition labeling regulations by updating the names and nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States based upon new data submitted or made available to the agency. In that document, we requested comments on the proposal by June 3, 2002. In the **Federal Register** of June 6, 2002 (67 FR 38913), we corrected the proposed rule that published with an incorrect docket number (i.e., Docket No. 01N–0458) and provided additional time to submit comments, until August 20, 2002.

In a comment to the proposed rule, USDA submitted nutrient data from its 2001–2002 nationwide sampling of fruits and vegetables (see *http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/080602/01n-0548-c000006-vol1.pdf*). USDA provided data for 16 of the 20 most frequently consumed fruits: Apple, avocado (California), banana, cantaloupe, grapefruit, honeydew melon, kiwifruit, nectarine, orange, peach, pear, pineapple, plums, strawberries, sweet cherries, and watermelon; and 12 of the top 20 vegetables: Bell pepper, broccoli, carrot, celery, cucumber, iceberg lettuce, leaf lettuce, onion, potato, radish, sweet potato, and tomato. At the time USDA submitted the comment, the data results for vitamin C, sodium, and potassium were not yet available, and the analysis of carotenoids for carrots, sweet potatoes, cucumbers, onions, and sweet peppers had not been completed. In June and July of 2003, after the close of the comment period, USDA provided sodium, potassium, and some carotenoid values that it did not submit earlier (Ref. 1). It also submitted vitamin C values for pineapple.

In other comments to the proposed rule, the Citrus Research Board and Food Research, Inc., provided nutrient data from 1998 for oranges, grapefruit, tangerines (Mandarin oranges), and lemons (see *http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/081602/8001f4e1.pdf*, *http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/082902/01N-0548-cr00001-01-vol1.htm*, and *http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/082902/8002574a.doc*).

Two comments recommended that Chinook salmon be included with the revised species of fish (see *http://*

www.fda.gov/ohrms/dockets/dailys/02/Aug02/082102/800222f0.pdf and *http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/082202/8002239d.pdf*). One comment noted that according to nutrient data from the USDA Nutrient Database for Standard Reference, the nutrient profile of Chinook salmon is most similar to the proposed category and values for Atlantic, Coho, and Sockeye salmon (Ref. 2).

Based upon data received during the comment period and USDA data received after the comment period, we have calculated updated nutrition labeling values for some of the 20 most frequently consumed raw fruits, vegetables, and fish. FDA is now reopening the comment period to allow the raw produce and fish industries and other interested parties the opportunity to review and react to updated nutrition labeling values based upon data FDA received within and after the comment period. Reopening the comment period may also provide an impetus for completion of additional nutrient analyses. We will evaluate any new data submissions received during this reopened comment period and will consider use of those data in a final rule.

II. Updating the Nutrition Labeling Values

We are reopening the comment period to revise the nutrition labeling values of the 20 most frequently consumed raw fruits, vegetables, and fish, which are included in appendices C and D to part 101. The proposed appendices C and D that we are publishing in this document include the updated values described in tables 1 and 2 of this document. As noted in the proposed rule, the agency believes that the values in proposed appendices C and D could be used on an interim basis prior to completion of the rulemaking, provided that the nutrition information is presented in a manner consistent with this document. However, firms should be aware that values included in a final rule may differ and would need to be changed.

Reference 3 provides complete documentation of the derivation of each nutrition labeling value for the 20 most frequently consumed raw fruits, vegetables, and fish.

A. FDA Analysis of the Data

1. Outlier Screening

Originally, for the proposed rule, we completed outlier screening of the data using the Grubbs outlier screening method to determine influential observations in the distributions of data for each nutrient and food. However, based upon comments received in response to the proposed rule and discussion of outliers in the statistical literature, we have determined not to conduct Grubbs outlier screening on the nutrient data for raw produce and fish.

In developing the nutrient values in the proposed rule, we took a conservative approach to outliers and deleted those data points identified through outlier screening.

There were several comments in response to the proposed rule that addressed outlier screening. Comments questioned the validity of using Grubbs outlier screening for fruits and recommended the use of visual scattergrams and bar graphs. Another comment questioned the removal of outliers.

The National Institute of Standards and Technology (NIST) *e-Handbook of Statistical Methods* states that the Grubbs test is based on the assumption of normality and should only be used with data that are normally distributed (Ref. 4). NIST also recommends that the test should not be used for sample sizes of six or less since it frequently tags most of the points as outliers. Many of the nutrient levels in the voluntary nutrition labeling program are based on small sample sizes because that is all the data that are available to FDA. Small sample sizes simply do not contain enough information to make inferences about the shape of the distribution in the entire population (Ref. 5).

Therefore, based on the information in the previous paragraphs, we have decided not to conduct Grubbs outlier screening on the nutrient data.

B. Changes in Nutrition Labeling Values for Raw Fruits and Vegetables

The following is a summary of tentative changes from the nutrition labeling values in the proposed rule for some of the 20 most frequently consumed raw fruits and vegetables. FDA derived the updated values from the raw data provided by USDA and the Citrus Research Board during the comment period, as well as existing data. We also considered data for sodium, potassium, carotenoids, and vitamin C that USDA submitted after the comment period. Other changes were related to discontinuance of outlier screening. As explained in the proposed rule, when possible, FDA used compliance calculations based on 95 percent intervals to derive nutrition labeling values.

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES

Food and Nutrient	2002 Proposed Values		Reopening Comment Period Proposed Values	
		% DV		% DV
Apple (154 grams (g))				
Potassium	170 milligrams (mg)	5%	160 mg	5%
Total carbohydrate	22 g	7%	21 g	7%
Dietary fiber	5 g	20%	3 g	12%
Iron		2%		0%
Avocado (30 g)				
Total fat	6 g	9%	5 g	8%
Saturated fat	0.5 g	3%	1 g	5%
Potassium	160 mg	5%	140 mg	4%

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—Continued

Food and Nutrient	2002 Proposed Values		Reopening Comment Period Proposed Values	
		% DV		% DV
Banana (126 g)				
Sodium	0 mg	0%	5 mg	0%
Potassium	400 mg	11%	450 mg	13%
Total carbohydrate	29 g	10%	30 g	10%
Dietary fiber	4 g	16%	2 g	8%
Sugars	21 g		19 g	
Cantaloupe (134 g)				
Sodium	25 mg	1%	20 mg	1%
Potassium	280 mg	8%	240 mg	7%
Total carbohydrate	13 g	4%	12 g	4%
Sugars	12 g		11 g	
Vitamin A		100%		120%
Calcium		2%		0%
Grapefruit (154 g)				
Potassium	230 mg	7%	160 mg	5%
Total carbohydrate	16 g	5%	15 g	5%
Dietary fiber	6 g	24%	2 g	8%
Sugars	10 g		11 g	
Vitamin A		15%		35%
Vitamin C		110%		100%
Calcium		2%		4%
Honeydew melon (134 g)				
Sodium	35 mg	1%	30 mg	1%
Potassium	310 mg	9%	210 mg	6%
Total carbohydrate	13 g	4%	12 g	4%
Sugars	12 g		11 g	
Kiwifruit (148 g)				
Calories	100		90	
Total fat	1 g	2%	1.5 g	2%
Potassium	480 mg	14%	450 mg	13%
Total carbohydrate	24 g	8%	20 g	7%
Sugars	16 g		13 g	
Protein	2 g		1 g	
Calcium		6%		4%
Iron		4%		2%

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—Continued

Food and Nutrient	2002 Proposed Values		Reopening Comment Period Proposed Values	
		% DV		% DV
Lemon (58 g)				
Sodium	5 mg	0%	0 mg	0%
Potassium	90 mg	3%	75 mg	2%
Sugars	1 g		2 g	
Nectarine (140 g)				
Calories	70		60	
Calories from fat	0		5	
Total fat	0 g	0%	0.5 g	1%
Potassium	290 mg	8%	250 mg	7%
Total carbohydrate	17 g	6%	15 g	5%
Sugars	13 g		11 g	
Orange (154 g)				
Potassium	260 mg	7%	250 mg	7%
Total carbohydrate	21 g	7%	19 g	6%
Dietary fiber	7 g	28%	3 g	12%
Vitamin A		2%		0%
Iron		2%		0%
Peach (147 g)				
Calories	70		60	
Total fat	0 g	0%	0.5 g	1%
Potassium	260 mg	7%	230 mg	7%
Total carbohydrate	18 g	6%	15 g	5%
Sugars	14 g		13 g	
Vitamin A		8%		6%
Pear (166 g)				
Calories from fat	10		0	
Total fat	1 g	2%	0 g	0%
Potassium	210 mg	6%	180 mg	5%
Sugars	17 g		16 g	
Protein	1 g		0 g	
Calcium		2%		0%
Pineapple (112 g)				
Calories	60		50	
Potassium	115 mg	3%	120 mg	3%
Total carbohydrate	16 g	5%	13 g	4%

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—Continued

Food and Nutrient	2002 Proposed Values		Reopening Comment Period Proposed Values	
		% DV		% DV
Sugars	13 g		10 g	
Vitamin A		0%		2%
Vitamin C		25%		50%
Iron		2%		0%
Plums (151 g)				
Calories	80		70	
Potassium	250 mg	7%	230 g	7%
Total carbohydrate	21 g	7%	19 g	6%
Dietary fiber	2 g	8%	1 g	4%
Sugars	13 g		16 g	
Iron		2%		0%
Strawberries (147 g)				
Potassium	270 mg	8%	170 mg	5%
Total carbohydrate	12 g	4%	11 g	4%
Dietary fiber	4 g	16%	2 g	8%
Sugars	8 g		6 g	
Calcium		2%		0%
Iron		4%		0%
Sweet cherries (140 g)				
Calories	90		100	
Potassium	300 mg	9%	350 mg	10%
Total carbohydrate	23 g	8%	26 g	9%
Dietary fiber	3 g	12%	1 g	4%
Sugars	20 g		16 g	
Protein	2 g		1 g	
Tangerine (109 g)				
Calories from fat	5		0	
Total fat	0.5 g	1%	0 g	0%
Sodium	0 g	0%	5 mg	0%
Potassium	180 mg	5%	160 mg	5%
Dietary fiber	3 g	12%	2 g	8%
Sugars	8 g		9 g	
Vitamin A		0%		6%
Vitamin C		50%		45%
Watermelon (280 g)				

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—Continued

Food and Nutrient	2002 Proposed Values		Reopening Comment Period Proposed Values	
		% DV		% DV
Calories	100		80	
Sodium	10 mg	0%	0 mg	0%
Potassium	230 mg	7%	270 mg	8%
Total carbohydrate	27 g	9%	21 g	7%
Dietary fiber	2 g	8%	1 g	4%
Sugars	25 g		20 g	
Vitamin A		20%		30%
Bell pepper (148 g)				
Calories	30		25	
Sodium	0 mg	0%	40 mg	2%
Potassium	270 mg	8%	220 mg	6%
Total carbohydrate	7 g	2%	6 g	2%
Vitamin A		8%		4%
Iron		2%		4%
Broccoli (148 g)				
Sodium	55 mg	2%	80 mg	3%
Potassium	540 mg	15%	460 mg	13%
Total carbohydrate	8 g	3%	10 g	3%
Dietary fiber	5 g	20%	3 g	12%
Sugars	3 g		2 g	
Protein	5 g		2 g	
Vitamin A		15%		6%
Iron		6%		4%
Carrot (78 g)				
Calories	35		30	
Sodium	40 mg	2%	60 mg	3%
Potassium	280 mg	8%	250 mg	7%
Total carbohydrate	8 g	3%	7 g	2%
Vitamin A		270%		110%
Celery (110 g)				
Calories	20		15	
Sodium	100 mg	4%	115 mg	5%
Potassium	350 mg	10%	260 mg	7%
Total carbohydrate	5 g	2%	4 g	1%
Dietary fiber	2 g	8%	1 g	4%

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—Continued

Food and Nutrient	2002 Proposed Values		Reopening Comment Period Proposed Values	
		% DV		% DV
Sugars	1 g		2 g	
Protein	1 g		0 g	
Vitamin A		2%		10%
Cucumber (99 g)				
Potassium	170 mg	5%	140 mg	4%
Protein	1 g		0 g	
Iceberg lettuce (89 g)				
Calories	15		10	
Potassium	120 mg	3%	125 mg	4%
Total carbohydrate	3 g	1%	2 g	1%
Vitamin A		4%		6%
Leaf lettuce (85 g)				
Sodium	30 mg	1%	35 mg	1%
Potassium	230 mg	7%	170 mg	5%
Total carbohydrate	4 g	1%	2 g	1%
Dietary fiber	2 g	8%	1 g	4%
Sugars	2 g		1 g	
Vitamin A		40%		130%
Iron		0%		4%
Onion (148 g)				
Calories	60		45	
Potassium	240 mg	7%	160 mg	5%
Total carbohydrate	14 g	5%	11 g	4%
Protein	2 g		1 g	
Calcium		4%		2%
Iron		2%		4%
Potato (148 g)				
Calories	40		110	
Sodium	10 mg	0%	0 mg	0%
Potassium	650 mg	19%	620 mg	18%
Total carbohydrate	7 g	2%	26 g	9%
Dietary fiber	4 g	16%	2 g	8%
Sugars	2 g		1 g	
Vitamin C		40%		45%
Iron		8%		6%

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—Continued

Food and Nutrient	2002 Proposed Values		Reopening Comment Period Proposed Values	
		% DV		% DV
Radishes (85 g)				
Calories	15		10	
Sodium	25 mg	1%	55 mg	2%
Potassium	230 mg	7%	160 mg	5%
Dietary fiber	0 g	0%	1 g	4%
Protein	1 g		0 g	
Iron		0%		2%
Sweet potato (130 g)				
Calories	140		100	
Sodium	45 mg	2%	70 mg	3%
Potassium	340 mg	10%	440 mg	13%
Total carbohydrate	32 g	11%	23 g	8%
Vitamin A		440%		120%
Calcium		2%		4%
Tomato (148 g)				
Calories	35		25	
Calories from fat	5		0	
Total fat	0.5 g	1%	0 g	0%
Sodium	5 mg	0%	35 mg	1%
Potassium	360 mg	10%	340 mg	10%
Total carbohydrate	7 g	2%	5 g	2%
Sugars	4 g		3 g	
Iron		2%		4%

C. Changes in Nutrition Labeling Values for Raw Fish

The following is a summary of tentative changes from the nutrition labeling values in the proposed rule for some of the 20 most frequently consumed raw fish. Changes were related to discontinuance of outlier screening and to inclusion of raw Chinook salmon with Atlantic, Coho, and Sockeye salmon. FDA derived values for fish using data from the USDA National Nutrient Databank (Ref. 6). When possible, FDA used compliance calculations based on 95 percent intervals to derive nutrition labeling values. When raw data were unavailable, FDA used data from the newest version of USDA Nutrient Database for Standard Reference, Release 17 (Ref. 2).

TABLE 2.—PROPOSED CHANGES TO THE NUTRITION LABELING FOR COOKED FISH

Food and Nutrient (per 84 grams (g)/3 ounces)	2002 Proposed Values		Reopening Comment Period Proposed Values	
		% DV		% DV
Cod				
Sodium	55 milligrams (mg)	2%	65 mg	3%
Flounder/sole				

TABLE 2.—PROPOSED CHANGES TO THE NUTRITION LABELING FOR COOKED FISH—Continued

Food and Nutrient (per 84 grams (g)/3 ounces)	2002 Proposed Values		Reopening Comment Period Proposed Values	
		% DV		% DV
Potassium	400 mg	11%	390 mg	11%
Calcium		0%		2%
Haddock				
Sodium	75 mg	3%	85 mg	4%
Halibut				
Cholesterol	35 mg	12%	40 mg	13%
Calcium		4%		2%
Ocean perch				
Cholesterol	50 mg	17%	45 mg	15%
Iron		6%		4%
Pollock				
Calories	100		90	
Rockfish				
Calories	100		110	
Total fat	1.5 g	2%	2 g	3%
Salmon, Atlantic/Coho/Sockeye—Chinook added in update				
Calories	190		200	
Cholesterol	65 mg	22%	70 mg	23%
Sodium	65 mg	3%	55 mg	2%
Potassium	320 mg	9%	430 mg	12%
Vitamin A		2%		4%
Vitamin C		2%		4%
Salmon, chum/pink				
Calories from fat	35		40	
Scallops				
Cholesterol	60 mg	20%	65 mg	22%
Vitamin C		6%		0%
Iron		2%		14%
Shrimp				
Sodium	250 mg	10%	240 mg	10%
Iron		6%		10%

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 comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Brandt, M.M., memo to the file: Nutrient data from U.S. Department of Agriculture received after close of comment period, Center for Food Safety and Applied Nutrition, FDA, February 2005.

2. U.S. Department of Agriculture, Agricultural Research Service, USDA Nutrient Database for Standard Reference, Release 17, 2004. Available on the Internet at USDA's Nutrient Data Laboratory home page, *http://www.nal.usda.gov/fnic/foodcomp/*.

3. LeGault, L.A. and M.M. Brandt, ''Documentation for the Nutrition Labeling Values for the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish,'' Center for Food Safety and Applied Nutrition, FDA, November 2004.

4. *NIST/SEMATECH e-Handbook of Statistical Methods*, *http://www.itl.nist.gov/div898/handbook/index.htm* and *http://www.itl.nist.gov/div898/handbook/eda/section3/eda35h.htm*. Accessed January 3, 2005.

5. The Prism Guide to Interpreting Statistical Results, excerpted from *Analyzing Data With GraphPad Prism*, *http://www.graphpad.com/articles/interpret/Analyzing_two_groups/choos_anal_comp_two.htm*. Accessed March 21, 2005.

6. U.S. Department of Agriculture, National Nutrient Data Bank, maintained at the Nutrient Data Laboratory, Agricultural Research Service, Beltsville Human Nutrition Research Center, Beltsville, MD.

BILLING CODE 4160–01–S

Appendix C to Part 101.–Nutrition Facts for Raw Fruits and Vegetables

Nutrition facts [1] for raw fruits and vegetables edible portion	Calories	Calories from fat	Total Fat		Saturated Fat		Trans Fat	Cholesterol		Sodium		Potassium		Total Carbohydrate		Dietary Fiber		Sugars	Protein	Vitamin A	Vitamin C	Calcium	Iron
			(g)	(%)	(g)	(%)	(g)	(mg)	(%)	(mg)	(%)	(mg)	(%)	(g)	(%)	(g)	(%)	(g)	(g)	(%)	(%)	(%)	(%)
Apple, 1 medium (154 g/5.5 oz)	80	0	0	0	0	0	0	0	0	0	0	160	5	21	7	3	12	16	0	2	8	0	0
Avocado, California, 1/5 medium (30g/ 1.1 oz)	50	45	5	8	1	5	0	0	0	0	0	140	4	2	1	1	4	0	1	0	4	0	0
Banana, 1 medium (126 g/4.5 oz)	110	0	0	0	0	0	0	0	0	5	0	450	13	30	10	2	8	19	1	0	15	0	2
Cantaloupe, 1/4 medium (134g/4.8 oz)	50	0	0	0	0	0	0	0	0	20	1	240	7	12	4	1	4	11	1	120	80	0	2
Grapefruit, 1/2 medium (154g/5.5 oz)	60	0	0	0	0	0	0	0	0	0	0	160	5	15	5	2	8	11	1	35	100	4	0
Grapes, 3/4 cup (126 g/4.5 oz)	90	0	0	0	0	0	0	0	0	15	1	240	7	23	8	1	4	20	0	0	2	2	0
Honeydew Melon, 1/10 medium melon (134 g/4.8 oz)	50	0	0	0	0	0	0	0	0	30	1	210	6	12	4	1	4	11	1	2	45	0	2
Kiwi fruit, 2 medium (148 g/5.3oz)	90	10	1.5	2	0	0	0	0	0	0	0	450	13	20	7	4	16	13	1	2	240	4	2
Lemon, 1 medium (58 g/2.1 oz)	15	0	0	0	0	0	0	0	0	0	0	75	2	5	2	1	4	2	0	0	40	2	0
Lime, 1 medium (67 g/2.4 oz)	20	0	0	0	0	0	0	0	0	0	0	75	2	7	2	2	8	0	0	0	35	0	0
Nectarine, 1 medium (140 g/5.0 oz)	60	5	0.5	1	0	0	0	0	0	0	0	250	7	15	5	1	4	11	1	8	15	0	2
Orange, 1 medium (154 g/5.5 oz)	80	0	0	0	0	0	0	0	0	0	0	250	7	19	6	3	12	14	1	0	130	6	0
Peach, 1 medium (147 g/5.3 oz)	60	0	0.5	1	0	0	0	0	0	0	0	230	7	15	5	2	8	13	1	6	15	0	2
Pear, 1 medium (166 g/5.9 oz)	100	0	0	0	0	0	0	0	0	0	0	180	5	25	8	4	16	16	0	0	10	0	0
Pineapple, 2 slices, 3" diameter, 3/4" thick (112 g/4 oz)	50	0	0	0	0	0	0	0	0	10	0	120	3	13	4	1	4	10	1	2	50	2	0
Plums, 2 medium (151 g/5.4 oz)	70	0	0	0	0	0	0	0	0	0	0	230	7	19	6	1	4	16	1	8	10	0	0
Strawberries, 8 medium (147g/5.3 oz)	50	0	0	0	0	0	0	0	0	0	0	170	5	11	4	2	8	6	1	0	160	0	0
Sweet cherries, 21 cherries; 1 cup (140 g/5.0 oz)	100	0	0	0	0	0	0	0	0	0	0	350	10	26	9	1	4	16	1	2	15	2	2
Tangerine, 1 medium (109 g/3.9 oz)	50	0	0	0	0	0	0	0	0	5	0	160	5	13	4	2	8	9	1	6	45	4	0
Watermelon, 1/18 medium melon; 2 cups diced pieces (280 g/10.0 oz)	80	0	0	0	0	0	0	0	0	0	0	270	8	21	7	1	4	20	1	30	25	2	4

Appendix C to Part 101.–Nutrition Facts for Raw Fruits and Vegetables-Continued

Nutrition facts [1] for raw fruits and vegetables edible portion	Calories	Calories from fat	Total Fat		Saturated Fat		Trans Fat	Cholesterol		Sodium		Potassium		Total Carbohydrate		Dietary Fiber		Sugars	Protein	Vitamin A	Vitamin C	Calcium	Iron
			(g)	(%)	(g)	(%)	(g)	(mg)	(%)	(mg)	(%)	(mg)	(%)	(g)	(%)	(g)	(%)	(g)	(g)	(%)	(%)	(%)	(%)
Asparagus, 5 spears (93 g/3.3 oz)	20	0	0	0	0	0	0	0	0	0	0	230	7	4	1	2	8	2	2	10	15	2	2
Bell pepper, 1 medium (148 g/5.3 oz)	25	0	0	0	0	0	0	0	0	40	2	220	6	6	2	2	8	4	1	4	190	2	4
Broccoli, 1 medium stalk (148 g/5.3 oz)	45	0	0.5	1	0	0	0	0	0	80	3	460	13	10	3	3	12	2	2	6	220	6	4
Carrot, 1 carrot, 7" long, 1 1/4" diameter (78 g/2.8 oz)	30	0	0	0	0	0	0	0	0	60	3	250	7	7	2	2	8	5	1	110	10	2	0
Cauliflower, 1/6 medium head (99 g/ 3.5 oz)	25	0	0	0	0	0	0	0	0	30	1	270	8	5	2	2	8	2	2	0	100	2	2
Celery, 2 medium stalks (110 g/3.9 oz)	15	0	0	0	0	0	0	0	0	115	5	260	7	4	1	1	4	2	0	10	15	4	2
Cucumber, 1/3 medium (99 g/3.5 oz)	15	0	0	0	0	0	0	0	0	0	0	140	4	3	1	1	4	2	0	4	10	2	2
Green (snap) beans, 3/4 cup cut (83 g/ 3.0 oz)	20	0	0	0	0	0	0	0	0	0	0	200	6	5	2	3	12	2	1	4	10	4	2
Green cabbage, 1/12 medium head (84 g/3.0 oz)	25	0	0	0	0	0	0	0	0	20	1	190	5	5	2	2	8	3	1	0	70	4	2
Green onion, 1/4 cup chopped (25 g/ 0.9 oz)	10	0	0	0	0	0	0	0	0	10	0	70	2	2	1	1	4	1	0	2	8	2	0
Iceberg lettuce, 1/6 medium head (89 g/ 3.2 oz)	10	0	0	0	0	0	0	0	0	10	0	125	4	2	1	1	4	2	1	6	6	2	2
Leaf lettuce, 1 1/2 cups shredded (85 g/ 3.0 oz)	15	0	0	0	0	0	0	0	0	35	1	170	5	2	1	1	4	1	1	130	6	4	4
Mushrooms, 5 medium (84 g/3.0 oz)	20	0	0	0	0	0	0	0	0	0	0	300	9	3	1	1	4	0	3	0	2	0	2
Onion, 1 medium (148 g/5.3 oz)	45	0	0	0	0	0	0	0	0	5	0	160	5	11	4	3	12	9	1	0	20	2	4
Potato, 1 medium (148 g/5.3 oz)	110	0	0	0	0	0	0	0	0	0	0	620	18	26	9	2	8	1	3	0	45	2	6
Radishes, 7 radishes (85 g/3.0 oz)	10	0	0	0	0	0	0	0	0	55	2	160	5	3	1	1	4	2	0	0	30	2	2
Summer squash, 1/2 medium (98 g/ 3.5oz)	20	0	0	0	0	0	0	0	0	0	0	260	7	4	1	2	8	2	1	6	30	2	2
Sweet corn, kernels from 1 medium ear (90g/ 3.2 oz)	90	20	2.5	4	0	0	0	0	0	0	0	250	7	18	6	2	8	5	4	2	10	0	2
Sweet Potato, 1 medium, 5" long, 2"diameter (130 g/ 4.6 oz)	100	0	0	0	0	0	0	0	0	70	3	440	13	23	8	4	16	7	2	120	30	4	4
Tomato, 1 medium (148 g/5.3 oz)	25	0	0	0	0	0	0	0	0	35	1	340	10	5	2	1	4	3	1	20	40	2	4

[1] Raw, edible weight portion. Percent Daily Values (%DV) are based on a 2,000 calorie diet.

Appendix D to Part 101.–Nutrition Facts for Cooked Fish

Nutrition facts [1] fish (84 g/3 oz)	Calories	Calories from fat	Total Fat		Saturated Fat		Trans Fat	Cholesterol		Sodium		Potassium		Total Carbohydrate		Dietary Fiber		Sugars	Protein	Vitamin A	Vitamin C	Calcium	Iron
			(g)	%DV	(g)	%DV	(g)	(mg)	%	(mg)	%	(mg)	%	(g)	%	(g)	%	(g)	(g)	%	%	%	%
Blue crab	100	10	1	2	0	0	0	95	32	330	14	300	9	0	0	0	0	0	20	0	4	10	4
Catfish	130	60	6	9	2	10	0	50	17	40	2	230	7	0	0	0	0	0	17	0	0	0	0
Clams, about 12 small	110	15	1.5	2	0	0	0	80	27	95	4	470	13	6	2	0	0	0	17	10	0	8	30
Cod	90	5	1	2	0	0	0	50	17	65	3	460	13	0	0	0	0	0	20	0	2	2	2
Flounder/sole	100	15	1.5	2	0	0	0	55	18	100	4	390	11	0	0	0	0	0	19	0	0	2	0
Haddock	100	10	1	2	0	0	0	70	23	85	4	340	10	0	0	0	0	0	21	2	0	2	6
Halibut	120	15	2	3	0	0	0	40	13	60	3	500	14	0	0	0	0	0	23	4	0	2	6
Lobster	80	0	0.5	1	0	0	0	60	20	320	13	300	9	1	0	0	0	0	17	2	0	6	2
Ocean perch	110	20	2	3	0.5	3	0	45	15	95	4	290	8	0	0	0	0	0	21	0	2	10	4
Orange roughy	80	5	1	2	0	0	0	20	7	70	3	340	10	0	0	0	0	0	16	2	0	4	2
Oysters, about 12 medium	100	35	4	6	1	5	0	80	27	300	13	220	6	6	2	0	0	0	10	0	6	6	45
Pollock	90	10	1	2	0	0	0	80	27	110	5	370	11	0	0	0	0	0	20	2	0	0	2
Rainbow trout	140	50	6	9	2	10	0	55	18	35	1	370	11	0	0	0	0	0	20	4	4	8	2
Rockfish	110	15	2	3	0	0	0	40	13	70	3	440	13	0	0	0	0	0	21	4	0	2	2
Salmon, Atlantic/Coho/Sockeye/Chinook	200	90	10	15	2	10	0	70	23	55	2	430	12	0	0	0	0	0	24	4	4	2	2
Salmon, Chum/Pink	130	40	4	6	1	5	0	70	23	65	3	420	12	0	0	0	0	0	22	2	0	2	4
Scallops, about 6 large or 14 small	140	10	1	2	0	0	0	65	22	310	13	430	12	5	2	0	0	0	27	2	0	4	14
Shrimp	100	10	1.5	2	0	0	0	170	57	240	10	220	6	0	0	0	0	0	21	4	4	6	10
Swordfish	120	50	6	9	1.5	8	0	40	13	100	4	310	9	0	0	0	0	0	16	2	2	0	6
Tilapia	110	20	2.5	4	1	5	0	75	25	30	1	360	10	0	0	0	0	0	22	0	2	0	2
Tuna	130	15	1.5	2	0	0	0	50	17	40	2	480	14	0	0	0	0	0	26	2	2	2	4

[1] Cooked, edible weight portion. Percent Daily Values (%) are based on a 2,000 calorie diet.

Dated: March 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6475 Filed 4–1–05; 8:45 am]

BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2004N–0463]

RIN 0910–AF22

Food Labeling; Prominence of Calories

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to request comment on whether to amend certain provisions of the agency's nutrition labeling regulations to give more prominence to calories on food labels. FDA is issuing this ANPRM in response to recommendations of the Obesity Working Group (OWG), which was created by the Commissioner of Food and Drugs (the Commissioner) to develop an action plan to address the Nation's obesity problem. Comments on whether and, if so, how to give greater emphasis to calories on the nutrition label will inform any FDA rulemaking that may result from this ANPRM.

DATES: Submit written or electronic comments by June 20, 2005.

ADDRESSES: You may submit comments, identified by Docket No. 2004N–0463 and/or RIN number 0910–AF22, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0463 and/or RIN number 0910–AF22 in the subject line of your e-mail message.
- Fax: 301–827–6870.
- Mail/Hand delivery/Courier [for paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jillonne Kevala, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

A. Nutrition Labeling Regulations

The Federal Food, Drug, and Cosmetic Act (the act) as amended by the Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101–535), together with FDA's implementing regulations, established mandatory nutrition labeling for packaged foods to enable consumers to make more informed and healthier food product choices in the context of their daily diet. The cornerstone of the NLEA is the requirement that packaged foods bear a Nutrition Facts Panel (NFP), which provides product-specific information on serving size, calories, and nutrient content. FDA's final regulations establishing nutrition labeling were published in 1993 (58 FR 2079, January 6, 1993) (the nutrition labeling final rule).

With respect to calorie information, FDA's nutrition labeling final rule requires the listing of total calories and calories from fat, with the exception that ''Calories from fat'' information is not required on products that contain less than 0.5 gram of fat in a serving (§ 101.9(c)(1)(ii). When ''Calories from fat'' is not listed, the statement ''Not a significant source of calories from fat'' must be placed at the bottom of the nutrition label (§ 101.9(c)(1)(ii) (21 CFR 101.9(c)(1)(ii))). In addition, manufacturers may voluntarily list calories from saturated fat (§ 101.9(c)(1)(iii)).

The nutrition labeling final rule specifies the format and content for the listing of calories in the NFP and provides that ''Calories'' must be in a type size no smaller than 8 point (§ 101.9(d)(1)(iii)) and be highlighted (§ 101.9(d)(1)(iv)). The nutrition labeling final rule also provides that information on ''Calories'' and ''Calories from fat'' in the NFP must follow the heading ''Amount Per Serving'' and be declared in one line with enough space to clearly differentiate between ''Calories'' and ''Calories from fat'' unless ''Calories from saturated fat'' is voluntarily declared, in which case they should appear in a column, with ''Calories'' at the top, followed by ''Calories from fat'' and ''Calories from saturated fat'' (§ 101.9(d)(5)). Exceptions to some of these provisions are provided for foods that contain two or more separately packaged foods that are intended to be eaten individually (§ 101.9(d)(13)), foods that contain insignificant amounts of seven or more of certain specified nutrients (§ 101.9(f)), foods intended for infants and children less than 2 years of age (§ 101.9(j)(5)), dietary supplements (§ 101.9(j)(6)), and foods in small and intermediate-sized packages (§ 101.9(j)(13)).

B. The Report of FDA's OWG

In August 2003, the Commissioner created the OWG and charged it to develop an action plan covering the critical dimensions of the obesity problem in America to help consumers lead healthier lives through better nutrition. The OWG was composed of professionals across FDA who provided a range of expertise in areas such as food labels; communication and education efforts; the role of industry and restaurants; and therapeutic interventions for obesity. The OWG met eight times and received briefings from several invited experts from other government agencies. In addition, the OWG held one public meeting, one workshop, two round table discussions (one with health professionals/academicians, and one with consumer groups), and solicited comments on obesity-related issues, directing them to a docket established in July 2003 (Docket No. 2003N–0338) (referred to in this ANPRM as ''the Obesity docket''). The final report issued by the OWG centered on the scientific fact that weight control is primarily a function of the balance of calories eaten and calories expended; and therefore, focused on a ''calories count'' emphasis for FDA actions (Ref. 1).

A principal aspect of the Commissioner's charge was for the OWG to ''develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity.'' After considering the legal requirements concerning food labeling and the limited data on consumer familiarity

with, and use of, food label information (described in section I.C of this document), the OWG recommended that FDA: (1) Develop options for revising or adding caloric and other nutritional information on food packaging, (2) obtain information on the effectiveness of these options in affecting consumer understanding and behavior relevant to caloric intake, and (3) evaluate this information to make evidence-based decisions on which options to pursue. This ANPRM will focus only on the OWG recommendations pertaining to giving more prominence to calories.

C. Data Concerning the NFP and Calorie Information

The OWG reviewed research conducted by FDA and others, described more fully in ''Calories Count'' (Ref. 1), that shows that most consumers are familiar with the nutrition information on food labels and that they use this information primarily for evaluating the nutrition quality of specific food products. However, the percentage of consumers who use the NFP information productively for weight management purposes is low (Ref. 1). In addition, the OWG also reviewed results of focus group research conducted by FDA in November and December 2003 to provide, among other things, preliminary information on the participants' attitudes and behaviors towards nutrition information on food labels. In this research, among other things, FDA asked participants questions aimed at determining consumer attitudes and behaviors towards changes in the presentation of calorie information in the NFP and calorie information on the front label of food packages.

Participants in FDA focus groups cared about nutrition labeling and reported using the NFP. While many participants said they were interested in calories, many also pointed to multiple concerns that went beyond the labeling of calories such as the level of saturated fat, total fat, cholesterol, carbohydrates and sodium (Ref. 1).

In terms of calorie-related variations in the NFP, the focus groups tested participant understanding of several food label designs, including one similar to the current NFP but with some modifications. These included a relatively larger font size for the calories line, a %DV (daily value) for calories, and removal of the listing for ''Calories from fat.'' Many of the participants in these studies did not comment on the changes in the label until they were pointed out to them (Ref. 1).

Focus group participants were also shown a design that included a ''starburst'' with the amount of calories per serving placed on the front of the label (i.e., the principal display panel (PDP)), as a way to give greater prominence to calories. The respondents felt that this design was misleading, i.e., that the manufacturer was trying to indicate that the entire product (as opposed to a single serving) had fewer calories than it actually had. Other groups were shown a design that included a white square with the amount of calories for the entire package. The responses of those shown this white square design were mixed (Ref. 1).

Findings from focus group research yield only qualitative data and should not be viewed as nationally representative of consumers' views. Quantitative experimental data are necessary to make reliable and verifiable conclusions of consumers' views. However, focus group research can shed some interesting light on the complex issues covered by the OWG and are useful for identifying quantitative research needs.

In addition to the literature review and focus group research described more fully in Ref. 1, we have also reviewed the written and public comments submitted to the Obesity docket. Several of these comments suggested that FDA develop ways to emphasize calories on the food label. In particular, these comments suggested that the label should focus less on fat and more on calories and overall diet, and that calories should be listed on the front, or on the PDP of the package in clear, bold lettering. Other comments noted that research should be conducted to determine whether the current calorie listing is meaningful to consumers. We agree with the comments that more research is needed, and that the highlighted comments are important considerations. However, before recommending changes to the food label, the agency wants to develop a better understanding of how consumers currently use calorie information on the NFP, and then assess whether the NFP requires modification to be effective in facilitating positive dietary change (Ref. 1).

D. Recommendations From the OWG Concerning Calorie Labeling

Based on information presented to and gathered by the OWG, its Report observed that, despite evidence of a positive correlation between label use and certain positive dietary choices (e.g., selection of lower sodium or lower fat content foods), the trend towards obesity has accelerated over the last decade (Ref. 1). The OWG hypothesized that consumers may not take advantage of the available information on the food label to control their weight, may not appreciate how the information could be used for weight management purposes, or may find it to hard to apply the available information to such purposes (Ref. 1). Therefore, the OWG recommended that FDA issue an ANPRM to solicit public comments on how to give more prominence to calories on the food label. Possible changes suggested by the OWG were as follows: (1) Increasing the font size for calories; (2) providing for a %DV for calories; and (3) eliminating the ''Calories from fat'' listing, as this may take the emphasis away from the listing of ''Calories'' (Ref. 1).

II. Agency Request for Information

The ability to determine the caloric content of packaged foods is critical for consumers, especially consumers who are trying to control total caloric intake and manage their weight. While the current NFP does allow consumers to determine the caloric content of packaged foods, it may be, as suggested by the OWG Report, that modifying the food label to give more emphasis to calorie information would benefit consumers in weight control and maintenance. To help the agency determine which regulatory options provide consumers with information that is most useful in weight control and weight management, and for any future analysis of benefits and costs associated with those regulatory options, we request comments and available data on the following questions.

A. Questions Concerning Prominence of Calorie Information on Food Labels

- Would consumer awareness of the caloric content of packaged foods be increased by amending nutrition labeling regulations to give more prominence to the declaration of calories per serving? Why or why not?
- How would a more prominent listing of calorie information change the way consumers use the NFP in deciding what to eat?
- What methods could be considered for increasing prominence? For example, should the font size be increased for the listing of ''Calories'' from the current requirement of 8-point type, and/or should extra bold type or a different style of type be used?
- Would providing for a %DV disclosure for total calories assist consumers in understanding the caloric content of the packaged food in the context of a 2,000 calorie diet? Why or why not?

B. Questions Concerning ''Calories From Fat''

Section 403(q)(1)(C)(ii) of the act (21 U.S.C. 343) states that total calories from fat must be declared on the food label, unless the Secretary [of Health and Human Services] determines that the listing is not necessary to assist consumers in maintaining healthy dietary practices. When the nutrition labeling final rule was published in 1993, the Dietary Guidelines for Americans (1990) recommended that diets be low in fat (Ref. 2). The current Dietary Guidelines for Americans (2005) recommends that diets be moderate in fat with most fats coming from polyunsaturated and monounsaturated fatty acids (Ref. 3). Moreover, the current Dietary Guidelines for Americans recommends maintaining body weight in a healthy range by balancing those calories consumed from foods and beverages with those calories expended. Based on the information in the previous sentences, we request comments and data on the following questions:

- What data is there on how consumers use the listing of ''Calories from fat?''
- How does the listing ''Calories from fat'' adjacent to ''Calories'' affect consumers' focus on the total calories of a food?
- What are the advantages or disadvantages of eliminating the listing for ''Calories from fat'' from the nutrition label?
- What data would be needed to determine whether the listing of ''Calories from fat'' is or is not necessary to assist consumers in maintaining healthy dietary practices?

C. Questions About Use of Calorie Information on Food Labels

Based on preliminary results from focus group research, discussed in this ANPRM, we request comments and data on the following questions:

- Is calorie content used to determine how much of a given food to eat, or to determine which foods, out of a range of similar products, to eat? Why or why not?
- If calorie labeling affects decisions on whether to eat a food and on how much to eat, how would the effects of the following requirements differ:

A requirement to display the number of calories per serving on the PDP or

A requirement to increase the prominence of the calories per serving in the NFP?

- What do consumers currently think the calories on packaged foods represent?

D. Questions About Reformulation of Foods Or Redesign of Packaging

Changing the regulations on calorie labeling may have an effect on what producers offer for sale. FDA has no prior information about whether new requirements for calorie labeling would simply change the way currently existing foods are packaged, or if the new requirements would change the formulation of foods offered for sale. In light of this information:

- Would the display of caloric content per package on PDPs encourage more competition based on the caloric content of packages and, if so, how?
- If the calorie content per serving were required to be more prominently displayed on the NFP, would it encourage more competition based on the calorie content of the food? Would the result be products reformulated to have fewer calories per serving, for example greater use of no calorie sweeteners? Would it result in any repackaging of products offered? How would this option change the kinds of products offered?
- If the calorie content per package were required to be prominently displayed on the PDP, would it encourage more competition based on the calorie content of the food? Would the result be repackaging of products into smaller units, for example repackaging cookies into 100 calorie packages? Would there be any incentive to reformulate under this option? How would this option change the kinds of products offered?
- Are you aware of any research, consumer or industry-based, that can assist the agency to answer any of the previous questions?

III. Future Analysis of Benefits and Costs

If the agency proposes regulatory changes based on the initiatives outlined in this ANPRM, we will estimate the costs of labeling changes and other potential costs (such as the costs of reformulating products) should the regulation create incentives for new products. The comments on this ANPRM may identify other costs as well. The benefits of the regulatory options depend on how consumers and producers respond to the changes in calorie labeling. We will use the information from comments to help determine ways to estimate the possible consumer responses to various changes. The comments will also contribute to our estimates of the effects of regulatory options on small entities.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

1. Report of the Obesity Working Group, ''Calories Count,'' March 12, 2004, (*http://www.cfsan.fda.gov/~dms/owg-toc.html*).

2. U.S. Department of Agriculture and U.S. Department of Health and Human Services, ''Dietary Guidelines for Americans,'' 3d ed., pp. 14–15, 1990.

3. U.S. Department of Agriculture and U.S. Department of Health and Human Services, ''Dietary Guidelines for Americans 2005,'' pp. vii-viii, 2005.

V. 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 comments 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6643 Filed 4–1–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2004N–0456]

RIN 0910–AF23

Food Labeling: Serving Sizes of Products That Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to request comment on whether to amend certain provisions of the agency's nutrition labeling regulations concerning serving size.

FDA is issuing this ANPRM in response to recommendations of the Obesity Working Group (OWG), which was created by the Commissioner of FDA (the Commissioner) to develop an action plan to address the Nation's obesity problem. Comments on whether, and if so, how to amend the agency's serving size regulations will inform any FDA rulemaking that may result from this ANPRM.

DATES: Submit written or electronic comments by June 20, 2005.

ADDRESSES: You may submit comments, identified by Docket No. 2004N–0456 and/or RIN number 0910–AF23, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0456 and/or RIN number 0910–AF23 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori LeGault, Center for Food Safety and Applied Nutrition (HFS–840), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1791.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Serving Size Regulations

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101–535), together with FDA's implementing regulations, established mandatory nutrition labeling for packaged foods to enable consumers to make more informed and healthier food product choices in the context of their daily diet. Section 403(q)(1)(A)(i) of the act (21 U.S.C. 343(q)(1)(A)(i)) requires that most foods under FDA's jurisdiction bear nutrition information based on a serving size that reflects the amount of food customarily consumed and is expressed in a common household measure appropriate to the food. The NLEA also required that FDA issue regulations that establish standards to define serving size.

To implement the serving size requirements of the NLEA, FDA underwent extensive notice-and-comment rulemaking (56 FR 60394, November 27, 1991 (the 1991 serving size proposed rule); 58 FR 2229, January 6, 1993 (the serving size final rule); and 58 FR 44039, August 18, 1993 (the serving size technical amendments)). Consistent with the act, the serving size regulations established a system to define ''serving size'' that was composed of two basic elements: (1) Reference amounts customarily consumed per eating occasion (reference amounts or RACCs) for specific food product categories; and (2) procedures for determining serving sizes for use on product labels derived from the reference amounts. The second element was necessary because the RACCs are provided primarily in metric units (based on data from nationwide food consumption surveys that are expressed in grams); however, the act requires that serving sizes be expressed in common household measures that are appropriate to the particular food.

In § 101.9(b)(1) (21 CFR 101.9(b)(1)), we defined the term ''serving'' or ''serving size'' to mean:

> an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the food. When the food is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

In § 101.12(b) (21 CFR 101.12(b)), we established RACCs (upon which label serving sizes are to be determined) for 129 food product categories representing the general food supply and 11 categories for infant and toddler foods. The general principles and factors that FDA considered in arriving at the RACCs are described in § 101.12(a). Among these principles, FDA sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform reference amount so that consumers could make nutritional comparisons of like products in the marketplace.

The RACCs represent the amount of food customarily consumed per eating occasion for each product category, and were derived primarily from data obtained from the 1977–1978 and 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture (58 FR 2229 at 2236–2237). We reviewed food consumption data for the foods in each product category and considered three statistical estimates, i.e., the mean (average), the median (50th percentile), and the mode (most frequent value). Following the procedures detailed in the 1991 serving size proposed rule (56 FR 60394 at 60403–60406), we determined the reference amount that was most likely to represent the amount customarily consumed for each product category.

In § 101.9(b), we established procedures for converting RACCs into appropriate label serving sizes. Among these provisions is § 101.9(b)(6), where we defined the criteria for products to be labeled as single-serving containers. (See 58 FR 2229 at 2232–2235 for FDA's evaluation of comments.) Most products packaged and sold individually that contain less than 200 percent of the applicable RACC must currently be labeled as a single serving. An exception to this rule occurs for products that contain between 150 percent and 200 percent of the RACC and that have a RACC of 100 grams (g) or 100 milliliters (mL) or larger. In this case, the product may be labeled as one or two servings, at the manufacturer's option.

For example, the RACC for carbonated beverages is 240 mL (i.e., 8 fluid (fl) ounces (oz)). Containers of carbonated beverages that weigh 360 mL (i.e., 12 fl oz, 150 percent of 240 mL) or less must be labeled as a single serving. Containers weighing between 360 mL and 480 mL (i.e., 16 fl oz, 200 percent of 240 mL) may be labeled as a single serving or as ''about 2'' servings per container (§ 101.9(b)(8)(i)).

For products packaged and sold individually that contain 200 percent or more of the RACC, it is the manufacturer's option to label the product as a single-serving container if

the entire content of the package can reasonably be consumed at a single-eating occasion. For example, the RACC for muffins is 55 g. If a single large muffin weighs 110 g (200 percent of 55 g), there are two options for the serving size declaration: ''1 muffin (110 g)'' or ''1/2 muffin (55 g).''

B. The Report of the FDA Obesity Working Group

In August 2003, the Commissioner created the OWG and charged it to develop an action plan covering the critical dimensions of the obesity problem in America to help consumers lead healthier lives through better nutrition. The OWG was composed of professionals across FDA who provided a range of expertise in areas such as food labels, communication and education efforts, the role of industry and restaurants, and therapeutic interventions for obesity. The OWG met eight times and received briefings from several invited experts from other government agencies. In addition, the OWG held one public meeting, one workshop, two round table discussions (one with health professionals/academicians, and one with consumer groups), and solicited comments on obesity-related issues, directing them to a docket established in July 2003 (Docket No. 2003N–0338). The final report issued by the OWG centered on the scientific fact that weight control is primarily a function of the balance of calories eaten and calories expended; and therefore, focused on a ''calories count'' emphasis for FDA actions (Ref. 1).

A principal aspect of the Commissioner's charge was for the OWG to ''develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity.'' To address this issue, among other actions, the OWG recommended that FDA reexamine its regulations on serving sizes by soliciting comment on the following topics: (1) Whether to require food packages that can reasonably be consumed at one eating occasion to declare the whole package as a single serving; (2) which, if any, RACCs of food categories need to be updated; and (3) whether to provide for comparative calorie claims for smaller portions of identical foods.

II. Agency Request for Information

FDA's research on consumers' use of the Nutrition Facts panel (NFP) has indicated that consumers' ability to quickly read and understand the NFP is an important factor in determining whether consumers use the NFP and whether the NFP is helpful to them. In focus groups, participants indicated that they cared about nutrition and reported using the NFP, but also said that they did not want to spend a lot of time reading labels and did not always consider nutrition when deciding what to eat. They were interested in calories, but were also concerned about saturated fat, total fat, cholesterol, carbohydrates, and sodium. Most participant comments indicated that they incorrectly thought a serving size was a recommended portion size, rather than a standardized unit of measure. Some participants said that typical serving sizes, as a recommended portion, are unrealistic and pointed out that some people need to eat different amounts, depending on their age, body type, and lifestyle. In the 2002 Health and Diet Survey (Ref. 2), respondents were asked how they used the NFP. The most common answers were: (1) To see if the product was high or low in a specific nutrient, (2) to decide how much to eat, and (3) to help in meal planning. To address these issues, we request comments on the following questions:

- How can FDA make serving size information on the NFP easier for consumers to use when deciding what foods and how much of these foods they should eat?
- Do consumers recognize the differences between serving sizes on food labels and servings recommended in dietary guidance? If so, what do consumers think the differences are? What information on a label would help make this distinction clearer? For example, should the serving size and/or servings per container on the food label be made more prominent? If so, how?
- Are there some alternative, simpler ways to help consumers determine their nutrient intake based on what they eat? If so, please describe. What are the advantages and disadvantages of these options?

A. Updating RACCs

The serving size is critical to nutrition labeling since all of the information on nutrient levels depends on the amount of the product represented. Because there is evidence that the U.S. population is eating larger portion sizes than they did in the 1970s and 1980s (Refs. 3 through 6), the OWG recommends that FDA determine whether to update the RACCs, and if so, how to update the RACCs. Changes to the RACCs, in most instances, would require changes to the serving size on products, which in turn would require changes to the nutrient values listed on the nutrition label.

Newer food consumption data are available from the 1999–2000 and the 2001–2002 National Health and Nutrition Examination Surveys (NHANES) (Ref. 7), and these data provide a more current indication of the amount of food being consumed by individuals. However, we do not want consumers to confuse the serving size on the food label (which is required by the act to be based on the amount customarily consumed) with an amount that is recommended for consumption. For example, if data show that consumers are drinking larger amounts of carbonated beverages and FDA increases the RACC, which will likely increase the serving size on the food label, additional educational efforts may be required to reinforce to consumers that a larger serving size on the container is not a ''recommended'' serving size.

We request comments on these issues and specifically on the following questions:

- How do recent food consumption data, such as data from the 1999–2000 and 2001–2002 NHANES, factor into the determination of which, if any, RACCs need to be updated? Are there other food consumption data sources that are available or that could be provided to the agency for our consideration?
- If we revise the RACCs, what criteria should be used as the basis for change? For example, would a percentage (e.g., 20 percent, 25 percent, or 30 percent) increase or decrease from current RACCs be a valid rationale for change?
- Would consumers think that an increase in serving size on food labels means more of the food should be eaten? What additional education efforts should be provided to consumers to avoid such a conclusion?
- We previously stated in the preamble to the serving size final rule under part 101 (21 CFR part 101) (58 FR 2229 at 2235): ''Section 403(q)(1)(A)(i) of the act, which states that a serving size is the amount customarily consumed, effectively requires the use of food consumption data as the primary basis for determining serving sizes.'' However, considering the issues raised previously in this document, should the agency reconsider its definition of ''serving'' and ''serving size'' or how the agency interprets ''customarily consumed''?

B. Single-Serving Containers

Several comments to the OWG docket strongly opposed the practice of individually packaged foods that appear to be single-serving containers, declaring two or more servings on the

label—such as sodas and snack packs. In addition, as noted in the OWG report, FDA initiated eight focus groups around the country and, among other questions, asked consumers about serving size information on small packages. Examples of food labels were presented for a 20 fl oz soda and an individually packaged large muffin. In general, focus group participants thought that having multiple servings listed on the label for these products was misleading and confusing. Many participants did realize that if the entire package of food is eaten, the number of servings should be multiplied by the amount of the nutrient of interest; though some participants were confused and made mistakes when trying to calculate the total amount in their heads.

To address this issue, we ask for comments on the following questions:

- Should FDA initiate rulemaking to require packages that can reasonably be consumed at one eating occasion to provide the nutrition information for the entire package? If so, what criteria should FDA use to determine which multiserving products would require nutrition information for the entire package? Should it be based on the total amount in the container, the type of food, or something else?
- Should such products be required to include an additional column within the NFP to list the quantitative amounts and % Daily Value for the entire package, as well as the preexisting columns listing the quantitative amounts and % Daily Value for a serving that is less than the entire package (i.e., the serving size derived from the RACC)? Alternatively, should the nutrition information only be declared for the entire package as a single serving?
- If the nutrient amount per serving size (derived from the RACC) and per package were listed side-by-side in separate columns, how would this affect consumers' ability to understand the label?

The current cutoff criteria for single serving containers (200 percent of the RACC (or 150 percent for products that have a RACC of 100 g or 100 mL or larger)) does not appear to be appropriate across the board for all food categories. As previously noted in this document, participants in focus groups said they thought that having multiple servings listed on the label of a 20 fl oz soda (250 percent of the RACC) was misleading and confusing.

- Should the current cutoff criteria to define single-serving containers be changed? Should criteria vary for different types of products? Explain why or why not. What criteria should be used to designate which package sizes should be required to list nutrition information for the entire package?

In addition to the three statistical estimates previously mentioned in this document (i.e., the mean, median, and mode), food consumption surveys allow calculation of intake estimates for individuals who eat a greater amount of food than average (e.g., those in the 90th and 95th percentiles). Should package sizes falling at these amounts (e.g., 90th or 95th percentile), as reported from nationwide food consumption surveys, be used as cut points at or below which nutrition information should be included for the entire package? If so, the RACC tables in § 101.12(b) would have to be modified to include a column for the amount specific to each product category as a cut point for when a product must be labeled as a single-serving container. Is this a viable option? If not, how can single-serving containers be defined?

New regulations can have indirect effects, such as the repackaging of a product by the manufacturer.

- If FDA requires that manufacturers list the nutrient content for the entire package for packages up to specified sizes, are manufacturers likely to repackage products in larger sizes to avoid this requirement? If so, what are the likely impacts of this repackaging?
- Conversely, manufacturers may have an incentive to lower the size, and therefore the total calories, of single serving packages. Would this be an option that manufacturers would consider? If so, what would be the likely consequences of this repackaging?

C. Comparison of Calories in Foods of Different Portion Sizes

As noted in the OWG Report, the Federal Trade Commission has suggested that FDA consider ''allowing food marketers to make truthful, non-misleading label claims comparing foods of different portion sizes.'' Our current regulations for comparative nutrient content claims, including calorie claims, require that all such comparisons be based on a uniform amount of food, i.e., per RACC for individual foods or per 100 g for meals and main dishes. Consequently, the current regulations (§ 101.60(b)) require that comparisons reflect actual nutrient differences in the same quantity of similar foods (e.g., ''Reduced calorie chocolate ice cream, 25% fewer calories than the leading brand of chocolate ice cream. The leading brand contains 150 calories per 1/2 cup serving. Our ice cream contains 100 calories per 1/2 cup serving''). The current regulations do not permit claims that compare the amount of calories based on different sized portions of the same food.

Nevertheless, as noted in the OWG report, ''using the food label to promote consumption of smaller portions may have merit [particularly] if consumers understand that (1) the calorie reduction is solely a function of the reduction in portion size and (2) the smaller portion size is actually less than what they usually consume.'' Thus, we solicit comments regarding the appropriateness of label claims based on the amount of calories in a specified portion of a product (i.e., the amount of food specified by the claim, e.g., one 15 g cookie) vs. claims based on the RACC and specified in the labeled serving size of a product (i.e., the amount specified in the Nutrition Facts panel, e.g., two 15 g cookies). We ask for specific comments on the following questions:

- Because all currently approved comparative claims are based on the difference in the amount of the nutrient in a uniform amount of food such as per RACC, or per 100 g, will it be confusing to consumers to have claims made only on the basis of the difference in the amount of calories in two different labeled servings (i.e., the serving size specified in two different Nutrition Facts panels, e.g., an 8 fl oz can vs. a 12 fl oz can of soda) or two different portions (i.e., amounts specified by the claim, e.g., one 15 g cookie vs. two 15 g cookies) of the same food? Explain why or why not.
- If a claim is made based only on the difference in the amount of calories in two different serving sizes or portions of the same food, what words should be used to ensure that consumers understand that comparisons are made only on this basis (i.e., the difference in the amount of product) and that there is not a difference based on product reformulation, e.g., ''the caloric savings is based on a smaller than normal portion?''
- Should the size of the compared servings, portions, or packages be part of the claim (e.g., ''this 8 fl oz bottle of juice has 33 percent fewer calories than our 12 fl oz bottle'')? Explain why or why not.
- Should these types of claims be limited to products that are identical except for the specified serving or portion size?
- Will such claims be misleading if the claim is based on the number of calories that are in an amount of food other than what is specified in the Nutrition Facts panel (e.g., claims based on half a ''labeled serving''—one cookie, compared to the amount specified in the Nutrition Facts panel—two cookies)?

• Should this claim be limited to single-serving containers, or is it appropriate on multi-serving packages? Explain why or why not.

• If claims are permitted on multi-serving packages, should these claims be limited to products that have portioned pieces, such as cookies or slices of bread, or should they be allowed on products that are not portion controlled, such as pies or bulk sodas? For example, might this claim be extended to ''bulk'' products such as pizza suggesting that if you cut a smaller slice, you will get a caloric savings?

• What comparative terms are appropriate? Because ''reduced'' has always been used to signal some type of reformulation (i.e., special processing, alteration, formulation, or reformulation to lower the nutrient content), is it appropriate to use the term ''reduced'' on products that have not been so altered? Is ''less than,'' which has been used more broadly to signal differences in nutrient levels derived through a variety of means, a more appropriate term?

• Currently all comparative calorie claims are limited to reductions of at least 25 percent. Should these comparisons (e.g., reduced or fewer calories) continue to be limited to reductions of at least 25 percent, and if not, what justification is there that a smaller reduction of calories would be meaningful and significant? Please provide data.

• What other requirements may be necessary to ensure that the claim is not confusing or misleading to consumers?

• If manufacturers are permitted to make such label comparisons of different portion sizes of food, what is the likely change in the distribution of package sizes that will become available to consumers?

• What other labeling changes, if any, would encourage a broader range of package sizes?

III. Future Analysis of Benefits and Costs

If the agency proposes regulatory changes based on the initiatives outlined in this ANPRM, we will estimate the costs of labeling changes and other potential costs (such as the costs of reformulating products) should the regulations create incentives for new products. The comments on this ANPRM may identify other costs as well. The benefits of the regulatory options depend on how consumers respond to the changes in label serving sizes or package sizes. We will use the information from comments to help determine ways to estimate the possible consumer responses to various changes. The comments will also contribute to our estimates of the effects of regulatory options on small entities.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) 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 is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Report of the Working Group on Obesity, ''Calories Count'' (Internet address: *http://www.cfsan.fda.gov/~dms/owg-toc.html*), March 12, 2004.

2. Food and Drug Administration, Center for Food Safety and Applied Nutrition, ''2002 Health and Diet Survey—Preliminary Topline Frequencies (Weighted),'' March 2004.

3. U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute, ''Portion Distortion! Do You Know How Food Portions Have Changed in 20 Years?'' (Internet address: *http://hin.nhlbi.nih.gov/portion/index.htm*).

4. Young, L. R. and M. Nestle, ''Expanding Portion Sizes in the U.S. Marketplace: Implications for Nutrition Counseling,'' *Journal of the American Dietetic Association*, Vol. 103, No. 2, pp. 231–234, February 2003.

5. Smiciklas-Wright, H., D. C. Mitchell, S. J. Mickle, J. D. Goldman, A. Cook, ''Foods Commonly Eaten in the United States, 1989–1991 and 1994–1996, Are Portion Sizes Changing?'' *Journal of the American Dietetic Association*, Vol. 103, No. 1, pp. 41–47, January 2003.

6. Nielsen, S. J. and B. M. Popkin, ''Patterns and Trends in Food Portion Sizes, 1977–1998,'' *Journal of the American Medical Association*, Vol. 289, No. 4, pp. 450–453, January 22/29, 2003.

7. U.S. Department of Health and Human Services, National Center for Health Statistics, NHANES 1999–2000 Data Files (Internet address: *http://www.cdc.gov/nchs/about/major/nhanes/NHANES99_00.htm*) and NHANES 2001–2002 Data Files (Internet address: *http://www.cdc.gov/nchs/about/major/nhanes/nhanes01–02.htm*).

V. 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 comments 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6644 Filed 4–1–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

[Docket No. IL–103–FOR]

Illinois Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are announcing receipt of a proposed amendment to the Illinois regulatory program (Illinois program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Illinois proposes to revise its regulations about revegetation success standards, to update statutory citations, to correct regulatory citations, and to clarify language in various provisions. Illinois intends to revise its program to clarify ambiguities and to improve operational efficiency.

This document gives the times and locations that the Illinois program and proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4 p.m., e.s.t., May 4, 2005. If requested, we will hold a public hearing on the amendment on April 29, 2005. We will accept requests to speak at a hearing until 4 p.m., e.s.t. on April 19, 2005.

ADDRESSES: You may submit comments, identified by Docket No. IL–103–FOR, by any of the following methods:

• E-mail: *IFOMAIL@osmre.gov.* Include Docket No. IL–103–FOR in the subject line of the message.

• Mail/Hand Delivery: Andrew R. Gilmore, Chief, Alton Field Division—Indianapolis Area Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana 46204

- Fax: (317) 226–6182
- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Illinois program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Indianapolis Area Office.

Andrew R. Gilmore, Chief, Alton Field Division—Indianapolis Area Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana 46204, Telephone: (317) 226–6700, E-mail: *IFOMAIL@osmre.gov.*

In addition, you may review a copy of the amendment during regular business hours at the following location: Illinois Department of Natural Resources, Office of Mines and Minerals, Land Reclamation Division, One Natural Resources Way, Springfield, Illinois 62701, Telephone: (217) 782–4970.

FOR FURTHER INFORMATION CONTACT: Andrew R. Gilmore, Chief, Alton Field Division—Indianapolis Area Office. Telephone: (317) 226–6700. E-mail: *IFOMAIL@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Illinois Program
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Procedural Determinations

I. Background on the Illinois Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Illinois program on June 1, 1982. You can find background information on the Illinois program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Illinois program in the June 1, 1982, **Federal Register** (47 FR 23858). You can also find later actions concerning the Illinois program and program amendments at 30 CFR 913.10, 913.15, 913.16, and 913.17.

II. Description of the Proposed Amendment

By letter dated February 1, 2005 (Administrative Record No. IL–5088), Illinois sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). Illinois sent the amendment at its own initiative. Illinois is proposing to amend its regulations at 62 Illinois Administrative Code (IAC) Parts 1816, 1817, and 1823. Below is a summary of the changes proposed by Illinois. The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES**.

A. 62 IAC 1816.116 Revegetation Success Standards

Illinois proposes to amend its regulations at 62 IAC 1816.116 to (1) incorporate a new productivity alternative to the Agricultural Lands Productivity Formula (ALPF), for determining success of revegetation of cropland, pasture land, hayland, and/or grazing land; (2) to update references to and requirements in existing regulations concerning the new productivity alternative; (3) to update requirements pertaining to adjustment for abnormal, catastrophic, growing conditions when the ALPF or the new productivity alternative is used for determining success of revegetation, (4) to remove references to oats as a crop that may be used to prove productivity success; (5) to update information in the soil master file, county average yield file, the agricultural lands productivity formula sampling methods, and Exhibit A in the ALPF, and (6) to delete Tables A through D from the ALPF.

1. *62 IAC 1816.116(a)(3)(C) and (E).* At subsections (a)(3)(C) and (E), Illinois proposes to add a reference to new subsection (a)(6) and to add the following requirement at the end of each of the subsections:

Once chosen by the permittee, the productivity alternative in subsection (a)(6) may not be modified without approval from the Department.

2. *62 IAC 1816.116(a)(4).* At subsection (a)(4), Illinois proposes to reference the new productivity alternative in subsection (a)(6); to update requirements pertaining to adjustment for abnormal, catastrophic, growing conditions when the ALPF or the new productivity alternative is used for determining success of revegetation; and to remove a reference to oat crops from several provisions.

a. In the introductory paragraph of subsection (a)(4), Illinois proposes to add a reference to the new productivity alternative at subsection (a)(6).

b. Illinois proposes to change the requirements of subsection (a)(4)(C) concerning adjustments for abnormal growing conditions to read as follows:

(C) Adjustments for abnormal growing conditions shall be accepted by the Department if such adjustments are certified by a qualified professional (American Society of Agronomy certified) or National Association of State Departments of Agriculture crop enumerators used under this Section, whose ability to perform such adjustments has been previously approved by the Department.

c. At subsection (a)(4)(D), Illinois proposes to remove a reference to ''oats'' as a type of crop commonly grown on surrounding unmined cropland and as a crop that may be used for one year to demonstrate productivity on prime farmland and other cropland areas. Illinois also proposes to add the following requirement concerning deep tillage of prime farmland and other cropland areas:

If deep tillage has been completed to a minimum depth of 36 inches prior to bond release, the applicant may use more than one successful year of hay or wheat as a crop to be used for the productivity demonstration. The requirement for one successful year of corn remains unchanged under this provision.

3. *62 IAC 1816.116(a)(6).* Illinois proposes a new productivity alternative at new subsection (a)(6). It reads as follows:

(6) In order to use the alternative to the Agricultural Lands Productivity Formula, Appendix A, to determine success of revegetation, the following shall apply: use of this alternative is contingent that the permittee can demonstrate for the entire field that the soil strength of the entire soil profile will average <= 200 psi or has been deep tilled to a minimum depth of 36 inches prior to bond release, and soil fertility will average Optimum Management for pH, P and K values as defined under the current Illinois Agronomy Handbook, and intensive land leveling is implemented, as needed, for the entire field. Areas to be tested are allowed under the provisions of subsections (a)(4)(B) or (C).

(A) The following substitution of Column F—Appendix A—County Average Yield File shall read:

Column F is a derived optimum management production (Figure) obtained by multiplying the figures in Column D times the figures in Column E. This production figure will normally exceed actual production because the optimum level management yield is used. The purpose of using the optimum management production is to derive a weighted average optimum management yield which is the total optimum management production (Column F) divided by the total grain acres in the county (Column D). The weighted optimum management yield figure will be used to derive a ''factor'' as described below:

Factor = Average of Official County Crop Yield for the Five Previous Years) Average of Weighted Optimum Management Yield for the Five Years

(B) When the above ''factor'' and hand sampling is used, the harvest loss will be calculated by averaging the harvest loss of the five previous years for the crop being tested.

4. *62 IAC 1816. Appendix A—ALPF.* Illinois proposes to update information in the soil master file, county cropped acreage file, county average yield file, the agricultural lands productivity formula sampling methods, and Exhibit A in the ALPF and to delete Tables A through D from the ALPF.

a. *Citation Corrections.* In the soil master file and the county cropped acreage file, Illinois is changing a citation reference to the Illinois Department of Agriculture from ''20 [Illinois Compiled Statutes] ILCS 205/40.38'' to ''20 ILCS 205–115.''

b. *Soil Master File.* Illinois proposes to revise the introductory paragraph by changing the word ''high'' to the word ''optimum'' in its reference to the ''high level of management yields'' and by adding the following sentence at the end of the paragraph:

The reference document for information contained in the soil master file shall be Bulletin 811, ''Optimum Crop Productivity Ratings for Illinois Soil,'' University of Illinois, College of Agricultural, Consumer and Environmental Sciences, Office of Research, August 2002.

Illinois also proposes to remove the information on additional components of the soil master file.

c. *County Average Yield File.* In the fifth paragraph, Illinois proposes to remove its reference to ''oats'' as a grain crop. In the seventh paragraph, Illinois proposes to change the word ''high'' to the word ''optimum'' in the phrase ''high management yield.'' In the eighth paragraph, Illinois proposes to change the word ''high'' to the word ''optimum'' in the phrase ''high management yield'' and to add the following new information:

If official county crop yields are unavailable for a specific crop in a given year, the Department, in consultation with the permittee, and with the concurrence of the Illinois Department of Agriculture, will substitute a county crop yield from an adjacent county with similar soils, if it can be determined that similar weather conditions occurred in that year.

d. *Agricultural Lands Productivity Formula Sampling Methods.* In the introductory paragraph, Illinois proposes to remove its reference to ''oats'' as a grain crop. Illinois proposes to revise Step 10 under the section heading ''Corn Sampling Technique'' by removing the existing information on the row factor and replacing this information with ''average row width in feet × 15 feet of row ÷ 43560 square feet/acre.'' Illinois also proposes to remove the sections ''Oats Sampling Technique (Rows <8″)'' and ''Oats Sampling Technique (Discernible Rows)'' from the ALPF.

e. *Exhibit A, County Crop Yields by Soil Mapping Unit.* Illinois proposes to change the word ''high'' to the word ''optimum'' in columns E and F and to remove a reference to oats.

f. Illinois proposes to delete tables A through D from the ALPF.

B. 62 IAC Part 1817 Permanent Program Performance Standards—Underground Mining Operations

Illinois proposes to update statutory citations, to correct regulation references, and to add clarifying language to several regulations.

1. *62 IAC 1817.42 Hydrologic Balance-Water Quality Standards and Effluent Limitations.* Illinois proposes to change the statutory citation for the Illinois Environmental Protection Act from ''(Ill. Rev. Stat. 1991, ch. 111½, pars. 1001 *et seq.*)'' to ''[415 ILCS 5].''

2. *62 IAC 1817.43 Diversions:*

a. At subsection (a)(2)(D) Illinois proposes to change the statutory citation for the Illinois Rivers, Lakes, and Streams Act from ''(Ill. Rev. Stat. 1991, ch. 19, pars. 52–79)'' to ''[615 ILCS 5].''

b. At subsections (b) and (c), Illinois is proposing to simplify its use of numbers.

3. *62 IAC 1817.116 Revegetation Success Standards:*

a. At subsections (a)(3)(C) and (E), Illinois proposes to add a reference to the newly proposed productivity alternative at 62 IAC 1816.116(a)(6) and to add the following requirement at the end of each subsection:

Once chosen by the permittee, the productivity alternative in subsection (a)(6) may not be modified without approval from the Department.

b. At subsection (a)(4), Illinois proposes to add a reference to the newly proposed productivity alternative at 62 IAC 1816.116(a)(6).

c. At subsection (b)(2), Illinois proposes to correct a regulation citation reference by changing it from ''62 IAC 1785.15'' to ''62 IAC 1823.15.''

4. *62 IAC 1817.121 Subsidence Control:*

a. At subsection (c), Repair of Damage, Illinois proposes to add the following new introductory paragraph:

The requirements of this subsection apply only to subsidence-related damage caused by underground coal extraction conducted after February 1, 1983, except as noted in Section 1817.41(j).

b. At subsection (c)(2), Illinois proposes to remove the last sentence.

C. 62 IAC Part 1823.15 Prime Farmland-Revegetation

a. At subsection (b)(2), Illinois proposes to add a reference to the newly proposed productivity alternative under 62 IAC 1816.116(a)(6).

b. At subsection (b)(3), Illinois proposes to add a reference to the newly proposed productivity alternative under 62 IAC 1816.116(a)(6), to simplify its use of numbers, and to add the following new requirement:

Once chosen by the permittee, the productivity alternative in subsection (a)(6) may not be modified without approval from the Department.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the State program.

Written Comments

Send your written or electronic comments to OSM at the address given above. Your written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of your recommendations. We will not consider or respond to your comments when developing the final rule if they are received after the close of the comment period (see DATES). We will make every attempt to log all comments into the administrative record, but comments delivered to an address other than the Indianapolis Area Office may not be logged in.

Electronic Comments

Please submit Internet comments as an ASCII or Word file avoiding the use of special characters and any form of encryption. Please also include ''Attn: Docket No. IL–103–FOR'' and your name and return address in your

Internet message. If you do not receive a confirmation that we have received your Internet message, contact the Indianapolis Area Office at (317) 226–6700.

Availability of Comments

We will make comments, including names and addresses of respondents, available for public review during normal business hours. We will not consider anonymous comments. If individual respondents request confidentiality, we will honor their request to the extent allowable by law. Individual respondents who wish to withhold their name or address from public review, except for the city or town, must state this prominently at the beginning of their comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public review in their entirety.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., e.s.t. on April 19, 2005. If you are disabled and need special accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be ''in accordance with'' the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations ''consistent with'' regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. This determination is based on the fact that the Illinois program does not regulate coal exploration and surface coal mining and reclamation operations on Indian lands. Therefore, the Illinois program has no effect on Federally-recognized Indian tribes.

Executive Order 13211—Regulations That Significantly Affect The Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was

prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of $100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 913

Intergovernmental relations, Surface mining, Underground mining.

Dated: March 1, 2005.

Charles E. Sandberg,

Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 05–6601 Filed 4–1–05; 8:45 am]

BILLING CODE 4310–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

[E–Docket ID No. OAR–2003–0079, FRL–7895–3]

RIN 2060–AJ99

Nonattainment Major New Source Review Implementation Under 8-Hour Ozone National Ambient Air Quality Standard: Reconsideration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of public hearing.

SUMMARY: The EPA is requesting comment on issues raised in a petition for reconsideration of EPA's rule to implement the 8-hour ozone national ambient air quality standard (NAAQS or 8-hour standard). On April 30, 2004, EPA took final action on key elements of the program to implement the 8-hour standard. In that final action, we (the EPA) addressed certain implementation issues related to the 8-hour standard, including aspects of implementation of the nonattainment major New Source Review (NSR) program mandated by part D of title I of the Act (CAA or Act).

Following this action, on June 29, 2004 and September 24, 2004, three different parties each filed a petition for reconsideration concerning implementation of the 8-hour standard, including both major NSR and other issues. By letter dated September 23, 2004, EPA granted reconsideration of three issues raised in the petition for reconsideration filed by Earthjustice on behalf of several environmental organizations. On February 3, 2005, we published a proposed rule providing additional information and soliciting comment on two of the issues on which we granted reconsideration. Today, we provide additional information and seek comment on the third issue, which relates to two aspects of the major NSR provisions in the April 30, 2004 final rules. Specifically, we request comment on whether we should interpret the Act to require areas to retain major NSR requirements that apply to certain 1-hour ozone nonattainment areas in implementing the 8-hour standard, and whether EPA properly concludes that a State's request to remove 1-hour major NSR programs from its State Implementation Plan (SIP) will not interfere with any applicable requirement within the meaning of Section 110(l) of the Act.

DATES: *Comments.* Comments must be received on or before May 4, 2005.

Public Hearing. The public hearing will convene at 9 a.m. and will end at 5 p.m. on April 18, 2005. All individuals who have registered to speak before the date of the public hearing will be given an opportunity to speak. Because of the need to resolve the issues raised in this in a timely manner, EPA will not grant requests for extension of the public comment period. For additional information on the public hearing and requesting to speak, see the **SUPPLEMENTARY INFORMATION** section of this proposed rule.

ADDRESSES: *Comments.* Submit your comments, identified by Docket ID No. OAR–2003–0079, by one of the following methods to the docket. If possible, also send a copy of your comments to Ms. Lynn Hutchinson by either mail or e-mail as identified in the **FOR FURTHER INFORMATION CONTACT** section.

1. Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

2. Agency Web site: *http://www.epa.gov/edocket.* EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

3. E-mail: *A-and-R-Docket@EPA.gov.* Attention E-Docket No. OAR–2003–0079.

4. Fax: The fax number of the Air Docket is (202) 566–1741. Attention E-Docket No. OAR–2003–0079.

5. Mail: Air Docket, Environmental Protection Agency, Attention E-Docket No. OAR–2003–0079, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.

6. Hand Delivery: Air Docket, Attention E-Docket No. OAR–2003–0079, Room B–102, Environmental Protection Agency West, 1301 Constitution Avenue, NW., 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. OAR–2003–0079. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/edocket,* 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 EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the Federal regulations.gov Web sites are ''anonymous access'' systems, 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 EDOCKET or 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.

Docket. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. This docket facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Air and Radiation Docket telephone number is (202) 566–1742. 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 (non-NSR notice says 566–1741).

FOR FURTHER INFORMATION CONTACT: Ms. Lynn Hutchinson, Office of Air Quality Planning and Standards, (C339–03), U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5795, fax number (919) 541–5509, e-mail: *hutchinson.lynn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

Entities potentially affected by the subject rule for today's action include sources in all industry groups. The majority of sources potentially affected are expected to be in the following groups.

Industry group	SIC [a]	NAICS [b]
Electric Services	491	221111, 221112, 221113, 221119, 221121, 221122
Petroleum Refining	291	324110
Industrial Inorganic Chemicals	281	325181, 325120, 325131, 325182, 211112, 325998, 331311, 325188
Industrial Organic Chemicals	286	325110, 325132, 325192, 325188, 325193, 325120, 325199
Miscellaneous Chemical Products	289	325520, 325920, 325910, 325182, 325510
Natural Gas Liquids	132	211112
Natural Gas Transport	492	486210, 221210
Pulp and Paper Mills	261	322110, 322121, 322122, 322130
Paper Mills	262	322121, 322122
Automobile Manufacturing	371	336111, 336112, 336211, 336992, 336322, 336312, 336330, 336340, 336350, 336399, 336212, 336213
Pharmaceuticals	283	325411, 325412, 325413, 325414

[a] Standard Industrial Classification.
[b] North American Industry Classification System.

Entities potentially affected by the subject rule for today's action also include State, local, and Tribal governments that are delegated authority to implement these regulations.

B. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments.

- Explain your views as clearly as possible.
- Describe any assumptions that you used.
- Provide any technical information and/or data you used that support your views.
- If you estimate potential burden or costs, explain how you arrived at your estimate.
- Provide specific examples to illustrate your concerns.
- Offer alternatives.
- Make sure to submit your comments by the comment period deadline identified.
- To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

C. Where Can I Get a Copy of This Document and Other Related Information?

In addition to being available in the docket, an electronic copy of today's notice is also available on the World Wide Web. Following signature by the EPA Administrator, a copy of today's notice will be posted in the regulations and standards section of the New Source Review home page located at *http://www.epa.gov/nsr.*

D. What Information Should I Know About the Public Hearing?

The public hearing will be held at the EPA's facility at 109 TW Alexander Drive, Research Triangle Park, NC, or at an alternate facility nearby. Please check our Web site at *http://www.epa.gov/nsr/* for information and updates concerning the public hearing.

The public hearing will provide interested parties the opportunity to present data, views, or arguments concerning the issues raised in this notice. People interested in attending or presenting oral testimony are encouraged to register in advance by contacting Ms. Chandra Kennedy, OAQPS, Integrated Implementation Group, Information Transfer and Program Integration Division (C339–03), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number (919) 541–5319 or e-

mail *kennedy.chandra@epa.gov* no later than April 14, 2005. Presentations will be limited to 5 minutes each. We will assign speaking times to speakers who make a timely request to speak at the hearing. We will notify speakers of their assigned times by April 18, 2005. We will attempt to accommodate all other people who wish to speak, as time allows.

The EPA's planned seating arrangement for the hearing is theater style, with seating available on a first come first served basis for about 250 people. Attendees should note that the use of pickets or other signs will not be allowed on either government or hotel property.

As of the date of this announcement, the Agency intends to proceed with the hearing as announced; however, unforeseen circumstances may result in a postponement. Therefore, we advise members of the public who plan to attend the hearing to contact Ms. Chandra Kennedy at the above referenced address to confirm the location and date of the hearing. You may also check our New Source Review Web site at *http://www.epa.gov/nsr* for any changes in the date or location.

The record for this action will remain open until May 19, 2005, to accommodate submittal of information related to the public hearing.

E. How Is This Notice Organized?

The information presented in this notice is organized as follows:

I. General Information
A. Does This Action Apply To Me?
B. What Should I Consider as I Prepare My Comments for EPA?
C. Where Can I Get a Copy of This Document and Other Related Information?
D. What Information Should I Know About the Public Hearing?
E. How Is This Notice Organized?
II. Background
III. Today's Action on Reconsideration
A. Reconsideration Petitions
B. Schedule for Reconsideration and Status of Final Rules
IV. Rational and Legal Basis
A. Overview
B. The Clean Air Act Does Not Compel EPA To Retain 1-Hour Major NSR Requirements in Implementing the 8-Hour Standard Because Major NSR Is Not a ''Control''.
C. No State's Removal of 1-Hour Major NSR Requirements From the SIP Will Interfere With Any Applicable Requirement Under the Act Within the Meaning of Section 110(l)
D. Request for Comment
V. Statutory and Executive Order Reviews
A. Executive Order 12866—Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*
D. Unfunded Mandates Reform Act
E. Executive Order 13132—Federalism
F. Executive Order 13175—Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045—Protection of Children From Environmental Health Risks and Safety Risks
H. Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act
J. Executive Order 12898—Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
VI. Statutory Authority

II. Background

On July 18, 1997, we revised and strengthened the ozone NAAQS to change from a standard measured over a 1-hour period (1-hour standard) to a standard measured over an 8-hour period (8-hour standard). Previously, the 1 hour standard was 0.12 ppm. We established the new 8-hour standard at 0.08 ppm. *See* 62 FR 38856. Following revision of the standard, we promulgated an implementation rule that provided for implementation of the 8-hour standard under the general nonattainment area provisions of Subpart 1 of Part D of the Act. *See* 62 FR 38421. Subsequently, the Supreme Court ruled that our implementation approach was unreasonable because we did not provide a role for the generally more stringent ozone specific provisions of Subpart 2 of Part D of the Act in implementing the 8-hour standard. *See Whitman* v. *Amer. Trucking Assoc.*, 531 U.S. 457, 471–476, 121 S.Ct. 903, 911–914 (2001). The Court remanded the implementation strategy to EPA to develop a reasonable approach for implementation. *Id.* Accordingly, on June 2, 2003 (68 FR 32802), we proposed various options for transitioning from the 1-hour to the 8-hour standard, and for how the 8-hour standard would be implemented under both subpart 1 and subpart 2. On August 6, 2003 (68 FR 46536), we published a notice of availability of draft regulatory text to implement the 8-hour standard. Among other things, this proposed rule included certain provisions for implementing major NSR. Specifically, we proposed that major NSR would generally be implemented in accordance with an area's 8-hour ozone nonattainment classification, but we would provide an exception for areas that were designated nonattainment for the 1-hour standard at the time of designation for the 8-hour standard. If the classification for a 1-hour nonattainment area is higher than its classification under the 8-hour standard, then under the proposed rule, the major NSR requirements in effect for the 1-hour standard would have continued to apply under the 8-hour standard even after we revoked the 1-hour standard. (68 FR 32821).

On April 30, 2004 (69 FR 23951), we promulgated Phase I of the new implementation rule. In response to comments received on the proposal, we revised the implementation approach for major NSR under the 8-hour standard. Specifically, we determined that major NSR would be implemented in accordance with an area's 8-hour ozone nonattainment classification. For those areas that we classify moderate and above, major NSR is implemented under subpart 2. We also indicated that, when we revoke the 1-hour standard, a State is no longer required to retain a nonattainment major NSR program in its SIP based on the requirements that applied by virtue of the area's previous classification under the 1-hour standard. We further indicated that we would approve a request to remove these requirements from a State's SIP because we determined based on section 110(l) of the Act that such changes will not interfere with any applicable requirements of the Act, including a State's ability to reach attainment of the 8-hour standard or reasonable further progress (RFP) (69 FR 23985). We noted that States will be required to implement a major NSR program based on the 8-hour classifications. We also emphasized that emission limitations and other requirements in major NSR permits issued under 1-hour major NSR programs will remain in effect even after we revoke the 1-hour standard (69 FR 23986).

III. Today's Action on Reconsideration

A. Reconsideration Petitions

Following publication of the April 30, 2004 final rule, the Administrator received three petitions, pursuant to section 307(d)(7)(B) of the Act, requesting reconsideration of certain aspects of the final rule.[1] On June 29,

[1] Petitioners are: (1) Earthjustice on behalf of the American Lung Association, Environmental Defense, Natural Resources Defense Council, Sierra Club, Clean Air Task Force, Conservation Law Foundation, and Southern Alliance for Clean Energy; (2) the National Petrochemical and Refiners Association and the National Association of Manufacturers; and (3) the American Petroleum Institute, American Chemistry Council, American Iron and Steel Institute, National Association of Manufacturers and the U.S. Chamber of Commerce.

2004, Earthjustice submitted one of the three petitions that we received. This petition seeks reconsideration of certain elements of the Phase I Ozone Implementation Rule, including elements of the major NSR provisions. With respect to major NSR, Petitioners contend that the final rules are unlawful because the rules violate Section 110(l) and Section 172(e) of the Act by not requiring 8-hour ozone nonattainment areas to continue to apply major NSR requirements based on the area's 1-hour ozone nonattainment classification. Petitioners also allege that EPA acted unlawfully by stating that we will approve a State's request to remove 1-hour requirements from the SIP based on our finding that such a revision would not violate Section 110(l) for any State. Petitioners assert that these major NSR provisions and our rationale for them were added to the final action after the close of the public comment period. Thus, Petitioners claim, EPA failed to provide notice and opportunity for public comment concerning these provision as required under CAA Section 307(d)(5). On September 23, 2004, we granted reconsideration of three issues raised in the Earthjustice Petition. In an action dated February 3, 2005, we issued a **Federal Register** notice addressing two of those issues: (1) The provision that section 185 fees would no longer apply for a failure to attain the 1-hour standard once we revoke the 1-hour standard; and (2) the timing for determining what is an ''applicable requirement.'' 70 FR 5593.

Today, we seek comment on the third issue raised in that petition, which related to elements of the major NSR program. Specifically, we request comment on: (1) Whether we must interpret the Act to require States to continue major NSR requirements under the 8-hour standard based on an area's higher classification under the 1-hour standard; and (2) whether revising a State SIP to remove 1-hour major NSR requirements is consistent with Section 110(l) of the Act. As previously discussed, we proposed an approach concerning whether 1-hour nonattainment major NSR requirements must remain in the SIP after we revoke the 1-hour standard. (68 FR at 32821–22.) The public had an opportunity to comment on the approach we proposed, and in fact some commenters advocated replacing the 1-hour major NSR program with the 8-hour program. Nonetheless, we want Petitioners and others to have every opportunity to comment on our approach and to provide additional information that they believe to be relevant. For these reasons, we provide further explanation of our rationale for this action and request public comment on this approach. We will consider these comments and then make a final decision regarding the implementation of the NSR program under the 8-hour standard.

B. Schedule for Reconsideration and Status of Final Rules

We plan to take final action on our grant of reconsideration by the end of May 2005. A State can only remove 1-hour NSR SIP provisions after we revoke the 1-hour standard. We plan to revoke the standard on June 15, 2005. Accordingly, no changes in 1-hour major NSR SIP programs could occur before June 15, 2005. The final rules concerning applicability of major NSR under the 8-hour standard remain in effect as promulgated until our final action on this reconsideration.

IV. Rationale and Legal Basis

A. Overview

It is a basic tenet of administrative law that expert agencies have discretion to interpret ambiguous statutory terms. *Chevron, U.S.A., Inc.* v. *NRDC*, 467 U.S. 387 (1984). We exercised this discretion in determining how to implement subpart 2 requirements for major NSR under the 8-hour standard, an issue that the Supreme Court has recognized is ''ambiguous.'' [2]

In determining how to implement the provisions of subpart 2 for the major NSR program under the 8-hour standard, we considered the statutory requirements, Congressional intent as expressed in the CAA legislative history, the history of the NSR regulatory program, and our actions on 1-hour ozone Rate of Progress (ROP) plans and attainment demonstrations in general as they relate to nonattainment major NSR programs. We discuss this information below.

Our review of this information, as well as public comments on the proposed rule, supports our conclusion that once we revoke the 1-hour standard, the Act does not require States to retain a nonattainment major NSR program in their SIPs based on the requirements that applied by virtue of the area's previous classification under the 1-hour standard. It also supports our conclusion that, based on section 110(l) of the Act, removing the 1-hour major NSR program does not interfere with any applicable requirements of the Act, including a State's ability to reach attainment of the 8-hour standard and RFP.

B. The Clean Air Act Does Not Compel EPA To Retain 1-Hour Major NSR Requirements in Implementing the 8-Hour Standard Because Major NSR Is Not a ''Control''

Section 172(e) applies when we relax a NAAQS. It specifies that we ''shall provide for controls which are not less stringent than the controls applicable to areas designated nonattainment before such relaxation.'' By its terms, it does not directly apply to requirements to implement the 8-hour standard, because we strengthened the ozone NAAQS when we enacted the 8-hour standard. Nonetheless, we view this provision as an expression of Congressional intent that States may not remove control measures in areas which are not attaining a NAAQS when EPA revises that standard to make it more stringent, as is the case with the 8-hour standard. *See* 68 FR 32819. Accordingly, we required States to retain certain requirements associated with the 1-hour ozone nonattainment classification in implementing the 8-hour standard. *See generally* 69 FR 23951.

Notwithstanding the requirement to retain certain 1-hour control measures, we determined that Section 172(e) and our interpretation of Congressional intent does not mandate that States retain 1-hour major NSR requirements under the 8-hour standard, because the major NSR program does not impose emissions ''controls'' that reduce a nonattainment area's emissions below that area's baseline year inventory. In this respect, major NSR is not a ''control'' within the meaning of Section 172(e). Thus, we concluded that because major NSR programs based on 1-hour classifications would not contribute emissions reductions below baseline levels, those provisions are not ''controls'' that need to be preserved in implementing the 8-hour standard.

The term ''controls'' as used in Section 172(e) is ambiguous. In determining whether the reference to ''controls'' in Section 172(e) covers 1-hour NSR requirements, and thus whether we should interpret the Act as requiring such controls to remain effective after revocation of the 1-hour standard, we looked first to the CAA statutory language and structure. We reasoned that ''[t]he role of the NSR permitting program as a growth measure, rather than a control measure, is evidenced in the structure of the Act,

We are continuing to review the issues raised in the second and third of these petitions for reconsideration.

[2] *See Whitman*, 531 U.S. at 484 (''The statute is in our view ambiguous concerning the manner in which Subpart 1 and Subpart 2 interact with regard to revised ozone standards, and we would defer to the EPA's reasonable resolution of that ambiguity.'')

which delineates nonattainment NSR and control measures as separate SIP requirements,'' citing, among other things, Section 110(a)(2)(A) and 110(a)(2)(C). (69 FR at 23986). Similarly, Section 172(c), which identifies the requirements for nonattainment plans, lists requirements for implementation of control measures separately from the provision requiring permits for new and modified major stationary sources. *Compare* Sections 172(c)(1) and (c)(6) (referring to control measures) *with* Section 172(c)(5) (referring to permits for new and modified major stationary sources).

Second, to resolve the ambiguity over whether the term ''controls'' in section 172(e) covers 1-hour NSR requirements, we further looked to Congress' purpose in creating the major NSR program. The 1970 statute did not contain any provisions concerning permitting of new sources, either in attainment or nonattainment areas. The statute set 1975 as the deadline to meet the NAQQS in most regions, with some extensions until 1977. By the time of the 1977 Amendments, many areas had missed their attainment deadlines, and it became apparent that, despite significant progress, SIPs were inadequate to achieve the NAAQS in many areas of the country.

In 1977 Congress considered whether new source growth could be allowed in areas not attaining the NAAQS.

> A major weakness in implementation of the 1970 Act has been the failure to assess the impact of emissions from new sources of pollution on State plans to attain air quality standards by statutory deadlines. States have permitted growth on the assumption that a deadline was sufficiently distant so that future emissions reductions could be made to compensate for the initial increases. It can now be seen that these assumptions were wrong. Some mechanism is needed to assure that before new or expanded facilities are permitted, a State demonstrate that these facilities can be accommodated within its overall plan to provide for attainment of air quality standards.
>
> One mechanism is a case-by-case review of each new or modified major source of pollution that seeks to locate in a region exceeding an ambient standard. Such a review requires matching reductions from existing sources against emissions expected from the new source *in order to assure that introduction of the new source will not prevent attainment of the applicable standard by the statutory deadline*. This is the mechanism adopted by the Committee as a condition for approval of an implementation plan revision under section 110(a)(3) and for extensions of the oxidant and carbon monoxide attainment deadlines beyond 1982. Sen. Rep. 95–127 at 55 (May 10, 1977).

Congress thus recognized the need for a balance between the goals of attaining air quality standards and providing for new economic growth. As part of the 1977 Amendments, Congress amended the Act to, among other things, establish a statutory approach to permit growth in polluted areas, while requiring attainment of the NAAQS by specific deadlines.[3] This approach established the basic SIP process and requirements for attaining the NAAQS.

The major NSR program's purpose ''is to permit States to allow continued growth or expansion in nonattainment areas, so long as this growth or expansion is undertaken in a manner consistent with the goals and objectives of the Clean Air Act.'' *See* H.R. Rpt. 95–294 at 210 (May 12, 1977). Section 172(a)(2) of the Act requires attainment as expeditiously as practicable considering the availability and feasibility of control measures and Section 172(c)(1) and (c)(6) require implementation of all reasonably available control measures as expeditiously as practicable to provide for attainment of the NAAQS by the area's attainment date. Conversely, Section 173(a)(1)(A) requires only that growth due to proposed sources, when considered together with the other plan provisions required under Section 172, be sufficient to ensure RFP toward attainment. Thus, unlike the control measures required by Section 172(c)(1) and (c)(6), major NSR is not a measure to reduce emissions to assure attainment; nor did Congress identify the program as a control measure to help areas achieve attainment ''as expeditiously as practicable.'' Rather, Congress intended that the effectiveness of major NSR in minimizing the impact of increased emissions should be considered together with the State's other SIP measures to assure, consistent with Section 172(a)(2), that emissions from new sources will be consistent with RFP. Our interpretation is supported by the legislative record wherein Congress stated that

> In allowing new sources to locate, and existing sources to expand, in presently unhealthy air areas, the committee realizes that some worsening of air quality or delay in actual attainment of the national ambient air standards will result. This is inevitable, as a result the committee had to accept as a consequence of allowing additional economic growth in these area. *Id.* at 214–215.

Accordingly, based on our analysis of the statutory language and structure, and Congress' purpose in creating the major NSR as a measure to mitigate emissions growth rather than a measure to reduce existing emissions levels, we conclude that Congress did not mean to include major NSR within the ''controls'' that are required to be maintained in the SIP under our antibacksliding approach and Section 172(e).

We note that recent case law upheld the Agency's approach of looking to Section 110 to determine the meaning of a similar phrase, ''measures with respect to the control,'' of pollutants in Section 175A of the Act concerning maintenance plans.[4] *Greenbaum* v. *U.S. EPA*, 370 F.3d 527, 536–37 (7th Cir. 2004). In reviewing EPA's determination that the phrase did not include nonattainment major NSR, the court found the phrase ambiguous, and stated:

> It was entirely permissible, and indeed logical, for the EPA to look to § 110 to determine the meaning of the word ''measure'' in § 175A as § 110 lists the provisions required to be included in a nonattainment SIP.
>
> Likewise, the EPA's argument that the reference to the Part D NSR program in subparagraph C of § 110 [110(a)(2)(C)] would be surplusage if it were among the control measures mentioned in subparagraph A of § 110 [110(a)(2)(A)] is reasonable.

The Court then deferred to EPA's determination that the phrase did not include nonattainment major NSR, and thus that major NSR provisions need not be retained in contingency plans. Thus, although major NSR, when triggered, results in the requirement to impose LAER and the requirement to obtain offsetting emissions, neither of these requirements are considered a ''measure with respect to the control'' of the relevant NAAQS pollutant within the meaning of Section 175A. That is, it is not relevant for determining which former nonattainment SIP provisions States must include in contingency provisions. We believe this decision supports our determination that a 1-hour major NSR program is not a ''control'' measure within the meaning of Section 172(e). Accordingly, we find that the Act does not mandate that States retain the program under the antibacksliding approach implemented in transitioning from the 1-hour to the 8-hour standard.

[3] Sections 107(d) and 172 of the Act (42 U.S.C. 7407(d) and 7502; Sections 129(a) and (c) of the 1977 Amendments, Pub. L. No. 95–95.

[4] Section 175A requires that when an area is redesignated from nonattainment to attainment, it must submit a plan to provide for maintenance of the Standard. The plan must include contingency provisions that, in the event of a violation of the Standard, would require the State to implement ''measures with respect to the control'' of the Standard pollutant that were in the SIP prior to redesignation.

Petitioners cite EPA's past characterization of major NSR in a Supreme Court brief and a **Federal Register** notice as a ''pollution-control measure'' and ''pollution control technology program.'' Pet. at 5 (June 29, 2004) (quoting EPA Opening Merits Brief in *Chevron, U.S.A.* v. *NRDC*, S.Ct. 82–1005 (Aug. 31, 1983), 1982 Lexis U.S. Briefs 1005, at n.5; *accord*, 67 FR 80187 (Dec. 31 2002)). These citations are somewhat misleading, however, because petitioners isolate single phrases and ignore the broader context in which we wrote the words. The Supreme Court brief addresses whether EPA reasonably used a plantwide definition of ''source'' in the NSR program, and the quoted phrase occurs in the context of comparing the NSR and New Source Performance Standards (NSPS) programs. *See Chevron U.S.A., Inc.* v. *NRDC*, 1982 LEXIS Briefs 1005 at n.55 (Aug. 31, 1983). The **Federal Register** notice provision cited by Petitioners makes the statement in a background section generally describing the NSR program as a combination of an air quality planning and control technology program. In that same paragraph of the notice, we also stated that one of the program's purposes is ''* * * to maximize opportunities for economic development consistent with the preservation of clean air resources.'' Moreover, this alleged characterization has no persuasive value in interpreting the meaning of ''controls'' in Section 172(e) nor the appropriateness of interpreting the Act as a whole with respect to backsliding because the cited brief and **Federal Register** notice do not address this issue, nor even touch on the subject of antibacksliding generally.

Petitioners also reference a 1990 House Report describing the Subpart 2 classification system as a ''graduated control program''. Pet. at 7. That Report states:

> Also included in the graduated control requirements are increasing offset ratios that require a greater level of pollution reductions from other sources in the nonattainment area to offset increases in pollution from new sources or modifications. This program is intended to allow economic growth and the development of new pollution sources and modifications to continue in seriously polluted areas, while assuring that emissions are actually reduced. H.R. Comm. on Energy and Commerce, *The Clean Air Act Amendments of 1990—Hearings of H.R.* 3030—101st Cong. 234 (May 17, 1990)

Read out of context, this legislative history could be interpreted to imply that Congress intended the higher offset requirements in subpart 2 to act as ''controls.'' However, this language must be read in context of the statutory framework.

First, unlike control measures for which emissions reductions can be quantified and relied on in a modeling demonstration to show how the measure helps an area reach attainment, the benefits of offsets are uncertain. This is because States generally do not know in advance when and if any major stationary source will become subject to the major NSR offsetting requirements. Accordingly, as discussed further below, States do not use the higher offset ratios as a SIP control strategy within their attainment plans. But even if a State could project the number of sources that would trigger the offset requirement, the State, still could not necessarily rely on the higher emissions offset ratios to reduce emissions in the area. This is because, in Section 173(c)(1), Congress allows a major stationary source to obtain offsets from other nonattainment areas. Such an area may be located in another State. In this context, offsets serve as a valuable tool in reducing regional pollutant transport, but may achieve no actual reductions in the area where the new emissions are locating. Accordingly, it would be inappropriate for a State to expressly rely on offsets as a State-imposed regulatory measure or ''control'' to achieve a defined quantity of emissions reductions from sources within the State for the purpose of reducing the existing emissions inventory. Based on this information, and because the legislative history does not address the issue of Congress's intent in using the term ''controls'' in Section 172(e), or the subject of antibacksliding generally, we conclude that it lacks persuasive value in interpreting the term ''controls'' in Section 172(e) or elsewhere in the Act.

Petitioners further claim that CAA Sections 173(d) and 173(a)(5), referring to lowest achievable emission reduction (LAER) requirements as a control technology and control technique, indicate NSR is a control measure. As we discuss in this proposed rule, the statute, our regulations, and our guidance have established NSR as a growth measure for SIP planning purposes. LAER is not a control measure, but instead is an emission limitation based on application of a particular control technology. Control measures such as reasonably available control technology (RACT), transportation control measures (TCM), and inspection and maintenance programs (I/M) reduce base year emissions to assure RFP and meet attainment. The LAER's purpose is to minimize the amount of emissions increase resulting from new or modified major stationary sources, not reduce emissions below the base year inventory. CAA Sections 173(d) and 173(a)(5) instead contain specific requirements related to LAER. CAA Section 173(d) requires States to report information on LAER to the RACT/BACT/LAER Clearinghouse.[5] CAA Section 173(a)(5) requires consideration of LAER in the alternative sites analysis.

While petitioners present a possible interpretation of the term ''controls'' as used by Congress in Section 172(e), we do not believe that the Statute compels this interpretation. Moreover, to accept the Petitioners' interpretation would essentially define ''controls'' in a way that would require States to retain all requirements in a SIP upon relaxation of the standard. If Congress meant to require States to retain all requirements, Congress would have stated so expressly. Instead, by using only the term ''controls,'' Congress implied an intent that some requirements under the old standard would no longer apply under the new standard. We think it is reasonable to interpret the term ''controls'' to exclude major NSR, whose purpose is to ensure that emissions growth does not interfere with attainment, and for which States can not reliably estimate the benefits of mitigating emissions increases for SIP planning purposes.

C. No State's Removal of 1-Hour Major NSR Requirements From the SIP Will Interfere With Any Applicable Requirement Under the Act Within the Meaning of Section 110(l)

Section 110(l) provides us the legal authority to approve revisions to SIPs when we determine that such revisions will not ''interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171), or any other applicable requirement of the Act.'' Petitioners suggest that Section 110(l) limits the Administrator's ability to approve any change in a State SIP if that change would relax requirements previously contained in the SIP. We disagree. Rather, we interpret Section 110(l) to allow such changes if the revision is consistent with reasonable further progress, and will not interfere either with the area's ability to achieve attainment or with any other requirement of the Act.

[5] In framing 173(d), Congress did not identify LAER as a control obligation. Instead, Congress clearly stated the purpose of including 173(d) was to make sure that the LAER control technology information is widely available. See The *Clean Air Act Amendments of 1990–Hearings of H.R. 3030*, 101st Cong. at 226.

To determine whether a change in major NSR requirements could satisfy these criteria, we first reviewed the statutory role of major NSR. As discussed above, Congress designed the major NSR program to mitigate emission increases from economic growth—not as a program to generate emissions reductions to bring an area into attainment. Congress distinguished those ''reasonably available control measures'' required to bring an area into attainment ''as expeditiously as practicable'' as specified in Section 172(c)(1) from the requirements of the major NSR program specified in Section 172(c)(4) and (5). Moreover, Congress recognized in allowing for growth in nonattainment areas, that some worsening of air quality may be inevitable. Accordingly, States do not rely on major NSR to achieve emissions reductions and reach attainment as expeditiously as practicable and thus a change in the program will not interfere with any applicable requirement concerning attainment and reasonable further progress.

We also reviewed the role major NSR plays in State attainment planning. While we disagree with Petitioners' assertion that the Section 110(l) analysis requires us to analyze changes relative to the 1-hour standard (after we revoke that standard), and we are not granting reconsideration on that issue, we nonetheless looked at the effect of removing the major NSR requirements on the State's existing 1-hour attainment plans to determine what effect it may have for future planning under the 8-hour standard.

Before 1990, Congress provided States with two options for managing the impact of economic growth on emissions. A State could either provide a case-by-case review of each new or modified major source and require such source to obtain offsetting emissions, or the State could implement a waiver provision which allowed the State to develop an alternative to the case-by-case emissions offset requirement. This alternative program became known as the ''growth allowance'' approach. In 1990, Congress invalidated some of the existing growth allowances and shifted the emphasis for managing growth from using growth allowances to using the case-by-case offset approach. Nonetheless, we still interpreted the inventory and SIP demonstration requirements in the Act to require States to continue to account for future growth in their demonstrations. *See* 57 FR 13554, 13567. In this way, State SIPs analyze the impact of growth on emissions in two overlapping ways: (1) By establishing a growth projection in the attainment demonstration, and (2) by requiring major sources to comply with the major NSR requirements.

In general, States use information from the Bureau of Economic Analysis (BEA) to derive growth factors which are then applied to different industrial categories to project emissions growth within the nonattainment area. Some States project growth based on industry data that is specific to their jurisdiction, rather than using national BEA data to project the source category increases. A few States project growth based on NO_X emissions caps imposed by SIP-approved regulations (*e.g.* NO_X-SIP call). Finally, a few States project no point source growth based on SIP-approved rules that limit VOC and NO_X emissions in the area. Regardless of which process is used, each State arrives at a specific tonnage of emissions that represents the expected increase in emissions due to economic growth in the State. This growth projection represents increases in emissions that come from a variety of different activities such as major and minor modifications and increases in utilization at existing sources. The SIPs then provide sufficient emissions reductions to bring the areas into attainment and provide reasonable further progress even accounting for this projected growth.

The next critical question in determining what effect a change in the major NSR requirements might have is whether States adjust this growth projection based on applicability of the major NSR program. A survey of current nonattainment areas shows that in general States do not discount the growth projection based on an assumption of the quantity of emissions increases that may be ''offset.'' In fact, we discourage States from including offsets as a source of emissions reductions in the attainment model because of the difficulties in accurately predicting the number of sources that will trigger offset reductions and the number of offsets actually achieved. Moreover, the method used to derive the growth projection allows no consideration of the major stationary source thresholds that apply under the 1-hour ozone classification. Finally, we are aware of only one district in California that discounts the growth projection assuming a LAER level of control in projecting emissions. However, this particular district also has a very stringent SIP-approved nonattainment major NSR rule in which LAER applies to all sources with potential to emit (PTE) greater than 1 lb/day and offsets are required for all sources with PTE greater than 4 tpy VOC or NO_X. A lower classification under the 8-hour standard than under the 1-hour standard thus would not change the number of sources in this district subject to LAER or offsets. Therefore, this district similarly did not rely on the major stationary source thresholds or the offset ratios that applied under the 1-hour classification as opposed to those that would apply under the 8-hour standard to assure RFP or attainment of the 1-hour standard.[6]

Once a State computes the growth projection, these emissions are added to the base year emissions inventory and used to project growth for rate of progress plan purposes, and to project growth through the attainment year in the attainment demonstration model. In the attainment demonstration model, States must demonstrate that other emissions reduction programs in the SIP will allow the area to reduce emissions over time to achieve attainment by the attainment date despite the economic growth. Furthermore, the State must also demonstrate that the phasing in of emission reductions over time is sufficient to achieve reasonable further progress toward attainment. This effectively means that whether or not major NSR applies to a given activity that increases emissions, the area is projected to reach attainment based on other control measures in the SIP.

This information shows that States have not directly relied on the major NSR program as a control measure to achieve reductions and move the area toward attainment. For the 8-hour standard, States will generally account for growth in the same manner to show attainment of the 8-hour standard. The only change may be that some States rely on EPA's Economic Growth Analysis System rather than BEA information, but these two systems are fundamentally similar in that they rely on economic forecasts to project growth in emissions. Accordingly, EPA concludes that the removal of 1-hour major NSR requirements from the SIP will not interfere with reasonable further progress or attainment in any area because all States' attainment demonstrations will account for emissions increases related to growth within the attainment demonstration, and these projections will not differ based upon the major NSR program

[6] We are referring to South Coast Air Quality Management District. There are several other State and local agencies, including some in California, in which the classification under the 8-hour standard is lower than that under the 1-hour standard. We are not aware of any of these agencies relying on the major stationary source thresholds or the offset ratios under the 1-hour classification to assure RFP or attain the 1-hour standard.

applicable to the area under its ozone classification.

Petitioners argue that if this logic is accepted, ''a state could pluck out any other requirement (including requirements such as enhanced I/M or stage II) * * * and argue that the requirement is dispensable in light of the area's attainment and RFP plans.'' Pet. at 12. We disagree that our logic as described here would lead to the same conclusion for all programs, because States rely on these other programs to generate emissions reductions in the modeling demonstration. Nonetheless, we agree with Petitioners that Congress ''prescribed specific program elements like NSR'' and each State must show how these statutory requirements are being met through their SIP programs. *Id.*

States satisfy this requirement by having the authority to issue permits in 8-hour nonattainment areas consistent with the requirements of major NSR for the 8-hour standard. Major NSR plays a role in assuring that growth from major stationary sources occurs consistent with States' plans for meeting reasonable further progress and reaching attainment. In 1990, Congress recognized that some States were not accurately predicting the growth within their attainment demonstrations. Accordingly, in Subpart 2 of the Act, Congress specified that areas with more severe ozone nonattainment problems should implement higher offset ratios and lower major stationary source thresholds. Likewise, we followed the same approach for the 8-hour standard by basing the major NSR requirements on the severity of the area's 8-hour ozone nonattainment problem. As a policy matter, we believe that it is appropriate to look at areas' present day air quality in determining what major NSR program requirements are necessary to assure future air quality improvements, because an area's ability to accommodate economic growth is related to its current air quality conditions. An area's classification under the 8-hour standard is a more accurate reflection of current day air quality then the classification we assigned under a different standard as far back as the early 1990's.

Together, the growth projection methods used in preparing attainment demonstrations and the 8-hour major NSR program requirements provide overlapping assurance that removing the 1-hour major NSR program from the SIP, will not ''interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171), or any other applicable requirement of the Act.''

D. Request for Comment

For the reasons discussed in this section, we continue to assert that at the time we revoke the 1-hour standard, a State is no longer required to retain a nonattainment major NSR program in its SIP based on the requirements that applied by virtue of the area's previous classification under the 1-hour standard. Instead, States must have authority to issue major NSR permits consistent with the requirements that are associated with the area's designation and classification under the 8-hour standard. For the reasons discussed in this section, we also continue to assert, based on section 110(l) of the Act, that removing the 1-hour nonattainment major NSR program will not interfere with any State's ability to achieve attainment of the 8-hour standard and will be consistent with RFP.

We request comment on our determination that the Act does not require States to apply major NSR requirements under the 8-hour standard based on an area's higher classification under the 1-hour standard after we revoke the 1-hour standard, and on our interpretation that the term ''control'' as used in Section 172(e) of the Act does not include major NSR requirements. We also request comment on our conclusion that a State's removal of 1-hour major NSR programs from its SIP will not interfere with any applicable requirements of the Act including attainment and RFP. We specifically request comment on our discussion regarding State and local agency emission projections used for RFP and attainment, including whether the statements we have made regarding those emission projections are accurate. We also request specific information on any instance in which a State or local agency relied on major NSR as a control measure to reduce overall base year emissions in a rate of progress plan or attainment demonstration.

V. Statutory and Executive Order Reviews

On April 30, 2004, we took final action on key elements of the program to implement the 8-hour NAAQS, including applicability of the nonattainment major NSR programs under the 8-hour ozone NAAQS. In that action, we did not revise the nonattainment major NSR regulations. With today's action we are also proposing no changes to the nonattainment major NSR rules. However, we are seeking additional comments on some of the provisions finalized in the April 2004 **Federal Register** notice (69 FR 23951).

A. Executive Order 12866—Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this proposed rule is not a ''significant regulatory action.'' Today's reconsideration notice proposes to retain the position we adopted in the final Phase I rule.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* This rule interprets the requirements to develop State or tribal implementation plans to satisfy the statutory requirements for major NSR. We are not imposing any new paperwork requirements. However, OMB previously approved the information collection requirements contained in the existing regulations (40 CFR parts 51 and 52) under the provisions of the Paperwork Reduction Act. A copy of the OMB approved Information Collection Request (ICR) may be obtained from Susan Auby, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW., Washington, DC 20460, or by calling (202) 566–1672. Please refer to OMB control number 2060–0003, EPA ICR number 1230.17 when making your request.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose

or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

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 OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedures 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 proposed rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined in the U.S. Small Business Administration (SBA) size standards (*See* 13 CFR 121.201); (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any requirements on small entities. The Phase 1 Rule addressed key elements of the program to implement the 8-hour ozone NAAQS, including the obligations under the major NSR program. This reconsideration notice addresses the statutory obligations for States and Tribes to implement the major NSR program for the 8-hour ozone NAAQS. For the same reasons that we concluded that the Phase 1 Rule will not have a significant economic impact on a substantial number of small entities, we conclude that our further action on aspects of that rule also not have a significant impact on small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective or least burdensome alternative if the Administrator publishes with the final rule an explanation as to why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan.

The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

In promulgating the Phase 1 Rule we determined that this proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any 1 year. Therefore, we concluded that the Phase 1 Rule is not subject to the requirements of sections 202 and 205 of the UMRA. For the same reasons stated when we promulgated the Phase I Rule, we conclude that the issues addressed in this notice on reconsideration of an aspect of that rule is not subject to the UMRA.

EPA also determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments, including tribal governments.

E. Executive Order 13132—Federalism

Executive Order 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 Executive Order 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 proposed 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 Executive Order 13132. This rule specifies the statutory obligations of States and Tribes in implementing the major NSR program in 8-hour ozone nonattainment areas. The Act establishes the scheme whereby States take the lead in developing plans for EPA to approve into the state plan for implementing the major NSR program. This rule would not modify the relationship of the States and EPA for purposes of developing programs to implement major NSR. Thus, Executive Order 13132 does not apply to this rule. Nonetheless, in the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of

regulatory policies that have tribal implications.'' This proposed rule does not have ''tribal implications,'' as specified in Executive Order 13175. The purpose of this proposed rule is to seek comment on EPA's reconsideration of an aspect of the Phase 1 8-hour ozone rule specifying the statutory obligations of States and Tribes in implementing the major NSR program in 8-hour ozone nonattainment areas. The tribal authority rule (TAR) gives Tribes the opportunity to develop and implement Act programs such as the major NSR program, but it leaves to the discretion of the Tribe whether to develop these programs and which programs, or appropriate elements of a program, they will adopt. For the same reasons that we stated in the Phase 1 Rule, we conclude that this proposed rule does not have Tribal implications as defined by Executive Order 13175. To date, no Tribe has chosen to implement a major NSR program. Moreover, this rule does not affect the relationship or distribution of power and responsibilities between the Federal government and Indian Tribes. Thus, Executive Order 13175 does not apply to this rule.

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

Executive Order 13045: ''Protection of Children from Environmental health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule relates to reconsideration of one aspect of the Phase 1 Rule to implement the 8-hour ozone NAAQS. For the same reasons stated with respect to the Phase 1 Rule, we do not believe the Rule, or this reconsideration notice, is subject to Executive Order 13045. The Phase 1 Rule implements a previously promulgated health based Federal standard, the 8-hour ozone NAAQS. Nonetheless, we have evaluated the environmental health or safety effects of the 8-hour ozone NAAQS on children. The results of this evaluation are contained in 40 CFR Part 50, National Ambient Air Quality Standards for Ozone, Final Rule (62 FR 38855–38896; specifically, 62 FR 38855, 62 FR 38860 and 62 FR 38865).

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

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

Information on the methodology and data regarding the assessment of potential energy impacts in implementing programs under the 8-hour ozone NAAQS is found in Chapter 6 of U.S. EPA 2003, *Cost, Emission Reduction, Energy, and Economic Impact Assessment of the Proposed Rule Establishing the Implementation Framework for the 8-hour, 0.08 ppm Ozone National Ambient Air Quality Standard,* prepared by the Innovative Strategies and Economics Group, Office of Air Quality Planning and Standards, Research Triangle Park, N.C. April 24, 2003.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical.

Voluntary consensus standards are technical standards (for example, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

Today's proposed rule does not involve technical standards. Therefore, EPA is not considering 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 12898 requires that each Federal agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionate high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations.

The EPA concluded that the Phase 1 Rule should not raise any environmental justice issues; for the same reasons, the issues raised in this reconsideration notice should not raise any environmental justice issues. The health and environmental risks associated with ozone were considered in the establishment of the 8-hour, 0.08 ppm ozone NAAQS. The level is designed to be protective with an adequate margin of safety. The proposed rule provides a framework for improving environmental quality and reducing health risks for areas that may be designated nonattainment.

VI. Statutory Authority

The statutory authority for this action is provided by sections 307(d)(7)(B), 101, 111, 114, 116, and 301 of the Act as amended (42 U.S.C. 7401, 7411, 7414, 7416, and 7601). This notice is also subject to section 307(d) of the Act (42 U.S.C. 7407(d)).

List of Subjects in 40 CFR Part 51

Environmental protection, Administrative practice and procedure, Air pollution control, Nitrogen oxides, Ozone, Volatile organic compounds.

Dated: March 25, 2005.

Jeffrey Holmstead,

Assistant Administrator for Office of Air and Radiation.

[FR Doc. 05–6630 Filed 4–1–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R03–OAR–2005–PA–0002; FRL–7894–6]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; VOC and NO_X RACT Determinations for Three Individual Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania for the purpose of establishing and requiring reasonably available control technology (RACT) for three major sources of volatile organic compounds (VOC) and nitrogen oxides (NO_X). In the Final Rules section of this **Federal Register**,

EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by May 4, 2005.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID Number R03–OAR–2005–PA–0002 by one of the following methods:

A. *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. *Agency Web site: http://www.docket.epa.gov/rmepub/* RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

C. *E-mail: morris.makeba@epa.gov*.

D. *Mail:* R03–OAR–2005–PA–0002, Makeba Morris, Chief, Air Quality Planning, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

E. *Hand Delivery:* At the previously-listed EPA Region III address. 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 RME ID No. R03–OAR–2005–PA–0002. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.docket.epa.gov/rmepub/*, 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 RME, regulations.gov or e-mail. The EPA RME and the Federal regulations.gov websites are 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 RME or 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.

Docket: All documents in the electronic docket are listed in the RME index at *http://www.docket.epa.gov/rmepub/*. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Amy Caprio, (215) 814–2156, or by e-mail at *caprio.amy@epa.gov*. Please not that while questions may be posed via telephone and e-mail, formal comments must be submitted, in writing, as indicated in the **ADDRESSES** section of this document.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the ''Rules and Regulations'' section of this **Federal Register** publication. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

Dated: March 23, 2005.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. 05–6497 Filed 4–1–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R03–OAR–2005–DC–0001, R03–OAR–2005–MD–0001, R03–OAR–2005–PA–0010; FRL–7894–3]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia, State of Maryland, Commonwealths of Virginia and Pennsylvania; Revised Carbon Monoxide Maintenance Plans for Washington Metropolitan, Baltimore and Philadelphia Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve State Implementation Plan (SIP) revisions submitted by the District of Columbia, the State of Maryland, and the Commonwealths of Virginia and Pennsylvania for the purpose of revising their respective Carbon Monoxide (CO) Maintenance Plans in support of the National Ambient Air Quality Standard (NAAQS). In the Final Rules section of this **Federal Register**, EPA is approving each State's SIP submittal as a direct final rule without prior proposal because the Agency views these as noncontroversial submittals and anticipates no adverse comments. A more detailed description of the state submittal and EPA's evaluation are included in a Technical Support Document (TSD) prepared in support of this rulemaking action. A copy of the TSD is available, upon request, from the EPA Regional Office listed in the **ADDRESSES** section of this document. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by May 4, 2005.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID Number [R03–OAR–2005–DC–0001, R03–OAR–2005–MD–

0001, and/or R03–OAR–2005–PA–0010] by one of the following methods:

A. *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. *Agency Web site: http://www.docket.epa.gov/rmepub/* RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

C. *E-mail: morris.makeba@epa.gov*.

D. *Mail:* R03–OAR–2005–DC–0001, R03–OAR–2005–MD–0001, and/or R03–OAR–2005–PA–0010, Makeba Morris, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

E. *Hand Delivery:* At the previously-listed EPA Region III address. 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 RME ID No. R03–OAR–2005–DC–0001, R03–OAR–2005–MD–0001, and/or R03–OAR–2005–PA–0010. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.docket.epa.gov/rmepub/*, 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 RME, regulations.gov or e-mail. The EPA RME and the Federal regulations.gov Web sites are 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 RME or 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.

Docket: All documents in the electronic docket are listed in the RME index at *http://www.docket.epa.gov/rmepub/*. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at District of Columbia Department of Public Health, Air Quality Division, 51 N Street, NE., Washington, DC 20002; Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland, 21230; Pennsylvania Department of Environmental Resources Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105; Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia, 23219; Department of Public Health, Air Management Services, 321 University Avenue, Philadelphia, Pennsylvania 19104.

FOR FURTHER INFORMATION CONTACT: Catherine L. Magliocchetti, (215) 814–2174, or by e-mail at *magliocchetti.catherine@epa.gov*.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the ''Rules and Regulations'' section of this **Federal Register** publication. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

Dated: March 18, 2005.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. 05–6502 Filed 4–1–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R04–OAR–2004–KY–0003–200502; FRL–7895–4]

Approval and Promulgation of Implementation Plans for Kentucky: Inspection and Maintenance Program Removal for Northern Kentucky; Commercial Motor Vehicle and Mobile Equipment Refinishing Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve four related revisions to the Kentucky State Implementation Plan (SIP) submitted by the Commonwealth of Kentucky on November 12, 2004. These revisions affect the Northern Kentucky area, which is comprised of the Kentucky Counties of Boone, Campbell, and Kenton, and is part of the Cincinnati-Hamilton Metropolitan Statistical Area. EPA is proposing to approve the movement of the regulation underlying the Northern Kentucky inspection and maintenance (I/M) program from the active portion of the Kentucky SIP to the contingency measures section of the Northern Kentucky 1-Hour Ozone Maintenance Plan. EPA is also proposing to approve revisions to a Kentucky rule which provides for the control of volatile organic compounds from new solvent metal cleaning equipment. Further, EPA proposes to add a new rule to the Kentucky SIP affecting commercial motor vehicle and mobile equipment refinishing operations in Northern Kentucky. Finally, EPA is proposing to approve updated mobile source category emission projections using MOBILE6.2, with updated, subarea motor vehicle emission budgets (MVEBs) for the year 2010. EPA's final approval is contingent upon Kentucky making some clarifications in the final SIP submittal.

DATES: Written comments must be received on or before May 4, 2005.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID No. R04–OAR–2004–KY–0003, by one of the following methods:

1. Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

2. Agency Web site: *http://docket.epa.gov/rmepub/.* RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Once in the

system, select ''quick search,'' then key in the appropriate RME Docket identification number. Follow the on-line instructions for submitting comments.

3. E-mail: *notarianni.michele@epa.gov.*

4. Fax: (404) 562–9019.

5. Mail: ''R04–OAR–2004–KY–0003,'' Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.

6. Hand Delivery or Courier. Deliver your comments to: Michele Notarianni, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, 12th floor, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

Instructions: Direct your comments to RME ID No. R04-OAR–2004–KY–0003. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://docket.epa.gov/rmepub/*, 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 RME, regulations.gov, or e-mail. The EPA RME Web site and the federal regulations.gov Web site are ''anonymous access'' systems, 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 RME or 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.

Docket: All documents in the electronic docket are listed in the RME index at *http://docket.epa.gov/rmepub/.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Michele Notarianni, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Phone: (404) 562–9031. E-mail: *notarianni.michele@epa.gov.*

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VI. Statutory and Executive Order Reviews

I. What Changes to the Kentucky SIP Were Submitted for EPA Approval?

In response to a Kentucky Legislative action signed by the Governor on April 9, 2004, Kentucky submitted to EPA a proposed revision to the Kentucky SIP on November 12, 2004, for parallel processing. This revision affects regulation 401 KAR 65:010, ''Vehicle emission control programs,'' which is a SIP-approved regulation underlying the Northern Kentucky I/M program, also known as the Northern Kentucky Vehicle Emissions Testing (VET) Program. Kentucky has requested to move the VET Program regulation from the active control measures portion of the SIP to the contingency measures portion of the Northern Kentucky 1-Hour Ozone Maintenance Plan, which is part of the Kentucky SIP. The Northern Kentucky VET Program is a basic I/M program that includes on-board diagnostics (*i.e.*, OBD) and results in emissions reductions of nitrogen oxides (NO_X), volatile organic compounds (VOC), and carbon monoxide (CO). The VET Program began testing vehicles in Boone, Campbell, and Kenton Counties in September 1999, to help meet nonattainment area requirements for the ozone NAAQS effective at the time.

The Northern Kentucky area is comprised of the Kentucky Counties of Boone, Campbell, and Kenton, and is part of the Cincinnati-Hamilton Metropolitan Statistical Area (MSA). Presently, Boone, Campbell, and Kenton Counties comprise the Northern Kentucky portion of the Cincinnati 1-Hour Ozone Maintenance Area. This maintenance status means these counties were formerly designated nonattainment for the 1-hour ozone standard, are now attaining this standard, and have since been redesignated to attainment for the 1-hour ozone standard effective July 5, 2000 (July 31, 2002, 67 FR 49600). This area was previously classified as a moderate ozone nonattainment area. As such, the area was required to

implement a basic I/M program under section 182(b)(4) of the Clean Air Act.

Kentucky's November 12, 2004, draft SIP submittal proposes to implement new emission reductions to compensate for the NO_X and VOC emission increases resulting from removing the Northern Kentucky VET Program as an active control measure in the SIP. To demonstrate non-interference with applicable requirements of the Act through replacement emissions reductions, the compensating emissions reductions must be equivalent to or greater than those achieved with the VET Program. Equivalent emissions reductions are needed to replace an anticipated increase of 0.78 tons per summer day (tpsd) of VOC and 0.29 tpsd of NO_X in the year 2005 due to closure of the VET Program. These replacement VOC and NO_X emissions reductions must also occur in a time period contemporaneous to the VET Program's closure, as explained further in section IV. The VOC and NO_X replacement emissions reductions are needed to support a demonstration of non-interference with the 8-hour ozone and fine particulate matter ($PM_{2.5}$) NAAQS.

The VET Program also reduces CO emissions. In response to EPA comments on the November proposal, Kentucky will also include a demonstration of non-interference with the CO NAAQS in the final SIP submittal to address the CO emission increases due to discontinuation of the VET Program.

The November 12, 2004, submittal proposes VOC emissions reductions from two Kentucky rules. The revisions to Kentucky rule 401 KAR 59:185, ''New solvent metal cleaning equipment,'' requires the use of VOC solvents with lower vapor pressures in batch cold cleaning machines used in specified facilities located in the Northern Kentucky Counties of Boone, Campbell, and Kenton. These revisions were originally submitted to EPA on July 16, 2004. Kentucky's public hearing on the proposed amendments to 401 KAR 59:185 was held August 25, 2004, with written comments due by August 31, 2004. In a letter dated August 31, 2004, EPA concurred with the revisions and the analysis for estimating VOC emissions reductions from these rule changes. (A copy of this letter is located on the RME Web site under the Docket ID, R04–OAR–2004–KY–0003.) The November 12, 2004, submittal, which replaces the July 16, 2004, proposed SIP revision, also proposes to add a new rule, 401 KAR 59:760, ''Commercial Motor Vehicle and Mobile Equipment Refinishing Operations,'' to the Kentucky SIP. This new regulation requires the use of high transfer efficiency application techniques at auto body repair and refinishing operations, and prescribes operating procedures to minimize the emissions of VOCs. The Commonwealth also enacted and included in the November 12, 2004, submittal an emergency version of rule 401 KAR 59:760, *i.e.*, 401 KAR 59:760E, with a State effective date of November 15, 2004, and a compliance date of February 1, 2005. EPA is not taking action on this emergency regulation, 401 KAR 59:760E. The public hearing on rule 401 KAR 59:760 and movement of the VET Program to the contingency measures list was held on January 4, 2005.

Under the parallel processing procedure, the Commonwealth of Kentucky submits a copy of the proposed regulation or other revisions to EPA before conducting its public hearing. EPA reviews this proposed State action, and prepares a notice of proposed rulemaking for publication in the **Federal Register** within the same general time frame as Kentucky's public comment period. After the Commonwealth submits a final SIP revision (including a response to public comments raised during the Commonwealth's public participation process) to EPA, the Agency will prepare a final rulemaking notice. If the Commonwealth's final SIP submittal contains changes which occur after EPA's notice of proposed rulemaking, such changes must be described in EPA's final rulemaking action. If the Commonwealth's changes are significant, then EPA must decide whether it is appropriate to re-propose the Commonwealth's action.

II. What Authorities Apply To Moving the Northern Kentucky I/M Program to a Contingency Measure in the Kentucky SIP?

Section 110(l) of the Clean Air Act (*i.e.*, ''Act'') states:

> Each revision to an implementation plan submitted by a State under this Act shall be adopted by such State after reasonable notice and public hearing. The Administrator shall not approve a revision to a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171), or any other applicable requirement of this Act.

The States' obligation to comply with each of the NAAQS is considered as ''any applicable requirement(s) concerning attainment.'' A demonstration is necessary to show that this revision will not interfere with attainment or maintenance of the NAAQS, including those for ozone, CO, and $PM_{2.5}$, or any other requirement of the Act.

With respect to the 1-hour ozone NAAQS, EPA redesignated the Kentucky portion of the Cincinnati-Hamilton area to attainment for the 1-hour ozone standard in a final action published July 31, 2002 (67 FR 49600). The Cincinnati-Hamilton moderate 1-hour ozone nonattainment area (Cincinnati-Hamilton area) includes the Ohio Counties of Hamilton, Butler, Clermont, and Warren, and the Kentucky Counties of Boone, Campbell, and Kenton. As part of its redesignation to attainment for a NAAQS, the area must have a plan to maintain the standard, called a ''maintenance plan.'' Under section 175A(a) of the Act, emission reduction programs in a maintenance plan for a NAAQS must be continued unless a demonstration is made that the future, projected emissions for the area, without credit for reductions due to the emission reduction program being removed, remain at or below the baseline attainment level of emissions identified in the maintenance plan. If such a demonstration is made, that program is eligible for removal from the SIP. However, section 175A(d) of the Act requires that available contingency measures in the maintenance plan include all measures in the SIP for the area before that area was redesignated to attainment. Since the VET Program was in the SIP prior to redesignation to attainment for the 1-hour ozone NAAQS, the VET Program must be listed in the contingency portion of the 1-hour ozone maintenance plan as required by section 175A(d). Kentucky was able to demonstrate continued maintenance of the 1-hour ozone standard for the requisite timeframe without taking credit for reductions from the Northern Kentucky VET Program, as summarized in section III below.

In addition, provisions in EPA's I/M rule, set forth in 40 CFR 51.372(c) under the heading ''Redesignation requests,'' apply to the Northern Kentucky VET Program situation. These provisions were published January 5, 1995, at 60 FR 1735. The provisions allow certain areas seeking redesignation to submit only the authority for an I/M program rather than an implemented program in satisfaction of the applicable I/M requirements. Under these I/M rule provisions, a basic I/M area (*i.e.*, was required to adopt a basic I/M program) which has been redesignated to attainment for the 1-hour ozone NAAQS can convert the I/M program to a contingency measure as part of the

area's 1-hour ozone maintenance plan, notwithstanding the new antibacksliding provisions in EPA's 8-hour ozone implementation rule published April 30, 2004 (69 FR 23858). A basic I/M area which is designated nonattainment for the 8-hour ozone NAAQS, yet not required to have an I/M program based on its 8-hour ozone designation, continues to have the option to move its I/M program to a contingency measure as long as the 8-hour ozone nonattainment area can demonstrate that doing so will not interfere with its ability to comply with any NAAQS or any other applicable Clean Air Act requirement pursuant to section 110(l) of the Act. For further details on the application of 8-hour ozone anti-backsliding provisions to basic I/M programs in 1-hour ozone maintenance areas, please refer to the May 12, 2004, EPA Memorandum from Tom Helms, Group Leader, Ozone Policy and Strategies Group, Office of Air Quality Planning and Standards, and Leila H. Cook, Group Leader, State Measures and Conformity Group, Office of Transportation and Air Quality, to the Air Program Managers, the subject of which is ''1 Hour Ozone Maintenance Plans Containing Basic I/M Programs.'' A copy of this memorandum may be obtained at *http://www.epa.gov/ttn/oarpg/t1pgm.html* under the file date ''5–12–04.''

III. What Is EPA's Analysis of Kentucky's Demonstration of Non-Interference With the 1-Hour Ozone and CO NAAQS?

A. EPA's Analysis of Kentucky's Demonstration of Non-Interference With the 1-Hour Ozone NAAQS

The November 12, 2004, Kentucky SIP revision seeking removal of the VET Program includes an evaluation for the 1-hour ozone NAAQS of the potential emission impacts associated with increased emissions that would result from removal of the Northern Kentucky VET Program as an active control measure in the SIP. For the 1-hour ozone NAAQS, the submittal provides VOC and NO_X emission inventory data for the Northern Kentucky portion (*i.e.*, Boone, Campbell, and Kenton Counties) of the Cincinnati-Hamilton MSA for 1996, the year the area met the 1-hour ozone NAAQS, and projected emissions through 2010. The emission inventory data for the ''Mobile'' source category are calculated using MOBILE6.2 because this same model was used to determine the emissions reductions from the VET Program needing to be replaced. MOBILE6.2 is a model which provides estimates of emissions from onroad mobile sources. The mobile source data updated with MOBILE 6.2 are to replace the MOBILE5a emissions data in the currently approved Northern Kentucky 1-Hour Ozone Maintenance Plan, which results in updated MVEBs for the year 2010 of 7.68 tons per summer day (tpsd) VOC and 17.42 tpsd NO_X.

In Tables 1 and 2 below, the emission inventory projections for 2005, 2008, and 2010 are updated to reflect the changes proposed by the November 12, 2004, submittal, namely removal of the VET Program as an active control measure and application of two rules to further control VOCs in the Northern Kentucky area. The VOC and NO_X emission totals for this area include emissions from the point, area, mobile, and non-highway (or nonroad) source categories. As shown in Tables 1 and 2 below, the projected, total VOC and NO_X emissions without the VET Program for 2005, 2008, and 2010 for the Northern Kentucky area all fall below the 1996 attainment year emission levels of 45.10 tpsd VOC and 74.13 tpsd NO_X. For example, Table 1 shows the current 2005 total VOC emissions projected for the area are 34.16 tpsd. By adding the predicted increase of 0.78 tpsd VOC in 2005 due to the closure of the VET Program, this results in 34.94 tpsd of VOC in 2005, which is below the 1996 attainment level of 45.10 tpsd VOC. This same analysis proves true when comparing the VOC emissions in tpsd of 34.01 in 2008 and 34.40 in 2010 to the 1996 attainment level of 45.10, and when comparing the NO_X emissions in tpsd for 2005, 2008, and 2010 of 69.13, 65.13, and 64.06, respectively, to the 1996 attainment level of 74.13 tpsd. The area does not exceed its 1-hour ozone maintenance level of emissions, even after removal of the VET Program. Thus, the Northern Kentucky area demonstrates continued maintenance of the 1-hour ozone NAAQS without the Northern Kentucky VET Program.

TABLE 1.—TOTAL VOC EMISSIONS FOR THE NORTHERN KENTUCKY COUNTIES (BOONE, CAMPBELL, KENTON); KENTUCKY PORTION OF THE CINCINNATI-HAMILTON 1-HOUR OZONE MAINTENANCE AREA

VOC (in tpsd)	1996	1999	2002	2005	2008	2010
Total VOC for Northern KY Area*	45.10	38.41	35.12	34.16	33.44	33.74
VOC Increase Without VET Program	.....	.....	.....	0.78	0.57	0.66
Total VOC for Northern KY Area Without VET Program	.....	.....	.....	34.94	34.01	34.40

*Emissions reflect updated mobile emissions using MOBILE6.2.

TABLE 2.—TOTAL NO_X EMISSIONS FOR THE NORTHERN KENTUCKY COUNTIES (BOONE, CAMPBELL, KENTON); KENTUCKY PORTION OF THE CINCINNATI-HAMILTON 1-HOUR OZONE MAINTENANCE AREA

NO_X (in tpsd)	1996	1999	2002	2005	2008	2010
Total NO_X for Northern KY Area*	74.13	74.82	71.53	68.84	65.11	63.97
NO_X Increase Without VET Program	.....	.....	.....	0.29	0.02	0.09
Total NO_X for Northern KY Area Without VET Program	.....	.....	.....	69.13	65.13	64.06

*Emissions reflect updated mobile emissions using MOBILE6.2.

B. Updated MVEBs for 2010

In the November 12, 2004, submittal, Kentucky notes that the MVEBs established for the year 2010 for the Kentucky portion of the Cincinnati-Hamilton MSA (*i.e.*, the Northern Kentucky area) are also updated using MOBILE6.2. A MVEB is the projected level of controlled emissions from the transportation sector (mobile sources) that is estimated in the SIP. The SIP controls emissions through regulations, for example, on fuels and exhaust levels for cars. The MVEB concept is further explained in the preamble to the November 24, 1993, transportation conformity rule (58 FR 62188). The preamble also describes how to establish the MVEB in the SIP and revise the MVEB.

The 2010 MVEBs were originally established by Kentucky and Ohio for this area as a part of the 1-hour ozone maintenance plan that was associated with the redesignation of this area to attainment of the 1-hour ozone NAAQS. Subsequently, both Kentucky and Ohio revised the 2010 MVEBs for this area, and established individual State MVEBs for their respective portions of the Cincinnati 1-hour ozone maintenance area. Kentucky's revised 2010 MVEBs, applicable only to Boone, Kenton and Campbell counties in Kentucky, were approved by EPA on May 30, 2003, through final rulemaking (68 FR 104). These MVEBs, which included an allocation from the available safety margin, were developed with the MOBILE5 emissions factor model, and are 7.02 tpsd of VOC and 17.33 tpsd of NO_X. The establishment of the individual State MVEBs for these areas allows each State to implement the conformity requirements independent of one another. Today's action relates only to revisions to the Kentucky 2010 MVEBs.

EPA is proposing to approve the updated 2010 MVEBs of 7.68 tpsd VOC and 17.42 tpsd NO_X because the total emissions from all sources in the Northern Kentucky area remain below the 1996 attainment levels, as depicted in Tables 1 and 2 above. These revised MVEBs were developed with the MOBILE6.2 mobile emissions factor model and do not include an allocation from the available safety margin. Upon final approval of these updated MVEBs, the budgets will be used by the Northern Kentucky area to determine transportation conformity.

C. EPA's Analysis of Kentucky's Demonstration of Non-Interference With the CO NAAQS

The November 12, 2004, submittal does not include a demonstration of non-interference with the CO standard to show that the CO increases expected from closure of the VET Program will not interfere with continued attainment of the CO NAAQS in the Northern Kentucky area. Because CO is one of the applicable requirements of the Act, Kentucky will need to include a demonstration of non-interference for CO in the final SIP submittal. In Kentucky's July 16, 2004, proposed SIP revision, the Commonwealth provided data showing that CO levels are expected to increase by 12.5 tpsd in 2005 due to discontinuation of the VET Program.

The Northern Kentucky area has always been attainment for the CO NAAQS, and CO monitoring data from the years 1991–2001 show CO levels trending downward. Specifically, in 1991, CO levels in Northern Kentucky were 77 percent below the 1-hour and 46 percent below the 8-hour CO standards. In contrast, monitored CO levels in 2001 fell 93 percent below the 1-hour and 80 percent below the 8-hour CO standards. Based on a preliminary review of this data, EPA believes closure of the VET Program will not interfere with continued attainment of the CO NAAQS in the Northern Kentucky area.

IV. What Is EPA's Analysis of Kentucky's Demonstration of Non-Interference With the 8-Hour Ozone and Fine Particulate Matter NAAQS?

A. What Criteria Must Be Met?

EPA designated the Kentucky Counties of Boone, Campbell, and Kenton nonattainment for the 8-hour ozone NAAQS on April 30, 2004 (69 FR 23858), effective June 15, 2004. EPA designated these same counties nonattainment for the $PM_{2.5}$ NAAQS in a final action published January 5, 2005 (70 FR 944), effective April 5, 2005. For an area such as the Northern Kentucky area that does not yet have an attainment demonstration for the new 8-hour ozone and $PM_{2.5}$ NAAQS, EPA has provided its interpretation of section 110(1) of the Clean Air Act in a May 11, 2004, letter from EPA to Louisville's Assistant County Attorney. (To view a copy of this letter, go to the RME Web site, *http://docket.epa.gov/rmepub/,* enter the Docket ID for this action, R04–OAR–2004–KY–0003, and click on the appropriate Document ID.) A strict interpretation of the requirement in section 110(1) of the Clean Air Act would allow EPA to approve a SIP revision removing a SIP requirement only after determining, based on a completed attainment demonstration, that it would not interfere with applicable requirements concerning attainment and reasonable further progress. However, EPA recognizes that prior to the time areas are required to submit attainment demonstrations for the 8-hour ozone and $PM_{2.5}$ NAAQS, this strict interpretation could prevent any changes to SIP control measures. EPA does not believe this strict interpretation is necessary or appropriate.

Prior to the time that attainment demonstrations are due for the 8-hour ozone and $PM_{2.5}$ standards, it is unknown what suite of control measures are needed for a given area to attain these standards. During this period, to demonstrate no interference with any applicable NAAQS or requirement of the Clean Air Act under section 110(l), EPA believes it is appropriate to allow States to substitute equivalent emissions reductions to compensate for the control measure being moved from the active portion of the SIP to the contingency provisions, as long as actual emissions in the air are not increased. EPA concluded that preservation of the status quo air quality during the time new attainment demonstrations are being prepared will prevent interference with the States' obligations to develop timely attainment demonstrations.

''Equivalent'' emissions reductions mean reductions which are equal to or greater than those reductions achieved by the control measure to be removed from the active portion of the SIP. To show the compensating, emissions reductions are equivalent, modeling or adequate justification must be provided. (EPA memorandum from John Calcagni, Director, Air Quality Management Division, to the Air Directors in EPA Regions 1–10, September 4, 1992, pages 10 and 13.) As stated in the May 11, 2004, letter referenced earlier, the compensating, equivalent reductions must represent actual, new emissions reductions achieved in a contemporaneous time frame to the termination of the existing SIP control measure, in order to preserve the status quo level of emissions in the air. In addition to being contemporaneous, the equivalent emissions reductions must also be permanent, enforceable, quantifiable, and surplus to be approved into the SIP.

B. What Is EPA's Analysis of Whether the Proposed Reductions Meet the Criteria of Contemporaneous, Equivalent, Quantifiable, Permanent, Enforceable, and Surplus?

The November 12, 2004, submittal proposes equivalent VOC emissions reductions for the Northern Kentucky VET Program from two Kentucky rules. The following is a description of how the proposed VOC emissions reductions from two Kentucky rules, 401 KAR 59:185 and 401 KAR 59:760, meet the six criteria of contemporaneous, equivalent (or greater), permanent, enforceable, quantifiable, and surplus.

1. Contemporaneous

While ''contemporaneous'' is not explicitly defined in the Clean Air Act, a reasonable interpretation is to enact the compensating, equivalent emissions reductions within one year (prior to or following) the cessation of the substituted control measure. The State effective date of revisions to regulation 401 KAR 59:185 is January 4, 2005. The State effective date of 401 KAR 59:760 is likely to occur, at the latest, during the March-April 2005 timeframe, contingent on the typical schedule of Kentucky's rulemaking process, with the emergency version of this rule already in effect as of November 15, 2004. The November 12, 2004, submittal requests two different effective dates for the VET Program's closure. Kentucky will clarify in the final submittal the correct date requested. The actual effective date is contingent upon EPA's final action. In accordance with Kentucky Senate Joint Resolution 3 dated March 29, 2004, the closure of the Northern Kentucky VET Program is legislated to occur once EPA approves, through rulemaking, a revision to the Kentucky SIP incorporating compensating, equivalent emissions reductions to replace the VET Program. (To view a copy of the Senate Joint Resolution 3, please see Appendix A of the November 12, 2004, submittal available in EPA's RME system.) As long as closure of the VET Program occurs within one year from the replacement emissions reductions, these reductions will be contemporaneous to the emissions reductions from both rules, 401 KAR 59:185 and 401 KAR 59:760.

2. Equivalent

The VET Program reduces emissions of VOC, NO_X, and CO. VOC and NO_X are contributors (''precursors'') to the formation of ground-level ozone and fine particulate matter. Thus, the increase in VOC and NO_X need to be offset with equivalent (or greater) emissions reductions from another control measure(s) in order to demonstrate non-interference with the 8-hour ozone and $PM_{2.5}$ NAAQS. Substitute CO emissions reductions are not needed for this demonstration because the area is attaining the CO NAAQS and CO levels in the area are well below the standard, as noted in section III.C. of this document. It is unlikely that removing the VET Program will interfere with the area's ability to continue to attain the CO NAAQS.

a. *Selection of the Year 2005 To Estimate Emission Increases From Closure of the Northern Kentucky VET Program.* To demonstrate that the VOC emissions reductions from 401 KAR 59:185 and 401 KAR 59:760 provide the equivalent benefit of the VOC and NO_X emissions reductions achieved by the VET Program, Kentucky first identified the expected increases in emissions due to closure of the program for the years 2005, 2008, and 2010. As shown in Table 3 below, VOC and NO_X emissions from onroad mobile sources are expected to increase in 2005 by 0.78 tpsd and 0.29 tpsd, respectively, due to closure of the Northern Kentucky VET Program. In 2008 and 2010, expected VOC and NO_X reductions from the VET Program decline. In particular, NO_X reductions are predicted to be 0.02 tpsd in 2008 and 0.09 tpsd for 2010. Thus, the year 2005 provides the greatest number of VET Program emissions that need to be replaced. For these reasons, EPA believes that analyzing emissions for 2005 is conservative, and represents the greatest impact on air quality from the Program's closure beginning in 2005, when emissions from the loss of the Program would first impact the area.

Kentucky used MOBILE6.2, EPA's latest version of the mobile model for estimating onroad mobile source emissions, to develop the onroad mobile emission estimates for the Northern Kentucky area. The MOBILE6.2-based emissions are proposed to replace the Mobile5a-generated emissions in the current, approved 1-hour ozone maintenance plan for the Northern Kentucky area.

TABLE 3.—EMISSION INCREASES FROM CLOSURE OF THE VET PROGRAM

Strategy	Onroad VOC mobile emissions (tpsd)			Onroad NO_X mobile emissions (tpsd)		
	2005	2008	2010	2005	2008	2010
With VET Program	8.98	7.33	7.02	24.21	19.30	17.33
Without VET Program	9.76	7.90	7.68	24.50	19.32	17.42
Emission Increases without VET Program	0.78	0.57	0.66	0.29	0.02	0.09

b. *Methodology for Substituting VOC for NO_X to Determine All ''VOC-Equivalent'' Needed To Replace the VET Program.* To determine the equivalent number of VOCs to replace 0.78 tpsd VOC and 0.29 tpsd NO_X emissions reductions predicted in 2005 from the VET Program, Kentucky converted the 0.29 tpsd of NO_X into VOC using an equation developed in accordance with the August 5, 1994, EPA memorandum, ''Clarification of Policy for Nitrogen Oxides (NO_X) Substitution,'' from John Seitz. This memorandum pertains to EPA's ''NO_X Substitution Guidance'' (December 1993). The guidance acknowledges that controlling only VOCs may not be the most effective approach in all areas for attaining the ozone standard, and allows for substitution of NO_X for VOC emissions reductions required for Reasonable Further Progress, contingent upon approval by EPA. The 1994 memorandum further clarifies that NO_X for VOC substitution is a viable approach prior to completing modeling to support an area's attainment demonstration. Using the principles of EPA's NO_X Substitution Guidance, EPA will similarly allow substitution of VOC for NO_X emissions reductions on a percentage basis, where it is demonstrated that VOC emissions reductions are effective in attaining or maintaining the ozone NAAQS. Furthermore, the most recent authoritative assessments of ozone control approaches [1] [2] have concluded that although a NO_X control strategy

[1] Ozone Transport Assessment Group OTAG Final Report, 1997.

[2] NARSTO, An Assessment of Tropospheric Ozone Pollution—A North American Perspective, July 2000.

would be most effective for reducing regional scale ozone transport, VOC reductions are most effective in more dense urbanized areas. The Kentucky Counties of Boone, Campbell, and Kenton are in the Cincinnati-Hamilton MSA adjacent to the highly populated Ohio Counties of Hamilton and Clermont.

To determine the amount of VOC that will provide equivalent ozone reduction benefits as the 0.29 tpsd of NO_X, Kentucky used the following equation in accordance with EPA guidance: (NO_X increase due to closure of the VET Program)/(Total NO_X Emissions for the Northern Kentucky Area) × (Total VOC Emissions for the Northern Kentucky Area) = Equivalent VOC emissions reductions required. This equation incorporates calculation of the VOC/NO_X ratio, which determines what a one percent reduction in VOC is equivalent to, in tpsd, for a one percent reduction in NO_X. This ratio is based upon EPA's NO_X Substitution Guidance (December 1993). To calculate the VOC/NO_X ratio, the area's total VOC emissions are divided by the area's total NO_X emissions from all source categories for a given year. For example, the 2005 VOC/NO_X ratio is: (32.56 tpsd VOC)/(64.77 tpsd NO_X) = (1 percent VOC reduction)/(1 percent NO_X reduction) = 0.50 tpsd VOC/1.0 tpsd NO_X. Thus, to reduce 1.0 tpsd of NO_X, 0.50 tpsd of VOC is required to be reduced. Using this same calculation, the ratios for 2008 and 2010 are 0.52 tpsd VOC/1.0 tpsd NO_X and 0.53 tpsd VOC/1.0 tpsd NO_X, respectively. In the 2005 example, the VOC/NO_X ratio is then applied as follows to solve for ''X'': 0.50 tpsd VOC/1.0 tpsd NO_X = X tpsd VOC/0.29 tpsd NO_X. For 2005, ''X'' equals 0.145 or, with rounding, 0.15 tpsd of VOC must be reduced to be equivalent to a 0.29 tpsd reduction of NO_X. Similar calculations for 2008 and 2010 show that the equivalent amount of VOC emissions reductions needed to replace the 0.29 tpsd NO_X are 0.151 tpsd and 0.154 tpsd, respectively, which both round to 0.15 tpsd VOC. This analysis shows that the year used to develop the VOC/NO_X ratio does not alter, after rounding, the resulting amount of 0.15 tpsd VOC-equivalent for 0.29 tpsd of NO_X.

In the November 2004 submittal, Kentucky's methodology applied total VOC and NO_X emission data for the year 2010 in the ''VOC Equivalent Emissions'' equation above because this provides the greatest number of VOC-equivalent emissions to replace. Kentucky computed the VOC-equivalent to the 0.29 tpsd of NO_X emissions reductions expected in 2005 from the VET Program as follows: (0.29 tpsd NO_X)/(63.77 tpsd NO_X) × (34.05 tpsd VOC) = 0.1548 or, with rounding, 0.15 tpsd VOC. In the final submittal, Kentucky will clarify references to the VOC/NO_X ratio in the November 2004 proposed revision to show how the ratios derived in Appendices B and E are used in the ''VOC Equivalent Emissions'' equation above.

c. *Equivalent Emissions Reductions From Two Kentucky Rules.* To calculate the total number of VOC emissions reductions needed to replace the VET Program, Kentucky added the 0.15 tpsd VOC-equivalent of 0.29 tpsd NO_X to the 0.78 tpsd VOC emissions increase expected in 2005 from closure of the program, yielding 0.93 tpsd VOC (*i.e.*, 0.15 + 0.78). Thus, 0.93 tpsd of VOC emissions reductions are needed to replace the VET Program.

As explained in the following section, ''4. Quantifiable,'' revisions to rule 401 KAR 59:185 and new rule 401 KAR 59:760 are expected to reduce VOCs in 2005 by 0.71 tpsd and 0.27 tpsd, respectively, yielding a total of 0.98 tpsd VOC emissions reductions (*i.e.*, 0.71 + 0.27 = 0.98) from these rules. These emissions reductions exceed the 0.93 tpsd VOCs needed to replace the VET Program by 0.05 tpsd (*i.e.*, 0.98–0.93 = 0.05).

Therefore, based on this conservative equivalency analysis, the proposed 0.98 tpsd of VOC reductions from the two Kentucky rules are equivalent, in terms of reduced ozone formation benefits, to the VOC and NO_X reductions from the VET Program. In addition, VOC and NO_X, the relevant pollutants controlled by the VET Program, are contributing precursors to the formation of $PM_{2.5}$ and thus, EPA concludes that these equivalent reductions also demonstrate non-interference with the $PM_{2.5}$ NAAQS.

3. Quantifiable

The November 12, 2004, submittal shows that in 2005, 0.71 tpsd of VOC will be reduced through the revisions to rule 401 KAR 59:185, and 0.27 tpsd of VOCs will be reduced through rule 401 KAR 59:760. The emissions reductions meet the criterion for quantifiable, as the VOC emissions reductions may be calculated as follows.

The rule revisions to 401 KAR 59:185 establish a vapor pressure limit for solvents used in cold cleaning degreasing operations in the Northern Kentucky Counties of Boone, Campbell, and Kenton. Section 4(3)(a) of the regulation requires that vendors provide in these counties only solvents with a vapor pressure at or below 1.0 millimeters (mm) of mercury measured at 20 degrees Celsius for solvents sold in units greater than five gallons for use in cold cleaners. Section 4(3)(b) prohibits operations of a cold cleaner using a solvent exceeding the vapor pressure limit described for section 4(3)(a). In addition, section 4(4) of the regulation requires users to keep records of their solvent purchases.

To determine the amount of VOC reductions from revisions to 401 KAR 59:185 affecting the Northern Kentucky counties, the projected 2005 cold cleaning degreasing emissions (in tpsd) for these counties are multiplied by 67 percent, which is the control efficiency (CE) of the rule, and 80 percent, which is the rule effectiveness (RE) factor. The CE provides an estimate of the percent VOC reduction expected from lowering the vapor pressure limit in the rule as described above. The 67 percent CE has been used in similar cold cleaning degreasing regulations in the States of Indiana, Illinois, and Maryland. The RE factor of 80 percent is an EPA estimate of the effectiveness of this type of rule. The results of this calculation provide the 2005 cold cleaning degreasing estimated emissions reductions. For example, in Boone County, 0.32 tpsd of VOC emissions are projected for 2005 from cold cleaning degreasing. This 2005 cold cleaning degreasing projection was derived from identifying the percent contribution to the 2005 VOC projections from the total solvent degreasing area source category listed in Appendix I of the Northern Kentucky 1-Hour Ozone Maintenance Plan approved by EPA into the Kentucky SIP. Using EPA emission factors, Kentucky determined that cold cleaning degreasing VOC emissions contribute 84 percent to the total solvent degreasing emission projection of 0.38 tpsd VOC, *i.e.*, (0.38 tpsd VOC) × (84 percent) = 0.32 tpsd VOC. Using the multipliers described above for the Boone County example, (0.32 tpsd VOC) × (67 percent CE) × (80 percent RE) = 0.17 tpsd VOC cold cleaning degreasing emissions are expected to be reduced in 2005 from the rule revisions. Table 4 below presents the VOC reductions expected for Boone, Campbell, and Kenton Counties from the revisions to 401 KAR 59:185, which total 0.71 tpsd VOC.

TABLE 4.—COLD CLEANING DEGREASING VOC EMISSIONS REDUCTIONS (TPSD)

County	Projected 2005 cold cleaning degreasing emissions (tpsd)	2005 Cold cleaning degreasing estimated emissions reductions (tpsd)—(CE) × (RE)	2005 Cold cleaning degreasing estimated emissions reductions (tpsd)
Boone	0.32	(67%) × (80%)	0.17
Campbell	0.36	(67%) × (80%)	0.19
Kenton	0.66	(67%) × (80%)	0.35
Total	1.34		0.71

To determine the amount of VOC reductions in the Northern Kentucky counties from new rule, 401 KAR 59:760, calculations similar to what are described for 401 KAR 59:185 are made. Kentucky applied a 35 percent CE for implementation of high transfer efficiency spray gun technology required by this rule. This 35 percent CE is based on figures provided in the Ozone Transport Commission Pechan Report, dated March 31, 2001, and CEs approved by EPA in other areas. Kentucky also applied EPA's default 80 percent RE factor, resulting in 0.27 tpsd VOC are predicted to be reduced in 2005 from 401 KAR 59:760. Table 5 below presents the VOC reductions expected for Boone, Campbell, and Kenton Counties from 401 KAR 59:760, which total 0.27 tpsd VOC.

TABLE 5.—2005 MOBILE EQUIPMENT REFINISHING VOC EMISSIONS REDUCTIONS (TPSD)

County	Projected 2005 mobile equipment refinishing emissions (tpsd)	Estimated mobile equipment refinishing emissions reductions (tpsd)—(CE) × (RE)	2005 Mobile equipment refinishing emissions reductions (tpsd)
Boone	0.27	(35%) × (80%)	0.08
Campbell	0.26	(35%) × (80%)	0.07
Kenton	0.43	(35%) × (80%)	0.12
Total	0.96		0.27

EPA has reviewed the calculations, methodology, and supporting analyses provided by Kentucky and agrees with the 2005 VOC emission reduction estimates of 0.71 tpsd and 0.27 tpsd for 401 KAR 59:185 and 401 KAR 59:760, respectively, described above and summarized in Tables 4 and 5.

4. Permanent

The emissions reductions from Kentucky rules, 401 KAR 59:185 and 401 KAR 59:760, are made permanent through Kentucky's rulemaking process. Once State effective, these regulations have the full force of a law and establish obligatory requirements applicable to affected groups. EPA's approval of the final SIP revision will incorporate revisions to 401 KAR 59:185 and new rule 59:760 into the federally enforceable Kentucky SIP. EPA is not taking action on emergency rule, 401 KAR 59:760E, included in the November 12, 2004, submittal because the rule has an expiration date under Kentucky Revised Statute 13A.190, and thus, is not permanent. Since the emissions reductions from the emergency rule are not included in the calculation of equivalent emissions reductions needed to replace the VET Program, EPA inaction on this rule does not affect the approvability of this proposed revision.

5. Enforceable

The emissions reductions are enforceable by the Commonwealth of Kentucky as of the State effective date of these regulations. Upon final approval into the Kentucky SIP, revised rule 401 KAR 59:185 and new rule 59:760 will be Federally enforceable by the EPA, as of the effective date of EPA's final rulemaking.

6. Surplus

The VOC emissions reductions from Kentucky's two rules are surplus for two reasons. The emissions reductions go beyond the reductions already required in the Kentucky SIP, and the reductions are not from a Federal Control Measure that would occur without any State or local action. Specifically, the 0.71 tpsd of VOC emissions reductions from revisions to 401 KAR 59:185 are due to new provisions created in sections 4(3) and 4(4) which prohibit the sale and use of solvents with vapor pressure limits exceeding that specified in the regulation. Rule 401 KAR 59:760 is a new regulation proposed for inclusion into the Kentucky SIP, which will provide 0.27 tpsd of VOC emissions reductions in 2005 from requirements to use high transfer efficiency spray gun technology at mobile equipment refinishing operations in Northern Kentucky.

V. What Is EPA's Proposed Action?

EPA is proposing to move 401 KAR 65:010, ''Vehicle emission control programs'' from the active control measure portion of the Kentucky SIP to the contingency measures section of the Northern Kentucky 1-Hour Ozone Maintenance Plan. EPA is also proposing to approve revisions to Kentucky rule 401 KAR 59:185, ''New solvent metal cleaning equipment'' and the addition of new rule 401 KAR 59:760, ''Commercial Motor Vehicle and Mobile Equipment Refinishing Operations,'' into the Kentucky SIP. Finally, EPA is proposing to approve updated mobile source category emission projections using MOBILE6.2, with updated, subarea MVEBs of 7.68 tpsd VOC and 17.42 tpsd NO_X for the year 2010. EPA's proposed approval is contingent upon Kentucky addressing

the requested clarifications in EPA's December 29, 2004, comment letter on this proposed SIP revision. Kentucky must include a demonstration of non-interference with the CO NAAQS, as demonstrated by very low levels of ambient CO—well below the NAAQS—and the fact that the area is in attainment of the CO NAAQS. Kentucky must also clarify references to the VOC/NO_X ratio and modify subsection (1)(j) of section 3, ''Operating requirements,'' of 401 KAR 59:760. This subsection uses language which mirrors that of the Ozone Transport Commission model rule. However, to be consistent with current Agency policy, this language needs to be revised to include some form of public review for determining other coating application methods which achieve emissions reductions equivalent to high volume low pressure or electrostatic spray application methods. In the current language proposed, the Kentucky Cabinet makes this determination.

VI. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This proposed action merely proposes to approve State law as meeting Federal requirements and imposes no additional requirements beyond those imposed by State law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does 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 Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

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

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

Dated: March 25, 2005.

J.I. Palmer, Jr.,

Regional Administrator, Region 4.

[FR Doc. 05–6631 Filed 4–1–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket No. FEMA–D–7616]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed Base (1% annual chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed below. The BFEs are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: FEMA proposes to make determinations of BFEs and modified BFEs for each community listed below, in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed base flood and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other

Federal, state or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

National Environmental Policy Act. This proposed rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this proposed rule is exempt from the requirements of the Regulatory Flexibility Act because proposed or modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to establish and maintain community eligibility in the NFIP. As a result, a regulatory flexibility analysis has not been prepared.

Regulatory Classification. This proposed rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This proposed rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This proposed rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR Part 67 is proposed to be amended as follows:

PART 67—[AMENDED]

1. The authority citation for Part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.4 [Amended]

2. The tables published under the authority of § 67.4 are proposed to be amended as follows:

Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
NEW JERSEY **Bergen County**				
Musquapsink Brook	Approximately 2,600 feet upstream of confluence with Pascack Brook at Saddle River Road.	*39 *241	*38 *243	Boroughs of Emerson, Westwood, Hillsdale, Woodcliff Lake, Paramus, Township of Washington.
Pascack Brook	Approximately 0.71 mile downstream of Brookside Avenue. Approximately 1,300 feet from the upstream side of Magnolia Avenue.	*25 204	*26 *205	Boroughs of Emerson, River Vale, Hillsdale, Woodcliff Lake, Park Ridge, Montvale, Harrington Park.
Musquasink Brook By-Pass	At the confluence of Musquapsink Brook ..... Just downstream of Washington Lake Dam South	*59 *63	*60 *68	Township of Washington.
Tandy Brook	At the confluence with Pascask Brook ..... Approximately 375 feet downstream of Saddlewood Drive.	*62 *62	*63 *63	Borough of Hillsdale.
Westdale Brook	At the confluence with Pascack Brook ..... Approximately 1,740 feet from upstream side of Harding Avenue.	*57 *57	*59 *59	Borough of Westwood.

Borough of Emerson
Maps available for inspection at the Emerson Borough Hall, Municipal Place, Emerson, New Jersey.
Send comments to The Honorable Steve Setteducati, Mayor of the Borough of Emerson, Municipal Place, Emerson, New Jersey 07630.
Borough of Harrington Park
Maps available for inspection at the Harrington Park Municipal Center, 85 Harriot Avenue, Harrington Park, New Jersey.
Send comments to The Honorable Paul A. Hoelscher, Mayor of the Borough of Harrington Park, Municipal Center, 85 Harriot Avenue, Harrington Park, New Jersey 07640.
Borough of Hillsdale
Maps available for inspection at the Hillsdale Borough Hall, 380 Hillsdale Avenue, Hillsdale, New Jersey.
Send comments to Mr. Harold Karns, Borough of Hillsdale Administrator, 380 Hillsdale Avenue, Hillsdale, New Jersey 07642.
Borough of Montvale
Maps available for inspection at the Montvale Borough Hall, 1 Memorial Drive, Montvale, New Jersey.
Send comments to The Honorable George Zeller, Mayor of the Borough of Montvale, 1 Memorial Drive, Montvale, New Jersey 07645.
Borough of Paramus
Maps available for inspection at the Paramus Borough Hall, 1 Jockish Square, Paramus, New Jersey.
Send comments to The Honorable James Tedesco, III, Mayor of the Borough of Paramus, 1 Jockish Square, Paramus, New Jersey 07652.
Borough of Park Ridge
Maps available for inspection at the Park Ridge Borough Hall, 55 Park Avenue, Park Ridge, New Jersey.
Send comments to The Honorable Don Ruschman, Mayor of the Borough of Park Ridge, 55 Park Avenue, Park Ridge, New Jersey 07656.
Township of River Vale
Maps available for inspection at the River Vale Township Office, 406 River Vale Road, River Vale, New Jersey.

Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	

Send comments to The Honorable George Paschalis, Mayor of the Township of River Vale, 406 River Vale Road, River Vale, New Jersey 07675.

Township of Washington

Maps available for inspection at the Washington Township Office, 350 Hudson Avenue, Washington, New Jersey.

Send comments to The Honorable Rudolph J. Wenzel, Jr., Mayor of the Township of Washington, 350 Hudson Avenue, Washington, New Jersey 07676.

Borough of Westwood

Maps available for inspection at the Westwood Borough Hall, 101 Washington Avenue, Westwood, New Jersey.

Send comments to The Honorable Skip Kelly, Mayor of the Borough of Westwood, 101 Washington Avenue, Westwood, New Jersey 07675.

Borough of Woodcliff Lake

Maps available for inspection at the Woodcliff Lake Municipal Building, 188 Pascack Road, Woodcliff Lake, New Jersey.

Send comments to The Honorable Josephine C. Higgins, Mayor of the Borough of Woodcliff Lake, Municipal Building, 188 Pascack Road, Woodcliff Lake, New Jersey 07677.

NORTH CAROLINA
Brunswick County

Allen Creek	At the confluence with McKinzie Pond	None	•9	Brunswick County (Unincorporated Areas), City of Boiling Spring Lakes.
	Approximately 675 feet downstream of West Boiling Spring Road.	None	•50	
Alligator Branch	At the confluence with Hood Creek	None	•19	Brunswick County (Unincorporated Areas).
	Approximately 0.5 mile downstream of Interstate 74/76	None	•60	
Batarora Branch	At the confluence with Hood Creek	None	•31	Brunswick County (Unincorporated Areas).
	Approximately 1,500 feet upstream of NC Highway 87	None	•36	
Batarora Branch Tributary	At the confluence with Batarora Branch	None	•36	Brunswick County (Unincorporated Areas).
	Approximately 1.3 miles upstream of the confluence with Batarora Branch.	None	•59	
Beaverdam Creek (near Henrytown).	At the confluence with Town Creek	None	•12	Brunswick County (Unincorporated Areas).
	Approximately 1.5 miles upstream of Town Creek Road Northeast.	None	•66	
Beaverdam Creek (near Southport).	Approximately 1.0 mile upstream of the confluence with Intracoastal Waterway.	None	•11	Brunswick County (Unincorporated Areas), Town of St. James
	At the confluence with Beaverdam Swamp	None	•12	
Beaverdam Swamp	At the confluence with Beaverdam Creek (near Southport).	None	•12	Brunswick County (Unincorporated Areas), Town of St. James.
	Approximately 1,650 feet upstream of Committee Drive Southeast.	None	•46	
Bell Swamp	At the confluence with Mill Creek (near Winnabow)	None	•10	Brunswick County (Unincorporated Areas).
	Approximately 2.0 miles upstream of Cherrytree Road Northeast.	None	•52	
Bishop Branch	At the confluence with Morgan Creek	None	•9	Brunswick County (Unincorporated Areas), Town of Leland.
	Approximately 0.3 mile upstream of Pinecliff Drive Northeast.	None	•64	
Cape Fear River	Approximately 1.1 miles downstream of the intersection of Pender, New Hanover, and Brunswick County boundary.	None	•7	Brunswick County (Unincorporated Areas), Town of Navassa.
	At the Brunswick/Columbus County boundary	None	•14	
Cherry Tree Swamp	At the confluence with Bell Swamp	None	•27	Brunswick County (Unincorporated Areas).
	Approximately 1.4 miles upstream of Cherrytree Road Northeast.	None	•62	
Cottage Creek	Approximately 1,000 feet downstream of 9th Street	None	•10	Brunswick County (Unincorporated Areas), City of Southport.
	Approximately 550 feet upstream of 11th Street	None	•20	
Daw's Creek	Approximately 850 feet upstream of the confluence with Town Creek.	None	•9	Brunswick County (Unincorporated Areas).
	Approximately 0.9 mile upstream of Daw's Creek Road	None	•16	

Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
Dutchman Creek (north of CP&L Canal).	At the confluence with CP&L Canal	None	•10	Brunswick County (Unincorporated Areas), City of Southport.
	Approximately 1.9 miles upstream of 211	None	•32	
Gapway Creek County boundary.	At the Brunswick/Columbus	None	•45	Brunswick County (Unincorporated Areas).
	Approximately 2.7 miles upstream of the Brunswick/Columbus County line.	None	•64	
Governors Creek	At the confluence with Walden Creek	None	•8	Brunswick County (Unincorporated Areas).
	Approximately 2.3 miles upstream of unnamed road	None	•8	
Harris Swamp	At the confluence with Mill Creek (near Winnabow)	None	•11	Brunswick County (Unincorporated Areas).
	Approximately 2.5 miles upstream of NC Highway 87	None	•27	
Hood Creek	At the confluence with Cape Fear River	None	•10	Brunswick County (Unincorporated Areas).
	Approximately 1.9 miles upstream of NC Highway 87	None	•61	
Hood Creek Tributary	At the confluence with Hood Creek	None	•29	Brunswick County (Unincorporated Areas).
	Approximately 300 feet upstream of Malmo Lake Road Northeast.	None	•55	
Jackeys Creek	Approximately 0.3 mile downstream of NC 17	•13	•10	Brunswick County (Unincorporated Areas), Town of Leland.
	Just upstream of abandoned railroad	•18	•17	
Jackeys Creek Tributary	At the confluence with Jackeys Creek	•18	•16	Brunswick County (Unincorporated Areas), Town of Leland.
	Approximately 425 feet upstream of Lanvale Road Northeast.	None	•39	
Lewis Branch	At the confluence with Lewis Swamp	None	•20	Brunswick County (Unincorporated Areas).
	Approximately 1.6 miles upstream of Lewis Swamp Road Northeast.	None	•62	
Lewis Swamp	At the confluence with Town Creek	None	•14	Brunswick County (Unincorporated Areas).
	Approximately 2.7 miles upstream of Beetree Farm Trail.	None	•65	
Lewis Swamp Tributary	At the confluence with Lewis Swamp	None	•32	Brunswick County (Unincorporated Areas).
	Approximately 1.5 miles upstream of the confluence with Lewis Swamp.	None	•52	
Liliput Creek	Approximately 1,450 feet of State Route 133	None	•9	Brunswick County (Unincorporated Areas).
	At the confluence with Allen Creek	None	•9	
Little Mallory Creek	Approximately 100 feet State Route 133	None	•9	Brunswick County (Unincorporated Areas).
	Approximately 250 feet upstream of Wire Road	None	•21	
Livingston Creek	Approximately 1.2 miles downstream of Columbus/Brunswick border.	None	•52	Brunswick County (Unincorporated Areas).
	At Columbus/Brunswick County border	None	•59	
McKinzie Creek	At the confluence with Allen Creek/McKinzie Pond	None	•9	Brunswick County (Unincorporated Areas).
	Approximately 570 feet upstream of Funston Road Southeast.	None	•25	
Mill Creek (near Leland)	Approximately 0.8 mile upstream of the confluence with Sturgeon Creek.	None	•7	Brunswick County (Unincorporated Areas), Town of Leland, Town of Navassa.
	Approximately 250 feet upstream of Post Office Road Northwest.	None	•9	
Mill Creek (near Winnabow)	At the confluence with Rice Creek	None	•10	Brunswick County (Unincorporated Areas).
	Approximately 1.7 miles upstream of Old Mill Creek Road Southeast.	None	•24	
Morgan Creek	Approximately 0.3 mile of the confluence with Town Creek.	None	•9	Brunswick County (Unincorporated Areas), Town of Leland.

Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	
	Approximately 0.8 miles upstream of Hewitt-Burton Road Southeast.	None	•21	
Nancy's Creek	At the confluence with Walden Creek	None	•8	Brunswick County (Unincorporated Areas).
	Approximately 0.6 mile upstream of railroad crossing	None	•8	
Nigis Creek	At the confluence with Walden Creek	None	•8	Brunswick County (Unincorporated Areas).
	Approximately 2.0 miles upstream of unnamed road	None	•26	
Orton Creek	Approximately 50 feet downstream of Plantation Road Southeast.	None	•9	Brunswick County (Unincorporated Areas).
	Approximately 1.5 miles upstream of NC 87	None	•44	
Prices Creek	At East Moore Street	None	•9	Brunswick County (Unincorporated Areas), City of Southport.
	Approximately 1,750 feet upstream of East Leonard Street.	None	•13,	
Rattlesnake Branch	At the confluence with Hood Creek	None	•14	Brunswick County (Unincorporated Areas), City of Northwest.
	Approximately 250 feet upstream of Saw Mill Road	None	•36	
Rice Creek	Approximately 1.9 miles downstream of Governors Road Southeast.	None	•9	Brunswick County (Unincorporated Areas).
	At the confluence with Mill Creek (near Winnabow)	None	•10	
Russells Creek	At the confluence with Town Creek	None	•9	Brunswick County (Unincorporated Areas).
	Approximately 0.3 mile upstream of Irvine Trail Northeast.	None	•47	
Sand Hill Creek	Approximately 0.8 mile upstream of the confluence with Cape Fear River.	None	•9	Brunswick County (Unincorporated Areas).
	Approximately 800 feet upstream of State Route 133	None	•12	
Town Creek	Approximately 600 feet downstream of the confluence with Russells Creek.	None	•9	Brunswick County (Unincorporated Areas).
	Approximately 2.6 miles upstream of Town Creek Road Northeast.	None	•63	
Turkey Branch	At the confluence with Town Creek	None	•15	Brunswick County (Unincorporated Areas).
	Approximately 0.5 mile upstream of Patrick Drive Northeast.	None	•61	
Walden Creek	Approximately 0.4 mile of the confluence with Governors Creek.	None	•9	Brunswick County downstream (Unincorporated Areas).
	Approximately 0.6 mile upstream of the confluence with White Spring Creek.	None	•8	
White Spring Creek	At the confluence with Walden Creek	None	•8	Brunswick County (Unincorporated Areas).
	Approximately 100 feet downstream of railroad	None	•8	
Atlantic Ocean	Approximately 500 feet south of the intersection of Southeast 52nd Street and East Pelican Drive in the Town of Oak Island.	•22	•21	Brunswick County (Unincorporated Areas), Town of Caswell Beach, Village of Bald Head Island, Town of Oak Island
	Along Bay Creek at the confluence with Deer Creek	•11	•14	

Village of Bald Head Island

Maps available for inspection at the Bald Head Island Town Hall, 106 Lighthouse Wynd, Bald Head Island, North Carolina.

Send comments to The Honorable Larry Lammert, Mayor of the Village of Bald Head Island, P.O. Box 3009, Bald Head Island, North Carolina 28461–3009.

City of Boiling Spring Lakes

Maps available for inspection at the Boiling Spring Lakes City Hall, 9 Boiling Spring Road, Boiling Spring Lakes, North Carolina.

Send comments to The Honorable Joan Kinney, Mayor of the City of Boiling Spring Lakes, 9 East Boiling Spring Road, Boiling Spring Lakes, North Carolina 28461.

Brunswick County (Unincorporated Areas)

Maps available for inspection at the Brunswick County Planning Department, 75 Courthouse Drive Northeast, Building I, Bolivia, North Carolina.

Send comments to Mr. Marty Lawing, Brunswick County Manager, P.O. Box 249, Bolivia, North Carolina 28422–0249.

Town of Caswell Beach

Maps available for inspection at the Caswell Beach Town Hall, 1100 Caswell Beach Road, Caswell Beach, North Carolina.

Send comments to The Honorable Harry Simmons, Jr., Mayor of the Town of Caswell Beach, 1100 Caswell Beach Road, Caswell Beach, North Carolina 28465.

Town of Leland

Maps available for inspection at the Leland Town Hall, 102 Town Hall Drive, Leland, North Carolina.

Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD) •Elevation in feet (NAVD)		Communities affected
		Existing	Modified	

Send comments to The Honorable Franky Thomas, Mayor of the Town of Leland, 102 Town Hall Drive, Leland, North Carolina 28451.

Town of Navassa

Maps available for inspection at the Navassa Town Hall, 334 Main Street, Navassa, North Carolina.

Send comments to The Honorable Eulis Willis, Mayor of the Town of Navassa, 334 Main Street, Navassa, North Carolina 28451.

City of Northwest

Maps available for inspection at the Northwest City Hall, 4889 Vernon Road, Leland, North Carolina.

Send comments to The Honorable James Knox, Mayor of the City of Northwest, P.O. Box 1509, Leland, North Carolina 28451.

Town of Oak Island

Maps available for inspection at the Oak Island Town Hall, 4601 East Oak Island Drive, Oak Island, North Carolina.

Send comments to The Honorable Helen Cashwell, Mayor of the Town of Oak Island, 4601 East Oak Island Drive, Oak Island, North Carolina 28465.

Town of St. James

Maps available for inspection at the St. James Town Hall, 3628 St. James Drive, Southport, North Carolina.

Send comments to The Honorable Leonard B. Harmon, Mayor of the Town of St. James, 3628 St. James Drive, Southport, North Carolina 28461.

City of Southport

Maps available for inspection at the Southport Town Hall, 201 East Moore Street, Southport, North Carolina.

Send comments to The Honorable Norman Holden, Mayor of the City of Southport, 201 East Moore Street, Southport, North Carolina 28461.

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: March 29, 2005.

David I. Maurstad,

Acting Director, Mitigation Division, Emergency Preparedness and Response Directorate.

[FR Doc. 05–6543 Filed 4–1–05; 8:45 am]

BILLING CODE 9110–12–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–718, MB Docket No. 05–106, RM–11196]

Radio Broadcasting Services; Ellaville, Milner, and Plains, GA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a Petition for Rule Making filed by Linda A. Davidson requesting the allotment of Channel 290A at Milner, Georgia, as the community's first local aural transmission service. Channel 290A can be allotted to Milner in compliance with the Commission's rules provided there is a site restriction of 11.9 kilometers (7.4 miles) northeast of Milner. The proposed reference coordinates for Channel 290A at Milner are 33–09–44 North Latitude and 84–04–51 West Longitude. To accommodate this allotment, this document also proposes the substitution of Channel 232A for vacant FM Channel 290A at Ellaville, Georgia. Channel 232A can be allotted to Ellaville in compliance with the Commission's rules provided there is a site restriction of 14.5 kilometers (9.0 miles) east at coordinates 32–16–53 NL and 84–09–52 WL. Petitioner also requests the allotment of Channel 290A at Plains, Georgia, as its first local aural transmission service. Channel 290A can be allotted to Plains in compliance with the Commission's rules provided there is a site restriction of 14.7 kilometers (9.1 miles) northeast at coordinates 32–06–51 NL and 84–16–10 WL.

DATES: Comments must be filed on or before May 9, 2005, and reply comments on or before May 24, 2005.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: Linda A. Davidson, 2134 Oak Street, Unit C, Santa Monica, California 90405.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MB Docket No. 05–106, adopted March 16, 2005, and released March 18, 2005. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center 445 Twelfth Street, SW., Washington, DC 20554. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center 445 Twelfth Street, SW., Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20054, telephone 1–800–378–3160 or *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).

Provisions of the Regulatory Flexibility Act of l980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making 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* contact.

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 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Georgia, is amended by removing Channel 290A and by adding Channel 232A at Ellaville, by adding Milner, Channel 290A and by adding Plains, Channel 290A.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–6558 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–727; MB Docket No. 05–125, RM–11176]

Radio Broadcasting Services; Alturas, Palo Cedro, and Weaverville, CA

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 Audio Division requests comment on a petition filed by George S. Flinn, Jr., pursuant to Section 1.420(i) of the Commission's rules, 47 CFR 1.420(i). Petitioner proposes to change the community of license for Station KWCA(FM) from Weaverville to Palo Cedro, California. Petitioner further proposes to upgrade from Channel 266A to Channel 266C3, and to change the FM Table of Allotments by deleting Channel 266A at Weaverville, California, and by adding Channel 266C3 at Palo Cedro, California, as the community's first local aural broadcast service. The proposed coordinates for Channel 266C3 at Palo Cedro, California, are 40–40–04 NL and 122–25–31 WL. The allotment will require a site restriction of 19.6 km (12.2 miles) northwest of Palo Cedro. In addition, in order to accommodate the allotment of Channel 266C3 at Palo Cedro, Petitioner further proposes to downgrade vacant Channel 267C at Alturas, California, to Channel 268C1, and to change the FM Table of allotments at Alturas, California, by deleting Channel 267C and adding Channel 268C1. The proposed coordinates for Channel 268C1 at Alturas, California, are 41–25–00 NL and 121–06–32 WL. The allotment will require a site restriction of 48.1 km (29.9 miles) west of Alturas.

DATES: Comments must be filed on or before May 9, 2005, and reply comments on or before May 24, 2005.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the petitioner as follows: Stephen C. Simpson, Esq., 1090 Vermont Avenue, NW., Suite 800, Washington, DC 20005.

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 Rule Making, MB Docket No. 05–125; adopted March 16, 2005, and released March 18, 2005. The full text of this Commission document 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. 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 Rule Making 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 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under California, is amended by removing Channel 267C and by adding Channel 268C1 at Alturas, by adding Palo Cedro, Channel 266C3, and by removing Channel 266A at Weaverville.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–6557 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–708; MB Docket No. 05–108, RM–11178]

Radio Broadcasting Services; Andover and Haverhill, MA

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 Audio Division requests comment on a petition filed by Beanpot Broadcasting Corp. pursuant to Section 1.420(i) of the Commission's rules, 47 CFR 1.420(i). Petitioner proposes to change the community of license for Station WXRV(FM) from Haverhill to Andover, Massachusetts, and to change the FM Table of Allotments by deleting Channel 223B at Haverhill, Massachusetts, and by adding Channel 223B at Andover, Massachusetts, as the community's first local aural broadcast service. The proposed coordinates for Channel 223B at Andover, Massachusetts, are 42–46–23 NL and 71–06–01 WL. The allotment will require a site restriction of 13.1 km (8.1 miles) north of Andover. Because the petitioner does not propose to change its transmitter site, there would be neither gain nor loss in the land area or number of persons served. Both Andover and

Haverhill are located within the Boston Urbanized Area. The proposed change of community requires concurrence in the allotment by the Government of Canada.

DATES: Comments must be filed on or before May 9, 2005, and reply comments on or before May 24, 2005.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the petitioner as follows: Barry A. Friedman, Esq., Thompson Hine LLP, 1920 N Street, NW., Suite 800, Washington, DC 20036.

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 Rule Making, MB Docket No. 05–108; adopted March 16, 2005, and released March 18, 2005. The full text of this Commission document 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. 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 Rule Making 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 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Massachusetts, is amended by removing Haverhill, Channel 223B and by adding Andover, Channel 223B.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–6556 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–706; MB Docket No. 05–112; RM–11185]

Radio Broadcasting Services; Fredericksburg, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition for rulemaking filed by Katherine Pyeatt requesting the allotment of Channel 256C3 at Fredericksburg, Texas. The coordinates for Channel 256C3 at Fredericksburg, Texas, are 30–13–21 NL and 99–02–15 WL. There is a site restriction 17 kilometers (10.6 miles) west of the community.

DATES: Comments must be filed on or before May 9, 2005, and reply comments on or before May 24, 2005.

ADDRESSES: Secretary, Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner as follows: Katherine Pyeatt, 6655 Aintree Circle, Dallas, Texas 75214 and Gene A. Bechtel, Law Office of Gene Bechtel, 1050 17th Street, NW., Suite 600, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Victoria M. McCauley, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 05–112, adopted March 16, 2005, and released March 18, 2005. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 Twelfth Street, SW., Washington, DC. This document may also be purchased from the Commission's duplicating contractors, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC, 20054, telephone 800–378–3160 or *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).

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 Rule Making 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 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding, Channel 256C3 at Fredericksburg.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–6554 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–711, MB Docket No. 05–113; RM–11195]

Radio Broadcasting Services; Ely and Spring Creek, NV

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document seeks comment on a petition for rulemaking filed by Ruby Radio Corporation, licensee of Station KCLS(FM), Ely, Nevada, proposing the substitution of Channel 269C1 for Channel 269C3 at Ely, the reallotment of Channel 269C1 from Ely to Spring Creek, Nevada, as the community's first local transmission service, and the modification of the license for Station KCLS(FM) to reflect the new community. Channel 269C1 has been proposed to be reallotted at Spring Creek at a site 31.1 kilometers (19.3 miles) northwest of the community at coordinates 40–5–18 NL and 115–50–58 WL.

DATES: Comments or counterproposals must be filed on or before May 9, 2005, and reply comments on or before May 24, 2005.

ADDRESSES: Secretary, Federal Communications Commission, 445 12th Street, SW., Room TW–A325, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: David Tillotson, Esq., Law Office of David Tillotson, 4606 Charleston Terrace, NW., Washington, DC 20007–1911.

FOR FURTHER INFORMATION CONTACT: Victoria M. McCauley, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking,* MB Docket No. 05–113, adopted March 16, 2005, and released March 18, 2005. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center 445 Twelfth Street, SW., Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC, 20054, telephone 800–378–3160 or *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 Rule Making* 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, and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Nevada, is amended by removing Channel 269C3 at Ely and adding Spring Creek, Channel 269C1.

Federal Communications Commission.

John A. Karousos

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–6553 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–716; MB Docket No. 05–124, RM–11174]

Radio Broadcasting Services; Killen, AL and Loretto, TN

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 Audio Division requests comment on a petition filed by Pulaski Broadcasting, Inc., pursuant to Section 1.420(i) of the Commission's rules, 47 CFR 1.420(i). Petitioner proposes to change the community of license for Station WKSR–FM from Killen, Alabama, to Loretto, Tennessee, and to change the FM Table of Allotments by deleting Channel 252C3 at Killen, Alabama, and by adding Channel 252C3 at Loretto, Tennessee, as the community's first local aural broadcast service. The proposed coordinates for Channel 252C3 at Loretto, Tennessee, are 35–00–47 NL and 87–34–06 WL. The allotment will require a site restriction of 13.8 km (8.5 miles) southwest of Loretto. Petitioner previously had proposed a change of community from Pulaski, Tennessee, to Killen, Alabama. Although that proposal was approved, Petitioner is not yet serving Killen, Alabama. Comment is sought on whether to allow a second change of community before the first change of community is effectuated.

DATES: Comments must be filed on or before May 9, 2005, and reply comments on or before May 24, 2005.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the petitioner as follows: Robert S. Stone, Esq., McCampbell & Young, PC, 2021 First Tennessee Plaza, Knoxville, Tennessee 37929.

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 Rule Making, MB Docket No. 05–124; adopted March 16, 2005, and released March 18, 2005. The full text of this Commission document 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. 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 Rule Making 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 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Alabama, is amended by removing Killen, Channel 252C3.

3. Section 73.202(b), the Table of FM Allotments under Tennessee, is amended by adding Loretto, Channel 252C3.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–6571 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–714; MB Docket No. 05–121, RM–11197; MB Docket No. 05–122, RM–11198]

Radio Broadcasting Services; Columbus and Monona, WI; and Knightdale and Wilson, NC

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes two changes of community reallotments for Columbus and Monona, Wisconsin; and Wilson and Knightdale, North Carolina.

The Audio Division requests comments on a petition filed by Capstar TX Limited Partnership proposing the reallotment of Channel 291C0 from Wilson to Knightdale, North Carolina, and the modification of Station WRDU(FM)'s license accordingly. Channel 291C0 can be reallotted to Knightdale in compliance with the Commission's minimum distance separation requirements with a site restriction of 10 kilometers (6.2 miles) east to avoid short-spacings to the licensed site of Station WFJA(FM), Channel 288A, Sanford, North Carolina, and the licensed site of Station WMNA–FM, Channel 292A, Gretna, Virginia. The Audio Division granted Station WRDU(FM) a license to specify operation on Channel 291C0 in lieu of Channel 291C on April 10, 2003. *See* BLH–20020607AAR. This change is not reflected in The FM Table of Allotments. The reference coordinates for Channel 291C0 at Knightdale are 35–47–50 NL and 78–22–15 WL. In accordance with the provisions of Section 1.420(i) of the Commission's Rules, we will not accept competing expressions of interest for the use of Channel 291C0 at Knightdale, North Carolina, or require petitioner to demonstrate the existence of an equivalent class channel for the use of other interested parties. *See* **SUPPLEMENTARY INFORMATION**, *infra*.

DATES: Comments must be filed on or before May 9, 2005, reply comments on or before May 24, 2005.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Mark N. Lipp, Esq., Vinson and Elkins, L.L.P., 1455 Pennsylvania Ave., NW., Suite 600, Washington, DC 20004–1008 (Counsel for Capstar TX Limited Partnerhip); and John D. Poutasse, Esq., Leventhal, Senter & Lerman, PLLC, 2000 K Street, NW., Suite 600, Washington, DC 20006–1809 (Counsel for Good Karma Broadcasting, LLC).

FOR FURTHER INFORMATION CONTACT: Sharon P. McDonald, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making*, MB Docket No. 05–121, MB Docket No. 05–122, adopted March 16, 2005, and released March 18, 2005. 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. This document may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20054, telephone 1–800–378–3160 or *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 Audio Division requests comments on a petition filed by Good Karma Broadcasting, LLC, proposing the reallotment of Channel 263A from Columbus to Monona, Wisconsin, and the modification of Station WTLX(FM)'s license accordingly. Channel 263A can be reallotted to Monona in compliance with the Commission's minimum distance separation requirements with a site restriction of 9.1 kilometers (5.7 miles) north to avoid a short-spacing to the licensed site of Station WJVL(FM), Channel 260B1, Janesville, Wisconsin. The reference coordinates for Channel 263A at Monona are 43–08–19 NL and 89–22–27 WL. In accordance with the provisions of Section 1.420(i) of the Commission's Rules, we will not accept competing expressions of interest for the use of Channel 263A at Monona, Wisconsin, or require petitioner to demonstrate the existence of an equivalent class channel for the use of other interested parties.

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 Rule Making 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 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under North Carolina, is amended by adding Knightdale, Channel 291C0, and removing Channel 291C at Wilson.

3. Section 73.202(b), the Table of FM Allotments under Wisconsin, is amended by removing Columbus, Channel 263A, and adding Monona, Channel 263A.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–6570 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–649; MB Docket No. 05–103, RM–11205]

Radio Broadcasting Services; Barnsboro and Gallitzin, PA

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 Audio Division requests comment on a petition filed by Vernal Enterprises, Inc., pursuant to Section 1.420(i) of the Commission's rules, 47 CFR 1.420(i). Petitioner proposes to change the community of license for Station WHPA(FM) from Barnsboro to Gallitzin, Pennsylvania, and to change the FM Table of Allotments by deleting Channel 228A at Barnsboro, Pennsylvania, and by adding Channel 228A at Gallitzin, Pennsylvania, as the community's first local aural broadcast service. The proposed coordinates for Channel 228A at Gallitzin, Pennsylvania, are 40–36–31 NL and 78–36–21 WL. The allotment will require a site restriction of 14.8 km (9.2 miles) north of Gallitzin.

DATES: Comments must be filed on or before May 9, 2005, and reply comments on or before May 24, 2005.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the petitioner as follows: John M. Pelkey, Esq., Garvey, Schubert Barer, 1000 Potomac Street, NW., Fifth Floor, Washington, DC 20007.

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 Rule Making, MB Docket No. 05–103; adopted March 16, 2005, and released March 18, 2005. The full text of this Commission document 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. 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 Rule Making 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 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Pennsylvania, is amended by removing Barnsboro, Channel 228A, and by adding Gallitzin, Channel 228A.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–6568 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–707; MB Docket No. 05–117, RM–11182; MB Docket No. 05–118, RM–11183; MB Docket No. 05–119, RM–11184]

Radio Broadcasting Services; Colfax, LA; Knoxville, IL; and Moody, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes new FM broadcast allotments in Colfax, Louisiana; Knoxville, Illinois; and Moody, Texas. The Audio Division, Media Bureau, requests comment on a petition filed by Charles Crawford, proposing the allotment of Channel 267A at Colfax, Louisiana, as the community's first local aural transmission service. Channel 267A can be allotted to Colfax in compliance with the Commission's minimum distance separation requirements with a site restriction of 13.0 kilometers (8.1 miles) southwest of the central city coordinates for Colfax. The reference coordinates for Channel 267A at Colfax are 31–27–53 North Latitude and 92–49–44 West Longitude. *See* **SUPPLEMENTARY INFORMATION**, *infra*.

DATES: Comments must be filed on or before May 9, 2005, and reply comments on or before May 24, 2005.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, his counsel, or consultant, as follows: Charles Crawford, 4553 Bordeaux Ave., Dallas, Texas 75205, and Paul B. Christensen, Esq., Law Offices of Paul B. Christensen, P.A., 3749 Southern Hills Drive, Jacksonville, Florida 32225.

FOR FURTHER INFORMATION CONTACT: R. Barthen Gorman, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket Nos. 05–117, 05–118, and 05–119, adopted March 16, 2005 and released March 18, 2005. The full text of this Commission document is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20054, telephone 1–800–378–3160 or *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 Audio Division requests comments on a petition filed by Paul B. Christensen, Esq., proposing the allotment of Channel 291A at Knoxville, Illinois, as the community's second local aural transmission service. Channel 291A can be allotted to Knoxville in compliance with the Commission's minimum distance separation requirements without any site restriction. The reference coordinates for Channel 291A at Knoxville are 40–54–30 North Latitude and 90–17–05 West Longitude.

The Audio Division requests comments on a petition filed by Charles Crawford proposing the allotment of Channel 256A at Moody, Texas, as the community's first local aural transmission service. Channel 256A can be allotted to Moody in compliance with the Commission's minimum distance separation requirements with a site restriction of 8.7 kilometers (5.4 miles) west of Moody. The reference coordinates for Channel 256A at Moody are 31–17–03 North Latitude and 97–26–35 West Longitude.

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 Rule Making 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* contact.

For information regarding proper filing procedures for comments, *see* 47 CFR sections 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 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Illinois, is amended by adding Channel 291A at Knoxville.

3. Section 73.202(b), the Table of FM Allotments under Louisiana, is amended by adding Colfax, Channel 267A.

4. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Moody, Channel 256A.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–6567 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–713; MB Docket No. 05–120, RM–11194]

Radio Broadcasting Services; Prospect, KY, and Salem, IN

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 Audio Division requests comment on a petition filed by Clear Channel Broadcasting Licenses, Inc., pursuant to Section 1.420(i) of the Commission's rules, 47 CFR 1.420(i). Petitioner proposes to change the community of license for Station WZKF(FM) from Salem, Indiana, to Prospect, Kentucky, and to change the FM Table of Allotments by deleting Channel 255B at Salem, Indiana, and by adding Channel 255B at Prospect, Kentucky, as the community's first local aural broadcast service. The proposed coordinates for Channel 255B at Prospect, Kentucky, are 38–25–59 NL and 85–50–01 WL. The allotment will require a site restriction of 21.4 km (13.3 miles) northwest of Prospect.

DATES: Comments must be filed on or before May 9, 2005, and reply comments on or before May 24, 2005.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the petitioner as follows: Mark N. Lipp, Esq., Scott Woodworth, Esq., Vinson & Elkins L.L.P., 1455 Pennsylvania Avenue, NW., Suite 600, Washington, DC 20004–1008.

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 Rule Making, MB Docket No. 05–120; adopted March 16, 2005, and released March 18, 2005. The full text of this Commission document 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. 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).

Channel 255B at Salem, Indiana under Section 73.202(b), FM Table of Allotments, was inadvertently removed from the 1992 Code of Federal Regulations. As such, Channel 255B at Salem is not listed under Indiana in the FM Table of Allotments.

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 Rule Making 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 and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Kentucky, is amended by adding Prospect, Channel 255B.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–6564 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 05–710; MB Docket No. 05–116; RM–11188]

Radio Broadcasting Services; Fisher and Thief River Falls, MN

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition for rule making filed by Citicasters Licenses, L.P., licensee of Station KSNR(FM), Channel 262C1, Thief River Falls, Minnesota. Petitioner requests that the Commission reallot Channel 262C1 from Thief River Falls to Fisher, Minnesota. The coordinates for Channel 262C1 at Fisher are 47–58–38 NL and 96–36–42 WL, with a site restriction of 24.2 kilometers (15.1 miles) northeast of Fisher.

DATES: Comments must be filed on or before May 9, 2005, and reply comments on or before May 24, 2005.

ADDRESSES: Secretary, Federal Communications Commission, 445 12th Street, SW., Room TW–A325, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve Petitioner's counsel, as follows: Marissa G. Repp, Esq., and Tarah S. Grant, Esq., Hogan & Hartson, L.L.P.; 555 Thirteenth Street, NW., Washington, DC 20004–1109.

FOR FURTHER INFORMATION CONTACT: R. Barthen Gorman, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 05–116, adopted March 16, 2005 and released March 18, 2005. The full text of this Commission decision is available for inspection and copying during regular business hours in the FCC's Reference Information Center at Portals II, 445 12th Street, SW., CY–A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractors, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *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 Rule Making 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, and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Minnesota, is amended by removing Channel 262C1 at Thief River Falls, and adding Fisher, Channel 262C1.

Federal Communications Commission

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 05–6563 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 70, No. 63

Monday, April 4, 2005

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

Submission for OMB Review; Comment Request

March 29, 2005.

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.

Rural Housing Service

Title: 7 CFR 1901–E, Civil Rights Compliance Requirements.

OMB Control Number: 0575–0018.

Summary of Collection: Rural Development (RD) is required to provide Federal financial assistance through its farmer, housing, and community and business programs on an equal opportunity basis. The laws implemented in 7 CFR 1901–E, require the recipients of Rural Development's Federal financial assistance to collect various types of information by race, color, and national origin.

Need and Use of the Information: RD will use the information to monitor a recipient's compliance with the civil rights laws, and to determine whether or not service and benefits are being provided to beneficiaries on an equal opportunity basis. This information is made available to USDA officials, officials of other Federal agencies and to Congress for reporting purposes. Without the required information, RD and its recipient will lack the necessary documentation to demonstrate that their programs are being administered in a nondiscriminatory manner and in full compliance with the civil rights laws.

Description of Respondents: Individuals or households; non-for-profit institutions; business or other for-profit; farms; State, local or tribal government.

Number of Respondents: 19,565.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 587,568.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 05–6531 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–XT–M

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Intergovernmental Advisory Committee

AGENCY: Office of the Secretary, USDA.

ACTION: Notice of intent to renew Federal advisory committee.

SUMMARY: The Department of Agriculture, in consultation with the Department of the Interior, intends to renew the Intergovernmental Advisory Committee (IAC). This renewal is in response to the continued need for the IAC to provide intergovernmental advice on coordinating the implementation of the Record of Decision of April 13, 1994, for Management of Habitat for Late-Successional and Old-Growth Forest Related Species Within the Range of the Northern Spotted Owl. The IAC also provides advice and recommendations to promote integration and coordination of forest management activities between Federal and non-Federal entities.

ADDRESSES: Copies of the April 13, 1994, Record of Decision can be obtained electronically at *http://www.reo.gov/library/*. Paper copies can be obtained from the Regional Ecosystem Office, P.O. Box 3623, Portland, OR 97208.

FOR FURTHER INFORMATION CONTACT: Geraldine Bower, Planning Specialist, Ecosystem Management Coordination Staff, Forest Service, USDA (202) 205–1022.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given that the Department of Agriculture, in consultation with the Department of the Interior, intends to renew the Intergovernmental Advisory Committee (IAC) to the Regional Interagency Executive Committee (RIEC). The purpose of the RIEC is to facilitate the coordinated implementation of the Record of Decision (ROD) signed April 13, 1994, for Management of Habitat for Late-Successional and Old-Growth Forest Related Species Within the Range of the Northern Spotted Owl. The RIEC consists of representatives of the following Federal agencies: Forest Service, Natural Resources Conservation Service, Bureau of Indian Affairs, Bureau of Land Management, National Marine Fisheries Service, National Park Service, U.S. Fish and Wildlife Service, U.S. Geological Survey Biological Resources Division, Environmental Protection Agency, and U.S. Army Corps of Engineers. The purpose of the IAC is to advise the RIEC on coordinating the implementation of the ROD. The IAC will provide advice and recommendations to promote integration and coordination of forest

management activities between Federal and non-Federal entities.

The IAC is in the public interest in connection with the duties and responsibilities of the managing agencies for developing an ecosystem management approach that is consistent with statutory authority for land use planning. Ecosystem management requires improved coordination among governmental entities responsible for land management decisions and the public they serve.

The chair of the IAC will alternate annually between representatives of the Forest Service and the Bureau of Land Management. The Executive Director, Regional Ecosystem Office, will serve as the Designated Federal Official under sections 10(e) and (f) of the Federal Advisory Committee Act (5 U.S.C. App.). Any vacancies on the committee will be filled in the manner in which the original appointment was made.

A meeting notice will be published in the **Federal Register** no less than 15 days before a scheduled meeting date. All advisory committee meetings are open to the public and typically include a 15-minute ''public forum'' for participants to present comments to the advisory committee. Alternates may choose not to be active during this session on the agenda. The chair of the given committee ultimately makes the decision whether to offer time on the agenda for the public to speak to the general body.

Renewal of the IAC does not require amendment of Bureau of Land Management or Forest Service planning documents because it does not affect the standards and guidelines or land allocations. The Bureau of Land Management and Forest Service will provide further notice, as needed, for additional actions or adjustments when implementing interagency coordination, public involvement, and other aspects of the ROD.

Equal opportunity practices will be followed in all appointments to the advisory committee. To ensure that the recommendations of the IAC have taken into account the needs of diverse groups served by the Departments, membership will, to the extent practicable, include individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

Dated: March 30, 2005.

John Surina,

Deputy Assistant Secretary for Administration.

[FR Doc. 05–6693 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Farm Service Agency

Request for Extension of a Currently Approved Information Collection; Representations for CCC and FSA Loans and Authorization To File a Financing Statement

AGENCY: Commodity Credit Corporation and Farm Service Agency, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intent of the Commodity Credit Corporation (CCC) and the Farm Service Agency (FSA) to request extension of the information collection currently used in support of the CCC and FSA Farm Loan Programs (FLP).

DATES: Comments on this notice must be received on or before June 3, 2005, to be assured consideration.

FOR FURTHER INFORMATION CONTACT: Chris Kyer, USDA, Farm Service Agency, Price Support Division, 1400 Independence Avenue, SW., STOP 0512, Washington, DC 20250–0512; Telephone (202) 720–7935; electronic mail: *chris.kyer@wdc.usda.gov*.

SUPPLEMENTARY INFORMATION:

Title: Representations for CCC or FSA Loans and Authorization to File a Financing Statement.

OMB Control Number: 0560–0215.

Expiration Date of Approval: September 30, 2005.

Type of Request: Extension of a Currently Approved Information Collection.

Abstract: Form CCC–10 is necessary to: (a) Gather or verify basic data provided by a CCC or FSA loan applicant that is required by a financing statement filed by CCC or FSA to perfect a security interest in collateral used to secure a loan; and (b) obtain loan applicant permission to file a financing statement prior to the execution of a security agreement.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 5 minutes per response.

Respondents: Individual farmers, farm or other business entities.

Estimated Number of Respondents: 105,500.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden On Respondents: 61,507 hours.

Comments are invited on the following: (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; or (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. These comments should be sent to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 and to Chris Kyer, Program Manager, USDA, Farm Service Agency, Price Support Division, 1400 Independence Avenue, SW., STOP 0512, Washington, DC 20250–0512.

All comments will become a matter of public record.

Signed in Washington, DC, on March 28, 2005.

James R. Little,

Executive Vice President, CCC and Administrator, Farm Service Agency.

[FR Doc. 05–6540 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Notice of Request for Revision of a Currently Approved Information Collection

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intent of the Foreign Agricultural Service (FAS) to request revision of the information collection currently approved in support of the Trade Adjustment Assistance (TAA) for Farmers Program. FAS invites public comments on this notice.

DATES: Comments on this notice should be received on or before June 3, 2005, in order to be assured of consideration. Comments received after this date may be considered to the extent practicable.

ADDRESSES: Comments should be mailed or delivered to Jean-Louis Pajot, Import Policies and Programs Division, Foreign Agricultural Service, 1400

Independence Avenue, SW. STOP 1021, U.S. Department of Agriculture, Washington, DC 20250–1021. Comments may also be inspected between 10 a.m. and 4 p.m., in room 5541–S, 1400 Independence Avenue, SW., Washington, DC 20250–1021.

FOR FURTHER INFORMATION CONTACT: Jean-Louis Pajot at the address above, or telephone (202) 720–2916, or e-mail at *Jean-Louis.Pajot@usda.gov.*

Copies of the information collection may be obtained from Liliana Silva-Castellanos, the Agency Information Collection Coordinator, at (202) 690–4055 or e-mail at *Liliana.Silva-Castellanos@usda.gov.* Persons with disabilities who require alternative means for communication (Braille, large print, audio tape, *etc.*) should contact the USDA Target Center at (202) 720–2600 (voice and TDD).

SUPPLEMENTARY INFORMATION: FAS invites interested persons to submit comments on this notice. Comments should reference the OMB control number and title of the program.

Title: Trade Adjustment Assistance for Farmers Program.

OMB Control Number: 0551–00–40.

Expiration Date of Approval: August 31, 2006.

Type of Request: Revision of a Currently Approved Information Collection.

Abstract: Form FSA–229, Application for Trade Adjustment Assistance (TAA) is used for producers who are applying for TAA benefits. The application requires the collection of personal information, production, certification of income, and compliance with program requirements. FAS proposes to revise form FSA–229 to incorporate a Part D to allow crewmembers to identify their share of production from a specific vessel. Acceptance of the modified form is contingent upon obtaining the vessel's captain or skipper signature.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 1 hour per response.

Respondents: Producers who are part of a certified petition for benefits.

Estimated Number of Respondents: 6,000.

Estimated Total Annual Burden on Respondents: 6,000.

Requests for comments: Comments are invited on the following: (a) Whether the collection of information will provide further assistance to the program applicant in providing production evidence to comply with existing requirements; (b) is necessary for the proper performance of the functions of the agency to identify and verify the production of each captain, skipper, and crew member of the vessel who are applying for TAA; (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 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.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission for OMB approval.

Dated: March 28, 2005.

A. Ellen Terpstra,

Administrator, Foreign Agricultural Service.

[FR Doc. 05–6608 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Trade Adjustment Assistance for Farmers

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

The Administrator, Foreign Agricultural Service (FAS), approved a petition for trade adjustment assistance (TAA) that was filed on February 25, 2005, by a group of Concord grape juice producers in New York, Pennsylvania, and Ohio (Tri-State). The certification date is March 28, 2005. Beginning on this date, Concord juice grape producers who produce and market Concord juice grapes will be eligible to apply for fiscal year 2005 benefits during an application period ending June 27, 2005.

SUPPLEMENTARY INFORMATION: Upon investigation, the Administrator determined that increased imports of grape juice contributed importantly to a decline in producer prices of Concord juice grapes in the Tri-State region by 22 percent during August 2003 through July 2004, when compared with the previous 5-year average.

Eligible producers must apply to the Farm Service Agency for benefits. After submitting completed applications, producers shall receive technical assistance provided by the Extension Service at no cost and may receive an adjustment assistance payment, if certain program criteria are satisfied. Applicants must obtain the technical assistance from the Extension Service by September 26, 2005, in order to be eligible for financial payments.

Producers of raw agricultural commodities wishing to learn more about TAA and how they may apply should contact the Department of Agriculture at the addresses provided below for General Information.

FOR FURTHER INFROMATION CONTACT: Producers certified as eligible for TAA should contact Farm Service Agency service centers in New York, Pennsylvania, and Ohio. For general information about TAA, contact Jean-Louis Pajot, Coordinator, Trade Adjustment Assistance for Farmers, FAS, USDA, (202) 720–2916, e-mail: *trade.adjustment@fas.usda.gov.*

Dated: March 24, 2005.

A. Ellen Terpstra,

Administrator, Foreign Agricultural Service.

[FR Doc. 05–6607 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Forest Service

Tehama County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Tehama County Resource Advisory Committee (RAC) will meet in Red Bluff, California. Agenda items to be covered include: Introductions, Approval of Minutes, Public Comment, Project Proposal Voting, Report on Reno Trip, General Discussion, County Update, Next Agenda.

DATES: The meeting will be held on April 21, 2005, from 9 a.m. and end at approximately 12 p.m.

ADDRESSES: The meeting will be held at the Lincoln Street School, Conference Room A, 1135 Lincoln Street, Red Bluff, CA. Individuals wishing to speak or propose agenda items must send their names and proposals to Jim Giachino, DFO, 825 N. Humboldt Ave., Willows, CA 95988.

FOR FURTHER INFORMATION CONTACT: Bobbin Gaddini, Committee Coordinator, USDA, Mendocino National Forest, Grindstone Ranger District, P.O. Box 164, Elk Creek, CA 95939. (530) 968–5329; e-mail *ggaddini@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Committee discussion is limited to Forest Service staff and Committee members. However, persons who wish to bring matters to the attention of the Committee may file written statements

with the Committee staff before or after the meeting. Public input sessions will be provided and individuals who made written requests by April 19, 2005, will have the opportunity to address the committee at those sessions.

Dated: March 28, 2005.

James F. Giachino,

Designated Federal Official.

[FR Doc. 05–6633 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Record of Decision for the Programmatic Environmental Impact Statement on the Emergency Watershed Protection Program

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Record of Decision.

SUMMARY: This notice presents the Record of Decision (ROD) regarding the Natural Resources Conservation Service (NRCS) implementation of revisions to the Emergency Watershed Protection (EWP) Program to allow NRCS to more effectively and efficiently meet EWP statutory requirements and improve the effectiveness of agency responses to sudden watershed impairments caused by natural disasters. NRCS prepared a Final Programmatic Environmental Impact Statement (FPEIS) for EWP Program changes and published the FPEIS on the NRCS Web site. A Notice of Availability (NOA) of the EWP FPEIS was published in the **Federal Register** on December 30, 2004 and all agencies and persons on the FPEIS distribution list were notified individually as well. Printed and CD-ROM versions of the FPEIS were made available and delivered to all those who requested. This Decision Notice summarizes the environmental, social, and economic impacts of the EWP Program alternatives identified in the FPEIS that were considered in making this decision, and explains why NRCS selected the Preferred Alternative—EWP Program Improvement and Expansion (Alternative 4) for improving the EWP Program. The public may access the NRCS responses to substantive comments on the FPEIS at *http://www.nrcs.usda.gov/programs/ewp/*.

FOR FURTHER INFORMATION CONTACT: Mr. Victor Cole, USDA/NRCS/Financial Assistance Programs Division, P.O. Box 2890, Washington, DC, 20013–2890, (202) 690–0793, or e-mail: *victor.cole@usda.gov*. The EWP FPEIS including appendices and this ROD may be accessed via the Internet on the NRCS Web site at: *http://www.nrcs.usda.gov/programs/ewp/*. More detailed information on this program may also be obtained from the NRCS web site, or by contacting Victor Cole using the information provided above.

Record of Decision

I. The Decision

A. FPEIS Preferred Alternative—EWP Program Improvement and Expansion—as the Basis for Implementing and Expanding the EWP Program

Based on a thorough evaluation of the resource areas affected by the EWP Program, a detailed analysis of four Program alternatives, and a comprehensive review of public comments on the Draft PEIS, NRCS has selected the Preferred Alternative—EWP Program Improvement and Expansion (Alternative 4) to improve and expand the EWP Program to improve the timeliness and environmental, economic, and social defensibility of activities conducted under the Program, as well as to ensure their technical soundness.

B. Overview

The EWP Program funds and provides technical assistance to sponsoring organizations (entities of local government) to implement emergency measures for runoff retardation and soil erosion prevention to assist in relieving imminent hazards to life and property from natural disasters, including, but not limited to, floods, fires, windstorms, ice storms, hurricanes, tornadoes, volcanic actions, earthquakes, and drought, and the products of erosion created by natural disasters that have caused or are causing sudden impairment of a watershed. The Program is authorized by Section 216 of the Flood Control Act of May 17, 1950 (Pub. L. 81–516; 33 U.S.C. 701b–1) and by Section 403 of Title IV of the Agricultural Credit Act of 1978, (Pub. L. 95–334), as amended by Section 382 of the Federal Agricultural Improvement and Reform Act of 1996 (Pub. L. 104–127; 16 U.S.C. 2204). The EWP Program is administered by NRCS on state, tribal, and private lands, with funding typically provided through Congressional emergency supplemental appropriations. NRCS regulations implementing the EWP Program are set forth in 7 CFR part 624.

C. Programmatic Changes to the EWP Program

Fifteen key aspects of the current EWP Program were considered for improvement or expansion in the PEIS, and were used to define the alternatives to the current program in the PEIS. To implement the Preferred Alternative—EWP Program Improvement and Expansion, NCRS would incorporate the following 15 elements to improve the delivery and defensibility of the Program and incorporate new restoration practices:

1. *Retain the term ''exigency''; eliminate ''non-exigency.''* NRCS would not eliminate the key term ''exigency'' because of its broad interagency use but would eliminate the term non-exigency and simply refer to them as emergencies.

2. *No State level funding for immediate exigency response. Change allowed time to address exigencies to 10 days.* Funding would not be set aside in each of the States to immediately address exigencies, though the time frame to respond to exigencies would be lengthened to 10 days to allow more time to request and secure funding and to allow NRCS and sponsors to secure any necessary emergency permits and comply with any applicable Federal and State laws or regulations.

3. *Set priorities for funding of EWP practices.* NRCS would suggest priorities to be applied consistently across the country for funding EWP measures. Exigency situations would have highest priority.

4. *Establish cost-share of up to 75 percent; up to 90 percent in limited-resource areas; and add a waiver provision allowing up to 100 percent in unique situations.* In addition to the changes in Federal cost-share rates, a waiver provision would be included allowing up to 100 percent cost-sharing for a sponsor in unique situations or when the sponsor demonstrates they have insufficient resources or finances to contribute the 25 percent cost-share.

5. *Stipulate that practices be economically, environmentally, and socially defensible.* In addition to environmental and economic defensibility, project alternatives would be reviewed to determine their acceptability according to the ideals and background of the community and individuals directly affected by the recovery activity.

6. *Improve disaster-readiness through interagency coordination, planning, and training.* Major steps would be taken to improve interagency coordination, planning, and training. Although Disaster Assistance Recovery Teams

would not become a major Program element, technical teams for specific disasters, or to provide programmatic training, would be assembled.

7. *Allow repair of impairments to agricultural lands using sound engineering alternatives.* This element would permit sound structural measures to be repaired where they are economically, environmentally, and socially defensible.

8. *Limit repair of sites to twice in any 10-year period.* Where a site has been restored twice and 10 or fewer years have elapsed since the first disaster event, the options remaining available under the EWP Program would be to acquire a floodplain easement, fund a buyout with structure removal as a recovery measure, or take no action at all.

9. *Eliminate the requirement that multiple beneficiaries (property owners) be threatened before a site would be eligible for EWP Program repairs.* NRCS recognized that in almost every instance benefits accrue to someone downstream of the impairment area.

10. *Apply the principles of natural stream dynamics and bio-engineering in restoration.*

11. *Simplify purchase of agricultural floodplain easements; eliminate land designation categories.* NRCS would establish a single agricultural floodplain easement category and would specify compatible landowner uses.

12. *Repair enduring (structural or long-life) conservation practices, except when such measures are under ECP jurisdiction.* Conservation practices, such as waterways, terraces, diversions, irrigation systems, and animal waste systems that are damaged during a disaster event would be eligible for EWP Program cost-share assistance. However, repair of enduring conservation practices or disaster-recovery work that is eligible for emergency assistance under the Emergency Conservation Program would not be eligible under EWP.

13. *Partially fund improved alternative solutions.* The EWP Program would be allowed to partially fund work that would be eligible for disaster recovery throughout the impaired watershed, but when a sponsor desires a more extensive or differently designed solution than NRCS would initially recommend, the sponsor is required to pay 100 percent of the additional costs.

14. *Allow disaster-recovery work in floodplains away from streams and in upland areas, where such measures are not under ECP jurisdiction.* Expansion of the EWP Program to include areas in an impaired watershed not directly adjacent to streams would allow the removal of sediment deposits from cropland and pastures and other debris (generally wind-blown material) from land and environmentally sensitive areas and plantings when necessary for runoff retardation or soil erosion prevention.

15. *Allow purchase of floodplain easements on non-agricultural lands only to fully restore floodplain function but not where small rural communities are at issue. Fund buyouts for recovery of small flood-prone communities through sponsors.* NRCS would not purchase floodplain easements on lands with multiple property owners and residences for the sole purpose of relocating small flood-prone rural communities under the floodplain easement portion of the EWP Program. However, as an EWP recovery measure, NRCS would consider cost-sharing with a sponsor to fund buyouts of residents in such flood-prone circumstances when it would be the most cost-effective and environmentally preferable recovery measure.

II. Description of the Current EWP Program

NRCS administers the EWP Program to respond to life and property-threatening watershed impairments caused by natural disasters. Local sponsors (e.g., counties, conservation districts) who request EWP assistance provide at least 20 percent of funding for EWP watershed repair practices. NRCS may provide up to 80 percent of funding and technical assistance (up to 100 percent for exigency) for EWP practices that remove disaster debris; repair damaged streambanks, dams, and dikes; protect floodplain structures; and restore critical watershed uplands. The EWP Program is one among a number of Federal and State-level programs dealing with disaster assistance and watershed management. It has been characterized in public comments as one of the most responsive to local needs in small, rural watersheds.

The major practices currently employed under EWP include stream flow capacity restoration; stream bank restoration and protection; dam, dike, and levee repair; protection of structures in floodplains; and restoration of critical upland portions of watersheds. The EWP practices generally share common activities: creating access to reach a damage site, use of heavy equipment on bank, in-stream, or on uplands, material disposal, and grading, shaping, and revegetating portions of the site as appropriate. EWP also currently administers a voluntary program of floodplain easement purchase on agricultural lands.

The EWP Manual documents NRCS policy governing EWP; the National EWP Handbook covers field procedures. NRCS staff administers the EWP Program in the field when sponsors request assistance with disaster damage. NRCS completes Damage Survey Reports (DSRs) describing the watershed impairments at a particular site, their eligibility for repairs, the cost and benefits of appropriate repair practices, and the environmental and technical soundness of the proposed measures. The EWP regulations, manual, and handbook (including the DSR) would be revised to reflect any Program changes NRCS decides to adopt.

The 1996 Farm Bill authorization of floodplain easements provides NRCS with an opportunity to purchase easements on flood-prone lands as an alternative to traditional eligible EWP practices. It is not intended to deny any party access to the traditional eligible EWP practices. It is intended to provide a permanent alternative solution to repetitive disaster assistance payments and to achieve greater environmental benefits where the situation warrants and where the affected landowner is willing to participate in the floodplain easement approach. The National Watersheds Manual 390–V, Circular 4, provides the current Program guidance for acquisition of floodplain easements. Currently, three categories of easements are eligible for purchase on agricultural lands that are frequently damaged: (1) Allows no agricultural uses, (2) allows certain compatible uses such as timbering, haying, and grazing, (3) allows cropping as well as timbering, haying, and grazing.

Exigency (high priority emergency situations) sites receive immediate attention and priority in funding. NRCS coordinates its work with Federal agencies, principally the U.S. Army Corps of Engineers (USACE), U.S. Fish and Wildlife Service (USFWS), Federal Emergency Management Agency (FEMA), Environmental Protection Agency (EPA), National Marine Fisheries Service (NMFS), and U.S. Forest Service (USFS), and with State agencies, including the relevant State Historic Preservation Office, Tribal Historic Preservation Officer, and other consulting agencies, such as federally recognized tribes, wildlife resource and water quality offices, tribal governments, and local communities. At issue are important regulatory and environmental requirements, such as protecting federally listed endangered or threatened species and preserving unique cultural and historic resources, including those listed on or eligible for the National Register of Historic Places.

III. Alternatives Considered

In September 1998, NRCS initiated a formal scoping process to solicit input on issues, concerns, and opportunities for EWP Program improvement from the public and other local and Federal agencies. Public scoping meetings were advertised in regional and local newspapers and held in six cities located throughout the country. NRCS published notices in the **Federal Register** and national newspapers stating that the agency was preparing a PEIS and that input was being sought through multiple venues, including the public scoping meetings, regular mail, e-mail, and a toll-free phone line. NRCS also held discussions with other agencies, including Farm Service Agency, EPA, USFS, FEMA, USACE, and USFWS, as well as NRCS field personnel who routinely deal with EWP projects. Based on input from scoping, NRCS developed, and evaluated in detail in the Draft EWP PEIS, three alternatives for future administration of the EWP Program, which are described in detail below: the No Action alternative (Alternative 1), NRCS' Draft PEIS Proposed Action (Alternative 2), and Prioritized Watershed Planning and Management (Alternative 3).

Based on comments from other agencies and the public on the Draft EWP PEIS, comments on the Proposed EWP Rule (published on November 19, 2003 in the **Federal Register**, Vol. 68, No. 223), and internal agency considerations concerning management, funding, and implementation feasibility of EWP Program changes, NRCS developed a fourth alternative (the Preferred Alternative—EWP Program Improvement and Expansion), which was fully evaluated in the Final EWP PEIS. The Preferred Alternative—EWP Program Improvement and Expansion—incorporates many of the elements of improvement and expansion proposed under the Draft PEIS Proposed Action, but leaves some elements unchanged or introduces only minor changes when compared with the No Action. The EWP FPEIS also fully described and evaluated the three Draft EWP PEIS alternatives.

A. Alternative 1—No Action (Continue the Current Program)

NRCS would continue to conduct the current EWP Program as it does now with no improvement or expansion. The 15 elements of the current EWP Program that would remain in effect under the No Action Alternative include:

1. *Continue using the terms ''exigency'' and ''non-exigency'' as they are now used.* An exigency exists when the near-term probability of damage to life or property is high enough to demand immediate Federal action. A non-exigency situation exists when the near-term probability of damage to life or property is high enough to constitute an emergency, but not sufficiently high to be considered an exigency.

2. *Continue current exigency response procedures.* NRCS National Headquarters would continue to respond to State requests to provide funding for exigency responses as they are received by NHQ and would not provide each State with separate ''pre-disaster'' funding for ''on the spot'' State-level responses. NRCS would continue to allow 30 days to address exigencies.

3. *Continue using current procedures for project prioritization.* NRCS State Conservationists would continue to prioritize EWP projects for their States in non-Presidentially declared disasters and may include input from the sponsors in these decisions. In Presidentially declared disasters, NRCS would continue working with FEMA and the USACE in establishing priorities.

4. *Continue to administer EWP under current cost-share rates.* NRCS would continue to provide EWP funding at a Federal cost-share of up to 100 percent for exigencies and up to 80 percent for non-exigencies. [**Note:** Although current regulations tie cost-sharing to the exigency/non-exigency designation, for the past 10 years, NRCS has been applying a single cost-share rate of 75 percent to both exigency and non-exigency situations.]

5. *Continue to employ current defensibility review requirements.* NRCS would continue to review EWP recovery practices to determine whether they are economically and environmentally defensible.

6. *Continue current EWP Program coordination, training and planning in each State.*

7. *Continue to disallow repair of impairments to agricultural lands.* This would preclude use of restoration measures to protect high-value croplands from continued erosion caused by future flooding.

8. *Continue to allow repeated repairs to EWP sites.* NRCS would impose no restrictions on the number of repeated repairs of damaged EWP sites that could be funded.

9. *Continue to require multiple beneficiaries for non-exigency measures.* NRCS would continue to require that multiple beneficiaries be identified and documented in the project Damage Survey Report (DSR) for site repair of non-exigency emergencies. This is not a requirement for exigencies where sites with single beneficiaries are eligible for EWP repairs.

10. *Continue to employ only least-cost restoration measures.* NRCS would continue to fund disaster recovery measures on a least-cost basis for repair of site damage alone, so long as they are environmentally defensible, without regard to ancillary environmental considerations or benefits.

11. *Continue to allow land-owner uses of floodplain easements under the three existing categories.* Under the No Action Alternative published in the Draft EWP PEIS, NRCS would have continued to fund agricultural floodplain easement purchases under three land-use categories. Since that time, NRCS has restricted compatible uses to a single category of uses.

12. *Continue to disallow repairs of enduring conservation practices.*

13. *Continue to disallow funding of improved alternative solutions.* NRCS would fund projects based on a least-cost design to achieve the specific site restoration objectives only, without regard to any additional benefits sponsors may wish to gain with an expanded but more expensive design.

14. *Continue to disallow disaster-recovery work away from streams and critical areas.*

15. *Continue to disallow purchase of floodplain easements on improved lands.* Under the No Action Alternative published in the Draft EWP PEIS, NRCS would have continued to disallow purchase of floodplain easements on improved lands. Since that time, NRCS has instituted procedures to acquire improved lands in connection with floodplain easement purchases where continued use of those lands would affect NRCS' ability to attain the benefits of the floodplain easement by restoring full floodplain function.

B. Alternative 2—EWP Program Improvement and Expansion (Draft PEIS Proposed Action)

The 15 specific EWP Program changes to improve the delivery and defensibility of the Program and incorporate new restoration practices under the Draft PEIS Proposed Action included:

1. *Eliminate the terms ''exigency'' and ''non-exigency.''*

2. *Stipulate that ''urgent and compelling'' situations be addressed immediately upon discovery.* In a situation that demands immediate action to avoid potential loss of life or property, employees with procurement authority would be permitted to hire a contractor to remedy a watershed

impairment immediately after evaluation of the site.

3. *Set priorities for funding of EWP measures.* NRCS would suggest priorities to be applied consistently across the country for funding EWP measures. Urgent and compelling situations would have highest priority.

4. *Establish a cost-share rate of up to 75 percent for all EWP projects (except for projects in limited-resource areas, where sponsors may receive up to 90 percent, and floodplain easements, which are funded at 100 percent).*

5. *Stipulate that measures be economically, environmentally, and socially defensible and identify the criteria to meet those requirements.* Project alternatives would be reviewed to determine their acceptability according to the ideals and background of the community and individuals directly affected by the recovery activity. A combination of all three categories would be used to determine defensibility.

6. *Improve disaster-recovery readiness through interagency coordination, training, and planning.* NRCS would employ Disaster Assistance Recovery Training teams to train its employees, evaluate and implement ways to improve coordination between EWP and other emergency programs, and assist State Conservationists in preparing Emergency Recovery Plans detailing working relationships with other Federal, State, and local groups.

7. *Allow repair of impairments to agricultural lands using sound engineering alternatives.*

8. *Limit repair of sites to twice in a 10-year period.* Where a site has been restored twice and 10 or fewer years have elapsed since the first disaster event, the options remaining available under the EWP Program would be to acquire a floodplain easement or take no action at all.

9. *Eliminate the requirement that multiple beneficiaries (property owners) be threatened before a site would be eligible for EWP Program repairs.*

10. *Apply the principles of natural stream dynamics and, where appropriate, use bioengineering in the design of EWP restoration practices.* DART teams would incorporate these design principles into disaster-readiness training of NRCS staff and provide more intensive training to NRCS staff responsible for EWP practice design and review.

11. *Simplify purchase of agricultural floodplain easements.* NRCS would establish a single agricultural floodplain easement category and would specify compatible landowner uses.

12. *Repair enduring (structural or long-life) conservation practices.* Conservation practices such as waterways, terraces, diversions, irrigation systems, and animal waste systems that are damaged during a disaster event would be eligible for EWP Program cost-share assistance.

13. *Partially fund expanded or improved alternative solutions.* This would allow the EWP Program to help fund work that would be eligible for disaster recovery throughout the impaired watershed, but that would constitute a more extensive or differently designed solution than NRCS would initially recommend.

14. *Allow disaster-recovery work in floodplains away from streams and in upland areas.* This change would allow the removal of sediment deposits from cropland and pastures and other debris from land and environmentally sensitive areas and plantings or other measures to prevent erosion.

15. *Purchase floodplain easements on non-agricultural lands.* Floodplain easements would be purchased on both unimproved and improved lands. For improved land, NRCS would provide 100 percent of the cost of an easement that conveys all interests and rights. Any structures would be demolished or relocated outside the 100-year floodplain at no additional cost to the government.

C. Alternative 3—Prioritized Watershed Planning and Management

This alternative would allow NRCS to focus EWP Program efforts proactively on disaster-prone watersheds and integrate those efforts with other USDA programs dealing with watershed issues. Prioritized watershed planning would combine the changes of Alternative 2 with focused, Program-neutral, disaster-readiness and mitigation planning for selected high-priority watersheds. In addition to instituting all 15 Program improvements and expansions described under the Draft PEIS Proposed Action (Alternative 2), the EWP Program elements implemented under Alternative 3 would include:

a. *Continuing to deliver EWP project funding and technical assistance to address immediate threats to life and property as required by law.* This would continue to be the highest, but not sole, priority in the EWP Program.

b. *Facilitating a locally led pre-disaster planning effort.* This locally-led effort initiated and coordinated by NRCS would address concerns about recurrent application of EWP repair measures in watersheds that have a history of frequent disasters and integrate EWP activities in those watersheds with NRCS programs dealing with other watershed issues.

c. *Funding of priority watersheds in each State for pre-disaster planning and management.* High priority watersheds and, as funding permits, medium priority watersheds would undergo pre-disaster planning and management providing there is a local sponsor (State, county, tribal organization or other eligible entity) who agrees to sponsor the pre-disaster planning.

d. *Coordinating pre-disaster planning and management efforts with Federal, State, and local agencies and interested stakeholders.* This would include establishing an overall watershed management plan; integrating other program authorities and practices available to NRCS; purchasing floodplain easements on a stepwise, proactive, risk-reduction basis; and combining EWP with other program authorities to enhance watershed values.

D. Alternative 4—EWP Program Improvement and Expansion (Preferred Alternative—EWP Program Improvement and Expansion)

The Preferred Alternative—EWP Program Improvement and Expansion—would incorporate the 15 changes discussed under ''Programmatic Changes to the EWP Program'' above.

IV. Impacts Under the Alternatives

This section summarizes some of the effects that would be expected to occur to such resource areas as aquatic, riparian, and floodplain ecosystems, wetland communities, and human communities under each of the four alternatives.

A. Alternative 1—No Action (Continue the Current Program)

This alternative has the lowest likelihood of addressing watershed level effects (*e.g.*, water quality). Minor adverse effects from restoration practices would continue to occur and would add to habitat loss in riparian, floodplain, and wetland ecosystems and loss of natural floodplain functioning that are a contributing part of general watershed decline. Agricultural floodplain easements may mitigate these effects in some watersheds.

Aquatic Ecosystems: Under Alternative 1, aquatic ecosystems would continue to benefit in the short-term from restoration of channel capacity and reduction of bank erosion at EWP repair sites. The hydrology of disaster-damaged stream reaches would be restored and turbidity and sedimentation reduced, which would improve conditions for aquatic life in

many respects. However, aquatic ecosystems would continue to be adversely affected in the longer-term primarily due to the widespread emphasis on the use of armoring and removal of in-stream debris. Generally, armoring and levee repairs would continue to provide lower quality habitat for aquatic life, limit riparian vegetation growth, and redirect stream energy to downstream locations with potentially damaging consequences, such as increased flow velocities and increased turbidity in downstream reaches. Adverse effects on habitat structure would likely continue to occur from almost complete removal of in-stream debris, as this removes habitat and nutrients. Continuing to use three easement categories would result in some easement lands serving as natural floodplains; others would support intensive agriculture. Category 1 easements would increase filtration, improve vegetation, and increase flood storage. Category 3 would continue to contribute to agricultural runoff and declines in water quality.

Riparian Ecosystems: Under Alternative 1, riparian communities and streambanks would continue to be adversely affected, primarily due to continued reliance on armoring practices and levee repairs. While these practices do stabilize streambanks, the structures used limit or damage riparian vegetation, reduce the quality of habitat for aquatic and riparian species, redirect streamflow energy further downstream, and restrict natural floodplain function. Additionally, current methods for creating access and clearing and snagging may adversely affect streambank stability and habitat quality. Increased use of natural structural materials may mitigate these impacts. Floodplain easements would offer improved habitat from increased vegetative cover. Category 1 would yield the greatest potential benefits, while Category 3 would yield minimal benefits.

Floodplain Ecosystems: Under Alternative 1, floodplain ecosystems would continue to be adversely affected, since armoring alters natural floodplain function and levees confine flood flows to the stream channel, protecting the lands behind them while preventing the development of natural floodplain function. Stream energy would continue to be channeled to downstream reaches and floodplain habitat would continue to be absent or underdeveloped. Substantive improvements would occur with Category 1 floodplain easements, as easement purchases would return developed lands to a more natural state, improving water quality, habitats, and infiltration. Category 3 easements offer minimal benefit, as intensive agriculture is allowed.

Wetland Communities: Under Alternative 1, wetland communities may continue to be adversely affected, as many restoration practices act to restrict stream hydrology and normal flood regime and may limit the water available for wetland functions. Filtration, flood retention, groundwater recharge and wetland habitat functions may be affected. However, continued purchase of agricultural floodplain easements would continue to restore some natural flooding conditions, improving wetland hydrology in some watersheds, and would continue to promote wetland creation or growth, resulting in increased wetland habitat.

Human Communities: Continuation of the current Program would be expected to have a minimal impact on the local economy of affected communities. Most of the proposed projects are relatively small in scope and the total dollar expenditures would not contribute substantially to the local economy. Alternative 1 would benefit the local economy from restoration of previous productive land use and value. Purchase of floodplain easements could result in a loss of employment and income from agricultural land, but would reduce demand for services and disaster assistance, and may provide the additional benefit of protecting open space and improving the visual or recreational quality of an area. With respect to infrastructure and social resources and services, the effect of the Program is generally beneficial. Some temporary disruption of social patterns during project construction may result, but no permanent disruption to local community. Short-term benefits would occur from protecting public health and safety; however, in disaster-prone areas, long-term public health and safety concerns would remain high.

B. Alternative 2—EWP Program Improvement and Expansion (Draft PEIS Proposed Action)

This alternative would have an increased likelihood of addressing watershed level effects than Alternative 1 from using environmentally preferable practices (design based on the principles of natural stream dynamics and bioengineering) and more floodplain easements on non-agricultural lands. There would be a reduced likelihood of adverse impacts on aquatic, riparian, wetland, and floodplain ecosystems. Use of non-agricultural floodplain easements would encourage more restricted land uses of floodplains.

Aquatic Ecosystems: Under Alternative 2, Program-wide training in and use of stream restoration design based on the principles of natural stream dynamics and floodplain easements would provide substantial benefits to aquatic ecosystems. These practices would help restore sinuosity, regulate stream flow, create aquatic habitat, increase channel structure quality, and improve water quality. Increased use of bioengineering may also better regulate water temperatures. Under the Alternative 2, only one category of agricultural floodplain easement would be available, which would allow compatible uses such as grazing, haying or timber. Purchase of agricultural and improved land floodplain easements would reduce urban and agricultural runoff, improving water quality. This type of easement would improve habitats, channel structure, and floodplain function. Requiring a buffer strip on all floodplain easements and fencing on grazing floodplain easements will help to maintain or improve environmental conditions.

Riparian Ecosystems: Under the Alternative 2, emphasis on stream restoration based on the principles of natural stream dynamics and increased floodplain easement purchases could provide considerable benefits for riparian communities. These practices would promote natural re-vegetation, stabilize streambanks, dissipate stream energy, establish aquatic and riparian habitat, and restore natural channel structure and morphology. Easements would serve to augment these benefits by restoring floodplain function and establishing riparian forests and buffer zones.

Floodplain Ecosystem Impacts: Under Alternative 2, inclusion of recovery measures to restore natural stream dynamics and an increased emphasis on easements would improve floodplain function, increase flood retention capabilities, substantially improve hydrology, and promote floodplain habitat. Natural stream dynamics may lead to change in land use to more natural land uses, as stream channel is allowed to meander. Limitations on compatible uses within floodplain easements may offer benefits to water quality, infiltration, and groundwater recharge.

Wetland Communities: Under Alternative 2, natural stream dynamics and a focus on floodplain easement purchase may lead to improvements in wetland communities. By restoring to more natural hydrologic regimes, wetlands may be restored in areas with appropriate soils and hydrology.

Easements would also likely restore wetlands and wetland functions, as periodic flooding would promote wetland growth and development.

Human Communities: Alternative 2 would be generally beneficial to affected human communities. Increased Federal cost-share for projects in limited resource communities and expansion of the defensibility criteria for EWP projects would substantially increase access to potentially beneficial effects of the projects for socially disadvantaged or minority persons who may have been previously excluded and would reduce the potential financial burden on these communities. By establishing a social rationale based on the use of the property by the landowner, the proposed action includes a category of participant who might otherwise have been excluded from the current Program, especially in circumstances where the economic value of a property may be low or difficult to calculate.

Expansion of the floodplain easement option to include non-agricultural and improved land would likely increase the potential for short-term disruption of local communities or neighborhoods by the displacement of residents, but it also represents an opportunity for the community to reduce the long-term impact of natural disasters and the associated recovery cost, especially on improved properties. The general effect on the local economy would be similar to Alternative 1; however, expansion of floodplain easements to improved land may have a greater impact on employment and income from affected properties. Easement purchases may result in the loss of business, commercial, or residential structures, or alter previous land uses on or land value of subject and neighboring properties. Where floodplain easements are purchased, there is some possibility that the easements could become part of an area's comprehensive plan for growth, by meeting a portion of the need for functional open space for the community.

C. Alternative 3—Prioritized Watershed Planning and Management

Alternative 3 would have the highest likelihood of planning for and addressing watershed level effects, as well as reducing adverse effects and increasing beneficial effects on aquatic, wetland, floodplain, and riparian ecosystems, especially in well-managed priority watersheds. This alternative would also have the highest likelihood of encouraging the best use of floodplains, but the highest potential for disruption of older rural communities.

Aquatic Ecosystems: Alternative 3 would have the same impacts on aquatic ecosystems as those described under Alternative 2, with the following additional benefits. Planning and coordination at the local level would act to focus restoration efforts on high priority disaster-prone watersheds. Through watershed scale management, the benefits realized with restoration design based on natural stream dynamics and purchase of floodplain easements could be amplified, as contiguous habitat areas and longer reaches of naturally flowing streams could be restored and improved. This would result in greater improvements in water quality and more permanent establishment of biotic populations.

Riparian Ecosystems: Alternative 3 would have the same impacts on riparian ecosystems as those described under Alternative 2, with the following additional benefits. Coordinated planning under Alternative 3 may result in: decreased emphasis on local impairments, focusing on watershed scale stream function; contiguous easement sections, reducing the need for streambank repairs and benefiting riparian ecosystems; and contiguous ecosystem components and habitat, such as riparian forests and buffer zones, which would benefit riparian biota.

Floodplain Ecosystems: Alternative 3 would have the same impacts on floodplain ecosystems as those described under Alternative 2, with the following additional benefits. Coordination and planning under Alternative 3 may lead to the establishment of large segments of contiguous, freely flowing stream and floodplain systems in priority watersheds. Floodplain land uses may be converted to more natural uses, improving floodplain function and reducing threats to life and property. Coordinated easement purchases may create contiguous reaches of well-regulated flows during flooding events and result in an overall reduction in stream energy and velocity thereby safeguarding lives and property within that portion of the watershed.

Wetland Communities: Alternative 3 would have the same impacts on wetland ecosystems as those described under Alternative 2, with the following additional benefits. Planning and coordination would likely lead to further improvements to wetland communities. Watersheds may be managed for natural stream flows, which may lead to contiguous reaches with sufficient flooding and natural hydrology to maintain, improve, and promote wetland areas. This may also result in contiguous segments of wetland, which would augment the quality of habitat and filtration capacity. Coordinated easement purchase may result in creation or growth of more extensive wetland habitat than Alternatives 1 or 2, resulting in large scale filtration and improving water quality.

Human Communities: The primary effect of the proposed watershed planning and management approach under Alternative 3 is the proactive benefit of allowing watershed planning on a macro scale. Where this alternative would continue to provide funding and technical assistance similar to that proposed under Alternative 2, similar impacts would be anticipated. However, the incorporation of pre-disaster planning and management of the watershed on a macro scale provides a greater understanding of a land use vision for the community. The integration of watershed planning into the process enables environmental concerns to be addressed as part of the community's long-term growth strategies. An integrated approach to program management allows for more efficient use of capital resources and the economic potential of the watershed, while minimizing adverse environmental effects. Some potential for loss of existing community resources may be possible, but this is offset by the increased availability of watershed related recreational, educational, or other uses. An important beneficial effect associated with this approach concerns the involvement of multiple program authorities, local and State agencies, and stakeholders in the process.

Proactive use of floodplain easements in a planned approach would minimize potential problems associated with reliance on a project-by-project approach, especially where neighboring or adjoining properties are volunteered for the Program at different times and under differing circumstances. Where easements are purchased, there is the potential that open spaces can be planned as integral components of the area landscape. Similar to Alternative 2, purchase of improved lands floodplain easements could alter the composition or structure of the community by displacing current residents. Easements could also alter the existing land uses or may result in the breakup of residential networks. These potentially adverse effects may be offset, however, by the more effective use of floodplain easement purchases as a part of a longer-term flood management and watershed planning approach and could reduce Federal funding outlays in the

long-term. This alternative would be the best long-term solution to protect public health and safety.

D. Alternative 4—EWP Program Improvement and Expansion (Preferred Alternative—EWP Program Improvement and Expansion)

Alternative 4 would have an increased likelihood of addressing watershed level effects than Alternative 1 from using environmentally preferable practices (design based on the principles of natural stream dynamics and bioengineering) and more floodplain easements on non-agricultural lands. There would be a reduced likelihood of adverse impacts on aquatic, riparian, wetland, and floodplain ecosystems due to emphasis on bio-engineering practices, but more limited reductions from more limited use of easements than under Alternative 2. Limited support for buyouts as part of the recovery program would encourage more restricted uses of the floodplain but may disrupt older rural communities.

Aquatic Ecosystems: The impacts on aquatic ecosystems under Alternative 4 would be similar to those described under Alternative 2.

Riparian Ecosystems: The impacts on riparian ecosystems under Alternative 4 would be similar to those described under Alternative 2.

Floodplain Ecosystems: The impacts on floodplain ecosystems under Alternative 4 would be similar to those described under Alternative 2.

Wetland Communities: The impacts on wetland communities under Alternative 4 would be similar to those described under Alternative 2.

Human Communities: In general, implementation of the Preferred Alternative—EWP Program Improvement and Expansion—would be beneficial to affected human communities. Funding changes for projects in limited resource communities and expansion of the defensibility criteria for EWP projects would substantially increase access to potentially beneficial effects of the projects for socially disadvantaged or minority persons who may have been previously excluded and would reduce the potential burden on these communities. By establishing a social rationale based on the use of the property by the landowner, the proposed action includes a category of participant who might otherwise have been left out of the current Program, especially in circumstances where the economic value of a property may be low or difficult to calculate.

The potential impact of the installation of engineered solutions at individual sites is similar to that under Alternative 1. Expansion of the floodplain easement option to include improved lands and limited funding of buyouts of small flood-prone rural communities would likely increase the potential for disruption of local communities or neighborhoods in the short-term by the displacement of some residents, but it would also present an opportunity for the community to reduce the long-term impact of natural disasters and the associated recovery cost on improved properties. Program modifications in funding priorities and floodplain easement purchase under the Preferred Alternative—EWP Program Improvement and Expansion—would influence the overall impact of the Program on the human social environment and may alter the proposed solutions or the manner of participation for affected communities. Additionally, the Preferred Alternative—EWP Program Improvement and Expansion—allows for greater opportunities for cooperation with local land use plans. Easement purchases may result in the loss of business, commercial, or residential structures, or alter previous land uses on or land value of subject and neighboring properties. Where easements are purchased, there is some possibility that the easements could become part of an area's comprehensive plan for growth, by meeting a portion of the need for functional open space for the community.

V. Rationale for the Decision

The Preferred Alternative—EWP Program Improvement and Expansion—expands and improves the EWP Program to allow NRCS to more effectively and efficiently meet EWP statutory requirements and improve the effectiveness of agency responses to sudden watershed impairments caused by natural disasters. The Preferred Alternative—EWP Program Improvement and Expansion—beneficially affects aquatic, riparian, floodplain, and wetland ecosystems and human communities. While NRCS recognizes that Alternative 3, ''Prioritized Watershed Planning and Management,'' would likely be the environmentally preferable alternative, the agency supports Alternative 4 (EWP Program Improvement and Expansion) as its Preferred Alternative because:

(1) Current law, as interpreted by USDA legal counsel, limits activities conducted under EWP primarily to disaster recovery work. Alternative 3 would add a substantial increment of preventative measures to reduce future flood damages. Legislative authority would be required to implement such a major expansion of the purpose of EWP under Alternative 3.

(2) To a large extent, NRCS has integrated the management of its water resources programs within the Water Resources Branch of the National Headquarters Financial Assistance Programs Division, working closely with the NHQ Easement Programs Branch. Together they oversee the recovery practices and floodplain easements portions of EWP and provide funding and technical assistance and training to the NRCS State Offices. NRCS is limited in fully implementing the scope of Alternative 3 primarily by funding constraints. Several NRCS watershed programs currently exist under P.L. 566 and P.L. 534 that address watershed-scale planning and management and include measures for watershed protection and flood prevention, as well as the cooperative river basin surveys and investigations. The structural and non-structural practices implemented and the easements purchased under those programs have greatly reduced the need for future EWP measures in project watersheds. Nevertheless, EWP must remain available to deal with the aftermath of major natural disasters regardless of improvements under the other watershed programs.

VI. Implementation and Mitigation

NRCS would continue to consult with the U.S. Fish and Wildlife Service (USFWS) or National Marine Fisheries Service (NMFS) in any situation where there is a potential to affect threatened or endangered species, critical habitat, and anadromous fish species and would work with USFWS and NMFS to develop adequate protective measures.

Aquatic Community, Wetland, Floodplain, and Riparian Resources

Many potentially adverse impacts to these resources could be minimized by reducing the use of structural EWP practices that harden stream banks, eliminate riparian vegetation, and generally increase runoff and the consequent delivery of pollution sources to the stream. Use of restoration designs based on the principles of natural stream dynamics, and bioengineering would help mitigate these impacts. Other governmental programs could be encouraged to restore and rehabilitate armoring sites to a more natural riparian state where practicable. Where such natural practices are inappropriate, ensuring that the structural EWP practices are properly maintained would help mitigate the

need for additional structural practices due to failure of the original structures.

Coordination with other Federal, State, and local agencies and the landowning public to encourage understanding of the concepts underlying the EPA 404(b)(1) guidelines for wetlands protection in land use activities, and ensuring that the guidelines are followed as a planning practice, as well as for wetlands mitigation, would help mitigate the loss of both wetlands and floodplain resources.

Watershed Upland Resources

Reducing the dependence of EWP Program activities on structural practices would help mitigate damage to terrestrial resources by reducing the use of heavy equipment in surrounding upland areas. Use of more advanced techniques such as helicopter seeding for critical area treatments would reduce heavy equipment impacts on soils.

Socioeconomic and Other Human Resources

Impacts on local economies resulting from funding EWP activities can potentially be mitigated by keeping bid packages for EWP work small, so that local contractors with the skills required would have a fair chance to obtain the work, thus returning some portion of the funds to the locality. Where floodplain easements are used in place of structural practices, floodplain usage may be reduced, requiring relocation of people and activities currently in those areas. Attention paid to preserving and protecting neighborhood structure and residential networking can mitigate the effects of this relocation. In rural communities, certain institutional structures, such as churches, schools, and other ''special'' places, may require special consideration to mitigate adverse effects from such changes.

Where land under floodplain easement purchase is removed from economically productive activities, which were contributing to the local economy and tax base, compensation can be encouraged through seeking alternative replacement activities through such vehicles as HUD's urban development block grants and similar public-private measures. There would be some measure of local economic self-correction inherent in the process anyway, because the community would no longer need to provide the same level of services (power, sewer, road repair) to the easement locality and would no longer have to pay their share of the cost of disaster damage repairs in the future. Nevertheless, NRCS would encourage income-producing activities on floodplain easement lands that would be compatible with their basic purpose. On improved lands floodplain easements where the sponsor gains title to the land, entry fee to open space uses such as trails, walkways, fishing and boat access might be feasible. On agricultural floodplain easements, the landowner keeping title might charge a fee for hunting.

Cultural Resources

If NRCS determines that an adverse effect is going to occur during program implementation, in accordance with 36 CFR 800.6, the agency will continue consultation to resolve (avoid, mitigate, or minimize) this effect. NRCS shall notify the Advisory Council on Historic Preservation (ACHP) of this determination and continued consultation and invite the Council to participate. The NRCS shall also involve all previous consulting parties (including but not limited to the State Historic Preservation Officer (SHPO), Tribal Historic Preservation Officer (THPO), and tribes) and provide them all, including the ACHP, with the full documentation and a recommendation regarding steps to be taken to resolve the adverse effect. NRCS will provide a draft of programmatic agreement that outlines the steps to resolve the adverse effects and advise the participants of the nature of the resources that are to be affected.

Currently, some NRCS field offices define the Area of Potential Effect (APE) for EWP projects as the immediate site location, which may inadvertently omit addressing potential adverse impacts to listed or eligible historic properties nearby or downstream. The Cultural Resource Coordinators in the example site states indicate that EWP activities need to be very near to historic resources for NRCS to consider the possibility of impacts. Therefore, at present, unless potential historic structures located in the floodplain, such as homes or mills, are directly affected by sudden impairments and NRCS is planning EWP work to protect them, such resources would not be considered to be in the APE. In addition, NRCS focus on historic structures may result in omitting cultural resources such as archaeological sites, viewsheds, historic landscapes, and cultural places. With narrowly defined APEs, cultural resources may also be affected by ancillary activities such as soil borrow and heavy equipment staging. NRCS' mandatory cultural resources training for field personnel, given to all new field personnel with cultural resources responsibilities, is customized in each state to cover the range and extent of historic, cultural and traditional cultural resources from region to region within the state. Treatments under Section 106 of the National Historic Preservation Act (NHPA) and implementing regulations must, necessarily, be tailored to address the specific values of these resources. This training, coupled with the EWP training and consultation with SHPOs, THPOs, and other consulting agencies, including federally recognized tribes, should ensure that mitigation is appropriate for cultural resources on a case-by-case basis.

Consultation with the SHPO, THPO, and other consulting parties, including federally recognized tribes is a part of the EWP planning and coordination function before a disaster occurs and contact with the SHPO/THPO is made before actions at EWP are taken. Because cultural resources are locality specific, mitigation to protect particular cultural resources would be developed if needed at the site level as part of the defensibility review of the EWP practice.

To minimize impacts to cultural resources, the definition of the APE will be changed to include the entire area of potential effect, including ancillary activities resulting form EWP restoration, such as soil borrow or heavy equipment use. Additionally, recovering information about cultural resources present in the APE will help the agency to design the undertaking to avoid adverse effects to historic properties or help NRCS determine what additional mitigation measures may be necessary to address the potential adverse effect of the projects or actions on NRHP-listed or eligible historic properties.

Signed in Washington, DC, on March 21, 2005.

Bruce I. Knight,

Chief, Natural Resources Conservation Service.

[FR Doc. 05–6097 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

TE–48 Raccoon Island Shore Protection/Marsh Creation Project Terrebonne Parish, Louisiana

AGENCY: Natural Resources Conservation Service, Agriculture.

ACTION: Notice of finding of no significant impact.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy

Act of 1969; the Council on Environmental Quality Guidelines (40 CFR part 1500); and the Natural Resources Conservation Service Guidelines (7 CFR part 650); the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Raccoon Island Shore Protection/Marsh Creation Project (TE–48), Terrebonne Parish, Louisiana.

FOR FURTHER INFORMATION, CONTACT: Donald W. Gohmert, State Conservationist, Natural Resources Conservation Service, 3737 Government Street, Alexandria, Louisiana 71302; telephone (318) 473–7751.

SUPPLEMENTARY INFORMATION: The environmental assessment of the federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Donald W. Gohmert, State Conservationist, has determined that preparation and review of an environmental impact statement is not needed for this project.

The project will protect the Raccoon Island rookery and seabird colonies threatened by a retreating shoreline by reducing the rate of erosion along the western end of the island and creating more land and avian habitat along the northern shoreline. The proposed project consists of installing eight segmented rock breakwaters immediately west of the existing Raccoon Island Breakwater Demonstration Project (TE–29); installing an eastern terminal groin structure extending to existing breakwater 0; and creating approximately 60 acres of new habitat for bird species on the northeast portion of the island by backfilling open water areas with suitable dredged material.

The Notice of Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various federal, state, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data collected during the environmental assessment are on file and may be reviewed by contacting Donald W. Gohmert.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register**.

Donald W. Gohmert,

State Conservationist.

[FR Doc. 05–6645 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Notice of Proposed Changes to Section IV of the Tennessee Field Office Technical Guide (FOTG)

AGENCY: Natural Resources Conservation Service (NRCS) in Tennessee, U.S. Department of Agriculture.

ACTION: Notice of availability of proposed changes in the Tennessee NRCS Field Office Technical Guide, Section IV, for review and comment.

SUMMARY: It has been determined by the NRCS State Conservationist for Tennessee that changes must be made in the NRCS Field Office Technical Guide, specifically in practice standard Critical Area Planting (342) to account for improved technology. This practice standard can be used in conservation systems designed to treat highly erodible cropland.

DATES: Comments will be received for a 30-day period commencing with the date of this publication.

FOR FURTHER INFORMATION CONTACT: Inquire in writing to James W. Ford, State Conservationist, Natural Resources Conservation Service (NRCS), 675 U.S. Courthouse, 801 Broadway, Nashville, Tennessee, 37203, telephone number (615) 277–2531. Copies of the practice standard will be made available upon written request.

SUPPLEMENTARY INFORMATION: Section 343 of the Federal Agriculture Improvement and Reform Act of 1996 states that revisions made after enactment of the law to NRCS state technical guides used to perform highly erodible land and wetland provisions of the law shall be made available for public review and comment. For the next 30 days, the NRCS in Tennessee will receive comments relative to the proposed changes. Following that period, a determination will be made by the NRCS in Tennessee regarding disposition of those comments and a final determination of change will be made to the subject practice standard.

Dated: March 21, 2005.

James W. Ford,

State Conservationist.

[FR Doc. 05–6635 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

White Tank Mountains Watershed, AZ

AGENCY: Natural Resources Conservation Service.

ACTION: Notice of deauthorization of Federal funding.

SUMMARY: Pursuant to the Watershed Protection and Flood Prevention Act, Pub. L. 83–566, and the Natural Resources Conservation Service Guidelines (7 CFR 622), the Natural Resources Conservation Service gives notice of the deauthorization of Federal funding for the White Tank Mountains Watershed, Maricopa County, Arizona effective on March 9, 2005.

FOR FURTHER INFORMATION CONTACT: David L. McKay, State Conservationist, Natural Resources Conservation Service, 230 North First Avenue, Suite 509, Phoenix, Arizona 85003–1706, telephone: 602–280–8810.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention. Office of Management and Budget Circular A–95 regarding State and local clearinghouse review of Federal and federally assisted programs and projects is applicable.)

Dated: March 24, 2005.

David L. McKay,

State Conservationist.

[FR Doc. 05–6646 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Great River Energy; Notice of Intent

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of intent to hold scoping meetings and prepare an environmental assessment.

SUMMARY: Notice is hereby given that the Rural Utilities Service (RUS), an agency delivering the U.S. Department of Agriculture's Rural Development Utilities Programs, pursuant to the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality (CEQ) Regulations for implementing NEPA (40 CFR Parts 1500–1508), and

RUS Environmental Policies and Procedures (7 CFR Part 1794) proposes to hold two scoping meetings and prepare an Environmental Assessment (EA) for its Federal action related to a project proposed by Great River Energy (GRE) of Elk River, Minnesota. The project consists of constructing a natural gas-fired simple cycle, combustion turbine power generation facility in Cambridge Township in Isanti County, Minnesota. An alternative location for the plant is also being proposed for consideration and comment. The alternative site location is at GRE's Elk River headquarters in Sherburne County, Minnesota. Total electrical output from the facility is expected to range from 150 megawatts (MW) to 190 MW depending upon operating conditions. Construction of the project at the proposed Cambridge site would necessitate upgrading approximately 47 miles of existing 69-kilovolt (kV) transmission lines to the latest design standards. Construction at the alternative Elk River site would necessitate upgrading approximately 27 miles of existing 69-kV.

Meeting Information: RUS will conduct two scoping meetings in open House forum as follows: Tuesday, April 19, 2005, 6 p.m. to 9 p.m., Cambridge Township Hall, Isanti County Fairgrounds, 3101 Hwy 95 NE., Cambridge, MN 55008, Telephone: 763–689–3768. Wednesday, April 20, 2005, 6 p.m. to 9 p.m., Elk River Parks & Recreation, 1104 Lions Park Drive NW., Elk River, MN 55330, Telephone: 763–635–1150.

FOR FURTHER INFORMATION CONTACT: Nurul Islam, Environmental Protection Specialist, RUS, Engineering and Environmental Staff, 1400 Independence Avenue, SW., Washington, DC 20250–1571, telephone (202) 720–1414, FAX: (202) 720–0820, e-mail: *nurul.islam@usda.gov*; or Mark Strohfus, Environmental Project Leader, GRE, 17845 East Highway 10, P.O. Box 800, Elk River, MN 55330–0800, telephone (763) 241–2491, FAX: (763) 241–6033, e-mail: Mark *Strohfus@grenergy.com*.

SUPPLEMENTARY INFORMATION: GRE proposes to construct the facility in Cambridge Township in Isanti County, Minnesota. The primary purpose of the facility is to meet GRE peak electrical load during hot summer weather. Under those conditions, the facility's expected output is about 170 MW of power. The proposed project will consist of one simple cycle combustion turbine. The combustion turbine will be fueled with natural gas.

The project is proposed to be constructed at Great River Energy's existing Cambridge Peaking Plant, 2438 349th Avenue, NE. A fuel oil-fired combustion turbine rated at approximately 20 MW exists at the site and will remain in operation at the site after construction of the proposed combustion turbine. The existing peaking plant occupies roughly 11 acres south of 349th Avenue. Additional land totaling approximately seven acres may be acquired to the south and east to facilitate construction activities for the proposed combustion turbine. The proposed combustion turbine would be fueled only with natural gas. Four 69-kilovolt (kV) transmission lines are currently connected to the existing substation at the Cambridge site. Three of these lines totaling about 47 miles will be upgraded to state-of-the-art 69-kV design standards to allow the electricity from the new generator to be reliably delivered from the site.

An alternative site for the plant is also being proposed at GRE's existing facilities at 17845 East Highway 10, Elk River, Minnesota GRE's headquarters and its 40-MW Elk River Station, which is fueled with refuse-derived fuel, are at this location and would remain if the proposed plant were to be constructed at the alternative site. No additional land would be purchased if the plant were to be constructed at this location. Due to constraints on natural gas availability, a combustion turbine at the Elk River site would be equipped to fire fuel oil as a backup fuel. The generator would be connected to the Elk River Substation. Approximately 27 miles of transmission line would have to be upgraded to allow the electricity from the new generator to be reliably delivered from the site.

Alternatives to be considered by RUS and GRE include no action, purchased power, upgrade of existing resources, new transmission facilities, alternative sites, alternative routes, fossil fuel technologies, customer-owned generation, energy conservation, renewable resources, and emerging technologies.

GRE has prepared an Alternative Evaluation and Site Selection Study for the project. The Alternative Evaluation and Site Selection Study is available at GRE's Web site at *http://www.greatriverenergy.com/projects/plants/proj_plants.html*. The study is also available for public review at the RUS or GRE at the addresses provided in this notice or at the following locations: Cambridge Public Library, 244 South Birch St., Cambridge, MN 55008, Phone 763–689–7390. Elk River Public Library, 413 Proctor Ave., Elk River, MN 55330, Phone 763–441–1641.

Federal, state and local agencies, private organizations, and the public are invited to participate in the planning and analysis of the proposed project. Representatives from RUS and GRE will be available at the scoping meetings to discuss RUS's environmental review process, the proposed project and the alternatives being considered, the scope of the environmental issues to be considered, and answer questions. Oral and written comments will be accepted at the scoping meetings. Written comments regarding the proposed project will also be accepted for 30 days after the scoping meetings. All written comments should be sent to RUS at the address provided in this notice.

Any final action by RUS related to the proposed project will be subject to, and contingent upon, compliance with all relevant Federal environmental laws and regulations and completion of environmental review procedures as prescribed by the CEQ Regulations and RUS Environmental Policies and Procedures.

Dated: March 29, 2005.

Glendon D. Deal,

Director, Engineering and Environmental Staff, Rural Utilities Service.

[FR Doc. 05–6539 Filed 4–1–05; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Docket T–2–2005]

Foreign–Trade Zone 105 North Kingstown, RI, Application for Temporary/Interim Manufacturing Authority, Southeastern New England Shipbuilding Corporation, (Shipbuilding), North Kingstown, RI

An application has been submitted to the Executive Secretary of the Foreign–Trade Zones Board (the Board) by the Rhode Island Economic Development Corporation, grantee of FTZ 105, requesting temporary/interim manufacturing (T/IM) authority within FTZ 105 at the Southeastern New England Shipbuilding Corporation (Senesco) shipbuilding facility located in North Kingstown, Rhode Island. The application was filed on March 25, 2005.

The Senesco shipyard (450 employees, 31 acres, capacity: up to 4 vessels/year) is located at 10 MacNaught Street within the Quonset Business Park (FTZ Site 2). Under T/IM procedures, Senesco would construct and repair

tugboats (HTSUS 8901.90), double–hulled liquid barges (HTSUS 8901.20) and articulating tug barges for domestic and international customers. Foreign components that would be used at the shipyard (up to 30% of total purchases) include: diesel engines (HTSUS 8408.10), sterntubes (8483.30), reduction gears (8483.40), shaft grounding systems and seals (8483.90), generators (8501.62 , 8501.63), overfill alarms (8531.90), tank washing machines (8537.10), valve remote operators (8537.10), tank gauging systems (8537.10), and ACCU automation/steering systems (8537.10) (duty rates: 1.3 4.5%). The request indicates that Senesco will not admit any foreign–origin steel mill products to the zone for use in FTZ manufacturing activity.

FTZ procedures would exempt Senesco from Customs duty payments on the foreign components used in export activity. On its domestic sales, the company would be able to choose the duty rate that applies to finished oceangoing vessels (duty free) for the foreign–origin components noted above. Duties would be deferred or reduced on foreign production equipment admitted by Senesco to the zone until which time it becomes operational. The manufacturing activity conducted under FTZ procedures would be subject to the ''standard shipyard restriction'' applicable to foreign–origin steel mill products (e.g., angles, pipe, plate), which requires that full Customs duties be paid on such items.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at one of the following addresses:

1. Submissions via Express/Package Delivery Services: Foreign–Trade Zones Board, U.S. Department of Commerce, Franklin Court Building 4100W, 1099 14th Street, NW, Washington, DC 20005; or,

2. Submissions via the U.S. Postal Service: Foreign–Trade Zones Board, U.S. Department of Commerce, FCB 4100W, 1401 Constitution Ave., NW, Washington, DC 20230.

The closing period for their receipt is May 4, 2005.

A copy of the application will be available for public inspection at the Office of the Foreign–Trade Zones Board's Executive Secretary at address No. 1 listed above.

Dated: March 25, 2005.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 05–6649 Filed 4–1–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

A–427–801, A–428–801, A–475–801, A–588–804, A–559–801, A–412–801

Antifriction Bearings and Parts Thereof From France, Germany, Italy, Japan, Singapore, and the United Kingdom: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: April 4, 2005.

FOR FURTHER INFORMATION CONTACT: Janis Kalnins or Richard Rimlinger, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–1392 or (202) 482–4477, respectively.

SUPPLEMENTARY INFORMATION:

Background

At the request of interested parties, the Department of Commerce (the Department) initiated administrative reviews of the antidumping duty orders on antifriction bearings and parts thereof from France, Germany, Italy, Japan, Singapore, and the United Kingdom for the period May 1, 2003, through April 30, 2004. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 69 FR 39409 (June 30, 2004). The

preliminary results of reviews are currently due no later than April 1, 2005. See *Antifriction Bearings and Parts Thereof From France, Germany, Italy, Japan, Singapore, and the United Kingdom: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Reviews*, 70 FR 3676 (January 26, 2005).

Extension of Time Limit for Preliminary Results of Reviews

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires the Department to make a preliminary determination within 245 days after the last day of the anniversary month of an order for which a review is requested and a final determination within 120 days after the date on which the preliminary determination is published. If it is not practicable to complete the review within these time periods, section 751(a)(3)(A) of the Act allows the Department to extend the time limit for the preliminary determination to a maximum of 365 days after the last day of the anniversary month.

We determine that it is not practicable to complete the preliminary results of these reviews within the original time limit because of the number of companies involved in these reviews, the complex issues surrounding the model–match methodology, and the additional time we need to conduct verifications. Therefore, we are extending the time period for issuing the preliminary results of these reviews by an additional 26 days, until April 27, 2005, which is 331 days after the last day of the anniversary month of the order.

This notice is published in accordance with section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2).

Dated: March 29, 2005.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. E5–1491 Filed 4–1–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

(A–583–008)

Certain Circular Welded Carbon Steel Pipes and Tubes from Taiwan: Initiation of Antidumping Duty Changed Circumstance Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) has received information sufficient to warrant initiation of a changed circumstance review of the antidumping order of certain circular welded carbon steel pipes and tubes from Taiwan. *See Certain Circular Welded Carbon Steel Pipes and Tubes From Taiwan: Antidumping Duty Order*, 49 FR 19369 (May 7, 1984). In response to this request made by Yieh Phui Enterprise Co., Ltd. (Yieh Phui), the Department is initiating a changed circumstance review to determine whether Yieh Phui is the successor–in-interest to Yieh Hsing Enterprise Co, Ltd (Yieh Hsing).

EFFECTIVE DATE: April 4, 2005.

FOR FURTHER INFORMATION CONTACT: Angela Strom or Robert James at (202) 482–2704 or (202) 482–0649, respectively; AD/CVD Operations, Office 7, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Ave. NW, Washington DC 20230.

SUPPLEMENTARY INFORMATION:

Background

In the context of the 2002–2003 administrative review of circular welded carbon steel pipe and tubes from Taiwan, the respondent,Yieh Hsing, had requested the Department to initiate a changed circumstance review to determine whether Yieh Phui is the successor–in-interest to Yieh Hsing. *See* Yieh Hsing Section A Questionnaire response dated September 11, 2003 (which will be made available upon publication of this notice in the Central Records Unit (CRU) at the Department of Commerce). At that time, the Department did not find the information in the request sufficient to warrant initiation of a changed circumstance review. *See* Letter from the Department to Yieh Hsing dated November 14, 2003 (also available upon the publication of this notice in CRU). On September 30, 2004, the Department published the final results of the administrative review and assigned a cash deposit rate of 1.61 percent to Yieh Hsing for sales of subject merchandise to the United States. *See Circular Welded Carbon Steel Pipes and Tubes From Taiwan: Final Results of Antidumping Duty Administrative Review*, 69 FR 58390 (September 30, 2004).

On February 15, 2005, Yieh Phui requested the Department to conduct an expedited changed circumstances review of the order on certain circular welded carbon steel pipes and tubes from Taiwan with respect to Yieh Phui. In the request, Yieh Phui included information relating to current and former operations of Yieh Phui and Yieh Hsing and provided documentation relating to Yieh Phui's acquisition of Yieh Hsing's steel pipe production facilities. Accordingly, Yieh Phui asked the Department to find Yieh Phui as the successor–in-interest to Yieh Hsing and to accord Yieh Phui the same antidumping duty treatment as its predecessor with respect to subject merchandise.

Scope of the Order

Imports covered by the order are shipments of certain circular welded carbon steel pipes and tubes. The Department defines such merchandise as welded carbon steel pipes and tubes of circular cross section, with walls not thinner than 0.065 inch and 0.375 inch or more but not over 4.5 inches in outside diameter. These products are commonly referred to in the industry as ''standard pipe'' and are produced to various American Society for Testing Materials specifications, most notably A–53, A–120 and A–135. Standard pipe is currently classified under Harmonized Tariff Schedule of the United States (HTSUS) item subheadings 7306.30.5025, 7306.30.5032, 7306.30.5040, and 7306.30.5055. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise under the order is dispositive.

Initiation of Changed Circumstance Review

Pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended, the Department will conduct a changed circumstance review upon request from an interested party or receipt of information concerning an antidumping duty order, which shows changed circumstances exist to warrant a review of the order. Pursuant to Yieh Phui's request dated February 15, 2005, the Department is initiating a changed circumstance review to determine whether Yieh Phui is the successor–in-interest to Yieh Hsing for purposes of determining antidumping liability with respect to imports of subject merchandise from Taiwan produced and exported by Yieh Phui.

In making a successor–in-interest determination, the Department examines several factors, including, but not limited to, changes in: 1) management; 2) production facilities; 3) supplier relationships; and 4) customer base. *See Notice of Final Results of Changed Circumstances Review: Polychloroprene Rubber from Japan*, 69 FR 67890 (November 22, 2004) citing, *Brass Sheet and Strip from Canada: Notice of Final Results of Antidumping Duty Administrative Review*, 57 FR 20460 (May 13, 1992) (*Brass Sheet*). While no single factor or a combination of these factors will necessarily provide a dispositive indication, the Department will generally consider the new company to be the successor to the previous company if its resulting operation is not materially dissimilar to that of its predecessor. *See e.g., Industrial Phosphoric Acid from Israel: Final Results of Changed Circumstances Review*, 59 FR 6944 (February 14, 1994), *Canadian Brass*, and *Certain Preserved Mushrooms from India: Final Results of Changed–Circumstances Review*, 68 FR 6884 (February 11, 2003). If evidence demonstrates that, with respect to the production and sale of the subject merchandise, the new company operates as the same entity as the former company, the Department will treat the successor company the same as the predecessor for antidumping purposes. *See Fresh and Chilled Atlantic Salmon from Norway: Final Results of Changed Circumstance Antidumping Administrative Review*, 64 FR 9979 (March 1, 1999).

While Yieh Phui claims it has been operating the steel pipe operations as the same entity as Yieh Hsing, the Department determines that Yieh Phui has not provided *prima facie* evidence that Yieh Phui is the successor–in-interest to Yieh Hsing. Because we find deficiencies in the information provided by Yieh Phui, we will collect additional information in the context of this review.

Section 351.211 (c)(3)(ii) of the Department's regulations permits the Department to combine the notice of initiation of a changed circumstance review and the notice of preliminary results in a single notice if the Department concludes that expedited action is warranted. As noted, although the Department finds the information submitted by Yieh Phui sufficient to warrant the initiation of a changed circumstance review, we do not find the information sufficient to make a preliminary finding. Because the record supporting Yieh Phui's claim is deficient, we find that expedited action is impracticable. Thus, the Department is not issuing the preliminary results of this antidumping duty changed circumstances review at this time.

The Department will publish in the **Federal Register** a notice of preliminary results of antidumping duty changed circumstance review, in accordance with 19 CFR 351.221(b)(4) and 19 CFR 351.221 (c)(3)(i). This notice will set forth the factual and legal conclusions upon which our preliminary results are based and a description of any action proposed based on those results. Pursuant to 19 CFR 351.221(b)(4)(ii), interested parties will have an opportunity to comment on the preliminary results of this review. In accordance with 19 CFR 351.216 (e), the Department will issue the final results of its antidumping duty changed circumstance review not later than 270 days after the date on which the review is initiated.

During the course of this antidumping duty changed circumstance review, we will not change the cash deposit requirements for the merchandise subject to review. The cash deposit will only be altered, if warranted, pursuant to the final results of this review.

This notice of initiation is in accordance with sections 751(b)(1) of the Tariff Act and 19 CFR 351.221(b)(1).

Dated: March 24, 2005.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

[FR Doc. E5–1489 Filed 4–1–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–828]

Notice of Extension of Time Limit for Preliminary Results of Antidumping Duty New Shipper Review: Certain Hot–Rolled Carbon Steel Flat Products From Brazil

AGENCY: AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: April 4, 2005.

FOR FURTHER INFORMATION CONTACT: Helen Kramer or Kristin Najdi at (202) 482–0405 or (202) 482–8221, respectively; AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On September 27, 2004, Companhia Siderúrgica de Tubarão (CST) requested that the Department conduct a new shipper review of its exports to the United States during the period March 1, 2004, through August 31, 2004. On October 28, 2004, the Department published the notice initiating a new shipper review of CSN. *See Notice of Initiation of Antidumping Duty New Shipper Review*, 69 FR 62866 (October 28, 2004). The preliminary results are currently due not later than April 20, 2005.

Extension of Time Limits for Preliminary Results

Section 751(a)(2)(B)(iv) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.214(i)(1) require the Department to issue the preliminary results of a new shipper review within 180 days after the date on which the new shipper review was initiated and final results of a review within 90 days after the date on which the preliminary results were issued. The Department may, however, extend the deadline for completion of the preliminary results of a new shipper review to 300 days if it determines that the case is extraordinarily complicated. *See* 19 CFR 351.214(i)(2). The Department has determined that additional time is necessary to complete the preliminary results because issues raised in the cost investigation and the scheduling of sales and cost verifications make this case extraordinarily complicated. Therefore, the preliminary results of this new shipper review cannot be completed within the statutory time limit of 180 days.

Section 751(a)(2)(B)(iv) of the Act and 19 CFR 315.214(i)(2) allow the Department to extend the deadline for the preliminary results of a new shipper review to 300 days after the date on which the new shipper review was initiated. For the reasons noted above, we are extending the time for the completion of preliminary results until no later than August 18, 2005. The deadline for the final results will continue to be 90 days after the date on which the preliminary results were issued.

Dated: March 29, 2005.

Barbara E. Tillman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. E5–1488 Filed 4–1–05; 8:45 am]

BILLING CODE: 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

Applications for Duty–Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M. in Suite 4100W, U.S. Department of Commerce, Franklin Court Building, 1099 14th Street, NW, Washington, D.C.

Docket Number: 05–014.

Applicant: Baylor College of Medicine, One Baylor Plaza, Houston, TX 77030.

Instrument: Electron Microscope, Model JEM–2100.

Manufacturer: JEOL, Ltd., Japan.

Intended Use: The instrument is intended to be used to study 3–dimensional structures, with 3 to 6 angstrom resolution, of materials to include proteins, viruses and receptors which are involved in a variety of biological processes including catalytic reactions, viral morphogenesis, signal transduction and molecular transport. Properties of materials to be studied have a tendency to form higher–order aggregates, which are radiation sensitive to the incident electrons. Specimens will be kept hydrated at 25–50 degrees K which is optimal for reducing microscope radiation.

Application accepted by Commissioner of Customs: March 7, 2005.

Docket Number: 05–015.

Applicant: Baylor College of Medicine, One Baylor Plaza, Houston, TX 77030.

Instrument: Electron Microscope, Model JEM–3200FSC.

Manufacturer: JEOL, Ltd., Japan.

Intended Use: The instrument is intended to be used to study 3–dimensional structures, with 3 to 6 angstrom resolution, of materials to include proteins, viruses and receptors which are involved in a variety of biological processes including catalytic reactions, viral morphogenesis, signal transduction and molecular transport. Properties of materials to be studied have a tendency to form higher–order aggregates, which are radiation sensitive to the incident electrons. Specimens will be kept hydrated at 25–50 degrees K which is optimal for reducing microscope radiation.

Application accepted by Commissioner of Customs: March 7,2005.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. E5–1493 Filed 4–1–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

University of Vermont; Notice of Decision on Application for Duty–Free Entry of Scientific Instrument

This decision is made pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Suite 4100W, U.S. Department of Commerce,

Franklin Court Building, 1099 14th Street, NW, Washington, D.C.

Docket Number: 05–005.

Applicant: University of Vermont, Burlington Vermont, 05405.

Instrument: Excimer Laser.

Manufacturer: TuiLaser AG, Germany.

Intended Use: See notice at 70 FR 9046, February 24, 2005.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument provides: (1) 300 mJ/pulse at 100 Hz at 248 nm, (2) a power level above the laser ablation threshold and (3) very fast rise time.

The National Institute of Standards and Technology and a university research laboratory advise that (1) these capabilities are pertinent to the applicant's intended purpose and (2) they know of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. E5–1492 Filed 4–1–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 122304A]

Taking of Marine Mammals Incidental to Specified Activities; On-ice Seismic Operations in the Beaufort Sea

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of issuance of an incidental harassment authorization.

SUMMARY: In accordance with provisions of the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that an Incidental Harassment Authorization (IHA) to take small numbers of marine mammals, by harassment, incidental to conducting on-ice vibroseis seismic operations from Milne Point to the eastern channel of the Colville River in the U.S. Beaufort Sea to a distance offshore of 2.3 nautical miles (nm)(4.3 kilometers (km)) has been issued to ConocoPhillips Alaska (CPA) for a period of one year.

DATES: Effective from March 29, 2005 through March 28, 2006.

ADDRESSES: The authorization and application containing a list of the references used in this document may be obtained by writing to this address or by telephoning the contact listed here. The application is also available at: *http://www.nmfs.noaa.gov/prot__res/PR2/Small__Take/smalltake__info.htm#applications.*

FOR FURTHER INFORMATION CONTACT: Kenneth Hollingshead, Office of Protected Resources, NMFS, (301) 713–2289, ext 128 or Brad Smith, Alaska Region, NMFS, (907) 271–5006.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Permission may be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses, and that the permissible methods of taking and requirements pertaining to the monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''...an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Except for certain categories of activities not pertinent here, the MMPA defines ''harassment'' as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Section 101(a)(5)(D) establishes a 45–day time limit for NMFS review of an application followed by a 30–day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

Summary of Request

On November 26, 2004, NMFS received an application from CPA for the taking, by harassment, of two species of marine mammals incidental to conducting an on-ice seismic survey program. The seismic operations will be conducted from Milne Point to the eastern channel of the Colville River in the Alaskan Beaufort Sea to a distance offshore of 2.3 nm (4.3 km), an area encompasing approximately 51 mi2 (132.1 km^2). Water depths in most (greater than 95 percent) of the planned survey area are less than 10 ft (3 m).

The purpose of the project is to gather information about the subsurface of the earth by measuring acoustic waves, which are generated on or near the surface. The acoustic waves reflect at boundaries in the earth that are characterized by acoustic impedance contrasts.

Description of the Activity

The seismic surveys use the ''reflection'' method of data acquisition. Seismic exploration uses a controlled energy source to generate acoustic waves that travel through the earth, including sea ice and water, as well as sub-sea geologic formations, and then uses ground sensors to record the reflected energy transmitted back to the surface. When acoustic energy is generated, compression and shear waves form and travel in and on the earth. The compression and shear waves are affected by the geological formations of the earth as they travel in it and may be reflected, refracted, diffracted or transmitted when they reach a boundary represented by an acoustic impedance contrast. Vibroseis seismic operations use large trucks with vibrators that systematically put variable frequency energy into the earth. At least 1.2 m (4 ft) of sea ice is required to support the various equipment and vehicles used to transport seismic equipment offshore for exploration activities. These ice conditions generally exist from 1 January until 31 May in the Beaufort Sea. Several vehicles are normally

associated with a typical vibroseis operation. One or two vehicles with survey crews move ahead of the operation and mark the energy input points. Crews with wheeled vehicles often require trail clearance with bulldozers for adequate access to and within the site. Crews with tracked vehicles are typically limited by heavy snow cover and may require trail clearance beforehand.

With the vibroseis technique, activity on the surveyed seismic line begins with the placement of sensors. All sensors are connected to the recording vehicle by multi-pair cable sections. The vibrators move to the beginning of the line and begin recording data. The vibrators begin vibrating in synchrony via a simultaneous radio signal to all vehicles. In a typical survey, each vibrator will vibrate four times at each location. The entire formation of vibrators subsequently moves forward to the next energy input point (e.g. 67 m, or 220 ft, in most applications) and repeats the process. In a typical 16- to 18–hour day, a surveys will complete 6–16 km (4 to 10 linear miles) in 2–dimensional seismic operations and 24 to 64 km (15 to 40 linear miles) in a 3–dimensional seismic operation.

Comments and Responses

A notice of receipt and request for 30–day public comment on the application and proposed authorization was published on February 8, 2005 (70 FR 6626). During the 30–day public comment period, NMFS did not receive any comments.

Description of Habitat, Marine Mammals Affected by the Activity, and the Impact on Affected Marine Mammals

A detailed description of the seismic survey activities, its associated marine mammals and the potential impacts on both the affected marine mammals and subsistence uses of those mammals can be found in the CPA application, a number of documents referenced in the CPA application (see **ADDRESSES**), and in the proposed IHA notice (70 FR 6626, February 8, 2005). That information is not repeated here.

Mitigation and Monitoring

The following mitigation measures will be implemented for the subject surveys: (1) All activities will be conducted as far as practicable from any observed ringed or bearded seal lair and no energy source will be placed over a ringed or bearded seal lair; (2) only vibrator-type energy-source equipment shown to have similar or lesser effects will be used; and (3) CPA will provide training for the seismic crews so they can recognize potential areas of ringed seal lairs and adjust the seismic operations accordingly.

Ringed seal pupping occurs in ice lairs from late March to mid-to-late April (Smith and Hammill, 1981). Prior to commencing on-ice seismic surveys in mid-March, a survey using experienced field personnel and trained dogs will be conducted along the planned on-ice seismic transmission routes in areas where water depths exceed 3 m (9.8 ft) to identify and determine the status of potential seal structures along the planned on-ice transit routes. The seal structure survey will be conducted before selection of precise transit routes to ensure that seals, particularly pups, are not injured by equipment. The locations of all seal structures will be recorded by Global Positioning System (GPS), staked, and flagged with surveyor's tape. Surveys will be conducted 150 m (492 ft) to each side of the transit routes. Actual width of route may vary depending on wind speed and direction, which strongly influence the efficiency and effectiveness of dogs locating seal structures. Few, if any, seals inhabit ice-covered waters shallower than 3 m (9.8 ft) due to water freezing to the bottom or poor prey availability caused by the limited amount of ice-free water.

The level of take, while anticipated to be negligible, will be assessed by conducting a second seal structure survey shortly after the end of the seismic surveys. A single on-ice survey will be conducted by biologists on snow machines using a GPS to relocate and determine the status of seal structures located during the initial survey. The status (active vs. inactive) of each structure will be determined to assess the level of incidental take by seismic operations. The number of active seal structures abandoned between the initial survey and the final survey will be the basis for enumerating harassment takes. If dogs are not available for the initial survey, takings will be determined by using observed densities of seals on ice reported by Moulton et al. (200I) for the Northstar development, which is approximately 24 nm (46 km) from the eastern edge of the proposed activity area.

CPA will also continue to work with NMFS, other Federal agencies, the State of Alaska, Native communities of Barrow and Nuiqsut, and the Inupiat Community of the Arctic Slope (ICAS) to assess measures to further minimize any impact from seismic activity. A Plan of Cooperation will be developed between CPA and Nuiqsut to ensure that seismic activities do not interfere with subsistence harvest of ringed or bearded seals.

In the event that seismic surveys can be completed in that portion of the activity area with water depths greater than or equal to 3 m (9.8 ft) before mid-March, no field surveys would be conducted of seal structures. Under this scenario, surveys would be completed before pups are born and disturbance would be negligible. Therefore, take estimates would be determined for only that portion of the activity area exposed to seismic surveys after mid-March, which would be in water depths of 3 m (9.8 ft) or less. Take for this area would be estimated by using the observed density (13/100 km^2) reported by Moulton *et al.* (2001) for water depths between 0 to 3 m (0 to 9.8 ft) in the Northstar project area, which is the only source of a density estimate stratified by water depth for the Beaufort Sea. This would be an overestimation requiring a substantial downward adjustment to reflect the actual take of seals using lairs, since few if any of the structures in these water depths would be used for birthing, and Moulton *et al.* (2001) estimate includes all seals.

This monitoring program was reviewed at the fall 2002 on-ice meeting sponsored by NMFS' National Marine Mammal Laboratory in Seattle and found acceptable.

Reporting

An annual report must be submitted to NMFS within 90 days of completing the year's activities.

Endangered Species Act (ESA)

NMFS has determined that no species listed as threatened or endangered under the ESA will be affected by issuing an incidental harassment authorization under section 101(a)(5)(D) of the MMPA to CPA for this on-ice seismic survey.

National Environmental Policy Act (NEPA)

The information provided in Environmental Assessments (EAs) prepared in 1993 and 1998 for winter seismic activities led NOAA to conclude that implementation of either the preferred alternative or other alternatives identified in the EA would not have a significant impact on the human environment. Therefore, an Environmental Impact Statement was not prepared. The proposed action discussed in this document is not substantially different from the 1992 and 1998 actions, and a reference search has indicated that no significant new scientific information or analyses have been developed in the past several years

that would warrant new NEPA documentation. Accordingly, this action is categorically excluded from further review under NOAA Administrative Order 216–6.

Determinations

The anticipated impact of winter seismic activities on the species or stock of ringed and bearded seals is expected to be negligible for the following reasons:

(1) The activity area supports a small proportion (<1 percent) of the ringed and bearded seal populations in the Beaufort Sea.

(2) Most of the winter-run seismic lines will be on ice over shallow water where ringed seals are absent or present in very low abundance. Over 90 percent of the activity area is near shore and/or in water less than 3 m (9.8 ft) deep, which is generally considered poor seal habitat. Moulton *et al.* (2001) reported that only 6 percent of 660 ringed seals observed on ice in the Northstar project area were in water between 0 to 3 m (0 to 9.8 ft) deep.

(3) For reasons of safety and because of normal operational constraints, seismic operators will avoid moderate and large pressure ridges, where seal and pupping lairs are likely to be most numerous.

(4) Many of the on-ice seismic lines and connecting ice roads will be laid out and explored during January and February, when many ringed seals are still transient, and considerably before the spring pupping season.

(5) The sounds from energy produced by vibrators used during on-ice seismic programs typically are at frequencies well below those used by ringed seals to communicate (1000 Hz). Thus, ringed seal hearing is not likely to be very good at those frequencies and seismic sounds are not likely to have strong masking effects on ringed seal calls. This effect is further moderated by the quiet intervals between seismic energy transmissions.

(6) There has been no major displacement of seals away from on-ice seismic operations (Frost and Lowry, 1988). Further confirmation of this lack of major response to industrial activity is illustrated by the fact that there has been no major displacement of seals near the Northstar Project. Studies at Northstar have shown a continued presence of ringed seals throughout winter and creation of new seal structures (Williams *et al.*, 2001).

(7) Although seals may abandon structures near seismic activity, studies have not demonstrated a cause and effect relationship between abandonment and seismic activity or biologically significant impact on ringed seals. Studies by Williams *et al.* (2001), Kelley *et al.* (1986, 1988) and Kelly and Quakenbush (1990) have shown that abandonment of holes and lairs and establishment or re-occupancy of new ones is an ongoing natural occurrence, with or without human presence. Link *et al.* (1999) compared ringed seal densities between areas with and without vibroseis activity and found densities were highly variable within each area and inconsistent between areas (densities were lower for 5 days, equal for 1 day, and higher for 1 day in vibroseis area), suggesting other factors beyond the seismic activity likely influenced seal use patterns. Consequently, a wide variety of natural factors influence patterns of seal use including time of day, weather, season, ice deformation, ice thickness, accumulation of snow, food availability and predators as well as ring seal behavior and population dynamics.

In winter, bearded seals are restricted to cracks, broken ice, and other openings in the ice. On-ice seismic operations avoid those areas for safety reasons. Therefore, any exposure of bearded seals to on-ice seismic operations would be limited to distant and transient exposure. Bearded seals exposed to a distant on-ice seismic operation might dive into the water. Consequently, no significant effects on individual bearded seals or their population are expected, and the number of individuals that might be temporarily disturbed would be very low.

As a result, CPA and NMFS believe the effects of on-ice seismic are expected to be limited to short-term and localized behavioral changes involving relatively small numbers of seals. NMFS has determined, based on information in the application and supporting documents, that these changes in behavior will have no more than a negligible impact on the affected species or stocks of ringed and bearded seals. Also, the potential effects of the on-ice seismic operations during 2005 are unlikely to result in more than small numbers of seals being affected and will not have an unmitigable adverse impact on subsistence uses of these two species.

Authorization

NMFS has issued an IHA to CPA for conducting seismic surveys from Milne Point to the eastern channel of the Colville River in the U.S. Beaufort Sea, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: March 29, 2005.

Laurie K. Allen,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 05–6612 Filed 4–1–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 032905B]

Caribbean Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Caribbean Fishery Management Council (Council) and its Administrative Committee will hold meetings.

DATES: The meetings will be held on May 3 and 4, 2005. The Council will convene on Tuesday, May 3, 2005, from 9 a.m. to 5 p.m., and the Administrative Committee will meet from 5:15 p.m. to 6 p.m. The Council will reconvene on Wednesday, May 4, 2005, from 8:30 a.m. to 5 p.m., approximately.

ADDRESSES: The meetings will be held at Frenchman's Reef and Morning Star Marriott Beach Resort, #5 Estate Bakkeroe, St. Thomas, USVI.

FOR FURTHER INFORMATION CONTACT: Caribbean Fishery Management Council, 268 Muńoz Rivera Avenue, Suite 1108, San Juan, Puerto Rico 00918–1920, telephone (787) 766–5926.

SUPPLEMENTARY INFORMATION: The Council will hold its 118th regular public meeting to discuss the items contained in the following agenda:

May 3, 2005

9 a.m.–5 p.m.

Call to Order
Adoption of Agenda
Consideration of 117th Council Meeting Verbatim Minutes
Executive Director's Report
R/V Nancy Foster USVI Survey Update
Proposed rule for *Acropora palmata/Acropora cervicornis*
SFA Document–Final Action
CFMC Research Needs

5:15 p.m.– 6 p.m.

Administrative Committee Meeting
-AP/SSC/HAP Membership
-Budget 2002, 2003, 2004/05
-Pending travel and Contracts
-Other Business

May 4, 2005

8:30 a.m.–5 p.m.

HMS Presentation–Russel Dunn

Enforcement Reports

-Puerto Rico

-US Virgin Islands

-NOAA

-US Coast Guard

Administrative Committee Recommendations from May 3, 2005

Meetings attended by Council members and staff

Other Business

Next Council Meeting

The meetings are open to the public, and will be conducted in English. Fishers and other interested persons are invited to attend and participate with oral or written statements regarding agenda issues. Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action 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 Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. For more information or request for sign language interpretation and/other auxiliary aids, please contact Mr. Miguel A. Rolón, Executive Director, Caribbean Fishery Management Council, 268 Muñoz Rivera Avenue, Suite 1108, San Juan, Puerto Rico, 00918–2577, telephone (787) 766–5926, at least five days prior to the meeting date.

Dated: March 30, 2005.

Emily Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E5–1480 Filed 4–1–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 032905C]

Western Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold meetings of its Pelagics Plan Team (PPT) in Honolulu, HI to discuss fishery issues and develop recommendations for future management.

DATES: The meeting of the PPT will be held on May 3–5, 2005, from 8:30 a.m. to 5 p.m. each day.

ADDRESSES: The meeting will be held at the Council Office Conference Room, Western Pacific Fishery Management Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813; telephone: (808) 522–8220.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: The PPT will meet on May 3–5, 2005, at the Council Conference Room to discuss the following agenda items:

Tuesday May 3, 2005, 8.30 a.m.

1. Introduction
2. Annual Report review

a. Review 2004 Annual Report modules and recommendations

b. 2004 Annual Report region-wide recommendations

Wednesday & Thursday, May 4–5, 2005, 8.30 a.m.

3. Bigeye tuna overfishing
4. Management of Hawaii offshore handline fishery
5. Status of North Pacific Albacore
6. International pelagic fishery management
7. Recreational fisheries
8. Economic research
9. Protected species research and management
10. Other business

The order in which the agenda items are addressed may change. The PPT will meet as late as necessary to complete scheduled business. Although non-emergency issues not contained in this agenda may come before the PPT for discussion, those issues may not be the subject of formal action during these meetings. Plan Team action will be restricted to those issues specifically listed in this document and any issue arising after publication of this document that requires emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

Dated: March 30, 2005.

Emily Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E5–1482 Filed 4–1–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 032805A]

Atlantic Highly Migratory Species; Environmental Assessment; Exempted Fishing Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability; request for comments.

SUMMARY: NMFS announces the availability of an Environmental Assessment (EA) prepared pursuant to the National Environmental Policy Act to analyze the potential impacts associated with exempting six pelagic longline vessels from existing area closures and other regulations for the purpose of evaluating whether gear modifications and/or various fishing techniques can avoid/reduce bycatch and associated regulatory discards of juvenile highly migratory species (HMS) in the Gulf of Mexico, Florida East Coast, South Atlantic Bight, Mid-Atlantic Bight, and Northeast Coastal statistical areas of the Atlantic Ocean. The EA examines alternatives available to authorize activities otherwise prohibited by regulations for the conduct of scientific research and the investigation of bycatch, consistent with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), and other relevant Federal laws. NMFS is requesting comments on the alternatives outlined in the EA.

DATES: Written comments on this action must be received no later than 5 p.m., local time, on April 11, 2005.

ADDRESSES: Copies of the EA can be obtained by contacting Heather Stirratt (see **FOR FURTHER INFORMATION CONTACT**) or by viewing the document online at *http://www.nmfs.noaa.gov/sfa/hms/*.

Comments regarding the EA and issuance of Exempted Fishing Permits

(EFPs) can be submitted by any of the following methods:

• Email: *ID032805A@noaa.gov*. Include in the subject line the following identifier: I.D.032805A.

• Mail: Heather Stirratt, NMFS Highly Migratory Species Management Division, 1315 East-West Highway, Silver Spring, MD 20910.

• Fax: (301) 713–1917.

FOR FURTHER INFORMATION CONTACT: Heather Stirratt at (301) 713–2347.

SUPPLEMENTARY INFORMATION: EFPs are requested and issued under the authority of the Magnuson-Stevens Act (16 U.S.C. 1801 *et seq.*) and/or the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*). Regulations at 50 CFR 600.745 and 635.32 govern scientific research activity, exempted fishing, and exempted educational activity with respect to Atlantic HMS.

Six operators of permitted Atlantic pelagic longline vessels have requested exemptions from certain regulations applicable to the harvest and landing of HMS in order to conduct bycatch reduction research in the following regions of the Atlantic Ocean: North of Cape Hatteras, South of Cape Hatteras, and Gulf of Mexico (GOM). Specifically, the vessels propose to test gear modifications and/or various fishing techniques to avoid incidentally-caught white marlin, blue marlin, bluefin tuna, and sea turtles, while allowing for the targeted catches of allowed species.

To conclusively demonstrate the effectiveness of gear modifications, in the shortest timeframe, it is necessary to test bycatch reduction measures in those areas where pelagic longlines are most likely to encounter the bycatch species of concern (i.e., juvenile HMS). As such, it is necessary to conduct comparison experiments both inside and outside of existing closed areas. Restricted access within existing closed areas has been proposed by the applicants as terms and conditions of the proposed research in order to minimize or eliminate the potential for gear and/or fishing grounds conflicts. Within the GOM region, two pelagic longline vessels propose to conduct 100 compensated bycatch reduction fishing sets (approximately 750 hooks/set) during a limited time period (late April through September). Within the North of Cape Hatteras region, two pelagic longline vessels propose to conduct 50 compensated bycatch reduction fishing sets (approximately 680 hooks/set) during a limited time period (June through August). Within the South of Cape Hatteras region, two pelagic longline vessels propose to conduct 50 compensated bycatch reduction fishing sets (approximately 556 hooks/set) during a limited time period (late April through June).

This research may benefit all interested parties by providing fishery managers with additional gear modifications and/or fishing techniques that reduce or avoid incidental capture/bycatch mortality of HMS in the research areas as proposed above.

The regulations that would prohibit the proposed activities include requirements for size limits (50 CFR 635.20), commercial retention limits for sharks and swordfish (50 CFR 635.24), and definitions as they apply to closed areas (50 CFR 635.2).

NMFS invites comments from interested parties on potential concerns should these EFPs be issued. Copies of the EA are now available for review and comment (see **ADDRESSES**).

Authority: 16 U.S.C. 971 *et seq.* and 16 U.S.C. 1801 *et seq.*

Dated: March 30, 2005.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 05–6598 Filed 3–30–05; 1:47 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 033005A]

Atlantic Coastal Fisheries Cooperative Management Act Provisions; Application for Exempted Fishing Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments.

SUMMARY: The Director, State, Federal and Constituent Programs Office, Northeast Region, NMFS (Office Director) has made a preliminary determination that the subject Exempted Fishing Permit (EFP) application contains all the required information and warrants further consideration. The Office Director has also made a preliminary determination that the activities authorized under the EFPs would be consistent with the goals and objectives of Federal management of the American lobster resource. However, further review and consultation may be necessary before a final determination is made to issue EFPs. Therefore, NMFS announces that the Office Director proposes to issue EFPs that would allow a maximum of seven vessels to conduct fishing operations involving the use of one juvenile lobster collector trap per vessel that are otherwise restricted by the regulations governing the American lobster fisheries of the Northeastern United States.

The EFP involves the non-destructive collection of size frequency and population data on legal and sublegal lobsters as part of an ongoing research project to monitor the offshore lobster fishery in Lobster Management Area 3. It would not involve the authorization of any additional trap gear in the area. A maximum of seven participating commercial fishing vessels will collect detailed abundance and size frequency data on the composition of lobsters in four general offshore study areas in a collaborative effort with the Atlantic Offshore Lobstermen's Association (AOLA). This EFP requests that each participating commercial fishing vessel utilize one modified juvenile lobster collector trap to collect population data. The lobster trap modifications are to the escape vents, and trap entrance head, not to the trap's size or configuration. Therefore, this modified trap would impact its environment no differently than the regular lobster trap it replaces and will add no additional traps to the area. After data is collected on lobsters in the trap, all sub-legal and berried female lobsters will be immediately returned to the sea. The EFP waives the American lobster escape vent requirement for a maximum of one trap per vessel for a maximum of seven vessels in the program. Therefore, this document invites comments on the issuance of EFPs to allow a maximum of seven commercial fishing vessels utilize a maximum of seven modified lobster traps and to collect statistical data using modified lobster trap gear.

DATES: Written comments on this lobster EFP notification for offshore lobster monitoring and data collection must be received on or before April 19, 2005.

ADDRESSES: Written comments should be sent to Patricia A. Kurkul, Regional Administrator, NMFS, Northeast Regional Office, 1 Blackburn Drive, Gloucester, MA 01930–2298. Mark the outside of the envelope ''Comments - Lobster EFP Proposal''. Comments also may be sent via fax to 978–281–9117. Or, comments may be submitted by e-mail to *Lob0205@noaa.gov*. Include in the subject line the following document identifier: ''Comments - Lobster EFP Proposal''.

FOR FURTHER INFORMATION CONTACT: Bob Ross, Fishery Management Specialist, 978–281–9234, fax 978–281–9117.

SUPPLEMENTARY INFORMATION:

Background

The regulations that govern exempted fishing, at 50 CFR 600.745(b) and 697.22 allow the Regional Administrator to authorize for limited testing, public display, data collection, exploration, health and safety, environmental clean-up, and/or hazardous removal purposes, and the targeting or incidental harvest of managed species that would otherwise be prohibited. An EFP to authorize such activity may be issued, provided there is adequate opportunity for the public to comment on the EFP application, the conservation goals and objectives of Federal management of the American lobster resource are not compromised, and issuance of the EFP is beneficial to the management of the species.

The American lobster fishery is the most valuable fishery in the northeastern United States. In 2003, approximately 72 million pounds (26,873 metric tons) of American lobster were landed with an ex-vessel value of approximately $286 million. American lobster experience very high fishing mortality rates and are overfished throughout their range, from Canada to Cape Hatteras. Although harvest and population abundance are near record levels due to high recent recruitment and favorable environmental conditions, there is significant risk of a sharp drop in abundance, and such a decline would have serious implications. Operating under the Atlantic States Marine Fisheries Commission's interstate management process, American lobster are managed in state waters under Amendment 3 to the American Lobster Interstate Fishery Management Plan (Amendment 3). In Federal waters of the Exclusive Economic Zone (EEZ), lobster is managed under Federal regulations at 50 CFR part 697. Amendment 3, and compatible Federal regulations established a framework for area management, which includes industry participation in the development of a management program that suits the needs of each lobster management area while meeting targets established in the Interstate Fisheries Management Program. The industry, through area management teams, with the support of state agencies, have played a vital role in advancing the area management program.

To facilitate the development of effective management tools, extensive monitoring and detailed abundance and size frequency data on the composition of lobsters throughout the range of the resource are necessary. This proposed EFP will continue a project involved in extensive monitoring and detailed population information of American lobster in four offshore study areas using modified lobster trap gear that would otherwise be prohibited.

Proposed EFP

The proposed EFP is a continuation of a project begun in 2003, and is submitted by the AOLA and seven commercial lobster fishing vessels that are also members of the AOLA. The EFP proposes to collect statistical and scientific information as part of a project designed to monitor the offshore American lobster fishery to collect data that will assist the development of management practices appropriate to the fishery.

Each of seven commercial fishing vessels involved in this monitoring and data collection program would collect detailed abundance and size frequency data on the composition of all lobsters collected from one modified juvenile lobster trap in a string of approximately 40 lobster traps, including data on sub-legal, and egg bearing females in addition to legal lobsters. This EFP would not involve the authorization of any additional lobster trap gear in the area. Vessels would collect data from each of four general study areas: The Mid-Atlantic - Chesapeake 50 Fathom Edge; the Southern - Hudson Canyon Area; the Middle - Veatch Canyon Area; and the Northern - Georges Bank and Gulf of Maine Area. The participating vessels may retain on deck sub-legal lobsters, and egg bearing female lobsters, in addition to legal lobsters, for the purpose of collecting the required abundance and size frequency data specified by this project. Data collected would include size, sex, shell disease index, and the total number of legals, sub-legals, berried females, and v-notched females. All sub-legals, berried females, and v-notched females would be returned to the sea as quickly as possible after data collection. Pursuant to 50 CFR 600.745(3)(v), the Regional Administrator may attach terms and conditions to the EFP consistent with the purpose of the exempted fishing.

This EFP requests the inclusion of a maximum of one modified lobster trap per vessel, designated as a juvenile lobster collector trap, in the string of approximately 40 traps. This modified lobster trap would have a smaller entrance head, no escape vents and would be made of a smaller mesh than the traditional offshore trap to catch and retain a high percentage of juvenile lobsters in the 30–65 mm carapace length range. The smaller entrance head would exclude large lobsters from this trap and decrease the probability of cannibalism within the trap. The modifications to the trap are to the escape vents, and trap entrance head, not to the trap's size or configuration, therefore this modified trap would impact its environment no differently than the regular lobster trap it replaces. This EFP will add no additional traps to the areas. Due to modifications to the escape vent, the EFP proposed to waive the American lobster escape vent requirement specified at 50 CFR 697.21(c) for a maximum of one trap per vessel for a maximum of seven vessels in the program. With the exception of the one modified juvenile lobster collector trap, all traps fished by a maximum of seven participating vessels would comply with all applicable lobster regulations specified at 50 CFR part 697.

All sample collections would be conducted by seven federally permitted commercial fishing vessels, during the course of regular commercial fishing operations. There would not be observers or researchers onboard the participating vessels.

This project, including the lobster handling protocols, was initially developed in consultation with NOAA Fisheries and University of New Hampshire scientists. To the greatest extent practicable, these handling protocols are designed to avoid unnecessary adverse environmental impact on lobsters involved in this project, while achieving the data collection objectives of this project.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: March 30, 2005.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E5–1481 4–1–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 031805C]

Marine Mammals; Permit No. 782–1719

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of permit amendment.

SUMMARY: Notice is hereby given that the National Marine Mammal Laboratory, National Marine Fisheries Service, NOAA, 7600 Sand Point Way, NE, BIN C15700, Bldg. 1, Seattle, WA 98115–0070, [John L. Bengtson, Ph.D., Principal Investigator] has been issued

an amendment to Permit No. 782–1719 for purposes of scientific research.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)713–0376; and

Assistant Administrator for Protected Resources,, Pacific Area Office, NMFS, 1601 Kapiolani Blvd., Rm, 1110, Honolulu, HI 96814–4700; phone (808)973–2935; fax (808)973–2941.

FOR FURTHER INFORMATION CONTACT: Ruth Johnson or Carrie Hubard, (301)713–2289.

SUPPLEMENTARY INFORMATION: On June 4, 2003, notice was published in the **Federal Register** (68 FR 33477) that requests for a scientific research permit to take various marine mammals, including calves less than six months of age, had been submitted by the above-named organizations. The requested permit amendment has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

Issuance of this permit, as required by the ESA, was based on a finding that such permit (1) was applied for in good faith, (2) will not operate to the disadvantage of the endangered species which is the subject of this permit, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: March 23, 2005.

Stephen L. Leathery,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 05–6613 Filed 4–1–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 030205A]

Endangered Species; File No. 1507

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of permit.

SUMMARY: Notice is hereby given that Llewellyn Ehrhart, University of Central Florida, 4000 Central Florida Blvd., Orlando, Florida 32816–2368 has been issued a permit to take green (*Chelonia mydas*), loggerhead (*Caretta caretta*), hawksbill (*Eretmochelys imbricata*), Kemp's ridley (*Lepidochelys kempii*), and leatherback (*Dermochelys coriacea*) sea turtles for purposes of scientific research.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)427–2521; and

Southeast Region, NMFS, 9721 Executive Center Drive North, St. Petersburg, FL 33702–2432; phone (727)570–5301; fax (727)570–5320.

FOR FURTHER INFORMATION CONTACT: Patrick Opay or Carrie Hubard, (301)713–2289.

SUPPLEMENTARY INFORMATION: On December 2, 2004, notice was published in the **Federal Register** (69 FR 70125) that a request for a scientific research permit to take loggerhead, Kemp's ridley, green, leatherback, and hawksbill sea turtles had been submitted by the above-named individual. The requested permit has been issued under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

Researchers will annually capture, flipper tag, PIT tag, measure, mark, weigh, blood sample, lavage, photograph, attach a satellite transmitter to, attach a tethered instrument to, release, and track loggerhead, green, hawksbill and Kemp's ridley sea turtles. The purpose of the research is to conduct in-water studies of marine turtle populations in the Indian River Lagoon (Project 1); to conduct studies of marine turtle populations residing on the Sabellariid Worm Reef of Indian River County, Florida (Project 2); to study sea turtle distribution and movement through the use of satellite telemetry (Project 3); to assess the juvenile green turtle population at the Trident Turning Basin, Cape Canaveral Air Force Station (Project 4); and to study juvenile green turtle and loggerhead habitat utilization in the central region of the Indian River Lagoon System, Florida (Project 5). The permit is issued for 5 years.

Issuance of this permit, as required by the ESA, was based on a finding that such permit (1) was applied for in good faith, (2) will not operate to the disadvantage of any endangered or threatened species, and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: March 29, 2005.

Stephen L. Leathery,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 05–6609 Filed 4–1–05; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 032905A]

Marine Mammals; File Nos. 434–1669, 1010–1641, 800–1664, 881–1668, 782–1768, 358–1769, 715–1784, and 1034–1773

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Receipt of applications.

SUMMARY: Notice is hereby given that the following individuals and institutions have applied for a permit or permit amendment to conduct research on Steller sea lions (*Eumetopias jubatus*): Oregon Department of Fish and Wildlife, Corvallis, OR (ODFW; File No. 434–1669); the Aleutians East Borough, Juneau, AK (AEB: File No. 1010–1641); Dr. Randall Davis, Texas A&M University, Galveston, TX (File No. 800–1664); the Alaska SeaLife Center, Seward, AK (ASLC: File No. 881–1668); the National Marine Mammal Laboratory, Alaska Fisheries Science Center, Seattle, WA (NMML: File No. 782–1768); the Alaska Department of Fish and Game, Anchorage, AK (ADF&G: File No. 358–1769); The North Pacific Universities Marine Mammal Research Consortium, University of British Columbia, Vancouver, B.C. (NPUMMRC: File No. 715–1784); and Dr. Markus Horning, Texas A&M University, Galveston, TX (File No. 1034–1773).

DATES: Written, telefaxed, or e-mail comments must be received on or before May 4, 2005.

ADDRESSES: The applications and related documents are available for review upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)427–2521;

Northwest Region, NMFS, 7600 Sand Point Way NE, BIN C15700, Bldg. 1, Seattle, WA 98115–0700; phone (206)526–6150; fax (206)526–6426; and

Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668; phone (907)586–7221; fax (907)586–7249.

Written comments or requests for a public hearing on these applications should be mailed to the Chief, Permits, Conservation and Education Division, F/PR1, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on a particular request would be appropriate.

Comments may also be submitted by facsimile at (301)427–2521, provided the facsimile is confirmed by hard copy submitted by mail and postmarked no later than the closing date of the comment period.

Additionally, comments may be submitted by e-mail. The mailbox address for providing email comments is *NMFS.Pr1Comments@noaa.gov*. Include the appropriate file number(s) in the subject line of the e-mail comment as a document identifier.

FOR FURTHER INFORMATION CONTACT: Tammy Adams or Amy Sloan, (301)713–2289.

SUPPLEMENTARY INFORMATION: The subject permits and permit amendments are requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222–226).

File No. 434–1669: Permit No. 434–1669, issued to ODFW on November 12, 2002 (67 FR 69724) authorizes takes of threatened Steller sea lions in California, Washington, and Oregon by capture, hot-branding, flipper tagging, collection of blood, tissue sampling, attachment external scientific instruments, harassment incidental to these activities and remote monitoring, and incidental mortality. The purpose of these activities is to continue monitoring the status of the Steller sea lion population in California, Oregon, and Washington. ODFW has requested an amendment to extend the duration of the permit for three years and also proposes to add a study on the effects of hot-brands. The proposed study of hot-brands does not include a request for an increase in numbers of animals captured and handled.

File No. 1010–1641: Permit No. 1010–1641, issued to AEB on November 12, 2002 (67 FR 69724), authorizes takes of Steller sea lions of all ages by harassment during aerial surveys and vessel-based behavioral observations in the western Gulf of Alaska, and scat collection at rookeries and haulouts along the Alaska Peninsula and Eastern Aleutian Islands. The permit also authorized mortality incidental to the research. AEB has requested an amendment to extend the duration of the permit, with an increase in the number of sea lions that may be harassed during aerial surveys annually. The purpose of the activities proposed by AEB is to provide additional information on seasonal prey consumption by Steller sea lions through analysis of scat collected at rookeries and haulouts along the Alaska Peninsula and Eastern Aleutian Islands, and to improve the accuracy and precision of population indices through expanded aerial and vessel surveys in the western Gulf of Alaska.

File No. 800–1664: Permit No. 800–1664, issued to Dr. Davis on November 12, 2002 (67 FR 69724), authorizes takes of threatened and endangered juvenile and adult female Steller sea lions in Alaska by capture, anesthesia, hot-branding, tissue sampling (including blood, skin, and blubber), attachment of scientific instruments (video system/data logger and satellite transmitters), and incidental mortality. Dr. Davis has requested an amendment to extend the duration of the permit and to modify some of the objectives and methods for taking Steller sea lions. The purpose of the activities proposed by Dr. Davis is to study the hunting behavior and three-dimensional movements of Steller sea lions. The results would be used, in conjunction with data on satellite remote sensing of hydrographic features, and on the abundance, distribution, and composition of prey at spatial and temporal scales, to address questions about Steller sea lion prey preference, predator/prey relationships, and ecological attributes of foraging habitat.

File No. 881–1668: Permit No. 881–1668, issued to the ASLC on November 12, 2002 (67 FR 69724), authorizes takes of threatened and endangered Steller sea lions in Alaska by capture, hot-branding, flipper tagging, collection of blood and tissue samples, attachment of external scientific instruments, incidental mortality, and harassment incidental to these activities and remote monitoring activities. The permit was amended on July 31, 2203 (68 FR 47294) to include capture and transport of up to 16 juvenile Steller sea lions per year to the ASLC for short-term captivity, health assessments (including anesthesia, blood sampling, blubber biopsy, diagnostic x-ray, endoscopy, bioelectric impedance analysis, deuterated water, and urinalysis), controlled fasting, and adrenocorticotrophic hormone challenge experiments. ASLC has requested permit amendments to extend the duration of the permit and modify some of the objectives, methods, and numbers of Steller sea lions taken. The ASLC states that the overall purpose of their activities, including the proposed amendments, is to collect information on the health status (e.g., morphometrics, body composition, immunology, epidemiology, endocrinology, viral serology), physiology (e.g., vitamin requirements, stress responses to capture, handling, and captivity), life history (e.g., ontogenetic and annual cycles, population dynamics), foraging behavior, and habitat use of Steller sea lions.

File No. 782–1768: The NMML has requested a five-year permit to collect information on the life history, foraging behavior, habitat use, physiology, population status and trends, survival and reproductive rates, and condition of Steller sea lions in the North Pacific. To accomplish this, NMML proposes to conduct aerial surveys and ground counts as well as capture, sample, and mark Steller sea lions. NMML has also requested a number of incidental mortalities.

File No. 358–1768: The ADF&G has requested a five-year permit to investigate the various hypotheses for the decline of Steller sea lions in western Alaska, including conducting studies of life history traits, physiological investigations of animal condition and time of weaning, and studies of animal movement and dive activity. To accomplish this, ADF&G proposes to conduct aerial surveys and ground counts as well as capture, sample, and mark Steller sea lions. ADF&G has also requested a number of incidental mortalities.

File No. 715–1784: The NPUMMRC has requested a five-year permit to collect data on sea lion distribution and diet compositions through aerial surveys of sea lion rookeries and haul outs in Southeast Alaska; collection of scat from rookeries and haul outs in Southeast Alaska; conducting

behavioral observations of sea lions on rookeries, haul outs and tagged sea lions at sea; and mortality incidental to research. The objectives of the study are to understand how diets vary temporally and spatially, and how this variation is related to population trends and abundance, nutritional stress, and commercial fishing activities.

File No. 1034–1773: Dr. Horning has requested a five-year permit to surgically implant dual ''Life History Transmitters'' into up to 80 free-ranging Steller sea lions ages nine months to four years, using ship-based surgical operations under gas anesthesia. The objectives of the proposed study are (1) to determine age specific survival rates for juvenile Steller sea ions, (2) to determine the time of year for the greatest mortality of juvenile Steller sea lions, (3) to determine approximate locations of mortalities, (4) to analyze ontogenetic and seasonal changes in the dive behavior and dive effort from deceased animals and relate these to environmental conditions and prey abundance as assessed by other groups, (5) to test the effects of body condition and health indicators on survival of juveniles, and (6) to assess the predictive power of parameters measurable in juvenile Steller sea lions for future survival. All animals captured would also be subject to comprehensive ''body condition and health assessments'' and would be hot-branded for future identification. Dr. Horning has also requested a number of incidental mortalities.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a draft Environmental Assessment (EA) has been prepared to examine whether significant environmental impacts could result from issuance of the proposed permits and permit amendments. The draft EA is available for review and comment simultaneous with the applications. The scope of the draft EA includes the following six environmental impact issues: (1) Is NMFS able to coordinate research under the various permits and ensure that activities are not unnecessarily duplicative and do not result in significant adverse impacts on threatened and endangered Steller sea lions? (2) Is NMFS able to adequately monitor the effects of the overall research program on Steller sea lions? (3) Can NMFS coordinate and synthesize the data generated by this research program in a way that is useful or meaningful for conservation of Steller sea lions? (4) Are all of the research proposals consistent with permit issuance criteria under the MMPA and ESA, such as whether all of the projects are likely to contribute to conservation of Steller sea lions? (5) Does the amount of incidental mortality to be authorized represent a significant adverse impact on Steller sea lions? (6) What are the potential effects of various research activities, either individually or cumulatively, on Steller sea lions as a species? Chapter 4 of the draft EA outlines NMFS analytical approach to evaluating alternatives.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the applications to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: March 29, 2005.

Stephen L. Leathery,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 05–6610 Filed 4–1–05; 8:45 am]

BILLING CODE 3510–22–S

COMMISSION OF FINE ARTS

Notice of Meeting

The next meeting of the Commission of Fine Arts is scheduled for April 21, 2005, at 10 a.m. in the Commission's offices at the National Building Museum, Suite 312, Judiciary Square, 401 F Street, NW., Washington, DC, 20001–2728. Items of discussion affecting the appearance of Washington, DC, may include buildings, parks and memorials.

Draft agendas and additional information regarding the Commission are available on our Web site: *http:www.cfa.gov.* Inquiries regarding the agenda and requests to submit written or oral statements should be addressed to Thomas Luebke, Secretary, Commission of Fine Arts, at the above address or call 202–504–2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated in Washington, DC, March 25, 2005.

Thomas Luebke,

Secretary.

[FR Doc. 05–6530 Filed 4–1–05; 8:45 am]

BILLING CODE 6330–01–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Request for Public Comments on Commercial Availability Petitionunder the United States-Caribbean Basin Trade Partnership Act(CBTPA)

March 31, 2005.

AGENCY: The Committee for the Implementation of Textile Agreements (CITA)

ACTION: Request for public comments concerning a request for a determinationthat certain 100 percent cotton, carbon-emerized, four-thread twill weavefabric cannot be supplied by the domestic industry in commercial quantitiesin a timely manner under the CBTPA.

SUMMARY: On March 29, 2005 the Chairman of CITA received a petition from Sandler,Travis, & Rosenberg, P.A., on behalf of their client, Dillard's Inc.,alleging that certain 100 percent cotton, carbon-emerized, four-threadtwill weave fabric, of the specifications detailed below, classified insubheading 5208.33.00.00 of the Harmonized Tariff Schedule of the UnitedStates (HTSUS), cannot be supplied by the domestic industry in commercialquantities in a timely manner. The petition requests that woven cottonshirts and blouses of such fabrics assembled in one or more CBTPAbeneficiary countries be eligible for preferential treatment under theCBTPA. CITA hereby solicits public comments on this request, in particularwith regard to whether such fabrics can be supplied by the domesticindustry in commercial quantities in a timely manner. Comments must besubmitted by April 19, 2005, to the Chairman, Committee for the Implementation of Textile Agreements,Room 3001, United States Department of Commerce, 14th and ConstitutionAvenue, N.W. Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textiles andApparel, U.S. Department of Commerce, (202) 482-3400.

SUPPLEMENTARY INFORMATION:

Authority: Section 213(b)(2)(A)(v)(II) of the Caribbean Basin Economic RecoveryAct, as added by Section 211(a) of the CBTPA; Section 6 of Executive OrderNo. 13191 of January 17, 2001.

BACKGROUND:

The CBTPA provides for quota- and duty-free treatment for qualifyingtextile and apparel products. Such treatment is

generally limited toproducts manufactured from yarns or fabrics formed in the United States ora beneficiary country. The CBTPA also provides for quota- and duty-freetreatment for apparel articles that are both cut (or knit-to-shape) andsewn or otherwise assembled in one or more CBTPA beneficiary countries fromfabric or yarn that is not formed in the United States, if it has beendetermined that such fabric or yarn cannot be supplied by the domesticindustry in commercial quantities in a timely manner. In Executive OrderNo. 13191, the President delegated to CITA the authority to determinewhether yarns or fabrics cannot be supplied by the domestic industry incommercial quantities in a timely manner under the CBTPA and directed CITAto establish procedures to ensure appropriate public participation in anysuch determination. On March 6, 2001, CITA published procedures that itwill follow in considering requests. (66 FR 13502).

On March 29, 2005 the Chairman of CITA received a petition on behalf ofDillard's Inc. alleging that certain 100 percent cotton, carbon emerized,four-thread twill weave fabrics, of the specifications detailed below,classified under HTSUS subheading 5208.33.00.00, for use in woven cottonshirts and blouses, cannot be supplied by the domestic industry incommercial quantities in a timely manner and requesting quota- andduty-free treatment under the CBTPA for apparel articles that are both cutand sewn in one or more CBTPA beneficiary countries from such fabrics.

Specifications:

HTS Subheading:	5208.33.00.00
Petitioner Style No.:	03842
Fiber Content:	100 percent cotton
Yarn Number:	39/1 - 41/1 metric combed ring spun warp; 39/1 - 41/1 carded ring spunfilling; overall average yarn number: 38 - 40 metric
Thread Count:	43 - 45 warp ends per centimeter; 24 - 26 filling picks percentimeter; total 61 - 71 threads per square centimeter
Weave:	4 thread twill
Weight:	176 - 182 grams per square meter
Width:	168 - 172 centimeters
Finish:	(Piece) dyed, carbon emerized on both sides

The petitioner states:

> The yarns must be ring spun, the warp yarn combed, and the fillingyarn carded. The yarn size and thread count and consequently, the weightof the fabric must be exactly or nearly exactly as specified in theaccompanying Exhibit or the fabric will not be suitable for its intendedus. The fabric must be carbon emerized, not napped, on both sides. Theinstant fabric has been lightly emerized on the technical back and somewhatmoreso on the face. Napping will produce a different and unacceptableproduct.

CITA is soliciting public comments regarding this request, particularlywith respect to whether these fabrics can be supplied by the domesticindustry in commercial quantities in a timely manner. Also relevant iswhether other fabrics that are supplied by the domestic industry incommercial quantities in a timely manner are substitutable for the fabricfor purposes of the intended use. Comments must be received no later thanApril 19, 2005. Interestedpersons are invited to submit six copies of such comments or information tothe Chairman, Committee for the Implementation of Textile Agreements, room3100, U.S. Department of Commerce, 14th and Constitution Avenue, N.W.,Washington, DC 20230.

If a comment alleges that these fabrics can be supplied by the domesticindustry in commercial quantities in a timely manner, CITA will closelyreview any supporting documentation, such as a signed statement by amanufacturer of the fabric stating that it produces the fabric that is thesubject of the request, including the quantities that can be supplied andthe time necessary to fill an order, as well as any relevant informationregarding past production.

CITA will protect any business confidential information that is marked''business confidential'' from disclosure to the full extentpermitted by law. CITA generally considers specific details, such asquantities and lead times for providing the subject product as businessconfidential. However, information such as the names of domesticmanufacturers who were contacted, questions concerning the capability tomanufacture the subject product, and the responses thereto should beavailable for public review to ensure proper public participation in theprocess. If this is not possible, an explanation of the necessity fortreating such information as business confidential must be provided. CITAwill make available to the public non-confidential versions of the requestand non-confidential versions of any public comments received with respectto a request in room 3100 in the Herbert Hoover Building, 14th andConstitution Avenue, N.W., Washington, DC 20230. Persons submittingcomments on a request are encouraged to include a non-confidential versionand a non-confidential summary.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of TextileAgreements.

[FR Doc. 05–6733 Filed 3–31–05; 3:53 pm]

BILLING CODE 3510–DS

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0101]

Federal Acquisition Regulation; Submission for OMB Review; Drug-Free Workplace

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning drug-free workplace. A request for public comments was published at 70 FR 5615 onFebruary 3, 2005. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, 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; ways to enhance the quality, utility, and clarity of the information to be collected; 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.

DATES: Submit comments on or before May 4, 2005.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the General Services

Administration, FAR Secretariat (VIR), 1800 F Street, NW, Room 4035, Washington, DC 20405. Please cite OMB Control No.9000–0101, drug-free workplace, in all correspondence.

FOR FURTHER INFORMATION CONTACT Craig Goral, Contract Policy Division, GSA (202) 501–3856.

SUPPLEMENTARY INFORMATION:

A. Purpose

The FAR clause at FAR 52.223–6, Drug-Free Workplace, requires (1) contract employees to notify their employer of any criminal drug statute conviction for a violation occurring in the workplace; and (2) Government contractors, after receiving notice of such conviction, to notify the contracting officer.

The information provided to the Government is used to determine contractor compliance with the statutory requirements to maintain a drug-free workplace.

B. Annual Reporting Burden

Respondents: 600.
Responses Per Respondent: 1.
Annual Responses: 600.
Hours Per Response: .17.
Total Burden Hours: 102.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (VIR), Room 4035, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0101, Drug-Free Workplace, in all correspondence.

Dated: March 24, 2005

Rodney P. Lantier

Director, Contract Policy Division.

[FR Doc. 05–6639 Filed 4–1–05; 8:45 am]

BILLING CODE 6820–EP–S

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0056]

Federal Acquisition Regulation; Submission for OMB Review; Report of Shipment

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning report of shipment. A request for public comments was published in the **Federal Register** at 70 FR 6423, on February 7, 2005. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, 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; ways to enhance the quality, utility, and clarity of the information to be collected; 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.

DATES: Submit comments on or before May 4, 2005.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat (VIR), 1800 F Streets, NW, Room 4035, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Jeritta Parnell, Contract Policy Division, GSA (202) 501–4082.

SUPPLEMENTARY INFORMATION:

A. Purpose

Military (and, as required, civilian agency) storage and distribution points, depots, and other receiving activities require advance notice of large shipments en-route from contractors' plants. Timely receipt of notices by the consignee transportation office precludes the incurring of demurrage and vehicle detention charges. The information is used to alert the receiving activity of the arrival of a large shipment.

*Respondents:*250.
Responses Per Respondent: 4.
Annual Responses: 1,000.
Hours Per Response: .167.
Total Burden Hours: 167.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, FAR Secretariat (VIR), Room 4035, 1800 F Street, NW, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0056, Report of Shipment, in all correspondence.

Dated: March 24, 2005

Rodney P. Lantier

Director,Contract Policy Division

[FR Doc. 05–6640 Filed 4–1–05; 8:45 am]

BILLING CODE 6820–EP–S

DEPARTMENT OF EDUCATION

Indian Education Demonstration Grants for Indian Children

AGENCY: Department of Education.

ACTION: Notice reopening the deadline for the Indian Education Demonstration Grants for Indian Children program.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.299A.

SUMMARY: On January 31, 2005 we published a notice in the **Federal Register** (70 FR 4822) that established a deadline of March 17, 2005 for mandatory electronic transmittal of applications for the fiscal year 2005 Indian Education Demonstration Grants for Indian Children competition through the Grants.gov system. The purpose of this notice is to reopen the notice inviting applications for this program, with a new deadline for transmittal of applications. The notice inviting applications is being reopened because some applicants may have experienced problems completing the multi-step Grants.gov registration process that prevented them from submitting timely applications or problems with server availability on the closing date.

DATES: The new deadline for the transmittal of applications or amendments to applications already submitted is April 25, 2005.

FOR FURTHER INFORMATION CONTACT: Lana Shaughnessy, Office of Indian Education, 400 Maryland Avenue, SW., Room 5C140, Washington, DC 20202–6335. Telephone: (202) 260–3774 or by e-mail: *oiegrants@ed.gov.*

Electronic Access to This Document

You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

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at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: March 29, 2005.

Victoria Vasques,

Assistant Deputy Secretary for Indian Education.

[FR Doc. 05–6581 Filed 4–1–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Indian Education Professional Development Grants

AGENCY: Department of Education.

ACTION: Notice reopening the deadline for the Indian Education Professional Development Grants program.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.299B.

SUMMARY: On January 31, 2005 we published a notice in the **Federal Register** (70 FR 4826) that established a deadline of March 17, 2005 for mandatory electronic transmittal of applications for the fiscal year 2005 Indian Education Professional Development Grants competition through the Grants.gov system. The purpose of this notice is to reopen the notice inviting applications for this program, with a new deadline for transmittal of applications. The notice inviting applications is being reopened because some applicants may have experienced problems completing the multi-step Grants.gov registration process that prevented them from submitting timely applications or problems with server availability on the closing date.

DATES: The new deadline for the transmittal of applications or amendments to applications already submitted is April 25, 2005.

FOR FURTHER INFORMATION CONTACT: Lana Shaughnessy, Office of Indian Education, 400 Maryland Avenue, SW., Room 5C140, Washington, DC 20202–6335. Telephone: (202) 260–3774 or by e-mail: *oiegrants@ed.gov*.

Electronic Access to This Document: You may view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister*.

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html*.

Dated: March 29, 2005.

Victoria Vasques,

Assistant Deputy Secretary for Indian Education.

[FR Doc. 05–6582 Filed 4–1–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board Chairs Meeting

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EMSSAB) Chairs. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, April 28, 2005, 8:30 a.m.–5:15 p.m.; Friday, April 29, 2005, 8:30 a.m.–12 p.m.

ADDRESSES: Augusta Towers Hotel & Conference Center (formerly the Sheraton Hotel), 2651 Perimeter Parkway, Augusta, GA 30909, (706) 855–8100.

FOR FURTHER INFORMATION CONTACT: Jay Vivari, Program Management Specialist (EM–30.1), Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–5143.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the EMSSAB is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

Thursday, April 28, 2005

8:30 a.m. Welcome and Overview. Jean Sulc, Savannah River Site (SRS) CAB Chair, welcome and introductions; Sandra Waisley, Designated Federal Officer, to open, followed by Mike Schoener, Facilitator, to review meeting objectives, agenda, and ground rules

8:45 a.m. Round Robin 1: Top Three Issues for Each Site-Specific Advisory Board Each Board has five minutes, followed by 30 minutes for questions and answers, and discussion

10 a.m. Break

10:15 a.m. Planning for the National Stakeholder Forum; members will discuss ideas for developing and conducting the National Stakeholder Forum on Waste Disposition

10:45 a.m. Stewardship Outreach; Presentation of the Oak Ridge Stewardship Education Resource Kit, followed by general discussion of stewardship outreach efforts across the complex

11:45 a.m. Public Comment Period

12 p.m. Lunch

1 p.m. Briefing by Principal Deputy Assistant Secretary Paul Golan (Tentative) and Chairs Discussion. Mr. Golan or his designee(s) will brief the Chairs on Accelerated Cleanup, the End States initiative and on Safety at EM Cleanup Sites. A discussion between Mr. Golan and the Chairs will follow the briefings

2:45 p.m. Break

3 p.m. Round Robin 2: Future of the EMSSAB (Part One). Site/SSAB Transfers from EM to Other DOE Offices. Each Board will have five minutes to describe the status of their individual site, indicating whether a transfer has or will soon occur from EM to another office within DOE, and the impact this transfer might have on the Board's future operation

3:45 p.m. Round Robin 2: Future of the EMSSAB (Part Two). General Discussion on the Impact of Site Transfers. Based on the information presented in Part One, the Chairs will discuss the impacts of these transfers on the EMSSAB as a whole

4:45 p.m. Public Comment Period

5 p.m. Review of Day One Discussions and Next Steps. Facilitated discussion of preliminary reactions to the information presented Friday, April 29, 2005

8:30 a.m. Opening; Welcome and Overview of Day Two Discussions

8:45 a.m. Consideration of National Forum Structure. Facilitated discussion to consider the structure

of the proposed National Forum on Waste Disposition
9:30 a.m. Planning for Future Chairs Meetings/Workshops
10 a.m. Break
10:15 a.m. DOE Organizational Updates. New Positions, Personnel and Budget, Acquisition Strategy (including A–76 Program: Competitive Sourcing)
11:30 a.m. Public Comment Period
11:45 a.m. Meeting Wrap-Up, Jean Sulc, SRS CAB Chair, Closing Remarks
12 p.m. Adjourn

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Jay Vivari at the address above or by telephone at (202) 586–5143. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: Minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585 between 9 a.m. and 4 p.m., Monday–Friday except Federal holidays. Minutes will also be available by calling Jay Vivari at (202) 586–5143.

Issued at Washington, DC on March 29, 2005.

Carol Matthews,

Acting Advisory Committee Officer.

[FR Doc. 05–6596 Filed 4–1–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Bonneville Power Administration

Big Horn Wind Energy Project

AGENCY: Bonneville Power Administration (BPA), Department of Energy (DOE).

ACTION: Notice of availability of Record of Decision (ROD).

SUMMARY: This notice announces the availability of the ROD to offer contract terms for interconnection of 200 megawatts of power to be generated by the proposed Big Horn Wind Energy Project into the Federal Columbia River Transmission System. The project would be interconnected at a proposed BPA switching substation along BPA's Big Eddy-Midway No. 1 230-kilovolt transmission line. The proposed BPA switching substation and Big Horn Wind Energy Project would be located near the town of Bickleton in Klickitat County, Washington. This decision is consistent with and tiered to BPA's Business Plan Environmental Impact Statement (DOE/EIS–0183, June 1995) and the Business Plan Record of Decision (August 15, 1995).

ADDRESSES: Copies of this ROD may be obtained by calling BPA's toll-free document request line, 1–800–622–4520. This ROD and the Business Plan EIS and ROD are also available on our Web site, *http://www.efw.bpa.gov.*

FOR FURTHER INFORMATION, CONTACT: Rick Yarde, Bonneville Power Administration—KEC–4, P.O. Box 3621, Portland, Oregon 97208–3621; toll-free telephone number 1–800–282–3713; fax number (503) 230–5699; or e-mail *rryarde@bpa.gov.*

Issued in Portland, Oregon, on March 24, 2005.

Stephen J. Wright,

Administrator and Chief Executive Officer.

[FR Doc. 05–6595 Filed 4–1–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

American Statistical Association Committee on Energy Statistics

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the American Statistical Association Committee on Energy Statistics with management and staff of the Energy Information Administration. The Federal Advisory Committee Act (Pub. L. 92–463,86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, April 28, 2005, 8:30 a.m.–5 p.m. Friday, April 29, 2005, 8:30 a.m.–12 noon.

ADDRESSES: U.S. Department of Energy, Room 8E–089, 1000 Independence Ave., SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Mr. William I. Weinig, EI–70, Advisory Committee Manager, Energy Information Administration, U.S. Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585. Telephone: (202) 287–1709. Alternately, Mr. Weinig may be contacted by e-mail at *william.weinig@eia.doe.gov* or by fax at (202) 287–1705.

Purpose of the Committee: To advise the Department of Energy, Energy Information Administration (EIA), on EIA technical statistical issues and to enable the EIA to benefit from the Committee's experience.

Tentative Agenda:

Thursday, April 28, 2005.

A. Opening Remarks by the ASA Committee Chair, the EIA Administrator and the Director, Statistics and Methods Group, EIA. Room 8E–089

B. Major Topics (Room 8E–089 unless otherwise noted)

1. Open Meeting.
2. Greetings and Remarks.
3. Updates for the Committee Since the Fall 2004, Meeting.
4. Regionalizing the Short-Term Energy Outlook (STEO) Forecast.
5. STEO Performance Indicators: Diagnostics and Forecast Errors.
6. STEO Electricity Modeling.
7. Bureau of Census Frames Comparisons (5E–069).
8. Invitation for Public Comments.
9. STEO Propane and Heating Oil Modules.
10. EIA's New Web site Design: Hands-On Usability Testing (BE–074).
11. Frames: What We Did, Our Results and Questions on What Next.
12. Residential Energy Consumption Survey (RECS): EIA's Proposed Reactions to Declining Response Rates.
13. Invitation for Public Comments.
14. Adjourn the Thursday Meeting.

Friday, April 29, 2005.

C. Major Topics

1. Assessments: Presentations and a Panel Discussion: External Review of Survey Progress; External Review of EIA Progress; Discussion: Where Next?
2. Progress on EIA's 914: Response Rate and Kinds of Challenges.
3. Estimate EIA's 826 Since the Last Time: Differences, Estimation Groups, Outliers and Test Results, Room 5E–069.
4. Committee Suggestions for the Fall 2005 Meeting.
5. Invitation for Public Comments.
6. Closing Remarks by the ASA Committee Chair.

Public Participation: The meeting is open to the public. The Chair of the Committee is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Written statements may be filed with the committee either before or after the meeting. If there are any questions,

please contact Mr. William I. Weinig, Advisory Committee Manager, at the address or telephone number listed above.

Minutes: A Meeting Summary and Transcript will subsequently be available through Mr. Weinig who may be contacted at (202) 287–1709 or by e-mail at *william.weinig@eia.doe.gov.*

Issued at Washington, DC, on March 29, 2005.

Carol Matthews,

Acting Advisory Committee Officer.

[FR Doc. 05–6594 Filed 4–1–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL05–82–000]

Alliant Energy Corporation Services, Inc., Complainant, v. Midwest Independent Transmission System Operator, Inc., Respondent; Notice of Complaint Fast Track

March 29, 2005.

Take notice that on March 28, 2005, Alliant Energy Corporate Services, Inc. (Alliant Energy), filed with the Federal Energy Regulatory Commission a Complaint Requesting Fast Track Processing against Midwest Independent Transmission System Operator, Inc. (Midwest ISO), to seek relief from Midwest ISO's failure to allocate certain Financial Transmission Rights.

Alliant Energy states that copies of the complaint were served on Midwest ISO.

Any person desiring 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. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protest must be served on the Complainants.

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 April 18, 2005.

Linda Mitry,

Deputy Secretary.

[FR Doc. E5–1485 Filed 4–1–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL05–81–000]

City of Westerville, OH, Complainant, v. Columbus Southern Power Company and American Electric Power Service Corporation, Respondents.; Notice of Complaint

March 29, 2005.

Take notice that on March 28, 2005, the City of Westerville, Ohio (Westerville) filed a formal complaint against Columbus Southern Power Company (CSP) and the American Electric Power Service Corporation (AEP) pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2000), and 18 CFR 385.206 (2004), seeking refunds for amounts associated with the Ohio Gross Receipts Tax that were included in CSP's Fuel Cost Adjustment during the period when CSP was exempted from and did not pay that tax, May 1, 2001, through December 31, 2003.

Westerville certifies that copies of the complaint were served on the CSP, AEP, and the Public Utilities Commission of Ohio.

Any person desiring 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. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protest must be served on the Complainants.

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 April 18, 2005.

Linda Mitry,

Deputy Secretary.

[FR Doc. E5–1486 Filed 4–1–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC05–48–000, *et al.*]

Kansas City Power & Light Company, et al.; Electric Rate and Corporate Filings

March 28, 2005.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. Kansas City Power & Light Company and Aquila, Inc.

[Docket No. EC05–48–000]

Take notice that on March 22, 2005, Kansas City Power & Light Company (KCPL) and Aquila, Inc., submitted an amended application pursuant to section 203 of the Federal Power Act for authorization of a disposition of jurisdictional facilities whereby KCPL seeks to sell a portion of KCPL's

transmission line known as Lake Road-Nashua Line to Aquila, Inc.

Comment Date: 5 p.m. eastern time on April 4, 2005.

2. Judith Gap Energy LLC; Spring Canyon Energy LLC

[Docket No. EC05–61–000]

Take notice that on March 21, 2005, Judith Gap Energy LLC (Judith Gap) and Spring Canyon Energy LLC (Spring Canyon) (collectively, Applicants) submitted an application pursuant to section 203 of the Federal Power Act for authorization of an indirect disposition of jurisdictional facilities through an upstream change in ownership of the Applicants that involves both an intra-corporate reorganization and the acquisition by one or more passive investors of an indirect non-voting, non-controlling equity interest in the Applicants (Transaction). Applicants state that once accepted for filing by the Commission, the jurisdictional facilities of the Applicants will be their respective market-based rate tariffs. Applicants further state that the transaction will not directly affect the Applicant's direct ownership of their respective jurisdictional facilities nor will the Transaction affect the operation of such facilities.

Comment Date: 5 p.m. eastern time on April 11, 2005.

3. New York Independent System Operator, Inc.

[Docket No. EL03–26–005]

Take notice that on March 21, 2005, the New York Independent System Operator, Inc. (NYISO) submitted a compliance filing in the above-referenced proceeding.

The NYISO states that it has electronically served a copy of this filing on the official representative of each of its customers, on each participant in its stakeholder committees, on the PSC, and on the electric utility regulatory agencies of New Jersey and Pennsylvania.

Comment Date: 5 p.m. eastern time on April 11, 2005.

4. PJM Interconnection, L.L.C.

[Docket No. ER03–1101–009]

Take notice that on March 22, 2005, PJM Interconnection, L.L.C. (PJM) filed the third of four six-month reports concerning the effects of PJM's credit policy for virtual bidders, as required by the Commission's September 22, 2003, Order in *PJM Interconnection, L.L.C.*, 104 FERC ¶ 61,309 (2003); *order on reh'g and compliance filings*, 109 FERC ¶ 61,286 (2004).

PJM states that copies of this filing have been served on all persons listed on the official service list compiled by the Secretary in this proceeding.

Comment Date: 5 p.m. eastern time on April 12, 2005.

5. California Independent System Operator Corporation

[Docket No. ER05–416–003]

Take notice that, on March 22, 2005, the California Independent System Operator Corporation (ISO) submitted an informational filing as to the ISO's revised transmission Access Charge rates effective January 1, 2005, to implement the revised Transmission Revenue Balancing Accounts of the current Participating Transmission Owners.

The ISO states that this filing has been served upon the Public Utilities Commission of the State of California, the California Energy Commission, the California Electricity Oversight Board, the Participating Transmission Owners, and upon all parties with effective Scheduling Coordinator Service Agreements under the ISO Tariff. In addition, the ISO states it is posting the filing on the ISO home page.

Comment Date: 5 p.m. eastern time on April 6, 2005.

6. Gexa Energy LLC

[Docket No. ER05–714–000]

Take notice that on March 21, 2005, Gexa Energy LLC (Gexa) submitted for filing its Rate Schedule FERC No. 1, under which Gexa seeks to engage in wholesale electric power and energy transactions as a retail marketer. Gexa further states that it is requesting the grant of certain blanket approvals and the waiver of certain applicable Commission regulations.

Comment Date: 5 p.m. eastern time on April 11, 2005.

7. ISO New England Inc.

[Docket No. ER05–715–000]

Take notice that on March 21, 2005, ISO New England Inc. (the ISO) filed the Installed Capacity Requirements for the 2005/2006 Power, which begins on June 1, 2005. The ISO requests an effective date of May 1, 2005.

The ISO states that copies of these materials were sent to the New England Power Pool Participants and the New England state governors and regulatory commissions.

Comment Date: 5 p.m. eastern time on April 11, 2005.

8. Unitil Energy Systems, Inc.

[Docket No. ER05–716–000]

Take notice that on March 22, 2005, Unitil Energy Systems, Inc. (UES) filed a Notice of Cancellation with the seeking to cancel its Rate Schedule FERC No. 3, including Supplements No. 1–3, which consist of a Wheeling Agreement and Interconnection Agreement with Concord Steam Corporation, a qualifying facility. UES requests that the cancellation be made effective as of January 26, 2005.

Comment Date: 5 p.m. eastern time on April 12, 2005.

9. Spring Canyon Energy LLC

[Docket No. ER05–717–000]

Take notice that on March 21, 2005, Spring Canyon Energy LLC (Applicant) filed an application for market-based rate authority and submitted Electric Tariff, Original Volume No. 1 for filing.

Comment Date: 5 p.m. eastern time on April 11, 2005.

10. Avista Corporation

[Docket No. ER05–720–000]

Take notice that on March 21, 2005, Avista Corporation submitted Original Service Agreement No. 321, which is an Agreement for Purchase and Sale of Power between Avista Corporation and Public Utility District No. 1 of Douglas County, Washington (hereinafter Service Agreement).

Avista states that copies of the filing were served upon Douglas, the sole party to the Service Agreement.

Comment Date: 5 p.m. eastern time on April 11, 2005.

11. Judith Gap Energy LLC

[Docket No. ER05–721–000]

Take notice that on March 21, 2005, Judith Gap Energy LLC (Applicant) filed an application for market-based rate authority and submitted Electric Tariff, Original Volume No. 1 for filing.

Comment Date: 5 p.m. eastern time on April 11, 2005.

Standard Paragraph

Any person desiring 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 comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all parties to this proceeding.

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.

Linda Mitry,

Deputy Secretary.

[FR Doc. E5–1484 Filed 4–1–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–324–008, et al.]

The Detroit Edison Company, et al.; Electric Rate and Corporate Filings

March 25, 2005.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

1. The Detroit Edison Company, DTE Energy Trading, Inc., DTE Edison America, Inc., DTE Energy Marketing, Inc., DTE Georgetown, L.P., DTE River Rouge No. 1, L.L.C., Crete Energy Venture, L.L.C.

[Docket Nos. ER97–324–008, ER97–3834–014, ER98–3026–009, ER99–3368–005, ER00–1746–003, ER00–1816–004, ER02–963–005]

Take notice that on March 21, 2005, The Detroit Edison Company, DTE Energy Trading, Inc., DTE Edison America, Inc., DTE Energy Marketing, Inc., DTE Georgetown, L.P., DTE River Rouge No. 1, L.L.C., and Crete Energy Venture, L.L.C. (collectively, the DTE Parties) submitted an amendment to their December 23, 2004 filing of an updated generation market power analysis.

The DTE Parties state that copies of the filing were served on parties on the official service list in these proceedings.

Comment Date: 5 p.m. eastern time on March 31, 2005.

2. Southwest Power Pool, Inc.

[Docket No. ER99–4392–006]

Take notice that on March 14, 2005, Southwest Power Pool, Inc. (SPP) submitted a compliance filing pursuant to the Commission's Order issued February 11, 2005, 110 FERC ¶ 61,133. SPP requested an effective date of March 15, 2005 for its compliance filing.

SPP states it has served a copy of this filing on all parties to the service list in this proceeding and all affected state commissions and also states that a complete copy will be posted on the SPP Web site *http://www.spp.org.*

Comment Date: 5 p.m. eastern time on April 5, 2005.

3. PJM Interconnection, L.L.C., Commonwealth Edison Co. and Commonwealth Edison Co. of Indiana

[Docket Nos. ER03–1335–004 and ER04–367–006]

Take notice that on March 18, 2005, PJM Interconnection, L.L.C. (PJM), in compliance with the Commission's December 22, 2004, Order,109 FERC ¶ 61,338, and the extension granted in this proceeding on January 25, 2005, submitted a refund report.

PJM states that copies of this filing have been served on all parties to these proceedings.

Comment Date: 5 p.m. eastern time on April 8, 2005.

4. PJM Interconnection, L.L.C.

[Docket No. ER04–608–004]

Take notice that on March 18, 2005, PJM Interconnection, L.L.C. (PJM) submitted a further status report on the stakeholder process regarding a proposal to expand the behind the meter generation rules to enable certain generation associated with a distribution system to be classified as behind the meter generation.

Comment Date: 5 p.m. eastern time on April 8, 2005.

5. Midwest Independent Transmission System Operator, Inc.

[Docket No. ER04–691–030]

Take notice that on March 18, 2005, Potomac Economics, Ltd. (Potomac Economics), the Independent Market Monitor for the Midwest Independent Transmission System Operator, Inc., submitted a compliance filing pursuant to the Commission's direction in its December 20, 2004 Order, 109 FERC ¶ 61, 285 (2004).

Potomac Economics states it has served a copy of this filing on the official service list.

Comment Date: 5 p.m. eastern time on April 8, 2005.

6. Florida Power & Light Company—New England Division

[Docket No. ER04–714–005]

Take notice that on March 14, 2005, Florida Power & Light Company—New England Division (FPL–NED), submitted a refund report in compliance with the Commission's Order issued January 26, 2005 in Docket No. ER04–714–000, 110 FERC ¶ 61,064.

Comment Date: 5 p.m. eastern time on April 5, 2005.

7. Trimont Wind I LLC

[Docket No. ER05–481–001]

Take notice that on March 4, 2005, Trimont Wind I LLC submitted a compliance filing pursuant to the Commission's March 2, 2005 Order, FERC ¶ 61,209 (March 2, 2005).

Comment Date: 5 p.m. eastern time on April 5, 2005.

8. Allegheny Power

[Docket No. ER05–512–001]

Take notice that on March 18, 2005 Monongahela Power Company, The Potomac Edison Company, and West Penn Power Company, all doing business as Allegheny Power, filed a limited revision to each of eight First Revised Interconnection and Operating Agreements entered into with Allegheny Power's affiliate, Allegheny Energy Supply Company, LLC (AE Supply) originally filed on January 31, 2005, in Docket No. ER05–512–000. Allegheny Power states that the purpose of the limit revisions is to revise the monthly charge set forth in the Agreements. Allegheny Power requests an effective date of April 1, 2005 for the agreements.

Allegheny Power states that a copy of the filing has been sent to AE Supply and PJM Interconnection, LLC.

Comment Date: 5 p.m. eastern time on April 4, 2005.

9. Westar Energy, Inc.

[Docket No. ER05–601–001]

Take notice that on March 14, 2005, Westar Energy, Inc. (Westar) submitted for filing a corrected Notice of Cancellation for Rate Schedule FERC No. 276, the Coal Participation Power Agreement between Westar and the City of Burlington, Kansas originally filed on February 3, 2005.

Comment Date: 5 p.m. eastern time on April 5, 2005.

10. Fitchburg Gas and Electric Light Company

[Docket No. ER05–620–001]

Take notice that on March 18, 2005, Fitchburg Gas and Electric Light Company submitted its First Revised Agreement for Network Integration

Transmission Service to Massachusetts Bay Transportation Authority under ISO New England, Inc. FERC Electric Tariff No. 3.

Fitchburg states that copies of the filing were served on Massachusetts Bay Transportation Authority and on the Massachusetts Department of Telecommunications and Energy.

Comment Date: 5 p.m. eastern time on April 8, 2005.

Standard Paragraph

Any person desiring 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 comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all parties to this proceeding.

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.

Linda Mitry,

Deputy Secretary.

[FR Doc. E5–1487 Filed 4–1–05; 8:45 am]

BILLING CODE 6717–01–P

EXPORT–IMPORT BANK OF THE UNITED STATES

Economic Impact Policy

This notice is to inform the public that the Export-Import Bank of the United States has received an application to finance the export of approximately $211.5 million in U.S. equipment and services to a petrochemicals facility in Qatar. The U.S. exports will enable the petrochemicals facility to produce approximately 1.3 million metric tons of ethylene as an intermediate product (of which 600,000 metric tons will be off-taken by a joint venture partner for its own use), 350,000 metric tons of high-density polyethylene per year and approximately 345,000 metric tons of normal alpha olefins per year.

Available information indicates the following: the ethylene to be off-taken by a joint venture partner will be consumed in Qatar; the high-density polyethylene will be consumed in Asia, Europe, Africa and the Middle East; and the normal alpha olefins will be consumed in Asia, Europe, the United States and the Middle East. Initial production is expected to commence in the latter part of 2008. Interested parties may submit comments on this transaction by e-mail to *economic.impact@exim.gov* or by mail to 811 Vermont Avenue, NW., Room 1238, Washington, DC 20571, within 14 days of the date this notice appears in the **Federal Register**.

Helene S. Walsh,

Director, Policy Oversight and Review.

[FR Doc. 05–6520 Filed 4–1–05; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission

March 25, 2005.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Pub. L. 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (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 the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before May 4, 2005. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments regarding this Paperwork Reduction Act submission to Judith B. Herman, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., DC 20554 or via the Internet to *Judith-B.Herman@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith B. Herman at 202–418–0214 or via the Internet at *Judith-B.Herman@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0734.

Title: Accounting Safeguards, CC Docket No. 96–150, 47 U.S.C. sections 260 and sections 271–276, Sections 54.209, 53.211, and 53.213.

Form No: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 50.

Estimated Time Per Response: 24–19,200 hours.

Frequency of Response: On occasion and biennial reporting requirements, third party disclosure requirement and recordkeeping requirement.

Total Annual Burden: 131,523 hours.

Total Annual Cost: $2,000,000.

Privacy Act Impact Assessment: N/A.

Needs and Uses: With this submission to the Office of Management and Budget (OMB), the Commission is extending this collection (no change in requirements) for this information collection in order to obtain the full three-year clearance from OMB. The Commission has adjusted the burden hours and burden costs to more accurately reflect the Commission's actual experience in conducting section 272 audits.

Under section 272 and the Commission's implementing rules, a Bell Operating Company (BOC) and its

section 272 affiliate may not jointly own transmission and switching equipment, although this restriction is subject to sunset. The separate section 272 affiliate must maintain separate books of account and have separate officers and directors. The separate section 272 affiliate may not obtain credit under arrangements that would permit the creditor to look to the assets of the BOC. The section 272 affiliate must conduct all transactions with the BOC on an arm's length basis, pursuant to the Commission's affiliate transaction rules, with the terms and conditions of such transactions reduced to writing and available for public inspection on the Internet. This collection has recordkeeping and reporting requirements. Section 272(d) states that companies required to maintain a separate affiliate ''shall obtain and pay for a Federal/State audit every two years conducted by an independent auditor to determine whether such company has complied with this section and the regulations promulgated under this section, and particularly whether such company has complied with the separate accounting requirements under [section 272(b)].'' The information collected in this submission to OMB is intended to prevent discrimination, cost misallocation and other anti-competitive conduct by the BOCs.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 05–6560 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted to OMB for Review and Approval

March 25, 2005.

SUMMARY: The Federal Communications Commissions, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (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 the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before May 4, 2005. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Cathy.Williams@fcc.gov* or Kristy L. LaLonde, Office of Management and Budget (OMB), Room 10236 NEOB, Washington, DC 20503, (202) 395–3087 or via the Internet at *Kristy_L._LaLonde@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information or copy of the information collection(s) contact Cathy Williams at (202) 418–2918 or via the Internet at *Cathy.Williams@fcc.gov*.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0016.

Title: Application for Authority to Construct or Make Changes to a Low Power TV, TV Translator, or TV Booster Station.

Form Number: FCC Form 346.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, local or tribal government.

Number of Respondents: 4,500.

Estimated Time Per Response: 7 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Total Annual Burden: 31,500 hours.

Total Annual Cost: $13,491,000.

Privacy Impact Assessment: No impact(s).

Needs and Uses: Licensees/permittees/applicants use FCC Form 346 to apply for authority to construct or make changes in a Low Power Television, TV Translator, or TV Booster broadcast station. On September 9, 2004, the Commission adopted a Report and Order, In the Matter of Parts 73 and 74 of the Commission's Rules to Established Rules for Digital Low Power Television, Television Translator, and Television Booster Stations and to Amend Rules for Digital Class A Television Stations, MB Docket Number 03–185, FCC 04–220. To implement the new rules, the Commission is revising FCC Form 346 to allow licensees/permittees/applicants to use the revised FCC Form 346 to file for digital broadcast stations or for conversion of their existing analog stations to digital stations.

Applicants are also subject to the third party disclosure requirements under 47 CFR 73.3580. Within 30 days of tendering the application, the applicant is required to publish a notice in a newspaper of general circulation when filing all applications for new or major changes in facilities—the notice is to appear at least twice a week for two consecutive weeks in a three-week period. A copy of this notice must be maintained with the application. FCC staff use the data to determine if the applicant is qualified, meets basic statutory and treaty requirements, and will not cause interference to other authorized broadcast services.

OMB Control Number: 3060–0027.

Title: Application for Construction Permit for Commercial Broadcast Station.

Form Number: FCC Form 301.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents: 3,247.

Estimated Time Per Response: 2 to 4 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Total Annual Burden: 8,380 hours.

Total Annual Cost: $44,630,924.

Privacy Impact Assessment: No impact(s).

Needs and Uses: FCC Form 301 is used to apply for authority to construct a new commercial AM, FM, or TV broadcast station, or to make changes in existing facilities of such a station. This collection also includes the third party disclosure requirement of 47 CFR 73.3580, requiring local public notice in a newspaper of general circulation of the filing of all construction permit applications. FM licensees or permittees may request, by application on FCC Form 301, upgrades on adjacent and co-channels, modifications to adjacent channels of the same class, and downgrades to adjacent channels

without first submitting a petition for rulemaking. All applicants using this one-step process must demonstrate that a suitable site exists which would comply with allotment standards with respect to minimum distance separation and city-grade coverage and which would be suitable for tower construction. To receive authorization for commencement of Digital Television (''DTV'') operation, commercial broadcast licensees must file FCC Form 301 for a construction permit. This application may be filed anytime after receiving the initial DTV allotment but must be filed before mid-point in a particular applicant's required construction period. The Commission will consider these applications as minor changes in facilities. Applications will not have to supply full legal or financial qualification information.

On June 24, 2004, the U.S. Court of Appeals for the Third Circuit (the ''Court'') issued an Opinion and Judgment (''*Remand Order*'') in which it upheld certain aspects of the Commission's new media ownership rules adopted on June 2, 2003 (*See* 18 FCC Rcd 13620 (2003)), specifically those dealing with local radio ownership, while requiring further explanation for all other aspects of the new rules. In particular, the Court held that the use of Arbitron Metro markets, the inclusion of noncommercial stations in determining radio market size, the attribution of joint sale agreements, and certain transfer restrictions are consistent with the Administrative Procedure Act. The Court stated that its prior stay of all new ownership rules would remain in effect pending the outcome of the remand proceeding. The Commission filed a petition for rehearing requesting that the Court lift the stay partially—*i.e.*, with respect to the radio ownership rules which the Court's *Remand Order* upheld. On September 3, 2004, the Court granted the Commission's petition, thus partially lifting the stay (''*Rehearing Order*''). As a result of the *Rehearing Order*, the new radio ownership rules took effect September 3, 2004.

Under the new radio ownership rules, radio Joint Sales Agreements (JSAs) are attributable and radio applicants are required to submit as a part of the FCC Form 301 a copy of any attributable JSA or time brokerage agreement.

OMB Control Number: 3060–0920.

Title: Application for Construction Permit for a Low Power FM Broadcast Station.

Form Number: FCC Form 318.

Type of Review: Extension of a currently approved collection

Respondents: Not-for-profit institutions; State, local or tribal government.

Number of Respondents: 2,283.

Estimated Time Per Response: 45 minutes to 6 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 6,315 hours.

Total Annual Cost: None.

Privacy Impact Assessment: No impact(s).

Needs and Uses: FCC Form 318 is required to apply for a construction permit for a new Low Power FM station, to make changes in the existing facilities of such a station, or to amend a pending FCC Form 318 application. The data is used by FCC staff to determine whether an applicant meets basic statutory and regulatory requirements to become a Commission licensee and to ensure that the public interest would be served by grant of the application.

OMB Control Number: 3060–0932.

Title: Application for Authority to Make Changes in a Class A TV Broadcast Station.

Form Number: FCC Form 301–CA.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, local or tribal government.

Number of Respondents: 650.

Estimated Time per Response: 7 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 4,550 hours.

Total Annual Cost: $3,703,700.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The FCC Form 301–CA is to be used in all cases by Class A television station licensees seeking to make changes in the authorized facilities of such station. The FCC Form 301–CA requires applicants to certify compliance with certain statutory and regulatory requirements. Detailed instructions provide additional information regarding Commission rules and policies.

On September 9, 2004, the Commission adopted a Report and Order, In the Matter of Parts 73 and 74 of the Commission's Rules to Established Rules for Digital Low Power Television, Television Translator, and Television Booster Stations and to Amend Rules for Digital Class A Television Stations, FCC 04–220, MB Docket Number 03–185. To implement these rules, the Commission is revising FCC Form 301–CA to allow licensees to use the revised FCC Form 301–CA to file for digital broadcast stations or conversion of their existing analog stations to digital stations.

Class A applicants are also subject to third party disclosure requirement of Section 73.3580 which requires local public notice in a newspaper of general circulation of the filing of all applications for major changes in facilities. This notice must be completed within 30 days of the tendering of the application. This notice must be published at least twice a week for two consecutive weeks in a three-week period. A copy of this notice must be placed in the public inspection file along with the application.

The FCC Form 301–CA is designed to track the standards and criteria which the Commission applies to determine compliance and to increase the reliability of applicant certifications.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 05–6561 Filed 4–1–05; 8:45 am]

BILLING CODE 6712–01–P

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 April 18, 2005.

A. Federal Reserve Bank of Kansas City (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. Joel H. Wiens, Cheyenne, Wyoming; to acquire voting shares of Union Bank Corporation, and thereby indirectly acquire voting shares of Union State Bank, both of Upton, Wyoming.

Board of Governors of the Federal Reserve System, March 29, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–6524 Filed 4–1–05; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Genetics, Health, and Society; Office of the Secretary, HHS; Request for Public Comment

ACTION: Request for public comment on a draft report on coverage and reimbursement of genetic tests and services.

SUMMARY: The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) is requesting public comment on a draft report on coverage and reimbursement of genetic tests and services.

DATES: Written or electronic comments should be submitted by May 6, 2005.

ADDRESSES: Comments can be sent by mail to the following address: Secretary's Advisory Committee on Genetics, Health, and Society, attn: Suzanne Goodwin, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, MD, 20892. Comments also can be sent via e-mail to Suzanne Goodwin at *goodwins@od.nih.gov* or via facsimile to 301–496–9839.

FOR FURTHER INFORMATION CONTACT: Suzanne Goodwin, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301–496–9838, *goodwins@od.nih.gov*.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies and, as warranted, to provide advice on these issues. For more information about the Committee, please visit its Web site: *http://www4.od.nih.gov/oba/sacghs.htm*.

In its first year, SACHGS identified coverage and reimbursement of genetic tests and services as a high priority because there are significant barriers to coverage and reimbursement as well as unmet data needs that are currently limiting appropriate access and clinical integration.

Its report, Coverage and Reimbursement of Genetic Tests and Services, describes the current state of, and problems associated with, coverage and reimbursement for genetic tests and services and offers recommendations on how current mechanisms for coverage and reimbursement for genetic tests and services might be improved. Once finalized, the report and recommendations will be transmitted to the Secretary of Health and Human Services.

SACGHS proposing to make the following recommendations in its report to the Secretary:

1. The Secretary should task an appropriate group or body to develop a set of principles to guide coverage decision making for genetic tests. The principles should identify criteria to help determine which types or categories of genetic tests should be covered, which should not be covered, and which fall into an uncertain gray zone. The group's guiding principles should address the issues of economic evaluation/cost-effectiveness, prevention, rare disease tests, and therapeutic versus informational benefit. The Committee also recommends that the existing evidence for specific tests be assessed in order to determine whether the evidence is adequate in type, quality, and quantity to establish analytical validity, clinical validity and clinical utility as well as to identify any gaps in evidence.

This body should include both relevant HHS agencies and private organizations and utilize resources of models in the public and private sector. The Evaluation of Genomic Applications in Practice and Prevention Work Group organized by the Centers for Disease Control and Prevention involves such a diverse range of stakeholders and is performing similar work and, thus, is an example of such a body to be tasked to develop these principles and address these issues.

The Committee also recommends a mechanism be established that would specifically promote and fund studies to address any identified gaps in the evidence base.

2. Genetic tests and services in pediatrics and those with a prevention component should be considered specifically with respect to the benefits they can offer the populations they serve. Although standardization of coverage decisions using best scientific evidence across public and private payers is ideal (see Recommendation 1), private payers should be supported with necessary information to make their own coverage determinations about these tests and services relative to the populations they serve.

3. Although a mixed national-local coverage decision-making process is a reasonable approach to making Medicare coverage decision for genetic tests and services, there are several aspects of the current national-local decision-making process that limit its utility. While not suggesting changes to the current system, SACGHS recommends that the Secretary encourage the Centers for Medicare & Medicaid Services (CMS) to move forward with the implementation of Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which requires the development of a plan to evaluate new local coverage decisions to determine which should be adopted nationally and to what extent greater consistency in Medicare coverage policy can be achieved.

4. Medicare beneficiaries who lack current signs, symptoms, or personal histories of illness stand to clinically benefit from predictive and predispositional genetic tests and services. As such, SACGHS recommends that preventive services, including predispositional genetic tests and services, meeting evidence standards should be covered under Medicare.

The Secretary should urge Congress to add a benefit category for preventive services that would enable CMS to determine through its national coverage decision-making process, which includes an assessment of existing evidence, whether an item or service is reasonable and necessary for the prevention or early detection of an illness or disability and, thus, ought to be covered. Such action would allow CMS to consider covering many more genetic tests and services that are used for preventive purposes.

More immediately, the Secretary should direct CMS to clarify, through appropriate guidance, that in certain circumstances and where scientific evidence warrants, ''personal history'' may include family history of a particular disease for purposes of establishing that a genetic test is ''reasonable and necessary'' and, therefore, covered under Medicare. CMS should specify the circumstances and criteria required to make such a determination.

5. The Secretary should broadly disseminate to all states information about the existing evidence base and other supporting information, such as guiding principles that serve as the basis for coverage decision-making, on genetic tests and services. This information could be utilized by the

states to inform their Medicaid coverage decisions.

HHS should continue to provide states with grants that encourage the coverage, adoption and provision of genetic services that have a sound evidence base.

6. In many cases, payment rates for genetic tests are lower than the actual cost of performing the test. Until the fee schedule can be reconsidered in a comprehensive way, the Secretary should direct CMS to address variations in payment rates for the genetic test Current Procedural Terminology (CPT) codes through its inherent reasonableness authority.

7. Genetic counseling is a critically important component of the appropriate use and integration of genetic tests and services. As such, SACGHS recommends the following:

- Qualified health providers should be allowed to bill directly for genetic counseling services. The Secretary should expeditiously identify an appropriate mechanism for determining the credentials and criteria needed for a health provider to be deemed qualified to provide genetic counseling services and eligible to bill directly for them.
- The Secretary should direct government programs to reimburse prolonged service codes when determined to be reasonable and necessary.
- HHS, with input from the various providers of genetic counseling services, should assess the adequacy of existing CPT Evaluation & Management (E&M) codes and their associated relative values with respect to genetic counseling services. Any inadequacies identified should be addressed as deemed appropriate.
- CMS should deem all non-physician health providers who are currently permitted to bill directly any health plan—public or private—eligible for a National Provider Identifier.
- The Secretary should direct CMS to allow non-physician health professionals who are qualified to provide genetic counseling services and who currently bill incident to a physician to utilize the full range of CPT E&M codes available for genetic counseling services.

8. Since providers act as intermediaries between health plans and plan members and thus have an important role in ensuring genetic tests and services are provided appropriately, there is a need to support the ongoing training and continued education of health providers in genetics and genomics. SACGHS's recommendations to the Secretary in 2004 included the following: the Secretary should develop a plan for HHS agencies to work collaboratively with state, federal and private organizations to support the development, cataloguing and dissemination of case studies and practice models that demonstrate the current relevance of genetics and genomics; and the Secretary should strive to incorporate genetics and genomics into relevant initiatives of HHS, including the National Health Information Infrastructure.

9. Reliable and trustworthy information about family history, genetics and genetic technologies should be developed and made more widely available through the internet and other mechanisms that allow patients and consumers to evaluate health plan benefits and health providers so that they may make the most appropriate and most financially responsible decisions for themselves and their families.

The Secretary should leverage HHS resources to develop and make widely available reliable and trustworthy information about genetics and genetic technologies to guide and promote informed decision making by healthcare consumers and providers. Such information should be made available though federal government Web sites and other appropriate mechanisms.

The full report is available electronically at *http://www4.od.nih.gov/oba/sacghs/public_comments.htm*. A paper or electronic copy also can be requested by calling the NIH Office of Biotechnology Activities at 301–496–9838– or by e-mailing Suzanne Goodwin at *goodwins@od.nih.gov*.

SACGHS is requesting comments on these recommendations and the overall content of the draft report. Public comments received by May 6, 2005, will be considered by SACGHS in preparing the final report. The report and the public comments will be discussed at SACGHS's next meeting on June 15–16, 2005, in Bethesda, MD. Comments also will be available for public inspection at the NIH Office of Biotechnology Activities Monday through Friday between the hours of 8:30 a.m. and 5 p.m.

Dated: March 28, 2005.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6614 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Preventing Sexual and Intimate Partner Violence Within Racial/Ethnic Minority Communities

Announcement Type: New.

Funding Opportunity Number: RFA 05043.

Catalog of Federal Domestic Assistance Number: 93.136.

Key Dates: Letter of Intent Deadline: May 4, 2005.

Application Deadline: May 19, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under section 391(a) of the Public Health Service Act (PHS Act), 42 U.S.C. 280b(a), section 393 of the PHS Act, 42 U.S.C. 280b–1a.

Background

The National Violence Against Women Survey (NVAWS) reports that approximately 1.5 million women are raped and/or physically assaulted by an intimate partner each year. Violence against women is a significant public health and criminal justice concern which disproportionately affects marginalized groups such as racial and ethnic minorities. This study further reports the racial and ethnic differences in the lifetime rates of rape, for example American Indian/Alaska Native women were identified as having almost twice the rate of African American or White women. Specifically, American Indian/Alaska Native women (34 percent) were significantly more likely to report that they were raped than African American women (19 percent) or White women (18 percent). The survey also found that women who identified themselves as Hispanic (14.6 percent) were significantly less likely to report they had ever been raped than women who identified themselves as non-Hispanic (18.4 percent). Additionally, American Indian/Alaska Native women (30.7 percent) were most likely to report Intimate Partner Violence, and Asian/Pacific Islander women (12.8 percent) were least likely to report Intimate Partner Violence. Other racial differences illustrate that close to one-third of African American women experience intimate partner violence in their lifetimes compared with one-fourth of White women. Furthermore, when you consider the rates for the most severe form of intimate partner violence, which is homicide, African American women (3.55) are three times as likely than White women (1.11) to die

as a result of intimate partner violence (CDC, 2001). There was little difference found in Hispanic (21.2 percent) and non-Hispanic women's (22.1 percent) reports of intimate partner violence.

More women than men experience intimate partner violence. According to the NVAWS, one out of four U.S. women has been physically assaulted or raped by an intimate partner and 1 out of every 14 U.S. men reported such an experience (Tjaden & Thoennes, 2000). Although women exhibit violent behavior in relationships with men and violence is also sometimes found in same sex partnerships, the overwhelming burden of intimate partner violence is experienced by women at the hands of men. Studies have consistently shown that in the case of female victims of sexual abuse, over 90 percent of the perpetrators are men (World Report on Violence and Health, 2002). Also, data from the NVAWS shows that 91.9 percent of the women reported that they were physically assaulted by a male (Tjaden & Thoennes, 2000). Therefore, there is a great need to work with men and boys as community leaders and change agents to prevent sexual violence/intimate partner violence (SV/IPV). As previously indicated, research suggests that racial/ethnic minorities bear a greater potential risk of victimization.

Purpose: The purpose of this program announcement is to integrate prevention principles, concepts and practices into racial/ethnic minority community efforts to address sexual and intimate partner violence. This program is intended to assist racial/ethnic minority communities to assess and prevent sexual and intimate partner violence. An emphasis will be placed on building capacity to work with men and boys in a culturally appropriate manner to prevent these forms of violence before they occur. The outcomes of interest will be achieved through four key processes: collaboration, planning, implementation, and evaluation. This program addresses the ''Healthy People 2010'' focus area(s) of Injury and Violence Prevention.

For the purposes of this program announcement the following definitions apply:

Sexual Violence (SV) includes a wide range of acts that occur in a variety of settings. There are four types of sexual violence (Basile & Saltzman, 2002): (1) A completed sex act without the victim's consent, or involving a victim who is unable to provide consent or refuse. A sex act is defined as contact between the penis and the vulva or the penis and the anus involving penetration, however slight; contact between the mouth and penis, vulva, or anus; or penetration of the anal or genital opening of another person by a hand, finger, or other object. (2) An attempted (but not completed) sex act without the victim's consent, or involving a victim who is unable to provide consent or refuse. (3) Abusive sexual contact including intentional touching, either directly or through the clothing, of the genitalia, anus, groin, breast, inner thigh, or buttocks of any person without his or her consent, or of a person who is unable to consent or refuse. (4) Non-contact sexual abuse including voyeurism; intentional exposure of an individual to exhibitionism; pornography; verbal or behavioral sexual harassment; threats of sexual violence to accomplish some other end; or taking nude photographs of a sexual nature of another person without his or her consent or knowledge, or of a person who is unable to consent or refuse.

Intimate Partner Violence (IPV) is actual or threatened physical or sexual violence or psychological and emotional abuse directed toward a spouse, ex-spouse, current or former boyfriend or girlfriend, or current or former dating partner. Intimate partners represent various types of relationships and may be heterosexual or of the same sex. Some of the common terms used to describe intimate partner violence are domestic abuse, spouse abuse, domestic violence, courtship violence, battering, marital rape, and date rape (Saltzman, *et al.* 1999).

Primary Prevention—Individual, relationship or family, and/or community level strategies, policies and actions that prevent violence from initially occurring, including risk reduction. Primary prevention efforts work to modify and/or entirely eliminate the event, conditions, situations, or exposure to influences (risk factors) that result in the initiation of violence and associated injuries, disabilities, and deaths. Additionally, prevention efforts seek to identify and enhance protective factors that may prevent violence not only in at-risk populations but also in the community at large.

Racial/Ethnic Minority Communities—For the purpose of this program announcement, racial minorities are African American, American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander. Ethnicity refers to Hispanic populations. Racial/ethnic minority communities are identified as experiencing a higher incidence and prevalence of SV/IPV as compared to the national average.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Injury Prevention and Control (NCIPC): Goal 1—Increase the capacity of injury prevention and control programs to address prevention of injuries and violence. This announcement is only for non-research activities supported by the Centers for Disease Control and Prevention. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address: *http://www.cdc.gov/od/ads/opspoll1.htm.*

Activities

Awardee activities for this program are as follows:

1. Conduct:

- An assessment of existing data that describes the known risk and protective factors related to the perpetration of SV/IPV within racial/ethnic minority populations.
- An analysis of existing program inventories directed at identifying program models and efforts to involve men and boys in ending SV/IPV and to determine the extent to which such efforts are reaching and/or applicable to working within racial/ethnic minority communities.
- An assessment of Baseline Knowledge, Attitudes, Beliefs and Behaviors (KABB) related to the prevention of SV/IPV. Examples can include men and boys knowledge, attitudes, beliefs or behavior around bystander action in relation to individual behavior and personal responsibility; assets or barriers at the community level; characteristics of community norms related to SV/IPV.

2. Create a leadership consortium. The leadership consortium must include participation from the recipient agency, and a minimum of four other agencies/organizations. The five organizations/agencies must represent and bring together a focus and understanding within the following areas of expertise:

- Sexual violence and intimate partner violence, including risk reduction and other public health approaches to preventing SV/IPV.
- Community leaders.
- Effective strategies to engage men and boys in preventing SV/IPV.
- Public health.
- Program evaluation.

3. Create an advisory committee that includes public and private partners that can facilitate reaching men and boys and other partners. The applicant should distinguish the function of the

advisory committee from those of the leadership consortium.

4. Participate in a cross-site evaluation.

5. Develop or adapt a culturally relevant program model that engages men and boys in the prevention of SV/IPV. The awardee should take into consideration relevance and community salience and existing program models identified through the analysis of existing program inventories.

6. Deliver, test and evaluate this program model in at least one and no more than three communities. This program model should include efforts addressing multiple system levels of prevention (at least 2, individual, relationship, and/or, community). *Note:* Five to ten percent of the Awardee's budget should be allocated to support the evaluation component of this project (*e.g.* staff time, travel, subject matter expert speaker, data collection).

7. Develop and implement a comprehensive evaluation plan that supports:

- Baseline and follow-up assessments and the formative work necessary to develop and test the program model
- A logic model to support building capacity to work with men and boys in a culturally appropriate manner to prevent SV/IPV before they occur.
- Data collection required to assess the capacity building measures and impact of this program model

Activities to build capacity within Awardee's Organization:

- Participate in training and technical assistance activities and opportunities directly related to this program announcement provided by CDC and training and technical assistance activities and opportunities indirectly related to this program announcement (*i.e.* UNC PREVENT) where appropriate and feasible.
- Institutionalize prevention principles, concepts and practices within the recipient organization beyond the knowledge and skills of the funded program staff.
- Establish a two-way process for systems to monitor and provide feedback to and from racial/ethnic minority communities.
- Compile and disseminate program results, including but not limited to dissemination to other organizations that serve racial/ethnic minority communities and relevant CDC programs (Rape Prevention and Education RPE), Domestic Violence Prevention Enhancements Through Leadership and Alliances (DELTA), Enhancing State Capacity to Address Child and Adolescent Health Through Violence Prevention (ESCAPe).

Awardee activities to build capacity in racial/ethnic minority communities (in at least one and not more than three):

- Provide primary prevention-focused training (including risk reduction), technical assistance and funding. The awardee should establish and describe relevant selection criteria for the determination of these communities. Primary prevention-focused training and technical assistance for programs on working with men and boys to prevent SV/IPV should meet the definition of prevention principles, concepts and practices.
- Provide training and technical assistance to communities for programs on working with men and boys on the concepts of SV/IPV prevention including risk reduction, individual behavior change, community organizing, strategic planning, program development implementation and evaluation.
- Support and provide assistance to communities on the selected program model. Monitor the activities of the community to ensure that the model program is implemented in a comprehensive manner and with fidelity to the tested model.
- Assist communities in the development of an evaluation plan and monitor the extent to which this plan is implemented.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

1. Participate in the translation of prevention principles, concepts and practices into prevention-focused activities, strategies, and policies that can be integrated into the program model.

2. Provide guidance on how to identify an evaluation contractor and approving the hire of applicant's evaluation contractor.

3. Approve the staff and contractors funded through the program.

4. Provide support and assistance in the evaluation of the program model to be implemented within 1–3 communities (see Awardee Activity #5).

5. Facilitate and provide technical assistance for the cross-site evaluation.

6. Coordinate capacity-building prevention-focused training and technical assistance for the grantee.

7. Provide assistance in the management and technical performance of the implementation of prevention principles, concepts, practices, leadership, activities, and strategies.

8. Arrange for information sharing with other CDC grantees including but not limited to DELTA, RPE, and ESCAPe.

9. Share new evaluation/research information.

II. Award Information

Type of Award: Cooperative Agreement. CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: 2005.

Approximate Total Funding: $300,000.

Approximate Number of Awards: Two.

Approximate Average Award: $150,000. (This amount is for the first 12-month budget period, and includes both direct and indirect costs.)

Floor of Award Range: $150,000 (CDC will not make an award smaller than the floor amount).

Ceiling of Award Range: $150,000. (This ceiling is for the first 12-month budget period. CDC will not make an award for larger than the ceiling amount.)

Anticipated Award Date: September 29, 2005.

Budget Period Length: 12 months.

Project Period Length: Three years with a possibility for five years total. (An initial three-year project period is specified with the anticipation of an additional two years with year four and five contingent on the accomplishment of very specific outcomes in years one through three.)

Milestones and success necessary to continue into Years four and five.

The awardee has developed and implemented an inventory and series of KABB assessments that address the following:

- The presence or absence of efforts that are directed at engaging men and boys in ending SV/IPV.
- The individual, organizational and community level indicators that represent assets or barriers to implementing prevention strategies.
- The awardee has developed a leadership consortium comprised of adequate representation as outlined in the program announcement and has implemented a feedback mechanism that assesses the contribution and role of member organizations.
- The awardee has developed or modified an advisory committee comprised of adequate representation as outlined in the program announcement and has implemented a feedback mechanism that assesses the contribution and role of each member organization.
- The awardee has developed and tested (formative) a culturally relevant program model for working with men and boys in the prevention of SV/IPV.

• The awardee has developed a program logic model that specifies short term or intermediate markers (KABB, community capacity measures, *etc.*).

• The awardee has developed selection criteria to be used to objectively assess the sites being considered for the implementation of the program model.

• Implementation of the program model has been initiated in no more than three program sites.

• An evaluation plan has been developed, measures identified or developed and the baseline data collected.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the applicant (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

This program is directed to:

• Public and private nonprofit organizations with at least three years experience in addressing violence against women or women's health issues at a regional or national level. They must also demonstrate that 85 percent of the population served within the last three years represent one racial/ethnic minority population.

—Or—

• Regional or national organizations representing consortia or coalitions of American Indian communities or Alaska Native villages. Examples of such organizations would include area or regional health boards, inter-tribal councils, tribal chairmen's health boards.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

Special Requirements

If your application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

• Late applications will be considered non-responsive. See section ''IV.3. Submission Dates and Times'' for more information on deadlines.

• The application is required to clearly specify the one racial/ethnic community to be served.

• Non-profit 501(c)(3) status—provide copy of IRS determination letter with LOI and application.

• **Note:** Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity use application form PHS 5161–1.

Electronic Submission

CDC strongly encourages you to submit your application electronically by utilizing the forms and instructions posted for this announcement on *http://www.Grants.gov,* the official Federal agency wide E-grant Web site. Only applicants who apply online are permitted to forego paper copy submission of all application forms.

Paper Submission

Application forms and instructions are available on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

Pre-Application Conference Call

For interested applicants, one pre-application technical assistance call will be conducted. The call will be held for one hour on April 19, 2005, from 2–3 p.m. e.s.t. Please e-mail Rebeca Lee-Pethel at *rlee-pethel@cdc.gov* by April 11, 2005, to request the conference call number and code. The conference call number and code will be provided via e-mail. The conference call name is Preventing Sexual and Intimate Partner Violence within Racial/Ethnic Minority Communities.

IV.2. Content and Form of Submission

Letter of Intent (LOI): Your LOI must be written in the following format:

• Maximum number of pages: Two.
• Font size: 12-point unreduced.
• Double spaced.
• Paper size: 8.5 by 11 inches.
• Page margin size: One inch.
• Printed only on one side of page.
• Written in plain language, avoid jargon.

Your LOI must contain the following information:

• Name of organization.
• Stated intent to submit an application for the Preventing Sexual and Intimate Partner Violence within Racial/Ethnic Minority Communities and clearly specifying the one racial/ethnic community to be served.
• Signature of Program Official and Financial Officer.
• IRS 501(c)(3) determination letter as page 2.

Application

Electronic Submission: You may submit your application electronically at: *http://www.grants.gov.* Applications completed online through Grants.gov are considered formally submitted when the applicant organization's Authorizing Official electronically submits the application to *http://www.grants.gov.* Electronic applications will be considered as having met the deadline if the application has been submitted electronically by the applicant organization's Authorizing Official to Grants.gov on or before the deadline date and time.

It is strongly recommended that you submit your grant application using Microsoft Office products (*e.g.*, Microsoft Word, Microsoft Excel, *etc.*). If you do not have access to Microsoft Office products, you may submit a PDF file. Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than Microsoft Office or PDF may result in your file being unreadable by our staff.

CDC recommends that you submit your application to Grants.gov early enough to resolve any unanticipated difficulties prior to the deadline. You may also submit a back-up paper submission of your application. Any such paper submission must be received in accordance with the requirements for timely submission detailed in Section IV.3. of the grant announcement. The paper submission must be clearly marked: ''BACK-UP FOR ELECTRONIC SUBMISSION.'' The paper submission must conform with all requirements for non-electronic submissions. If both electronic and back-up paper submissions are received by the deadline, the electronic version will be considered the official submission.

Paper Submission: If you plan to submit your application by hard copy, submit the original and two hard copies of your application by mail or express delivery service. Refer to section IV.6. Other Submission Requirements for submission address.

You must submit a project narrative with your application forms. The

narrative must be submitted in the following format:

- Maximum number of pages: 25—If your narrative exceeds the page limit, only the first 25 pages will be reviewed.
- Font size: 12 point unreduced.
- Double spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire 3 year project period, and must include the following items in the order listed:

1. Applicant Organization History, Description and Capacity.
2. Applicant's Plan for Implementing This Cooperative Agreement.
3. Collaboration.
4. Evaluation.
5. Applicant's Management and Staffing.
6. Measures of Effectiveness.
7. Budget Justification (does not count towards 25 page limit).

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit (do not use staples). This additional information includes:

1. Curriculum Vitae.
2. Job Descriptions.
3. Resumes.
4. Organizational Charts.
5. Letters of Support, *etc.*
6. Logic Model.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.* If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section ''VI.2. Administrative and National Policy Requirements.''

IV.3. Submission Dates and Times

LOI Deadline Date: May 4, 2005. CDC requests that you submit a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into review of your subsequent application, the LOI will be used to gauged the level of interest in this program, and to allow CDC to plan the application review.

Application Deadline Date: May 19, 2005.

Explanation of Deadlines: LOIs and Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date. If you submit your LOI or application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives your submission after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

This announcement is the definitive guide on LOI and application content, submission address, and deadline. It supersedes information provided in the application instructions. If your submission does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that you did not meet the submission requirements.

Electronic Submission: If you submit your application electronically with Grants.gov, your application will be electronically time/date stamped which will serve as receipt of submission. In turn, you will receive an e-mail notice of receipt when CDC receives the application. All electronic applications must be submitted by 4 p.m. Eastern Time on the application due date.

Paper Submission: CDC will *not* notify you upon receipt of your paper submission. If you have a question about the receipt of your LOI or application, first contact your courier. If you still have a question, contact the PGO–TIM staff at: 770–488–2700. Before calling, please wait two to three days after the submission deadline. This will allow time for submissions to be processed and logged.

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

IV.5. Funding restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- Funds may not be used for research.
- Reimbursement of pre-award costs is not allowed.
- Budgets for each program year should include travel costs for a representative from each of the organizations on the leadership consortium and the applicant's evaluation contractor to attend a 3-day planning and training meeting in Atlanta, Georgia with CDC staff.
- Applicants are required, at a minimum, to have the equivalent of one full time employee assigned to the programmatic activities.
- Funding may not be used for construction.
- Funding may be used to purchase computer equipment and software and internet connection equipment and software.
- Funding may not be used to provide direct services to victims or perpetrators of SV/IPV.
- Funding will not be given to two applicants representing the same racial/ethnic minority population. It is necessary for the project to ensure that funding will go towards more than one particular racial or ethnic minority.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age. Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/funding/budgetguide.htm.*

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, or delivery service to: Rebeca Lee-Pethel, Project Officer, National Center for Injury Prevention and Control, Koger/Vanderbilt Building, 2939 Flowers Road, Atlanta, GA 30341, Telephone: 770–488–1224, Fax: 770–488–1360, E-mail: *rlee-pethel@cdc.gov.*

Application Submission Address

Electronic Submission: CDC strongly encourages applicants to submit electronically at: *http://www.grants.gov.* You will be able to download a copy of the application package from *http://www.grants.gov*, complete it offline, and then upload and submit the application via the Grants.gov site. E-mail

submissions will not be accepted. If you are having technical difficulties in Grants.gov they can be reached by e-mail at *support@grants.gov* or by phone at 1–800–518–4726 (1–800–518–GRANTS). The Customer Support Center is open from 7 a.m. to 9 p.m. eastern time, Monday through Friday.

Paper Submission: If you chose to submit a paper application, submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—RFA 05043, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

V. Application Review Information

V.1. Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives within the Purpose and Awardee Activities sections of the cooperative agreement. Measures effectiveness must relate to the performance goals stated in the ''Purpose'' section of this announcement: Increase the capacity of injury prevention and control programs to address the prevention of injuries and violence. Measures must be objective and quantitative, and must measure the intended outcome. Applicants are expected to develop four measures of effectiveness, one for each level of capacity-building: collaboration, planning, implementation and evaluation. Measures of effectiveness will be an element of evaluation.

Your application will be evaluated against the following criteria:

1. Plans for Development and Implementation (30 Points)

a. Does the applicant adequately describe the problem of SV/IPV within the population they serve? Is this supported by government reports and credible research sources?

b. Does the applicant describe plans for conducting an assessment of existing data that describes known risk and protective factors for SV/IPV within one specific racial/ethnic community?

c. Does the applicant describe plans for conducting an analysis of existing prevention program inventories?

d. Does the applicant describe plans for conducting a baseline assessment of Knowledge, Attitudes, Beliefs and Behaviors (KABB) and community assets and barriers related to the prevention of SV/IPV?

e. Does the applicant describe plans for selecting the one to three racial/ethnic communities for technical assistance and funding?

f. Does the applicant describe plans for developing the leadership consortium?

g. Does the applicant describe plans for developing an advisory committee?

h. Does the applicant include plans for working with CDC, the advisory committee and leadership consortium to reach consensus and uniformity in selecting core measures, tools and processes for capacity building measures and the program model development and implementation?

i. Does the applicant demonstrate a clear plan for effectively involving various stakeholders (state, local, regional, and/or racial/ethnic minority communities) in the assessment and planning processes?

j. Is the plan adequate to carry out the proposed objectives? Are the proposed methods feasible and to what extent will they accomplish the program goals? Are the goals and objectives specific, measurable, achievable, realistic and time-specific? Are roles and responsibilities clearly identified?

k. Does the applicant describe a plan to identify model programs or resources that are directed to work with men and boys and a plan for testing these messages, strategies and approaches with approaches within one racial/ethnic minority community?

2. Applicant Organization History, Description and Capacity (25 Points)

a. Does the applicant demonstrate its history and capacity in providing leadership and guidance to racial/ethnic minority community efforts, including a clear description of its linkages with and role in support for the racial/ethnic minority community addressed in this proposal? Does the applicant demonstrate 85 percent of the population they serve are of the racial/ethnic minority group proposed in this application? Does the applicant demonstrate experience addressing violence against women or women's health issues (minimum of three years)?

b. Does the applicant demonstrate its experience as well as its current ability to provide leadership at a regional or national organizational level?

c. Does the applicant demonstrate its experience and a description of its current capacity to provide leadership in involving other agencies?

d. Does the applicant demonstrate its organizational experience and current capacity to provide training and technical assistance?

e. Does the applicant demonstrate experience in developing and implementing an evaluation plan? Does the applicant have experience using data to determine organizational priorities?

3. Collaboration (20 Points)

a. Does the applicant describe the composition, role and involvement of the leadership consortium, and identify or propose participants representing a broad range of disciplines that include expertise in SV/IPV, Tribal or community leaders and/or elders, prevention and public health approaches to preventing SV/IPV, and evaluation?

b. Does the applicant include resource agreements between leadership consortium agencies (this can be included as direct contracts or in-kind reflected within the proposed budget)? Does the applicant include memorandum of agreement or contractual agreements with the leadership consortium organizations? Does the applicant describe how the partner organizations will be involved in the data identification, collection, *etc*?

c. Does the applicant describe the composition, role and involvement of the advisory committee, and identify or propose participants representing public and private partners that can facilitate reaching men and boys and other partners?

d. Does the applicant describe the roles and responsibilities for both the advisory committee and leadership consortium? Does the applicant describe how these two groups will work together?

e. Does the applicant demonstrate a willingness to collaborate with CDC on all aspects of this project? Does the applicant demonstrate a willingness to collaborate with relevant CDC awardees and partners?

f. Does the applicant demonstrate experience and leadership in working with racial/ethnic minority communities by also including letters of support and/or memoranda of agreement from organizations, research and/or academic experts/institutions, and other agencies and organizations, including public health agencies and organizations that work with racial/ethnic minority communities and agencies working with men and boys?

4. Evaluation (15 Points)

a. Does the applicant provide a draft logic model that supports building capacity to work with men and boys in a culturally appropriate manner to prevent SV/IPV before they occur and represents the program model being delivered? Does this draft logic model identify outcome measures at a minimum of 2 levels and include

individual behavior and personal responsibility? For assistance on how to design a logic model, access CDC's Web site: *http://www.cdc.gov/nccdphp/dnpa/physical/handbook/step2.htm*.

b. Does the applicant demonstrate a willingness to collaborate with CDC evaluation experts?

c. Does the applicant allocate 5–10 percent of the budget to support the evaluation component of this project?

5. Staffing (10 Points)

a. Does the applicant describe the responsibilities of individual staff members, including their level of effort and allocation of time? Does the applicant identify at least one full time employee to manage this project?

b. Does the applicant describe project staff and their relevant skills and expertise working with racial/ethnic minority communities and for their assigned tasks relative to this announcement? Are Curriculum Vitas and job descriptions provided?

c. Does the applicant include an organizational chart?

6. Measures of Effectiveness (Not Scored)

7. Proposed Budget and Justification (Not Scored)

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Center for Injury Prevention and Control (NCIPC). Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel comprised of CDC employees will evaluate complete and responsive applications according to the criteria listed in the ''V.1. Criteria'' section above. In addition, the following factors may affect the funding decision:

- Maintaining geographic diversity.
- Ensuring that racial/ethnic minority communities are represented by funding two applicants which reflect racial/ethnic minority communities who experience a higher incidence and prevalence of SV/IPV as compared to the national average through adequate service experience and organizational representation.
- Ensuring that the two awardees are not representing the same racial/ethnic minority population.

CDC will provide justification for any decision to fund out of rank order.

V.3. Anticipated Announcement and Award Dates

Anticipated Announcement Date: September 1, 2005.

Anticipated Award Date: September 1, 2005.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Award (NOA) from the CDC Procurement and Grants Office. The NOA shall be the only binding, authorizing document between the applicant and CDC. The NOA will be signed by an authorized Grants Management Officer, and mailed to the applicant fiscal officer identified in the application. Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html*.

An additional Certifications form from the PHS5161–1 application needs to be included in your Grants.gov electronic submission only. Refer to *http://www.cdc.gov/od/pgo/funding/PHS5161–1-Certificates.pdf*. Once the form is filled out attach it to your Grants.gov submission as Other Attachments Form.

The following additional requirements apply to this project:

- AR–9 Paperwork Reduction Act Requirements.
- AR–10 Smoke-Free Workplace Requirements.
- AR–11 Healthy People 2010.
- AR–12 Lobbying Restrictions.
- AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities.
- AR–14 Accounting System Requirements.
- AR–15 Proof of Non-Profit Status.
- AR–16 Security Clearance Requirement.
- AR–25 Release and Sharing of Data.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm*.

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, due no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives (for first six months of budget period).

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives (provides updated logic models and narratives).

d. Budget.

e. Measures of Effectiveness.

f. Additional Requested Information.

2. Annual progress report, due 90 days after the end of the budget period.

a. Current Budget Period Activities Objectives (for second six months of budget period).

b. New Budget Period Program Proposed Activity Objectives (provides updated logic models and narratives).

c. Measures of Effectiveness.

d. Additional Requested Information.

3. Financial status report, due no more than 90 days after the end of the budget period.

4. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

We encourage inquiries concerning this announcement. For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For program technical assistance, contact: Rebeca Lee-Pethel, Project Officer, National Center for Injury Prevention and Control, 4770 Buford Highway, NE Mailstop K60, Atlanta, GA 30341, Telephone: 770–488–1224, Fax: 770–488–1360, E-mail: *rlee-pethel@cdc.gov*.

For financial, grants management, or budget assistance, contact: Brenda Hayes, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2741, Fax: 770/488–2670, E-mail: *BKH4@cdc.gov*.

VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *http://www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: March 28, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–6580 Filed 4–1–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health Advisory Board on Radiation and Worker Health

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH).

Place: Teleconference call will originate at the Centers for Disease Control and Prevention, National Institutes for Occupational Safety and Health, Atlanta, Georgia. Please see **SUPPLEMENTARY INFORMATION** for details on accessing the teleconference.

Status: Open to the public, teleconference access limited only by ports available.

Background: The ABRWH was established under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000 to advise the President, delegated to the Secretary of Health and Human Services (HHS), on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by HHS as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000 the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, and renewed on August 3, 2003.

Purpose: This board is charged with (a) providing advice to the Secretary, HHS on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS on the scientific validity and quality of dose reconstruction efforts performed for this Program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Discussed: Agenda for this meeting will focus on Status of Activities concerning Iowa Army Ammunition Plant and Mallinckrodt Downtown Site; Special Exposure Cohort Task for SC&A, Inc.; and review of Draft Agenda for the upcoming meeting. The agenda is subject to change as priorities dictate. In the event an individual cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Supplementary Information: This conference call is scheduled to begin at 1:30 p.m. eastern time. To access the teleconference you must dial 1–888–391–6569. You will need to provide the passcode 51897 to be connected to the call.

This notice is being published less than 15 days prior to the meeting due to the unexpected urgency of the topics that will be discussed.

Contact Person for More Information: Larry Elliott, Director of Office of Compensation, Analysis, and Support, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533–6825, fax 513/533–6826.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 29, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–6576 Filed 4–1–05; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10140, CMS–460, CMS–R–65]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Claims Error Rate Testing (CERT)/Electronic Medical Records Exploratory Survey; *Form No.:* CMS–10140 (OMB# 0938–NEW); *Use:* The Centers for Medicare and Medicaid Services (CMS) is using a private vendor to conduct market research to assess the value of electronic patient medical records relative to the Claims Error Rate Testing (CERT) program and determine what actions CMS can take to encourage the use of electronic records for the purpose of lowering the CERT error rate. The proposed effort will test the hypothesis that increased functionality of electronic records (meaning, greater connectivity and features), is associated with lower CERT error rates related to coding, non-response and incomplete documentation. The project is expected to assist CMS in identifying a strategy to improve the CERT claims error rate by developing an approach that would both facilitate and encourage the use of electronic patient medical records in the health care setting. This research focuses on physician practices, outpatient hospitals, durable medical equipment (DME) providers and skilled nursing facilities (SNFs) that have been

randomly sampled as part of the CERT process; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 1600; *Total Annual Responses:* 1600; *Total Annual Hours:* 454.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Participating Physician or Supplier Agreement; *Form No.:* CMS–460 (OMB# 0938–0373); *Use:* Form number CMS–460 is completed by nonparticipating physicians and suppliers if they choose to participate in Medicare Part B. By signing the agreement, the physician or supplier agrees to take assignment on all Medicare claims. To take assignment means to accept the Medicare allowed amount as payment in full for the services they furnish and to charge the beneficiary no more than the deductible and coinsurance for the covered service. In exchange for signing the agreement, the physician or supplier receives a significant number of program benefits not available to nonparticipating suppliers. The information associated with this collection is needed to identify the recipients of the program benefits; *Frequency:* Other—when starting a new business; *Affected Public:* Business or other for-profit; *Number of Respondents:* 6000; *Total Annual Responses:* 6000; *Total Annual Hours:* 1500.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in Final Peer Review Organization Regulations, 42 CFR Sections 1004.40, 1004.50, 1004.60, 1004.70; *Form No.:* CMS–R–65 (OMB# 0938–0444); *Use:* This final rule updates the procedures governing the imposition and adjudication of program sanctions predicated on the recommendations of Peer Review Organizations (PROs). These changes are being made as a result of statutory revisions designed to address health care fraud and abuse issues in the OIG sanction process. The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act, creating the Utilization and Quality Control Peer Review Organization program. Section 1156 of the Social Security Act imposes obligations on health care practitioners and other persons who furnish or order services or items under Medicare. This section also provides for sanction actions, if the Secretary determines that the obligations as stated by this section are not met. Quality Improvement Organizations (QIOs) are responsible for identifying violations. QIOs may allow practitioners or other persons, opportunities to submit relevant information before determining that a violation has occurred. These requirements are used by the QIOs to collect the information necessary to make their determinations; *Frequency:* On occasion; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 53; *Total Annual Responses:* 1060; *Total Annual Hours:* 22,684.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/regulations/pra/*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Reduction Act Reports Clearance Officer designated at the address below:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: William N. Parham, III, Room C5–13–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 24, 2005.

John P. Burke, III,

CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.

[FR Doc. 05–6533 Filed 4–1–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10008]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection:* Revision of a currently approved collection; *Title of Information Collection:* Process and Information Required to Determine Eligibility of Drugs, Biologicals, and Radio-pharmaceutical Agents for Transitional Pass-Through Provisions Under the Hospital Outpatient Prospective Payment System (OPPS) and Supporting Regulations in 42 CFR, Section 419.43; *Use:* Section 1833(t)(6) of the Social Security Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biological agents. Interested parties such as hospitals, pharmaceutical companies, and physicians can apply for transitional pass-through payment for drugs and biologicals used with services covered under the OPPS. CMS uses this information to determine if the criteria for making a transitional pass-through payment are met and if an interim HCPCS code for a new drug or biological is necessary. The revisions made to this collection include the addition of Section 303 of the MMA. This new section establishes the use of the average sales price (ASP) methodology for payment; *Form Number:* CMS–10008 (OMB# 0938–0802); *Frequency:* On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 58; *Total Annual Responses:* 58; *Total Annual Hours:* 203.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/regulations/pra/*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human

Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: March 24, 2005.

John P. Burke, III,

CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.

[FR Doc. 05–6534 Filed 4–1–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0112]

Draft Guidance for Industry on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics.''

This is the first of a series of guidances that will provide recommendations to sponsors on endpoints for cancer clinical trials submitted to FDA to support effectiveness claims in new drug applications (NDAs), biologics license applications (BLAs), or supplemental applications. Sponsors are encouraged to use this draft guidance to design cancer clinical trials and to discuss protocols with the agency. This draft guidance provides background information and discusses general regulatory principles. Each subsequent guidance will focus on endpoints for specific cancer types (e.g., lung cancer, colon cancer) to support drug approval or labeling claims. These guidances are expected to speed the development and improve the quality of protocols submitted to the agency to support anticancer effectiveness claims.

DATES: Submit written or electronic comments on the draft guidance by June 3, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research Voice Information System at 1–800–835–4709 or 301–827–1800. Submit written comments on the draft guidance 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Grant Williams, Center for Drug Evaluation and Research (HFD–150), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–5758;

Patricia Keegan, Center for Drug Evaluation and Research (HFD–107), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–827–5097; or

Steven Hirschfeld, Center for Biologics Evaluation and Research (HFM–755), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6536.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics.'' FDA is developing guidance on oncology endpoints through a process that includes public workshops of oncology experts and discussions before FDA's Oncologic Drugs Advisory Committee. This draft guidance is the first in a planned series of cancer endpoint guidances. It provides background information and general principles. The endpoints discussed in this draft guidance are for drugs to treat patients with an existing cancer. This draft guidance does not address endpoints for drugs to prevent or decrease the incidence of cancer.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on clinical trial endpoints for the approval of cancer drugs and biologics. 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 on the draft guidance. Submit one copy of electronic comments 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 guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6647 Filed 4–1–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; Survey of Colorectal Cancer Screening Policies, Programs, and Systems in U.S. Health Plans

SUMMARY: In compliance with the provisions of section 3507(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comments on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 29, 2004 (Volume 69, No. 209, pages 63159–63160) and allowed 60 days for public

comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised or implemented on or after October 1, 1995, unless it displays a currently valid OMB number.

Proposed Collection: Title: Survey of Colorectal Cancer Screening Policies, Programs, and Systems in U.S. Health Plans. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will obtain information on policies, programs, and practices for colorectal cancer screening among health plans in the U.S. The purpose of the study is to assess (1) health plan policies, programs, and practices for colorectal cancer screening; (2) health plan activities in response to the National Committee on Quality Assurance's new Health Employer Data Information Set measure for colorectal cancer screening; and (3) characteristics of health plans and plan policies and activities that may be associated with higher rates of colorectal cancer screening. A questionnaire will be administered by mail or Internet using a national sample of health plans. Study participants will be health plan medical directors or administrators, and they will select their preferred response mode. Burden estimates are as follows:

Type of respondents	Estimated number respondents	Estimated number responses per respondent	Average burden hours per response	Estimated total annual burden hours
Health plan medical directors	400	1	0.333	133

Request For Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Carrie N. Klabunde, Ph.D., Epidemiologist, National Cancer Institute, EPN 4005, 6130 Executive Boulevard, Bethesda, Maryland 20892–7344. Telephone: (301) 402–3362; e-mail: *ck97b@nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: March 21, 2005.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 05–6603 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Outcome Evaluation of the Small Grants Program for Behavioral Research in Cancer Control

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the (National Cancer Institute), the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 31, 2004, page 53079 and allowed 60 days for public comment. No public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Outcome Evaluation of the Small Grants Program for Behavioral Research in Cancer Control. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The Small Grants Program support projects that can be completed in a short period of time, such as pilot projects, development and testing of new methodologies, secondary data analyses, or innovative studies that provide a basis for more extended research. This evaluation is being conducted to identify progress of this program in establishing a cohort of scientists with a high level of research expertise in behavioral research cancer control. A primary objective of this study is to determine if the program's small grants R03 funding mechanism is effective in attracting investigators to the field of behavioral research and if so, what impact does the program have on the career of successful applicants. The findings will provide valuable information regarding (1) effectiveness of the program in attracting investigators to the field; (2) the impact of the program on investigators careers; and (3) the overall benefit provided by the program through the R03 funding mechanism and assist the agency in determining whether changes to the program are necessary in future. *Frequency of Response:* On occasion. *Affected Public:* Individuals; teaching institutions or other non-profit. *Type of Respondents:* Grantees funded under PAR 99–006 (n = 80). *Type of Respondents:* Principal Investigator awarded grants funded by PAR 00–006 (Dec. 1999–Nov. 2001); *Estimated Number of Respondents:* 80; *Estimated Number of Response Per Respondent:* 1; *Average Burden Hours Per Response:* 75; and *Estimated Total Annual Burden Hours Requested:* 60.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Principal Investigators awarded grants funded by PAR 99–006 (Dec. 1999–Nov. 2001)	80	1	0.75	60.0
Total				60.0

There is no cost to respondents. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (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 those who are able to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Veronica Chollette, RN, MS Program Director, Applied Cancer Screening Research Branch, Behavioral Research Program Division of Cancer Control and Population Sciences, National Cancer Institute, 6130 Executive Blvd., Room 4100, Rockville, MD 20852 or call non-toll free number 301–435–2837 or e-mail your request to: *vc24a@nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: March 21, 2005.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 05–6604 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 496–7057; fax: (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Biomarkers for Tissue Status

Joseph Riss and J. Carl Barrett (NCI).
U.S. Provisional Application No. 60/649,208 filed 01 Feb 2005 (DHHS Reference No. E–064–2005/0–US–01).
Licensing Contact: Thomas P. Clouse; (301) 435–4076; *clouset@mail.nih.gov*.

Certain biomarkers are differentially expressed in various tissue samples, including those of renal cancer and in kidney ischemia/reperfusion. The technology relates to methods of quickly and accurately diagnosing and monitoring progression of cancer and ischemically-injured tissue. The technology provides sensitive diagnostic and therapeutic methods using identified biomarkers associated with RCC, acute renal failure, renal regeneration and repair (RRR), organ transplantation and shipment, wound healing, tumors, and organ failure. The potential market for diagnostics and therapeutics in this area is substantial. For example, Renal Cell Carcinoma (RCC) accounts for three (3) percent of all adult male malignancies in the United States. Patent protection for this technology is pending.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Methods of Diagnosing and Treating VHL Associated and Sporadic Renal Cell Carcinoma, and Other VHL Associated and Sporadic Counterpart Tumors Which Co-Express Epo and the Epo Receptor

Zhengping Zhuang *et al.* (NINDS).
U.S. Provisional Application No. 60/611,616 filed 20 Sep 2004 (DHHS Reference No. E–274–2004/0–US–01).
Licensing Contact: Thomas P. Clouse; (301) 435–4076; *clouset@mail.nih.gov*.

While von Hippel-Lindau (VHL) gene germline mutations have been identified as the cause of tumors in VHL patients, the link between gene mutation and tumor development has remained unclear, *e.g.*, it is unknown why only selected organs and cell types are affected. The inventors have discovered that EPO and EPOR are co-expressed in tumors of VHL patients. The co-expression of the EPO and EPO-receptor is also related to the tumor growth and progression in sporadic renal tumors and tumors in kidney dialysis patients. Since the co-expression of EPO and EPOR are not present in most normal adult tissues, ligands that bind to EPOR but do not activate the receptor can target specific tumor cells with minimal detrimental effect on normal cells.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Metastasis Suppressor Gene on Human Chromosome 8 and Its Use in the Diagnosis, Prognosis and Treatment of Cancer

J. Carl Barrett *et al.* (NCI).

U.S. Provisional Application No. 60/591,028 filed 26 Jul 2004 (DHHS Reference No. E–226–2004/0–US–01).

Licensing Contact: Mojdeh Bahar; (301) 435–2950; *baharm@mail.nih.gov.*

This invention is directed to an isolated or purified ribonucleic acid (RNA) molecule comprising a nucleotide sequence encoded by a human Tey1 metastasis suppressor gene located at p21–p12 on chromosome 8 or a fragment thereof, wherein the isolated or purified RNA molecule comprises from about 10 to about 100 nucleotides. The invention also provides methods of diagnosis, prognosis, and treatment of cancer, such as prostate cancer, using the isolated or purified RNA molecule.

Use of a Promoter of T-Cell Expansion and an Inducer of CD40 Stimulation in the Treatment or Prevention of a Pathologic State

William J. Murphy *et al.* (NCI).

U.S. Patent Application No. 10/226,959 filed 23 Aug 2002 (DHHS Reference No. E–150–2001/1–US–01).

Licensing Contact: Michelle A. Booden; (301) 451–7337; *boodenm@mail.nih.gov.*

Originally described as a protein important in humoral immune responses, it is now known that CD40 plays a wider role in regulating immune function by increasing both costimulatory molecules and antigen presentation. CD40 also contributes to the inflammatory process by inducing the secretion of various inflammatory cytokines including interleukin (IL)–1, IL–6, IL–12, and TNF-α. CD40 is expressed on a variety of cell types including monocytes, dendritic cells, endothelial cells, and carcinomas. The expression of CD40 on a variety of carcinoma cells including but not limited to those of the bladder, kidney, ovary, skin, and breast and the role of CD40 in the promotion of immune function makes CD40 an attractive target for immunotherapy.

Single agent modalities in disease therapy often fail, particularly when given for advanced disease. Previous studies have reported that CD40 stimulation can result in significant antitumor effects in various preclinical models. Additionally, various cytokines such as IL–2 and IL–12 have also been shown to have antitumor efficacy in preclinical and clinical trials.

The present invention describes a method for treating or preventing a disease state such as cancer by administrating a combination of a promoter of T-cell expansion, a cytokine such as IL–2 or IL–12, and an inducer of CD40 stimulation. As claimed in the above patent and reported in several publications by Murphy et al, the combination of a cytokine and a CD40 stimulator can result in synergistic antitumor effects in multiple advanced disease models in which neither agent alone resulted in protection or efficacy. This preventative or therapeutic intervention could be directed toward multiple human carcinomas as well as viral, bacterial, or fungal infections and allergic reactions.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Nucleotide and Deduced Amino Acid Sequences of a New Tumor Gene, Int6

Robert Callahan, Antonio Marchetti, Fiamma Buttitta, Gilbert Smith (NCI).

U.S. Patent 6,255,104 issued 03 Jul 2001 (DHHS Reference No. E–265–1994/1–US–01), claiming priority to U.S. Patent Application No. 08/385,998 filed 09 Feb 1995, now abandoned (DHHS Reference No. E–265–1994/0–US–01) and PCT Application No. PCT/US96/01884 filed 09 Feb 1996, which published as WO 96/24672 on 15 Aug 1996 (DHHS Reference No. E–265–1994/0–PCT–02).

U.S. Patent 6,342,392 issued 29 Jan 2002 (DHHS Reference No. E–265–1994/1–US–02).

U.S. Patent 6,737,251 issued 18 May 2004 (DHHS Reference No. E–265–1994/1–US–03).

U.S. Patent Application No. 10/783,415 filed 19 Feb 2004 (DHHS Reference No. E–265–1994/1–US–04).

Licensing Contact: Jesse Kindra; (301) 435–5559; *kindraj@mail.nih.gov.*

Murine retroviruses have been useful in the identification of mammalian genes involved in tumor development. Five loci have been previously identified as integration sites for one specific retrovirus, mouse mammary tumor virus (MMTV). This work describes a sixth site of integration for MMTV, the Int6 gene. The Int6 gene is highly conserved among vertebrate species, including humans. This invention embodies a series of reagents derived from the nucleic acid and amino acid sequences of the Int6 gene and the use of these reagents in diagnostic methods, immunotherapy, gene therapy, and as vaccines.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Dated: March 24, 2005.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 05–6638 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Special Emphasis Panel, Spore in Ovarian—GYN Cancer.

Date: May 19–20, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Hotel and Convention Center, 5701 Marinelli Road, North Bethesda, MD 20852

Contact Person: Shamala K. Srinivas, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8133, Bethesda, MD 20892, (301) 594–1224.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 24, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee.

[FR Doc. 05–6616 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Review of RFA HL–04–036, Causes and Mechanisms of COPD Exacerbations.

Date: May 9, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Shelley S Sehnert, PhD, Scientific Review Administrator, Review Branch, NIH/NHLBI, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892–7924, 301/435–0303, *ssehnert@nhlbi.nih.gov*.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Review of Specialized Centers Applications (P50s).

Date: May 17–18, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Judy S Hannah, PhD, Scientific Review Administrator, Review Branch, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892, (301) 435–0387.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 24, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6618 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung and Blood Institute Special Emphasis Panel, Review of Research Demonstration and Dissemination Project (R18) Applications.

Date: May 6, 2005.

Time: 10 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Patricia A. Haggerty, PhD, Scientific Review Administrator, National Heart, Lung, and Blood Institute/NIH, Clinical Studies & Training Studies Rev. Grp., Division of Extramural Affairs/Section Chief, 6701 Rockledge Drive, Room 7194, Bethesda, MD 20892 (301) 435–0288.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 24, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6620 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases, 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 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 of Allergy and Infectious Diseases Special Emphasis Panel Virology Quality Assurance.

Date: April 21, 2005.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIAID, 6700 B, 3143, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Keyonna A. Earle, Grants Clerks, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–594–0921, *earleke@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 24, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6615 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Drug Abuse Special Emphasis Panel, March 15, 2005, 9 a.m. to March 15, 2005, 5 p.m. Double Tree Rockville, 1750 Rockville Pike, Rockville, MD, 20852 which was published in the **Federal Register** on January 21, 2005, Vol. 70, Num. 13.

The date of the meeting was changed to April 5, 2005. The meeting is closed to the public.

Dated: March 24, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6619 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

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 meeting will be closed to the public in accordance with the provisions set forth in section 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, Residential Research Support.

Date: March 29, 2005.

Time: 9 a.m. to 1 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

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*.

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.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Real-Time Data Collection Paired With Ecological Momentary Assessment (EMA).

Date: April 11, 2005.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Eric Zatman, 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) 435–1438.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS.)

Dated: March 24, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6621 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes 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.

Date: April 11–12, 2005.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Mark R. Green, PhD, Deputy Director, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301) 435–1431.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: March 24, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6622 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of 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 a meeting of the National Advisory Council on Drug Abuse.

The meeting will be open to the public as indicated below, 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.

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 Advisory Council on Drug Abuse.

Date: May 17, 2005.

Closed: 8:30 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Open: 12:30 p.m. to 4 p.m.

Agenda: This portion of the meeting will be open to the public for announcements and reports of administration, legislative and program developments in the drug abuse field.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Teresa Levitin, PhD, Director, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301) 443–2755.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations

may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their 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.drugabuse.gov/NACDA/NACDAHome.html*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: March 24, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6623 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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 of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel. To review NIH Clinical Trial Planning Grant Program (R34s).

Date: April 29, 2005.

Time: 10 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH–NIAMS Institute, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20814, (telephone conference call).

Contact Person: Yan Z. Wange, PhD, Scientific Review Administrator, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Blvd., Suite 820, Bethesda, MD 20892, (301) 594–4957.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6632 Filed 4–1–05; 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 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 Aging Special Emphasis Panel, Cognitive Aging.

Date: April 6, 2005.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Ave., 2C212, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ramesh Vemuri, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7700, *rv23r@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. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: March 24, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6636 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 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 of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Kidney Related Program Project Grant Applications.

Date: April 14, 2005.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Lakshmanan Sankaran, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 777, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *ls38oz@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.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Cystic Fibrosis Research and Translation Core Centers.

Date: April 19, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel, 1300 Concourse Drive, Linthicum, MD 21090.

Contact Person: Dan E. Matsumoto, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 749, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892–5452, (301) 594–8894, *matsumotod@extra.niddk.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.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Variceal Bleeding.

Date: April 19, 2005.

Time: 4 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carol J. Goter-Robinson, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 748, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791, *goterrobinsonc@extra.niddk.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. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 24, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6637 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine, 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 the fourth meeting of the Commission on Systemic Interoperability.

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.

The mission of the Commission on Systemic Interoperability is to submit a report to the Secretary of Health and Human Services and to Congress on a comprehensive strategy for the adoption and implementation of health care information technology standards that includes a timeline and prioritization for such adoption and implementation. In developing that strategy, the Commission will consider: (1) The costs and benefits of the standards, both financial impact and quality improvement; (2) the current demand on industry resources to implement the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and other electronic standards, including HIPAA standards; and (3) the most cost-effective and efficient means for industry to implement the Standards.

Name of Committee: Commission on Systemic Interoperability.

Date: April 22, 2005.

Time: 8 a.m. to 4 p.m.

Agenda: Healthcare Information Technology Standards.

Place: Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, Washington, DC 20201.

Contact Person: Ms. Dana Haza, Director, Commission on Systemic Interoperability, National Library of Medicine, National Institutes of Health, Building 38, Room 2N21, Bethesda, MD 20894, 301–594–7520.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The comments should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person.

Dated: March 24, 2005.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6617 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP); Liaison and Scientific Review Office (LSRO); Announcement of National Toxicology Program (NTP) Workshop on ''Animal Models for the NTP Rodent Cancer Bioassay: Strains & Stocks—Should We Switch?''

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Meeting Announcement.

SUMMARY: Over the past year, the National Toxicology Program (NTP) has developed and refined a vision for toxicology in the 21st century (''NTP Vision'') and a roadmap for implementing this vision (''NTP Roadmap'') that will strategically position the program at the forefront for providing scientific data and the interpretation of those data for public health decision-making (*see* **SUPPLEMENTARY INFORMATION** for additional detail). As part of the NTP Roadmap, the program will convene a series of public workshops to review aspects of the existing testing program. The first workshop is scheduled for June 16–17, 2005, at the NIEHS in Research Triangle Park, NC and will focus on evaluating stocks and strains currently used in the NTP rodent cancer bioassay in order to improve the ability of the bioassay to identify substances that may pose a carcinogenic hazard for humans. In particular, the goal of this workshop is to seek scientific input as to whether the NTP should continue to use both the F344 rat and B6C3F1 mouse models, use other strains, and/or use multiple strains as previously suggested (Festing, 1995). Future workshops will address other study design issues such as diet, length of study, and age at exposure. The NTP invites public comments on the appropriateness of the F344N and B6C3F1 models currently used and the submission of historical control data for rodent models that the NTP might consider at the workshop. The program will include plenary sessions as well as three breakout group meetings for in-depth discussions of rat models, mouse models, and the multiple strain approach. Following the meeting, the NTP will prepare a workshop report and present its proposed testing strategy to the NTP Board of Scientific Counselors for their consideration and input.

Attendance at the meeting is limited only by the space available. Members of the public may register to attend the workshop on a first-come, first-served basis per the procedures outlined below. A copy of the agenda and any additional information on the workshop, including participants and background materials, will be posted on the NTP Web site when available (*http://ntp.niehs.nih.gov* select ''Meetings and Workshops'')

DATES: The workshop will be held June 16–17, 2005. The meeting will begin at 8:30 a.m. each day and end at 5 p.m. on June 16 and approximately 12 p.m. on June 17.

Comments: Written comments and historical control data should be received by May 19, 2005, to enable review by NIEHS/NTP staff and workshop panelists prior to the meeting (*see* **FOR FURTHER INFORMATION CONTACT** below). The deadline for registration to present oral comments at the meeting is June 9, 2005.

Registration: Individuals who plan to attend are strongly encouraged to register by June 9, 2005, in order to ensure access to the NIEHS campus (*see* **FOR FURTHER INFORMATION CONTACT** below). Persons needing special assistance, such as sign language

interpretation or other reasonable accommodation, in order to attend are asked to notify the NTP at least 7 business days in advance of the meeting.

ADDRESSES: The meeting will be held in the Rodbell Auditorium, Rall Building at the National Institute of Environmental Health Sciences, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Public comments, data submission and any other correspondence should be submitted to Dr. Angela King-Herbert (NIEHS, P.O. Box 12233, MD B3–06, Research Triangle Park, NC 27709; telephone: 919–541–3464, fax 919–541–7666; or e-mail: *kingher1@niehs.nih.gov*).

SUPPLEMENTARY INFORMATION:

Background on the NTP Vision and Roadmap to Achieve the Vision

The NTP was established in 1978 to coordinate toxicological testing programs within the Department of Health and Human Services, develop and validate improved testing methods, develop approaches and generate data to strengthen scientific knowledge about potentially hazardous substances and communicate with stakeholders. In its more than 25 years of existence, NTP has become a world leader in providing scientific information that improves our nation's ability to evaluate potential human health effects from chemical and physical exposures. The NTP maintains a number of complex, interrelated research and testing programs that provide unique and critical information needed by health regulatory and research agencies to protect public health.

The last decade of the 20th century and the turn of the 21st century have produced dramatic technological advances in molecular biology and computer science. The NTP is ready to evaluate its key activities and, in a focused and concerted effort, determine how best to incorporate these new scientific technologies into its research and testing strategies and broaden scientific knowledge on the linkage between mechanism and disease. In August 2003, the NTP defined its vision for the 21st century and undertook a yearlong process to refine that vision and develop a roadmap for its implementation. The NTP Vision is to support the evolution of toxicology from a predominately observational science at the level of disease-specific models to a predominately predictive science focused upon a broad inclusion of target-specific, mechanism-based, biological observations. The NTP roadmap for implementation of the vision will strategically position the program at the forefront for providing scientific data and the interpretation of those data for public health decision-making. The NTP Roadmap was developed with input from numerous groups including its federal partners, its advisory committees, and the public. In carrying out the NTP Roadmap, the program plans to formally review the designs of NTP assays to determine whether protocol changes are needed. Additional information about the NTP Vision and Roadmap is available on its Web site (*http://ntp.niehs.nih.gov/ntp* select ''NTP Vision and Roadmap'').

The NTP periodically conducts reviews of animal models used in the NTP cancer bioassay including recent evaluations on the use of fish and transgenic mouse models as alternative approaches (Board of Scientific Counselors, 2004; NTP Board of Scientific Counselors Technical Reports Review Subcommittee, 2003; Scientific Advisory Committee on Alternative Toxicological Methods, 2004). However, the last formal review of the NTP rodent bioassay occurred in August 1984 (Report of the Ad Hoc Panel on Chemical Carcinogenesis Testing and Evaluation of the NTP Board of Scientific Counselors, August 17, 1984). Although the NTP has expanded the breadth of its evaluation of individual agents and the number of endpoints critically assessed in the bioassay, the rodent cancer bioassay study design has been minimally modified over the past 30 years. For this reason, the program intends to convene a series of workshops to evaluate the rodent cancer bioassay, beginning with choice of species and strain. Future workshops will address other study design issues, such as diet, study length, and age at exposure. The ultimate goal of any change to the NTP cancer bioassay is to improve the identification of carcinogenic potential (*i.e.*, hazard identification) and/or improve our ability to predict cancer in humans.

Request for Comments

Public input at this meeting is invited and time is set aside for the presentation of public comments on any agenda topic. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes. Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less then that for pre-registered speakers and will be determined by the number of persons who register at the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution and to supplement the record. Written comments received in response to this notice will be posted on the NTP Web site (*http://ntp.niehs.nih.gov* select ''Meetings and Workshops'').

Persons submitting written comments should include their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any) with the document. Individuals wishing to submit historical control data are encouraged to contact Dr. Angela King-Herbert prior to submission (*see* **FOR FURTHER INFORMATION CONTACT** above).

References

Festing, MF. (1995). Use of a multistrain assay could improve the NTP carcinogenesis bioassay. Environ Health Perspect. 1995 Jan;103(1):44–52. Available: *http://ehp.niehs.nih.gov/*.

Meeting Minutes of the NTP Board of Scientific Counselors (BSC)—June 29, 2004. Available: *http://ntp-server.niehs.nih.gov/ntpweb/index.cfm?objectid=720164F2-BDB7-CEBA-F5C6A2E21851F0C4.*

Meeting Minutes of the NTP Board of Scientific Counselors Technical Reports Review Subcommittee (TRR Subcommittee)—May 22, 2003. Available: *http://ntp-server.niehs.nih.gov/ntpweb/index.cfm?objectid=9404F3B3-F1F6–975E–70F0DB8B0FDF8F86.*

Meeting Minutes of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)—March 10–11, 2004. Available: *http://ntp-server.niehs.nih.gov/ntpweb/index.cfm?objectid=AF6CC417-F1F6–975E–75B5F3FF7DF1CDDC.*

Dated: March 22, 2005.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 05–6605 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Office of Dietary Supplements: Notice of Opportunity for Public Comment and Public Meeting

Background

The Office Dietary Supplements (ODS) was established in the Office of

the Director, NIH, in 1995 as a major provision of the Dietary Supplement Health and Education Act of 1994 (DSHEA). A key early activity was the development of a Strategic Plan to define the mission of ODS and to define program goals. It was prepared with considerable input from NIH Institutes and Centers, several Federal agencies, consumers, and other interested parties. The original Strategic Plan guided ODS activities and programs from 1998 to 2003.

In 2003, the Office of Dietary Supplements undertook a public process to review its original Strategic Plan and developed a revised Strategic Plan for 2004–2009 entitled, ''Promoting Quality Science in Dietary Supplement Research, Education, and Communication''. This document was published in January 2004 and is available by e-mail request to *ods@nih.gov*, and on the ODS Web site at *http://ods.od.nih.gov*.

The revised ODS Strategic Plan for 2004–2009 reviews the programs and activities that were initiated under the original Strategic plan during 1998–2003 and identified five major program goals related to research, education and communication for 2004–2009:

- Expand the evaluation of the role of dietary supplements in disease prevention and in reduction of risk factors associated with disease.
- Foster research that evaluates the role of dietary supplements in maintaining and improving optimal physical and mental health and performance.
- Stimulate and support research to further understanding of the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle.
- Promote and support the development and improvement of methodologies appropriate to the scientific study of dietary supplement ingredients.
- Expand and conduct outreach activities that inform and educate the public, health care providers, and scientists about the benefits and risks of dietary supplements.

Since its inception in 1995 under DSHEA, the original and revised strategic plans focus on implementation of the ODS Mission: ''to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population.''

The ODS will hold an open public meeting on May 20, 2005 at the location and time listed below to receive comments and suggestions on additional needs and opportunities related to the 2004–2009 ODS Strategic Plan. Information about the meeting, including a link to the registration form and the tentative agenda, is available on ODS Web site *http://ods.od.nih.gov.* There is no registration fee. The overall purpose of this public meeting is to provide interested parties a time to identify new opportunities and emerging needs for possible incorporation in the ODS research, education, and communication programs and activities. To address this purpose, guidance is being requested from all persons and organizations in the dietary supplement community.

Materials that describe the current ODS programs and activities, information about the public meeting, and a link to the meeting registration form are available on the ODS Web site at *http://ods.od.nih.gov.* In addition, the materials are available from the Office at the address listed below. On or about April 15, 2005, information and data on ODS programs and activities will be updated and will be available on the ODS Web site and at the address listed below as well as at the public meeting.

The open meeting will begin with a brief presentation of the current and emerging programs and activities of the ODS. Several invited speakers representing the broad range of interests in the dietary supplement user community will be asked to comment on emerging needs and opportunities that can enhance the scope and depth of ODS programs. There will be an opportunity for individuals and organizations to provide their views and suggestions on possible additional directions that ODS should consider in its five year Strategic Plan.

We will use all information received at the meeting as well as written comments received by 5 p.m. e.s.t., on June 30, 2005 in response to this request in considering modifications to the ODS Strategic Plan for 2004–2009. Comments and suggestions should be forwarded to the address listed below or sent to *ODSplan@od.nih.gov.* Results of this review will be shared with the ODS Trans-NIH/Agency Working Group, a Federal interagency group convened by ODS to enhance cooperation and communication across Federal departments, agencies, institutes, centers, and offices concerning research, education , and communication about dietary supplements. In addition, results of this review will be posted on the ODS Web site and will be available upon request.

Meeting Title: Office of Dietary Supplements Public Meeting.

Date: May 20, 2005.

Time: 9 a.m.–4 p.m.

Place: Marriott Bethesda North Hotel and Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Kenneth D. Fisher, Ph.D., Office of Dietary Supplements, 6100 Executive Boulevard, Room 3B01, Bethesda, MD 20892–7517, Phone: (301) 435–2920, Fax: (301) 480–1845, e-mail: *ODSplan@od.nih.gov.*

Public Participation

The meeting is open to the public with attendance limited by the availability of space on a first come, first served basis. Interested persons and organizations that wish to present oral comments should indicate this when registering on the ODS Web site or at *http://www.scgcorp.com/odspublicmtg*, no later than May 6, 2005.

Oral comments will be limited to three minutes; however, submission of additional documentation is encouraged. Individuals who register to speak will be assigned in the order in which they registered. Due to time constraints, only one representative from each organization will be allotted time for oral presentation. We may limit the number of speakers and the time allotted depending on the number of registrants. All requests to register should include the name, address, telephone number, and business or professional affiliation of the interested party. If time permits, we will allow any person attending the meeting who has not registered to speak in advance of the meeting to make a brief oral statement during the time set aside for public comments and at the chairperson's discretion.

We encourage individuals unable to attend the meeting and all interested parties to send written comments to the Office of Dietary Supplements by mail, fax, or electronically. If possible, comments that are mailed or faxed should also be forwarded electronically.

Persons needing special assistance, such as sign language interpretation or other special accommodations at the meeting should indicate this when registering or contact the Office of Dietary Supplements at the address or telephone number listed no later than April 29, 2005.

Dated: March 23, 2005.

Paul M. Coates,

Director, Office of Dietary Supplements, Office of the Director, National Institutes of Health.

[FR Doc. 05–6606 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, U.S. Department of Homeland Security.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the following information collection to the Office of Management and Budget (OMB) for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments FEMA will use.

Title: Implementation of Coastal Barrier Resources Act.

OMB Number: 1660–0010.

Abstract: When an application for flood insurance is submitted for buildings located in Coastal Barrier Resources (CBRS) communities, one of the following types of documentation must be submitted as evidence of eligibility:

—Certification from a community official stating the building is not located in a designated CBRS area.

—A legally valid building permit or certification from a community official stating that the building's start of construction date precede the date that the community was identified in the system.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions; Farms; Federal Government; and State, Local or Tribal Government.

Number of Respondents: 60.

Estimated Time per Respondent: 1.5 hours.

Estimated Total Annual Burden Hours: 90 hours.

Frequency of Response: Once.

Comments: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs at OMB, Attention: Desk Officer for the Department of Homeland Security/FEMA, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503, or facsimile number (202) 395–7285. Comments must be submitted on or before 30 days from the date of this notice is published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Muriel B. Anderson, Section Chief, Records Management, FEMA at 500 C Street, SW., Room 316, Washington, DC 20472, facsimile number (202) 646–3347, or e-mail address *FEMA-Information-Collections@dhs.gov.*

Dated: March 18, 2005.

George S. Trotter,

Acting Branch Chief, Information Resources Management Branch, Information Technology Services Division.

[FR Doc. 05–6544 Filed 4–1–05; 8:45 am]

BILLING CODE 9110–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1584–DR]

Alaska; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Alaska (FEMA–1584–DR), dated March 14, 2005, and related determinations.

EFFECTIVE DATE: March 14, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated March 14, 2005, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act), as follows:

I have determined that the damage in certain areas of the State of Alaska, resulting from a severe winter storm on January 7–12, 2005, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such a major disaster exists in the State of Alaska.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas; Hazard Mitigation throughout the State; and any other forms of assistance under the Stafford Act you may deem appropriate. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible cost. If Other Needs Assistance under Section 408 of the Stafford Act is later warranted, Federal funding under that program will also be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, William Lokey, of FEMA is appointed to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Alaska to have been affected adversely by this declared major disaster:

North Slope Borough for Public Assistance.

All boroughs and Regional Education Attendance Areas in the State of Alaska are eligible to apply for assistance under the Hazard Mitigation Grant Program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs; 97.036, Public

Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–6549 Filed 4–1–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1577–DR]

California; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of California (FEMA–1577–DR), dated February 4, 2005, and related determinations.

EFFECTIVE DATE: March 16, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of California is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of February 4, 2005:

Kern County for Individual Assistance.

Orange, Riverside, San Bernardino, San Diego and Santa Barbara Counties for Individual Assistance (already designated for Public Assistance).

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–6546 Filed 4–1–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1573–DR]

Indiana; Amendment No. 6 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Indiana (FEMA–1573–DR), dated January 21, 2005, and related determinations.

EFFECTIVE DATE: March 18, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Indiana is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of January 21, 2005:

Starke County for Public Assistance (already designated for Individual Assistance.)

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–6545 Filed 4–1–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3205–EM]

Maine; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Maine (FEMA–3205–EM), dated March 14, 2005, and related determinations.

EFFECTIVE DATE: March 14, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated March 14, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act), as follows:

I have determined that the impact in certain areas of the State of Maine, resulting from the record and/or near record snow on January 22–23, 2005, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of Maine.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide emergency protective measures under the Public Assistance program to save lives, protect public health and safety, and property. Other forms of assistance under Title V of the Stafford Act may be added at a later date, as you deem appropriate. You are further authorized to provide this emergency assistance in the affected areas for a period of 72 hours. You may extend the period of assistance, as warranted. This assistance excludes regular time costs for sub-grantees' regular employees. Assistance under this emergency is authorized at 75 percent Federal funding for eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Under Secretary for Emergency

Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, James N. Russo, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Maine to have been affected adversely by this declared emergency:

The counties of Cumberland and York for emergency protective measures (Category B) under the Public Assistance program for a period of 72 hours.

(Catalog of Federal Domestic Assistance No. 97.036, Disaster Assistance)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–6550 Filed 4–1–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–3206–EM]

Maine; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Maine (FEMA–3206–EM), dated March 14, 2005, and related determinations.

EFFECTIVE DATE: March 14, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated March 14, 2005, the President declared an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act), as follows:

I have determined that the impact in certain areas of the State of Maine, resulting from the record and/or near record snow on February 10–11, 2005, is of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (the Stafford Act). Therefore, I declare that such an emergency exists in the State of Maine.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide emergency protective measures under the Public Assistance program to save lives, protect public health and safety, and property. Other forms of assistance under Title V of the Stafford Act may be added at a later date, as you deem appropriate. You are further authorized to provide this emergency assistance in the affected areas for a period of 48 hours. You may extend the period of assistance, as warranted. This assistance excludes regular time costs for sub-grantees' regular employees. Assistance under this emergency is authorized at 75 percent Federal funding for eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Under Secretary for Emergency Preparedness and Response, Department of Homeland Security, under Executive Order 12148, as amended, James N. Russo, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following areas of the State of Maine to have been affected adversely by this declared emergency:

The counties of Androscoggin, Aroostook, Cumberland, Franklin, Hancock, Knox, Oxford, Penobscot, Piscataquis, Somerset, and York for emergency protective measures (Category B) under the Public Assistance program for a period of 48 hours.

(Catalog of Federal Domestic Assistance No. 97.036, Disaster Assistance)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–6551 Filed 4–1–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1580–DR]

Ohio; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Ohio (FEMA–1580–DR), dated February 15, 2005, and related determinations.

EFFECTIVE DATE: March 18, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Ohio is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of February 15, 2005:

Montgomery and Putnam Counties for Public Assistance.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–6547 Filed 4–1–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1580–DR]

Ohio; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Ohio (FEMA–1580–DR), dated February 15, 2005, and related determinations.

EFFECTIVE DATE: March 18, 2005.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the

State of Ohio is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of February 15, 2005:

Miami County for Individual Assistance.

Ashland, Auglaize, Huron, and Wyandot Counties for Individual Assistance (already designated for Public Assistance).

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

Michael D. Brown,

Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.

[FR Doc. 05–6548 Filed 4–1–05; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Extension of a Currently Approved Information Collection; Comment Request

ACTION: 60-day notice of information collection under review; baggage and personal effects of detained aliens; Form I–43.

The Department of Homeland Security, U.S. Citizenship and Immigration Services has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until June 3, 2005.

Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate 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;

(2) Evaluate the accuracy of the agencies estimate of the burden of the 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 collection.

(2) *Title of the Form/Collection:* Baggage and Personal Effects of Detained Aliens.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–43. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals and Households. The form is used by the arresting officer to ensure that the alien is afforded a reasonable opportunity to collect his or her property. The USCIS also uses this form to protect the government from possible fraudulent claims.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 600,000 responses at 1 minute (.017) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 10,200 annual burden hours.

If you have comments, suggestions, or need a copy of the information collection instrument, please contact Richard A. Sloan, Director, Regulatory Management Division, U.S. Citizenship and Immigration Services, 111 Massachusetts Avenue, NW., Washington, DC 20529; (202) 272–8377.

Dated: March 21, 2005.

Richard A. Sloan,

Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. 05–6419 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Extension of a Currently Approved Information Collection; Comment Request

ACTION: 60-day notice of information collection under review; application for waiver of the foreign residence requirement of section 212(e) of the Immigration and Nationality Act; Form I–612.

The Department of Homeland Security, U.S. Citizenship and Immigration Services has 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 June 3, 2005.

Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate 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;

(2) Evaluate the accuracy of the agency's estimate of the burden of the 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 a currently approved collection.

(2) *Title of the Form/Collection:* Application for Waiver of the Foreign Residence Requirement of Section 212(e) of the Immigration and Nationality Act.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security*

sponsoring the collection: Form I–612. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals and households. This form is used by the USCIS to determine eligibility for a waiver.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,300 responses at 20 minutes (.333) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 432 annual burden hours.

If you have comments, suggestions, or need a copy of the information collection instruments, please contact Richard A. Sloan, Director, U.S. Citizenship and Immigration Services, 111 Massachusetts Avenue, NW., Washington, DC 20529; (202) 272–8377.

Dated: March 21, 2005.

Richard A. Sloan,

Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. 05–6420 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Extension of a Currently Approved Information Collection; Comment Request

ACTION: 60-day notice of information collection under review; notice of appeal of decision under Section 210, Form I–694.

The Department of Homeland Security, U.S. Citizenship and Immigration Services has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until June 3, 2004.

Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate 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;

(2) Evaluate the accuracy of the agencies estimate of the burden of the 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 a currently approved collection.

(2) *Title of the Form/Collection:* Notice of Appeal of Decision Under 210.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–694. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. This information collection will be used by the Service in considering appeals of denials of temporary and permanent residence status by legalization applicants and special agricultural workers, under sections 210 and 245A of the Immigration and Nationality Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,192 respondents at 30 Minutes (.5) hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 596 annual burden hours.

If you have comments, suggestions, or need a copy of the information collection instrument, please contact Richard A. Sloan, Director, Regulatory Management Division, U.S. Citizenship and Immigration Services, 111 Massachusetts Avenue, NW., Washington, DC 20529; (202) 272–8377.

Dated: March 21, 2005.

Richard A. Sloan,

Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. 05–6421 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Extension of a Currently Approved Information Collection; Comment Request

ACTION: 60-day notice of information collection under review; petition to classify orphan as an immediate relative and application for advance processing of orphan petition, Form I–600, I–600A.

The Department of Homeland Security, U.S. Citizenship and Immigration Services has 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 June 3, 2005.

Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate 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;

(2) Evaluate the accuracy of the agency's estimate of the burden of the 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 a currently approved collection.

(2) *Title of the Form/Collection:* Petition to Classify Orphan as an Immediate Relative and Application for Advance Processing of Orphan Petition.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–600

and I–600A. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals and households. This form is used by the USCIS to determine immigrant eligibility and advance processing of orphans.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 34,000 responses at 30 minutes (.50) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 17,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the information collection instrument with instructions, please contact Richard A. Sloan, Director, Regulatory Management Division, U.S. Citizenship and Immigration Services, 111 Massachusetts Avenue, NW., Washington, DC 20529; (202) 272–8377.

Dated: March 23, 2005.

Richard A. Sloan,

Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. 05–6422 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Extension of a Currently Approved Information Collection; Comment Request

ACTION: 60-day notice of information collection under review; waiver of rights, privileges, exemptions and immunities; Form I–508.

The Department of Homeland Security, U.S. Citizenship and Immigration Services has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until June 3, 2005.

Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate 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;

(2) Evaluate the accuracy of the agency's estimate of the burden of the 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 submissions of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Waiver of Rights, Privileges, Exemptions and Immunities.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–508. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. This form is used by the USCIS to determine eligibility of an applicant to retain the status of alien lawfully admitted to the United States for permanent residence.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,800 responses at 5 minutes (.083) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 150 annual burden hours.

If you have comments, suggestions, or need a copy of the information collection instrument with instructions, please contact Richard A. Sloan, Director, Regulatory Management Division, U.S. Citizenship and Immigration Services, 1111 Massachusetts Avenue, NW., Washington, DC 20529.

Dated: March 23, 2005.

Richard A. Sloan,

Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. 05–6423 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Comment Request

ACTION: 60-day notice of information collection under review; medical certification for disability exceptions, Form N–648.

The Department of Homeland Security, U.S. Citizenship and Immigration Services has 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 June 3, 2005.

Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate 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;

(2) Evaluate the accuracy of the agencies estimate of the burden of the 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:* Reinstatement without change of a previously approved collection.

(2) *Title of the Form/Collection:* Medical Certification for Disability Exceptions.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form N–648. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or

households. The USCIS uses the Form N–648 medical certification issued by the licensed medical professional to substantiate a claim for an exception to the requirements of section 312(a) of the Immigration and Nationality Act. This certification is needed to support the applicant's claim of an exception to this naturalization requirement.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 20,000 responses at 2 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 40,000 annual burden hours.

If you have comments, suggestions, or need a copy of the information collection, please contact Richard A. Sloan, Director, Regulatory Management Division, U.S. Citizenship and Immigration Services, 111 Massachusetts Avenue, NW., Washington, DC 20529, (202) 272–8377.

Dated: March 28, 2005.

Stephen R. Tarragon,

Acting Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. 05–6425 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Comment Request

ACTION: 60-day notice of information collection under review; request for the return of original document(s), form G–884.

The Department of Homeland Security, U.S. Citizenship and Immigration Services has 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 June 3, 2005.

Written comments and suggestions from the public and affected agencies concerning the collection of information should address one or more of the following four points:

(1) Evaluate 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;

(2) Evaluate the accuracy of the agency's estimate of the burden of the 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:* Reinstatement without change of a previously approved collection.

(2) *Title of the Form/Collection:* Request for the Return of Original Document(s).

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form G–884. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The information provided will be used by the USCIS to determine whether a person is eligible to obtain original document(s) contained in an alien file.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 2,500 responses at 15 minutes (0.25) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 625 annual burden hours.

If you have additional comments, suggestions, or need a copy of the information collection instrument, please contact Richard A. Sloan, Director, Regulatory Management Division, U.S. Citizenship and Immigration Services, 111 Massachusetts Avenue, NW., Washington, DC 20529; (202) 272–8377.

Dated: March 28, 2005.

Stephen R. Tarragon,

Acting Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. 05–6426 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: The public is invited to comment on the following applications to conduct certain activities with endangered species and/or marine mammals.

DATES: Written data, comments or requests must be received by May 4, 2005.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents within 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax (703) 358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone (703) 358–2104.

SUPPLEMENTARY INFORMATION:

Endangered Species

The public is invited to comment on the following application(s) for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (address above).

Applicant: Albuquerque Biological Park, Albuquerque, New Mexico, PRT–098648.

The applicant requests a permit to import one live female captive-born jaguar (*Panthera onca*) from the Leon Zoo, Leon, Mexico for the purpose of enhancement of the survival of the species.

Applicant: Jeffrey K. Chaulk, Gaylord, MI, PRT–101773.

The applicant requests a permit to import the sport-hunted trophy of one male black-faced impala (*Aepyceros melampus petersi*) taken in Namibia, for the purpose of enhancement of the survival of the species.

Applicant: Jeffrey K. Chaulk, Gaylord, MI, PRT–101772.

The applicant requests a permit to import the sport-hunted trophy of one cheetah (*Acinonyx jubatus*) taken in Namibia, for the purpose of enhancement of the survival of the species.

Endangered Marine Mammals

The public is invited to comment on the following application(s) for a permit to conduct certain activities with endangered marine mammals. The application was submitted to satisfy requirements of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*) and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361, *et seq.*), and the regulations governing endangered species (50 CFR part 17) and marine mammals (50 CFR part 18). Written data, comments, or requests for copies of the complete applications or requests for a public hearing on these applications should be submitted to the Director (address above). Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Director.

Applicant: Hubbs-SeaWorld Research Institute, San Diego, CA, PRT–060373.

The applicant requests a permit to conduct experiments with up to 600 manatees (*Trichechus manatus latirostris*) in the wild to determine probability of entanglement in modified fishing gear for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a two-year period.

Concurrent with the publication of this notice in the **Federal Register**, the Division of Management Authority is forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Dated: March 18, 2005.

Michael Carpenter,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. 05–6517 Filed 4–1–05; 8:45 am]

BILLING CODE 4310–55–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–528]

In the Matter of Certain Foam Masking Tape; Notice of a Commission Determination Not To Review an Initial Determination Granting Complaints' Motion To Amend the Complaint and Notice of Investigation by Adding Two Respondents

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the initial determination (''ID'') of the presiding administrative law judge (''ALJ'') granting the motion of complainants 3M Company, 3M Innovative Properties Company, and Jean Silvestre (collectively ''3M'') to amend the complaint and notice of investigation by adding two respondents.

FOR FURTHER INFORMATION CONTACT: Michael Diehl, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone (202) 205–3095. Copies of the ALJ's ID and all other nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS–ON–LINE) at *http://dockets.usitc.gov/eol/public.*

SUPPLEMENTARY INFORMATION: By a notice published on January 4, 2005, the Commission instituted this investigation based on a complaint and an amended complaint filed by 3M. The amended complaint alleged a violation of section 337 of the Tariff Act of 1930 in the importation into the United States, and the sale for importation and/or sale within the United States after importation of certain foam masking tape by reason of infringement of certain claims of U.S. Patent Nos. 4,996,092 and 5,260,097. Named as respondents in the notice of investigation were Boss Auto Import, S.A. of Barcelona, Spain; Chemicar USA, Inc. of Memphis, Tennessee; EMM America, Inc. of Campton, New Hampshire; E.M.M. International B.V. of Zwolle, the Netherlands; Indasa, S.A. of Aveiro, Portugal; Indasa U.S.A., Inc. of Passaic, New Jersey; Intertape Polymer Corporation of Bradenton, Florida; IPG Administrative Services, Inc. of Bradenton, Florida; Intertape Polymer Group, Inc., of Montreal, Canada; Saint-Gobain Abrasifs (France) of Conflans-Saint-Honorine, France; Saint-Gobain Abrasives, Inc. of Worcester, Massachusetts; Transtar Autobody Technologies, Inc. of Brighton, Michigan; and Vosschemie GmbH of Uetersen, Germany.

On February 10, 2005, complainants filed a motion to amend the complaint and notice of investigation by adding new respondents Continental Marketing International of Taichung, Taiwan and Jevtech, Ltd. of Macclesfield, United Kingdom. On March 1, 2005, the ALJ issued an ID (Order No. 14) granting the motion to amend.

No party petitioned for review of the ID.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and Commission rule 210.42, 19 CFR 210.42.

Issued: March 29, 2005.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–6532 Filed 4–1–05; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–536]

In the Matter of Certain Pool Cues With Self-Aligning Joint Assemblies and Components Thereof; Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on February 28, 2005, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of J. Pechauer Custom Cues Incorporated of Green Bay, Wisconsin. A supplemental letter was filed on March 18, 2005. The complaint alleges violations of section 337 in the importation into the United States, the

sale for importation, and the sale within the United States after importation of certain pool cues with self-aligning joint assemblies and components thereof by reason of infringement of claims 1–29 of U.S. Patent No. 6,582,317. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a permanent exclusion order and permanent cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Erin D.E. Joffre, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2550.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2004).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on March 28, 2005, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain pool cues with self-aligning joint assemblies or components thereof by reason of infringement of one or more of claims 1–29 of U.S. Patent No. 6,582,317, and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—

J. Pechauer Custom Cues Incorporated, 4140 Velp Avenue, Green Bay, Wisconsin 54313.

(b) The respondents are the following companies alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Kaokao Industrial Co. LTD., aka Kaokao (Zhang Zhou) Sports Equipment Co. Ltd., P.O. Box 65–203 Taichung, Taiwan, 14–B Floor No. 270, Chung Ming South Road, Taichung, Taiwan 403;

CueStix International, 1668 Overlook Drive #104, Lafayette, Colorado 80026;

Sterling Gaming, 3372 Smith Farm Road, Matthews, North Carolina 28104;

CueSight, 3372 Smith Farm Road, Matthews, North Carolina 28104;

Imperial International, 621 West Route 46, Hasbrouck Heights, New Jersey 07604;

Sigel's Unlimited Cues & Accessories, 730 South Dillard Street, Winter Garden, Florida 34787;

Nick Varner Cues and Cases, 1400–B Triplett Street, Owensboro, Kentucky 42303;

J–S Sales Co. Inc., 102 Fairview Park Drive, Elmsford, New York 10523; and

GLD Products, S84 W19093 Enterprise Drive, Muskego, Wisconsin 53150.

(c) Erin D.E. Joffre, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Suite 401, Washington, DC 20436, who shall be the Commission investigative attorney, party to this investigation; and

(3) For the investigation so instituted, the Honorable Sidney Harris is designated as the presiding administrative law judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter a final determination containing such findings, and may result in the issuance of a limited exclusion order or cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: March 29, 2005.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–6529 Filed 4–1–05; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. TA–204–12]

Steel: [1] Evaluation of the Effectiveness of Import Relief

AGENCY: United States International Trade Commission.

ACTION: Institution of an investigation and scheduling of hearings.

SUMMARY: Pursuant to section 204(d) of the Trade Act of 1974 (19 U.S.C. 2254(d)) (the Act), the Commission has instituted investigation No. TA–204–12, Steel: Evaluation of the Effectiveness of Import Relief, for the purpose of evaluating the effectiveness of the relief action imposed by the President on imports of certain steel products under

[1] Subheadings 9903.72.30 through 9903.74.24 of the Harmonized Tariff Schedule of the United States set forth safeguard measures applicable to covered steel products and specified products and sources excluded from the safeguard measures. In the 2003 HTS, subheadings 9903.72.30 through 9903.72.48 covered carbon and alloy steel slabs; subheadings 9903.72.50 through 9903.73.39 covered carbon and alloy steel flat-rolled products (including plates and other hot-rolled steel, cold-rolled steel other than grain-oriented steel, and clad, coated, and plated steel); subheadings 9903.73.42 through 9903.73.62 covered certain carbon and alloy steel bars, rods, and light shapes; subheadings 9903.73.65 through 9903.73.71 covered carbon steel concrete reinforcing bars (rebars); subheadings 9903.73.74 through 9903.73.86 covered certain carbon and alloy steel non-seamless pipes and tubes; subheadings 9903.73.88 through 9903.73.95 covered certain tube and pipe fittings; subheadings 9903.73.97 through 9903.74.16 covered stainless steel bars, rods, angles, shapes, and sections; and subheadings 9903.74.18 through 9903.74.24 covered stainless steel wire.

section 203 of the Act. The remaining portion of the action terminated on March 21, 2005.

EFFECTIVE DATE: March 21, 2005.

FOR FURTHER INFORMATION CONTACT: Elizabeth Haines (202–205–3200) or Douglas Corkran (202–205–3057), Office of Investigations, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*).

Background: The President announced the relief action on March 5, 2002. In a proclamation of that date (Proclamation 7529, published in the **Federal Register** of March 7, 2002, at 67 FR 10553), the President announced that he would impose safeguard measures on imports of certain steel products in the form of a tariff-rate quota and increased import duties effective March 20, 2002, for a period of 3 years and 1 day (to March 21, 2005). In a memorandum of that same date relating to these measures, the President instructed the Secretary of the Treasury and the Secretary of Commerce to establish a system of import licensing to facilitate the monitoring of imports of certain steel products (67 FR 10953). The Department of Commerce published regulations establishing such a system in the **Federal Register** on December 31, 2002 (67 FR 79845). On December 4, 2003, the President issued a proclamation that terminated the tariff-rate quota and the increased import duties on certain steel products, but directed the Secretary of Commerce to continue the monitoring system until the earlier of March 21, 2005, or such time as the Secretary establishes a replacement program (Proclamation 7741, published in the **Federal Register** of December 8, 2003, at 68 FR 68483). Proclamation 7741 also authorized the United States Trade Representative, upon his determination that the Secretary of Commerce has established a replacement program, to terminate the action under section 203(a)(3)(I) of the Trade Act and the licensing system, and to publish notice of this determination and action in the **Federal Register**. On December 9, 2003, the Department of Commerce published a notice stating that the system would continue in effect as described in the Proclamation until March 21, 2005 (68 FR 68594). On March 11, 2005, the Department of Commerce published an interim final rule to implement a replacement program for the period beyond March 21, 2005 (70 FR 12133).

Section 204(d) of the Act requires the Commission, following termination of a relief action, to evaluate the effectiveness of the action in facilitating positive adjustment by the domestic industry to import competition, consistent with the reasons set out by the President in the report submitted to the Congress under section 203(b) of the Act. The Commission is required to submit a report on the evaluation to the President and the Congress no later than 180 days after the day on which the relief action was terminated.

For further information concerning the conduct of this investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201, subparts A through and E), and part 206, subparts A and F (19 CFR part 206, subparts A and F).

SUPPLEMENTARY INFORMATION:

Participation in the investigation and service list.—Persons wishing to participate in the investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, not later than 14 days after publication of this notice in the **Federal Register**. The Secretary will prepare a service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance.

Public hearing.—The Commission has scheduled hearings in connection with this investigation. The hearings will be held beginning at 9:30 a.m. on July 19, 2005 (carbon and alloy flat products), July 21, 2005 (carbon and alloy long products), July 26, 2005 (carbon and alloy tubular products), and July 28, 2005 (stainless steel products), at the U.S. International Trade Commission Building. Requests to appear at a specific hearing should be filed in writing with the Secretary to the Commission on or before June 20, 2005, so that the Commission may determine the level of interest in the hearings. All persons desiring to appear at a hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on July 15, 2005, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the hearing are governed by sections 201.6(b)(2) and 201.13(f) of the Commission's rules.

Written submissions.—Each party is encouraged to submit a prehearing brief to the Commission. The deadline for filing prehearing briefs is July 12, 2005. Parties may also file posthearing briefs. The deadlines for filing posthearing briefs are July 27, 2005 (for material covered at the hearing on July 19, 2005), July 29, 2005 (for material covered at the hearing on July 21, 2005), August 3, 2005 (for material covered at the hearing on July 26, 2005) and August 5, 2005 (for material covered at the hearing on July 28, 2005). In addition, any person who has not entered an appearance as a party to the investigation may submit a written statement concerning the matters to be addressed in the report on or before August 5, 2005. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain confidential business information must also conform with the requirements of section 201.6 of the Commission's rules. The report that the Commission sends to the President may include confidential business information. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's rules, as amended, 67 FR 68036 (November 8, 2002).

In accordance with section 201.16(c) of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by the service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under the authority of section 204(d) of the Trade Act of 1974; this notice is published pursuant to section 206.3 of the Commission's rules.

By order of the Commission.

Issued: March 30, 2005.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E5–1483 Filed 4–1–05; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-day notice of information collection under review: personnel security request.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 69, Number 238, page 72219 on December 13, 2004, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until May 4, 2005. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- 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 agencies 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.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Personnel Security Request.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form Number: ATF 8620.5. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. *Other:* None. ATF F 8620.5 is an internal use form to gather preliminary information from an individual desiring access to ATF facilities, information or data. The information requested is necessary to permit ATF to begin the preliminary criminal records search on the applicant.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 1000 respondents will complete a 5 minute form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 83 annual total burden hours associated with this collection.

If additional information is required contact: Brenda E. Dyer, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: March 29, 2005.

Brenda E. Dyer,

Department Clearance Officer, Department of Justice.

[FR Doc. 05–6525 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-day notice of information collection under review: a national repository for the collection and inventory of information related to arson and the criminal misuse of explosives.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 69, Number 247, page 77269 on December 27, 2004, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until May 4, 2005. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- 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 agencies 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.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *Title of the Form/Collection:* A National Repository for the Collection and Inventory of Information Related to Arson And the Criminal Misuse of Explosives.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form Number: None. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: State, local or tribal government. Other: Federal Government. The Federal explosive laws require all Federal agencies to report to the Attorney General (AG) information relating to arson and criminal misuse of explosives for entry into a national repository. In addition, the law provides that such a repository will contain information on arson and explosives incidents voluntarily reported to the Attorney General by State, local or tribal authorities. The ATF National Repository maintains all explosive incident databases within the Department.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 2,000 respondents will report the information within approximately 10 minutes.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 333 annual total burden hours associated with this collection.

If additional information is required contact: Brenda E. Dyer, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: March 29, 2005.

Brenda E. Dyer,

Department Clearance Officer, Department of Justice.

[FR Doc. 05–6526 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-day notice of information collection under review: application for registration of firearms acquired by certain governmental entities.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 69, Number 238, page 72220 on December 13, 2004, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until May 4, 2005. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

• 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 agencies 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.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Application for Registration of Firearms Acquired by Certain Governmental Entities.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form Number: ATF F 10 (5320.10). Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: State, local or tribal government. The form is required to be submitted by State and local government entities wishing to register an abandoned or seized and previously unregistered National Firearms Act weapon. The form is required whenever application for such a registration is made.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 1500 respondents will complete a 30 minute form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 3000 annual total burden hours associated with this collection.

If additional information is required contact: Brenda E. Dyer, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: March 29, 2005.

Brenda E. Dyer,

Department Clearance Officer, Department of Justice.

[FR Doc. 05–6527 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Antitrust Division

Proposed Final Judgment and Competitive Impact Statement; United States v. Bluefield Regional Medical Center, Inc. and Princeton Community Hospital Associations, Inc.

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. section 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the Southern District of West Virginia in *United States* v. *Bluefield Regional Medical Center, Inc. and Princeton Community Hospital Association, Inc.*, Civil Case No. 1:05–0234. On March 21, 2005, the United States filed a Complaint alleging that, on January 30, 2003, Bluefield Regional Medical Center, Inc. (BRMC) and Princeton Community Hospital Association, Inc. (PCH) entered into two agreements in which BRMC agreed not to offer many cancer services and PCH agreed not to offer cardiac-surgery services. The BRMC–PCH agreements effectively allocated markets for cancer and cardiac-surgery services and restrained competition to the detriment of consumers in violation of section 1 of the Sherman Act.

The proposed Final Judgment filed with the Complaint will enjoin BRMC and PCH from enforcing the BRMC–PCH agreements. BRMC and PCH also will be enjoined from entering into, continuing, maintaining, or enforcing any agreement to allocate markets, territories, or customers concerning cancer services or cardiac surgery. In addition, BRMC and PCH will be enjoined from entering into, continuing, maintaining, or enforcing any other agreement that (1) prohibits or restricts a health-care facility from obtaining a certificate of need relating to cancer services or cardiac surgery or (2) otherwise prohibits or restricts a health-care facility from taking actions related to providing cancer services or cardiac surgery without prior notice to and prior written approval of the United States. Finally, BRMC and PCH are enjoined from entering into, continuing, maintaining, or enforcing any agreement with each other concerning cancer services or cardiac surgery without prior notice to and prior written approval of the United States.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection at the Department of Justice, Antitrust Documents Group, 325 Seventh Street, NW., Room 215 North, Washington, DC 20530 and at the Office of the Clerk of the United States District Court for the Southern District of West Virginia, 601 Federal Street, Room 2303, Bluefield, West Virgina 24701.

Public comment is invited within 60 days of the date of this notice. Such comments, and responses thereto, will be published in the **Federal Register** and filed with the Court. Comments should be directed to Mark J. Botti, Chief, Litigation I Section, Antitrust Division, U.S. Department of Justice, 1401 H Street, NW., Suite 4000, Washington, DC 20530 (Telephone (202) 307–0001).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

Final Judgment

Whereas, Plaintiff, the United States of America, filed its Complaint on March 21, 2005 alleging that Defendants, Bluefield Regional Medical Center, Inc. and Princeton Community Hospital Association, Inc., entered into agreements in violation of section 1 of the Sherman Act, 15 U.S.C. 1, and Plaintiff and Defendants, by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against, or any admission by, any party regarding any such issue of fact or law;

And whereas, Defendants agree to be bound by the provisions of the Final Judgment pending its approval by this Court;

And whereas, the essence of this Final Judgment is to enjoin the Defendants from allocating markets for the provision of certain medical services and to restore lost competition as alleged in the Complaint;

And whereas, the United States requires Defendants to agree to certain procedures and prohibitions for the purpose of restoring the loss of competition alleged in the Complaint;

Now therefore, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is *ordered, adjudged and decreed:*

I. Jurisdiction

This Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against Defendants under section 1 of the Sherman Act, as amended (15 U.S.C. 1).

II. Definitions

As used in this Final Judgment:

A. ''Agreement'' means any kind of formal or informal agreement, arrangement, contract, understanding, memorandum of understanding, interim contract, contract appendix, addendum, attachment, amendment, waiver, or modification. Agreements that solely concern patient-treatment protocols or the transfer of patients necessary to render patient care that is unavailable at BRMC or PCH shall not be deemed an agreement within the scope of this Final Judgment. An agreement solely for the merger of BRMC and PCH, the acquisition by one of the other, or bringing all or substantially all of the operations or assets of BRMC and PCH under common control shall not be deemed an agreement within the scope of this Final Judgment if BRMC and PCH give at least thirty days advance notice of such merger, acquisition, or transaction to the United States.

B. ''BRMC'' means Defendant Bluefield Regional Medical Center, Inc. a non-profit corporation organized and existing under the laws of the State of West Virginia with its headquarters in Bluefield, West Virginia, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.

C. ''Cancer and Open-Heart Agreements'' means (1) the contract dated January 30, 2003 between BRMC and PCH concerning cancer services and all amendments and other agreements ancillary to that contract and (2) the contract dated January 30, 2003 among BRMC, PCH, and Charleston Area Medical Center, Inc. concerning cardiac surgery and all amendments and other agreements ancillary to that contract.

D. ''Cancer Services'' means any health or other service relating to any service performed by cancer specialists such as radiation oncologists, medical oncologists, surgical oncologists, gynecological oncologists, and other oncologic physician specialists. This term includes any equipment, technology, or modality used in providing such services.

E. ''Cardiac Surgery'' means any health or other services relating to surgery on the heart or major blood vessels of the heart (including both open and closed heart surgery) and therapeutic cardiac catherization. This term includes any service, equipment, technology, or modality relating to the services of an open-heart surgeon, cardiovascular surgeon, cardiovascular anesthesiologist, interventional cardiologist, or perfusionist.

F. ''Certificate of Need'' means certificate of need as recognized by the

State of West Virginia (W. Va. Code § 16–2D–1 *et seq.*) and a certificate of public need as recognized in the Commonwealth of Virginia (Va. Code Ann. § 32.1–102.1 *et seq.*).

G. ''Health-Care Facility'' means any facility providing health-care services, including hospitals, hospital-owned or managed physician practices, ambulatory-care centers, clinics, urgent-care centers, free-standing emergency-care centers, and ambulatory-surgery centers.

H. ''PCH'' means Defendant Princeton Community Hospital Association, Inc., a non-profit corporation organized and existing under the laws of the State of West Virginia with its headquarters in Princeton, West Virginia, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.

I. The terms ''and'' and ''or'' have both conjunctive and disjunctive meanings.

III. Applicability

This Final Judgment applies to BRMC and PCH, as defined above, and all other persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

IV. Prohibited Conduct

A. BRMC and PCH are enjoined from enforcing all or any part of the Cancer and Open-Heart Agreements. BRMC's and PCH's obligations under this Final Judgment supersede their obligations under either of these agreements, and BRMC and PCH shall not object to the performance of their obligations under this Final Judgment on the grounds that those obligations would cause them to breach either agreement.

B. BRMC and PCH are enjoined from, in any manner, directly or indirectly, entering into, continuing, maintaining, or enforcing any agreement to allocate any cancer or cardiac-surgery service, market, territory, or customer.

C. BRMC and PCH are enjoined from, in any manner, directly or indirectly, entering into, continuing, maintaining, or enforcing any other agreement that (1) prohibits or restricts a health-care facility from obtaining a certificate of need relating to cancer services or cardiac surgery or (2) otherwise prohibits or restricts a health-care facility from taking actions related to providing cancer services or cardiac surgery without prior notice to and prior written approval of the United States, which will not be withheld unreasonably.

D. BRMC and PCH are enjoined from, in any manner, directly or indirectly, entering into, continuing, maintaining, or enforcing any agreement with each other concerning cancer services or cardiac surgery without prior notice to and prior written approval of the United States, which will not be withheld unreasonably.

V. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment, or of determining whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, from time to time duly authorized representatives of the United States Department of Justice, including consultants and other persons retained or designated thereby, shall, upon written request of a duly authorized representative of the Assistant Attorney General in charge of the Antitrust Division and on reasonable notice to Defendants, be permitted:

1. Access during Defendants' office hours to inspect and copy, or at the United States' option, to require that Defendants provide copies of, all books, ledgers, accounts, records and documents in their possession, custody, or control relating to any matters contained in this Final Judgment; and

2. To interview, either informally or on the record, Defendants' officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

B. Upon the written request of a duly authorized representative of the Assistant Attorney General in charge of the Antitrust Division, Defendants shall submit written reports, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested.

C. No information or documents obtained by the means provided in this section shall be divulged by Plaintiff to any person other than an authorized representative of the executive branch of the United States except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. If at the time Defendants furnish information or documents to the United States, they represent and identify in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(7) of the Federal Rules of Civil Procedure, and mark each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure,'' then the United States shall give Defendants ten calendar days notice prior to divulging such material in any legal proceeding (other than a grand jury proceeding).

VI. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

VII. Expiration of Final Judgment

Unless this Court grants an extension, this Final Judgment shall expire ten years from the date of its entry.

VIII. Correspondence

BRMC and PCH shall provide notice and seek prior written approval as contemplated by this Final Judgment by sending correspondence to Chief, Litigation I, Antitrust Division, United States Department of Justice, 1401 H Street, NW., Suite 4000, Washington, DC 20530, or such other address as the United States shall designate.

IX. Public Interest Determination

Entry of this Final Judgment is in the public interest.

Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. § 16.

United States District Judge.

Stipulation

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

1. The Court has jurisdiction over the subject matter of this action and each of the parties hereto, and venue of this action is proper in this District.

2. The parties stipulate that a proposed Final Judgment in the form attached as Exhibit A may be entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the antitrust Procedures and Penalties Act, 15 U.S.C. 16, and without further notice to any party or other proceedings, provided that the United States has not withdrawn its consent, which it may do at any time before the entry of the proposed final

Judgment by serving notice thereof on defendants and by filing that notice with the Court.

3. Defendants shall abide by and comply with the provisions of the proposed Final Judgment, pending the Judgment's entry by the Court, or until expiration of time for all appeals of any Court ruling declining entry of the proposed Final Judgment, and shall, from the date of the signing of this Stipulation by the parties, comply with all the terms and provisions of the proposed Final Judgment as though the same were in full force and effect as an order of the Court.

4. This Stipulation shall apply with equal force and effect to any amended proposed Final Judgment agreed upon in writing by the parties and submitted to the Court.

5. In the event (a) the United States has withdrawn its consent, as provided in section 2 above, or (b) the proposed Final Judgment is not entered pursuant to this Stipulation, the time has expired for all appeals of any Court ruling declining entry of the proposed Final Judgment, and the Court has not otherwise ordered continued compliance with the terms and provisions of the proposed Final Judgment, then the parties are released from all further obligations under this Stipulation, and the making of this Stipulation shall be without prejudice to any party in this or any other proceeding.

For Plaintiff United States of America:

Dated: March 21, 2005.

Peter J. Mucchetti, Esq.,
Litigation I Section, Antitrust Division, United States Department of Justice.

For Defendant Bluefield Regional Medical Center, Inc.:

Dated: March 18, 2005.

Arthur N. Lerner, Esq.,
Crowell & Moring LLP, Counsel for Defendant Bluefield Regional Medical Center, Inc.

For Defendant Princeton Community Hospital Association, Inc.

March 14, 2005.

Kevin E. Grady, Esq.,
Alston & Bird LLP, Counsel for Defendant Princeton Community Hospital Association, Inc.

Competitive Impact Statement

The United States of America, pursuant to section 2(b) of the Antitrust Procedures and Penalties Act, (''APPA''), 15 U.S.C. 16(b)–(h), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

On March 21, 2005, the United States filed a civil antitrust Complaint alleging that Bluefield Regional Medical Center, Inc. (BRMC) and Princeton Community Hospital Association, Inc. (PCH) had violated Section 1 of the Sherman Act, 15 U.S.C. 1. BRMC owns and operates a 265-bed, general acute-care hospital in Bluefield, West Virginia. PCH owns and operates a 211-bed general acute-care hospital in Princeton, West Virginia. PCH also owns and operates St. Luke's Hospital, LLC (St. Luke's), a 79-bed, general acute-care hospital in Bluefield, West Virginia.

The Complaint alleges that, on January 30, 2003, BRMC and PCH entered into two agreements (the ''cancer and open-heart agreements'') in which BRMC agreed not to offer certain cancer services and PCH agreed not to offer certain cardiac-surgery services. The cancer and open-heart agreements effectively allocated markets for cancer and cardiac-surgery services and restrained competition to the detriment of consumers. With the Complaint, the United States, BRMC, and PCH filed an agreed-upon proposed Final Judgment that annuls the cancer and open-heart agreements and prohibits BRMC and PCH from taking actions that would reduce competition between the two hospitals for patients needing cancer and cardiac-surgery services.

The United States, BRMC, and PCH have agreed that the proposed Final Judgment may be entered after compliance with the APPA, provided that the United States has not withdrawn its consent. Entry of the Final Judgment would terminate the action, except that the Court would retain jurisdiction to construe, modify, or enforce the Final Judgment's provisions and to punish violations thereof.

II. Description of Practices and Events Giving Rise to the Alleged Violations of the Antitrust Laws

A. Services Provided by the Defendants and Events Preceding the Parties' Cancer and Open-Heart Agreements

At all times relevant to the matters alleged in the Complaint, BRMC and PCH have been significant competitors in general acute-care hospital services and in cancer services. PCH is located about fifteen miles from BRMC. PCH's St. Luke's Hospital is located about two miles from BRMC. BRMC, PCH, and St. Luke's are the only general acute-care hospitals in Mercer County, West Virginia.

BRMC and PCH also have been potential competitors in cardiac-surgery services. BRMC sought to develop cardiac-surgery services since at least 1999. Similarly, from at least 1999 until PCH agreed not to compete with BRMC in cardiac-surgery services, PCH sought to develop cardiac-surgery services by working with other hospitals in southern West Virginia.

The State of West Virginia and the Commonwealth of Virginia require that a hospital obtain a certificate of need or a certificate of public need (collectively, ''CON'') from a state agency before a hospital may provide either cardiac-surgery services or radiation-therapy services (using a linear accelerator) for treating patients with cancer. The West Virginia Health Care Authority (WVHCA) administers the CON program in West Virginia. The Virginia Department of Health's Certificate of Public Need Division and regional health planning agencies administer the CON program in Virginia.

In January 1999, BRMC submitted a CON application to the WVHCA to develop a cardiac-surgery program in Mercer County, West Virginia. At that time, neither BRMC, PCH, nor St. Luke's had a CON to operate a cardiac-surgery program. PCH, St. Luke's, and other hospitals opposed BRMC's application. PCH and St. Luke's argued, in part, that BRMC's application should be denied because it did not provide a role for PCH and St. Luke's in the provision of cardiac-surgery services in southern West Virginia.

In February 2000, the WVHCA issued a written decision that denied BRMC's application for a CON to develop a cardiac-surgery program because BRMC was unable to show that, without working with other hospitals, it would be able to attract a sufficient number of patients. In its decision, the WVHCA wrote that PCH, St. Luke's and other hospitals had:

> failed to successfully negotiate with [BRMC] to reach a shared goal. The goal being to provide advanced cardiology services to the citizens of southern West Virginia and southwestern Virginia * * *. [The WVHCA] would have preferred that the parties work together to present a project that could have been approved under the existing law. Instead, the parties fought among themselves, failed to resolve their differences, and in return, the citizens of southern West Virginia will be inconvenienced and suffer by not having a regional open-heart service provider.

On one or more occasions during 2002, BRMC and PCH representatives met with WVHCA officials. The WVHCA officials encouraged BRMC and PCH to reach an understanding that would enable the parties to submit an application for an open-heart surgery

CON that the WVHCA would be able to approve. The WVHCA officials, however, neither instructed nor encouraged BRMC and PCH to allocate markets.

B. The Cancer and Open-Heart Agreements

On January 30, 2003, BRMC and PCH entered into the cancer and open-heart agreements. The cancer agreement concerned PCH's provision of certain cancer services, including radiation-therapy services, and the open-heart agreement concerned BRMC's plan to develop cardiac-surgery services (open-heart surgery and therapeutic cardiac-catheterization services). The agreements applied to McDowell, Mercer, Monroe, Raleigh, Summers, and Wyoming counties in southern West Virginia and Bland, Giles, and Tazewell counties in western Virginia. In the agreements, BRMC agreed to submit a joint CON application with PCH to transfer BRMC's CON to operate radiation-therapy equipment to PCH. PCH agreed to submit a joint CON application with BRMC for BRMC to receive a cardiac-surgery CON.

As part of the cancer and open-heart agreements, BRMC agreed to refrain from competing with PCH in various ways, none of which was related to a procompetitive purpose. BRMC agreed, among other things:

- Not to apply for, finance, encourage, or participate in a CON to provide cancer services by itself or with any entity other than PCH;
- That, in the event that the State of West Virginia or the Commonwealth of Virginia no longer requires a CON to provide cancer services, BRMC would not develop, finance, encourage, participants in, or support the development or provision of cancer services by BRMC or any entity other than PCH;
- Not to engage in, support, finance, encourage, or participate in the recruitment of any physician cancer specialists to BRMC's medical staff or for any other entity or individual, other than PCH;
- To provide to PCH information relating to cancer services provided by BRMC;
- Not to market or advertise that BRMC has a cancer center;
- Not to provide outpatient chemotherapy services (except for those services ordered or performed by either of two physicians currently practicing at BRMC);
- Not to lease space in its existing or future medical office buildings to any cancer specialists, except for those cancer specialists leasing space as of the date of the agreement; and
- That, in the event that any new technology or modality for the diagnosis or treatment of cancer becomes available that is not offered generally at hospitals similar to PCH and BRMC, BRMC would not acquire, develop, offer or provide such technology or modality, and BRMC would not finance, encourage, participate in, or support the development or offering of such technology or modality by any entity other than PCH.

As part of the cancer and open-heart agreements, PCH also agreed to refrain from competing with BRMC is various ways, none of which was related to a procompetitive purpose. PCH agreed, among other things:

- Not to apply for, finance, encourage, or participate in a CON to provide cardiac-surgery services by itself or with any entity other than BRMC;
- That, in the event that the State of West Virginia or the Commonwealth of Virginia no longer requires a CON to provide cardiac-surgery services, PCH would not develop, finance, encourage, participate in, or support the development or provision of cardiac-surgery services by PCH or any entity other than BRMC;
- Not to engage in, support, finance, encourage, or participate in the recruitment of any cardiac-surgery specialists to PCH's medical staff or for any other entity or individual, other than BRMC;
- To provide to BRMC information relating services provided by PCH;
- Not to solicit, entertain, finance, aid, support, or participate in any competing proposal from any entity or physician to develop cardiac-surgery services;
- Not to lease space in its existing or future medical office buildings to any open-heart surgery specialist; and
- That, in the event that any new technology or modality for the diagnosis or treatment or cardiovascular disease becomes available that is not offered generally at hospitals similar to PCH and BRMC, PCH would not acquire, develop, offer or provide such technology or modality, and PCH would not finance, encourage, participate in, or support the development or offering of such technology or modality by any entity other than BRMC.

The term of the cancer and open-heart agreements commend on January 30, 2003 and terminates five years after the first open-heart surgery is performed at BRMC or the first cancer patient is treated at a PCH comprehensive cancer center, whichever is later. Neither agreement can last longer than eight years. Each agreement automatically terminates if, within three years from commencement, either party has not received all government approvals needed to provide its services.

PCH and BRMC structured the agreements such that PCH would independently own its cancer-treatment facilities and provide its cancer services independently of BRMC, BRMC would independently own its cardiac-surgery facilities and provide its cardiac-surgery services independently of PCH, and BRMC and PCH would not provide these services as part of a joint venture.

On January 23, 2003, BRMC submitted to the WVHCA a CON application, with PCH as a joint applicant, to develop a cardiac-surgery program at BRMC. On July 30, 2003, PCH submitted to the WVHCA an application, with BRMC as a joint applicant, to transfer BRMC's CON to operate radiation-therapy equipment to PCH. The WVHCA approved BRMC's cardiac-surgery CON application on August 1, 2003. PCH's application to transfer BRMC's radiation-therapy equipment CON to PCH remains pending with the WVHCA.

Because of the cancer and open-heart agreements, BRMC and PCH have refrained and, if not enjoined, likely would continue to refrain from competing to serve patients that need cancer and cardiac-surgery services. The cancer and open-heart agreements have had and, unless enjoined, likely would have the following harmful effects:

- Managed-care purchasers, their enrollees and employees, and other patients in southern West Virginia and western Virginia have been denied and would be denied the benefits of price competition between PCH and BRMC;
- The quality of services has decreased and likely would decrease in the absence of competition between PCH and BRMC to provide cancer and cardiac-surgery services;
- Patients have lost and would lose the ability to choose between PCH and BRMC when selecting a hospital to provide cancer services;
- Patients have lost and would lose the benefit of potential competition between PCH and BRMC in cardiac-surgery services; and
- PCH's and BRMC's incentives to innovate or offer new cancer and cardiac-surgery services have been and would be decreased.

C. The Cancer and Open-Heart Agreements Are Not Entitled to Federal Antitrust Immunity Under the State-Action Doctrine

The state-action doctrine provides immunity from Federal antitrust liability where a party can satisfy a two-part test. First, the party must show that the challenged restraint is one clearly articulated and affirmatively expressed as state policy. *California Retail Liquor Dealers Association* v. *Midcal Aluminum*, 445 U.S. 97, 105 (1980). To satisfy the clear-articulation requirement, a defendant must show only that ''the legislature contemplated the kind of action complained of.'' *Town of Hallie* v. *City of Eau Claire*, 471 U.S. 34, 44 (1985). Second, the state must actively supervise the challenged conduct. *Midcal*, 445 U.S. at 105.

As discussed below, no state action in either West Virginia or Virginia shields the cancer and open-heart agreements from federal antitrust review. The West Virginia legislature has not enpowered the WVHCA to authorize hospitals to enter into market-allocation agreements. Furthermore, the WVHCA is not empowered to exercise, and has not exercised, active supervision over the cancer and open-heart agreements. Indeed, the WVHCA did not purport to authorize the parties to enter into the agreements. Similarly, in Virginia, no state agency or official encouraged or authorized BRMC and PCH to reach an understanding or agreement concerning cardiac-surgery or cancer services.

1. The West Virginia Legislature Did Not Empower the WVHCA To Authorize Private Market-allocation Agreements

The West Virginia legislature empowered the WVHCA to administer West Virginia's CON program according to legislatively established criteria. W. Va. Code § 16–2D–1 *et seq.*, W. Va. Code St. R. § 65–7–1 *et seq.*, W. Va. Code § 16–29B–1 *et seq*. Although the West Virginia legislature granted the WVHCA significant regulatory powers over competition in West Virginia health-care markets, it limited the means by which the WCHCA can regulate competition among health-care providers principally to granting or denying CONs to firms wishing to compete. W. Va. Code § 16–2D–1 *et seq.*, W. Va. Code St. R. § 65–7–1 *et seq.*, W. Va. Code § 16–29B–1 *et seq*.

In administering the CON program, the WVHCA is called upon to review and, if appropriate, to grant or deny CON applications for certain medical services. W. Va. Code § 16–29–11. The statutory framework grants third parties the right to intervene to protect their interests; affords adversely affected parties the right of judicial review; requires written findings as to whether approval of a CON would further legislatively established criteria; and establishes other procedural safeguards. W. Va. Code §§ 16–29B–12(f), 16–29B–13, and 16–2D–9. When reviewing CON applications, the WVHCA must follow established procedures and act within the CON process. *See* W. Va. Code § 16–2D–1 *et seq.*, W. Va. Code St. R. § 65–7–1 *et seq.*, W. Va. Code § 16–29B–1 *et seq*. The statutes and regulations delineating the responsibilities of the WVHCA do not explicitly empower it to consider, or to issue opinions concerning, private market-allocation agreements. *See, e.g.*, W. Va. Code § 16–2D–1 *et seq.*, W. Va. Code St. R. § 65–7–1 *et seq.*, W. Va. Code § 16–29B–1 *et seq.*, W. Va. Code St. R. § 65–5–1 *et seq.*, W. Va. Code St. R. § 65–26–1 *et seq*.

Nor does the WVHCA have implicit authority to approve private agreements as a means of regulating competition. In light of the rights and procedural safeguards afforded in the statutory framework to affected parties, to conclude that WVHCA has implied authority to authorize private market-allocation agreements would be inconsistent with that framework and effectively would give to the WVHCA unreviewable discretion to regulate health-care markets. To the contrary, the legislature generally has left West Virginia health-care providers free to make market decisions on how to compete as long as they are not (1) adding or expanding health-care services; (2) incurring a capital expenditure of $2 million or more; (3) obtaining major medical equipment valued at $2 million or more; or (4) developing or acquiring new health-care facilities. W. Va. Code § 16–2D–3.

Because the West Virginia legislature has not granted to the WVHCA the explicit authority to approve private market-allocation agreements such as the cancer and open-heart agreements, because any implicit authority of the WVHCA to approve such agreements would be inconsistent with the statutory framework that the legislature did create, and because the legislature clearly contemplated that West Virginia hospitals would compete in the free market for many of the activities covered by the cancer and open-heart agreements, these agreements cannot be considered part of a ''clearly articulated and affirmatively expressed state policy.'' *Midcal*, 445 U.S. at 105.

2. The WVHCA Is Not Empowered To Exercise, and Has Not Exercised, Active Supervision Over the Cancer and Open-Heart Agreements

The active-supervision requirement of the state-action doctrine requires that the State actively supervise and exercise ultimate control over the challenged anticompetitive conduct. *Midcal*, 445 U.S. at 105, *Patrick* v. *Burget*, 486 U.S. 94, 100–101 (1988). ''The requirement is designed to ensure that the state-action doctrine will shelter only the particular anticompetitive acts of private parties that, in the judgment of the State, actually further state regulatory policies.'' *Patrick*, 486 U.S. at 100–101.

The West Virginia legislature, however, has not empowered the WVHCA to require parties to private agreements to maintain, alter, or abandon their agreements. Thus, the WVHCA has no power to exercise active supervision or control over private agreements such as the cancer and open-heart agreements. Moreover, the WVHCA has not purported to actively supervise the cancer and open-heart agreements, as it did not (1) develop a factual record concerning the initial or ongoing nature and effect of the agreements; (2) issue a written decision approving the agreements; or (3) assess whether the agreements further criteria established by the West Virginia legislature. *See FTC* v. *Ticor Title Ins. Co.*, 504 U.S. 621, 637–639 (1992).

The WVHCA, in its February 2000 decision and in the actions of its officials during 2002, did not purport to authorize BRMC and PCH to enter into market-allocation agreements. In its February 2000 decision denying BRMC's cardiac-surgery CON application, the WVHCA simply stated a preference that BRMC and PCH work together to develop a cardiac-surgery project and encouraged the parties to submit a cardiac-surgery CON application that could be approved under the law. The decision did not encourage or instruct BRMC and PCH to allocate cardiac-surgery or cancer services. Similarly, during meetings in 2002 with representatives of BRMC and PCH, WVHCA officials neither instructed nor encouraged BRMC and PCH to allocate markets or to agree to anticompetitive conduct such as that later contained in the cancer and open-heart agreements.

Regulation by the WVHCA of the rates charged by BRMC and PCH, *see, e.g.*, W. Va. Code § 16–29B–1 *et seq.*, W. Va. Code St. § 65–5–1 *et seq.*, W. Va. Code St. R. § 65–26–1 *et seq.*, also does not satisfy the active-supervision requirement. In this case, the

anticompetitive conduct is not the prices charged by the hospitals; rather, it is the terms of the cancer and open-heart agreements. The WVHCA's regulation of rates does not directly address market-allocation issues or the potential anticompetitive effects of such allocations, as rate regulation may fail to ensure that the hospitals charge rates equal to those rates that would have prevailed in a competitive market and it fails to address decreases in quality of service, innovation, and consumer choice that result from an agreement not to compete.

3. No Virginia Official or Agency Encouraged or Authorized BRMC and PCH To Reach an Agreement Concerning Cardiac-Surgery or Cancer Services

Although the cancer and open-heart agreements allocate markets for cancer and cardiac surgery in three Virginia counties, no Virginia state action immunizes the agreements from federal antitrust review. An extensive discussion of why the state-action doctrine does not apply in Virginia is not necessary as BRMC and PCH has no contacts with any Virginia agency or official that might suggest a state-action defense. No Virginia agency or official encouraged or authorized BRMC and PCH to enter into the agreements or reach any understanding concerning cardiac-surgery or cancer services. BRMC and PCH also never sought or received approval for the agreements from any Virginia agency or official.

III. Explanation of the Proposed Final Judgment

The proposed Final Judgment would enjoin BRMC and PCH from enforcing any part of the cancer and open-heart agreements. BRMC and PCH also would be enjoined from entering into, continuing, maintaining, or enforcing any agreement to allocate any cancer or cardiac-surgery service, market, territory, or customer. In addition, BRMC and PCH would be enjoined from entering into, continuing, maintaining, or enforcing any other agreement that (1) prohibits or restricts a health-care facility from obtaining a certificate of need relating to cancer services or cardiac surgery or (2) otherwise prohibits or restricts a health-care facility from taking actions related to providing cancer services or cardiac surgery without prior notice to and prior written approval of the United States. Finally, BRMC and PCH would be enjoined from entering into, continuing, maintaining, or enforcing any agreement with each other concerning cancer services or cardiac surgery without prior notice to and prior written approval of the United States. The effect of the proposed Final Judgment would be to restore competition between BRMC and PCH that the cancer and open-heart agreements eliminated, and would prevent BRMC and PCH from engaging in similar conduct in the future.

IV. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of such actions. Under the provisions of section 5(a) of the Clayton Act, 15 U.S.C. 16(a) the Final Judgment has no *prima facie* effect in any subsequent lawsuits that may be brought against the Defendant.

V. Procedures Available for Modifications of the Proposed Final Judgment

The United States and the Defendant have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty days of the date of publication of this Competitive Impact Statement in the **Federal Register**. All comments received during this period will be considered by the Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of the United States will be filed with the Court and published in the **Federal Register**.

Written comments should be submitted to: Mark J. Botti, Chief, Litigation I Section, Antitrust Division, United States Department of Justice, 1401 H Street, NW., Suite 4000, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

The United States considered, as an alternative to the proposed Final Judgment, a full trial on the merits against defendants BRMC and PCH. The United States is satisfied, however, that the Final Judgment, with its prohibition on anticompetitive conduct, will more quickly achieve the primary objectives of a trial on the merits—reestablishing competition in the relevant markets.

VII. Standard of Review Under the APPA for the Proposed Final Judgment

The APPA requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the Court shall consider:

> (A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration or relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1)(A) and (B). As the United States Court of Appeals for the District of Columbia Circuit has held, the APPA permits a court to consider, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1458–62 (D.C. Cir. 1995).

''Nothing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2). Thus, in conducting this inquiry, ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the

benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Senator Tunney).[1] Rather:

[a]bsent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should * * * carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.

United States v. *Mid-America Dairymen, Inc.,* 1977–1 Trade Cas. (CCH) ¶ 61,508, at 71,980 (W.D. Mo. 1977).

Accordingly, with respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States* v. *BNS, Inc.,* 858 F.2d 456, 462 (9th Cir. 1988) (citing *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see also* Microsoft, 56 F.3d at 1460–62. Courts have held that:

[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is *''within the reaches of the public interest.''* More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[2]

The proposed Final Judgment, therefore, should not be reviewed under a standard of whether it is certain to eliminate every anticompetitive effect of a particular practice or whether it mandates certainty of free competition in the future. Court approval of a final judgment requires a standard more flexible and less strict than the standard required for a finding of liability. ''[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.''' *United States* v. *AT&T,* 552 F. Supp. 131, (D.D.C. 1982) (citations omitted) (quoting Gillette, 406 F. Supp. at 716), aff'd sub nom. *Maryland* v. *United States,* 460 U.S. 1001 (1983); *see also United States* v. *Alcan Aluminum Ltd.,* 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint; the APPA does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' Microsoft, 56 F.3d at 1459. Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecurtorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Id.* at 1459–60.

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: March 21, 2005.

Respectfully submitted,

Mark J. Botti,
Chief, Litigation I.

Kasey Warner,
United States Attorney.

Peter J. Mucchetti,
Joan S. Huggler,
Mitchell H. Glende,
Attorneys for the United States, United States Department of Justice, 1401 H Street, NW., Suite 4000, Washington, DC 20530. Telephone: (202) 353–4211. Facsimile: (202) 307–5802.

Stephen M. Horn,
Assistant United States Attorney.

[FR Doc. 05–6536 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–11–M

[1] *See United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (recognizing it was not the court's duty to settle; rather, the court must only answer ''whether the settlement achieved [was] within the reaches of the public interest''). A ''public interest'' determination can be made properly on the basis of the Competitive Impact Statement and Response to Comments filed by the Department of Justice pursuant to the APPA. Although the APPA authorizes the use of additional procedures, 15 U.S.C. 16(f), those procedures are discretionary. A court need not invoke any of them unless it believes that the comments have raised significant issues and that further proceedings would aid the court in resolving those issues. *See* H.R. Rep. No. 93–1463, 93rd Cong 2d Sess. 8–9 (1974), reprinted in 1974 U.S.C.C.A.N. 6535, 6538.

[2] Cf. BNS, 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); Gillette, 406 F. Supp. at 716 (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass''). *See generally* Microsoft, 56 F3.d at 1461 (discussing whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest'''

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importation of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(1), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under 21 U.S.C. 952(a)(2)(b) authorizing the importation of such substances, provide manufacturers holding registrations for the bulk manufacture of the substances an opportunity for a hearing.

Therefore, in accordance with Title 21 CFR 1301.34(a), this is notice that on July 26, 2004, Aveva Drug Delivery Systems Inc., 3250 Commerce Parkway, Miramar, Florida 33025–3907, made application to the Drug Enforcement Administration (DEA) for registration as an importer of Fentanyl (9801), a basic class of controlled substance listed in Schedule II.

The company plans to import the listed controlled substance for the manufacture of analytical reference standards.

Any manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances may file written comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections being sent via regular mail may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative, Liaison and Policy Section (ODL); or any being sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than May 4, 2004.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745–46), all applicants for registration to import the basic class of any controlled substance listed in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office

of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: March 25, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 05–6585 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated December 21, 2004, and published in the **Federal Register** on January 4, 2005, (70 FR 390), Cedarburg Pharmaceuticals, Inc., 870 Badger Circle, Grafton, Wisconsin 53024, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in Schedule II:

Drug	Schedule
Dihydrocodeine (9120)	II
Remifentanil (9739)	II
Sufentanil (9740)	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cedarburg Pharmaceuticals, Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Cedarburg Pharmaceuticals, Inc. 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. 823, and in accordance with 21 CFR 1301.33(a), the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: March 25, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 05–6592 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to 21 CFR 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on February 7, 2005, Johnson Matthey, Inc., Custom Pharmaceuticals Department, 2003 Nolte Drive, West Deptford, New Jersey 08066, made application by letter to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of Methamphetamine (1105), a basic class of controlled substance listed in Schedule II.

The company plans to manufacture the listed controlled substance in bulk for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative, Liaison and Policy Section (ODL); or any being sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than June 3, 2005.

Dated: March 25, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 05–6586 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to section 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on January 4, 2005, Mallinckrodt Inc., Mallinckrodt & Second Streets, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in Schedules I and II:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Difenoxin (9168)	I
Heroin (9200)	I
Morphine-N-oxide (9307)	I
Nicomorphine (9312)	I
Normorphine (9313)	I
Norlevorphanol (9634)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylophenidate (1724)	II
Codeine (9050)	II
Diprenorphine (9058)	II
Etorphine HCL (9059)	II
Dihydrocodeine (9120)	II
Hydromorphone (9150)	II
Oxycodone (9143)	II
Diphenoxylate (9170)	II
Benzoylecgonine (9180)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone Intermediate (9254)	II
Metopon (9260)	II
Dextropropoxyphene (9273)	II
Morphine (9300)	II
Thebaine (9333)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances for internal use and for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative, Liaison and Policy Section (ODL); or any being sent via express mail should be sent to

DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than June 3, 2005.

Dated: March 25, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 05–6589 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under 21 U.S.C. 952(a)(2)(B) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on January 4, 2005, Mallinckrodt Inc., Mallinckrodt & Second Streets, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in Schedule II:

Drug	Schedule
Phenylacetone (8501)	II
Coca Leaves (9040)	II
Raw Opium (9600)	II
Opium poppy (9650)	II
Concentrate of Poppy Straw (9670).	II

The company plans to import the listed controlled substances for the manufacture of controlled substances in bulk for distribution to its customers.

Any manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections being sent via regular mail may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Attention: DEA Federal Register Representative, Liaison and Policy Section (ODL); or any being sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than May 4, 2005.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e) and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745–46), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(b), (c), (d), (e) and (f) are satisfied.

Dated: March 25, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 05–6591 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated December 21, 2004, and published in the **Federal Register** on January 4, 2005, (70 FR 392), Noramco Inc., 1440 Olympic Drive, Athens, Georgia 30601, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Dihydrocodeine (9120), a basic class of controlled substance listed in Schedule II.

The company plans to manufacture the listed controlled substance in bulk for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Noramco Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Noramco Inc. 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. 823, and in accordance with 21 CFR 1301.33(a), the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: March 25, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 05–6584 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated December 21, 2004, and published in the **Federal Register** on January 4, 2005, (70 FR 393), Organix Inc., 240 Salem Street, Woburn, Massachusetts 01801, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Codeine (9041), a basic class of controlled substance listed in Schedule II.

The company plans to manufacture small quantities of the listed controlled substance for use in drug abuse detection kits.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Organix Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Organix Inc. 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. 823, and in accordance with 21 CFR 1301.33(a), the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: March 25, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 05–6588 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under 21 U.S.C. 952(a)(2)(B) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on January 5, 2005, Roche Diagnostics Operations Inc., Attention: Regulatory Compliance, 9115 Hague Road, Indianapolis, Indiana 46250, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in Schedules I and II:

Drug	Schedule
Lysergic acid diethylamide (7315)	I
Tetrahydrocannabinols (7370)	I
Cocaine (9041)	II
Ecgonine (9180)	II
Methadone (9250)	II
Morphine (9300)	II
Alphamethadol (9605)	II

The company plans to import the listed controlled substances for the manufacture of diagnostic products for distribution to its customers.

Any manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections being sent via regular mail may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Attention: DEA Federal Register Representative, Liaison and Policy Section (ODL); or any being sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than May 4, 2005.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e) and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745–46), all applicants for registration to import a basic class of any controlled substance listed in Schedule I or II are, and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(b), (c), (d), (e) and (f) are satisfied.

Dated: March 25, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 05–6590 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under 21 U.S.C. 952(a)(2)(B) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on April 27, 2004, Wildlife Laboratories, 1401 Duff Drive, Suite 400, Fort Collins, Colorado 80524, made application 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 small quantities of the listed controlled substance for the manufacture of analytical reference standards.

Any manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections, or requests for hearing being sent via regular mail may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative, Liaison and Policy Section (ODL); or any being sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than May 4, 2005.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e) and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745–46), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are, and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(b), (c), (d), (e) and (f) are satisfied.

Dated: March 25, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 05–6593 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-day notice of information collection under review: promising programs for substance abuse prevention: replication and evaluation initiative.

The Department of Justice (DOJ), Office of Justice Programs (OJP) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with

the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register**, Volume 69, Number 235, page 71074 on December 8, 2004, allowing for a 60-day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until May 4, 2005. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- 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.

Overview of This Information Collection

(1) *Type of Information Collection:* New Collection.

(2) *Title of the Form/Collection:* Promising Programs for Substance Abuse Prevention: Replication and Evaluation Initiative.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* There is no agency form number. Office of Juvenile Justice and Delinquency Prevention, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals. Other: Not-for profit. Two substance abuse prevention programs for middle school and alternative high school students will be evaluated for effectiveness by independent evaluators, potentially establishing them as effective programs. Middle schools and high schools will be asked to assist in study implementation.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 7,000 respondents will complete a 35–40 minute survey three times (pre-test, post-test, and one-year follow-up post-test) over the next four years.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated total burden to complete the nominations is 12, 600 hours. The average annual hour burden (over four years) is 3,150.

If additional information is required contact: Brenda E. Dyer, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Brenda E. Dyer,

Department Clearance Officer, Department of Justice.

[FR Doc. 05–6528 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJP)–1416]

Meeting of the Global Justice Information Sharing Initiative Federal Advisory Committee

AGENCY: Office of Justice Programs, Justice.

ACTION: Notice of meeting.

SUMMARY: This is an announcement for a meeting of the Global Justice Information Sharing Initiative Federal Advisory Committee (GAC) to discuss the Global Initiative, as described at *http://www.it.ojp.gov/global.*

DATES: The meeting will take place on Wednesday, April 27, 2005, from 1 p.m. to 5 p.m. ET, and Thursday, April 28, 2005, from 8:30 a.m. to 12 noon ET.

ADDRESSES: The meeting will take place at the Wyndham Washington, DC, 1400 M Street, NW., Washington, DC 20005; Phone: (202) 429–1700.

FOR FURTHER INFORMATION CONTACT: J. Patrick McCreary, Global Designated Federal Employee (DFE), Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street, Washington, DC 20531; phone: (202) 616–0532 (note: this is not a toll-free number); e-mail: *James.P.McCreary@usdoj.gov.*

SUPPLEMENTARY INFORMATION:

Purpose

The GAC will act as the focal point for justice information systems integration activities in order to facilitate the coordination of technical, funding, and legislative strategies in support of the Administration's justice priorities.

The GAC will guide and monitor the development of the Global Information Sharing concept. It will advise the Assistant Attorney General, OJP; the Attorney General; the President (through the Attorney General); and local, State, tribal, and Federal policymakers in the executive, legislative, and judicial branches. The GAC will also act as an advocate of strategies for accomplishing Global information sharing capability.

Meeting Registration and Accommodation

This meeting is open to the public. Due to security measures, however, members of the public who wish to attend this meeting must register with Mr. J. Patrick McCreary, at the above address, at least (7) days in advance of the meeting. Registrations will be accepted on a space available basis. Access to the meeting will not be allowed without registration. All attendees will be required to sign in at the meeting registration desk. Please bring photo identification and allow extra time prior to the meeting.

Anyone requiring special accommodations should notify Mr. McCreary at least seven (7) days in advance of the meeting.

Interested persons whose registrations have been accepted may be permitted to participate in the discussions at the discretion of the meeting chairman and with approval of the DFE.

J. Patrick McCreary,

Global DFE, Bureau of Justice Assistance, Office of Justice Programs.

[FR Doc. 05–6583 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–18–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–382]

Entergy Operations, Inc.; Waterford Steam Electric Station, Unit 3, Final Environmental Assessment and Finding of No Significant Impact, Related to the Proposed License Amendment To Increase the Maximum Reactor Power Level

AGENCY: Nuclear Regulatory Commission (NRC).

SUMMARY: The NRC has prepared a final environmental assessment as its evaluation of a request by Entergy Operations, Inc., Entergy, the licensee) for a license amendment to increase the maximum thermal power at the Waterford Steam Electric Station, Unit 3 (Waterford 3) from 3441 megawatts thermal (MWt) to 3716 MWt. This represents a power increase of approximately 8 percent for Waterford 3. The NRC staff has the option of preparing an environmental impact statement if it believes a power uprate will have a significant impact on the human environment. The NRC staff did not identify any significant impact from the information provided in the licensee's extended power uprate (EPU) application for Waterford 3 or the NRC staff's independent review; therefore, the NRC staff is documenting its environmental assessment. The final environmental assessment and finding of no significant impact is being published in the **Federal Register**.

Environmental Assessment

Background

Plant Site and Environs

The NRC is considering issuance of an amendment to Facility Operating License No. NPF–38, issued to Entergy for Waterford 3 which has been in operation since March 4, 1985. The facility is located on the west (right descending) bank of the Mississippi River, approximately 40 kilometers (25 miles) west of New Orleans on Louisiana Highway 18 (River Road) in St. Charles Parish, in the city of Killona, Louisiana. The plant's topography, except for the levee along the Mississippi River, is generally flat with an elevation of 8 to 16 feet above mean sea level. Electricity is generated using a pressurized water reactor and steam turbine with a maximum generating capacity of 1,104 Megawatts electric. The fuel source for the unit is enriched Uranium-235. The exhaust steam is condensed using a once-through circulating water system with the Mississippi River as a heat sink. Additionally, the component cooling water system serves as the station's ultimate heat sink and is designed to remove heat from the plant during normal operation, shutdown, or emergency shutdown.

Three-quarters of a mile downstream from the Waterford 3 site is the Bonnet Carré Spillway. The Bonnet Carré Spillway is a vital element of the comprehensive plan for flood control in the Lower Mississippi Valley. It is located on the east bank of the Mississippi River, approximately 25 miles above New Orleans and was constructed to divert approximately 250,000 cubic feet per second of floodwaters from the Mississippi River to Lake Pontchartrain to prevent overtopping of levees at and below New Orleans, assuring the safety of New Orleans and the downstream delta area during major floods on the Lower Mississippi.

Identification of the Proposed Action

By letter dated November 13, 2003, Entergy proposed to increase the maximum thermal power level of Waterford 3 by approximately 8 percent, from 3441 MWt to 3716 MWt. The change is considered an EPU because it would raise the reactor core power level more than 7 percent above the originally licensed maximum power level. The NRC originally licensed Waterford 3 on March 16, 1985, for operation at a reactor core power not to exceed 3390 MWt. On March 29, 2002, the NRC staff approved a power increase of approximately 1.5 percent allowing Waterford 3 to operate at a core power level not to exceed 3441 MWt. Therefore, this proposed action would result in a total increase of approximately 9.6 percent over the originally licensed maximum power level. The amendment would allow the heat output of the reactor to increase, which would increase the flow of steam to the turbine. This would allow the turbine generator to increase the production of power as well as increase the amount of heat dissipated by the condenser. Moreover, this would result in an increase in temperature of the water being released into the Mississippi River.

Need for the Proposed Action

Entergy is requesting an amendment to the operating license for Waterford 3 to increase the maximum thermal power level, thereby increasing the electric power generation. The increase in electric power generation provides Entergy with lower cost power than can be obtained in the current and anticipated energy market.

Environmental Impacts of the Proposed Action

This assessment summarizes the non-radiological and radiological impacts on the environment that may result from the licensee's amendment request application dated November 13, 2003.

Non-Radiological Impacts

Land Use Impacts

The potential impacts associated with land use for the proposed action include impacts from construction and plant modifications. The Waterford 3 property is made up of 52 percent wetlands and 22 percent of the land is used for agriculture. There is no residential or recreational land on the property. There is no plan to construct any new facilities or expand buildings, roads, parking lots, equipment storage, or laydown areas. No changes to the onsite transmission and distribution equipment, including power line rights-of-way, are anticipated to support this action. No new construction outside of the existing facilities will be necessary.

The proposed EPU will require a modification to the high pressure turbine. The turbine is located within the turbine building, and the modification will not require any land disturbance. The EPU would not significantly affect material storage, including chemicals, fuels, and other materials stored aboveground or underground. There is no modification to land use at the site, and no impact on the lands with historic or archeological significance. The proposed EPU would not modify the current land use at the site significantly over that described in the Final Environmental Statement (FES).

The licensee has stated that the proposed EPU will not change the character, sources, or energy of noise generated at the plant. Modified structures, systems, and components necessary to implement the power uprate will be installed within existing plant buildings and no noticeable increase in ambient noise levels within the plant is expected.

Therefore, the NRC staff concludes that the environmental impacts of the proposed EPU are bounded by the impacts previously evaluated in the FES.

Transmission Facility Impacts

The potential impacts associated with transmission facilities for the proposed action include changes in transmission line corridor right-of-way maintenance and electric shock hazards due to increased current. The proposed EPU would not require any physical

modifications to the transmission lines. Entergy's transmission line right-of-way maintenance practices, including the management of vegetation growth, would not be affected. No new requirements or changes to onsite transmission equipment, operating voltages, or transmission line rights-of-way would be necessary to support the EPU. The main plant transformers will be modified and replaced to support the uprate; however, replacement of the transformers would have been required before the end of plant life as part of the licensee's ongoing maintenance program. Therefore, no significant environmental impact beyond that considered in the FES is expected from this kind of replacement of onsite equipment.

The National Electric Safety Code (NESC) provides design criteria that limit hazards from steady-state currents. The NESC limits the short-circuit current to ground to less than 5 milli-ampere. There will be an increase in current passing through the transmission lines associated with the increased power level of the proposed EPU. The increased electrical current passing through the transmission lines will cause an increase in electromagnetic field strength. Since the increase in power level is approximately 8 percent, the increase in the electromagnetic field will not be significant. The licensee's analysis shows that the transmission lines will continue to meet the applicable shock prevention provisions of the NESC. Therefore, even with the slight increase in current attributable to the EPU, adequate protection is provided against hazards from electric shock.

The impacts associated with transmission facilities for the proposed action will not change significantly over the impacts associated with current plant operation. There are no physical modifications to the transmission lines; transmission line right-of-way maintenance practices will not change. There are no changes to transmission line rights-of-way or vertical clearances and the electric current passing through the transmission lines will increase only slightly. Therefore, the NRC staff concludes that there are no significant impacts associated with transmission facilities for the proposed action. The transmission lines are designed and constructed in accordance with the applicable shock prevention provisions of the NESC.

Water Use Impacts

Potential water use impacts from the proposed action include hydrological alterations to the Mississippi River and changes to the plant water supply. The Mississippi River is the source of water for cooling and most auxiliary water systems at Waterford 3. The cooling water is withdrawn from the Mississippi River via an intake canal approximately 49 meters (m) (162 feet (ft)) long leading from the river to an intake structure containing four water pumps. The cooling water for the circulating water system (CWS) is pumped through the condenser to condense the turbine exhaust steam to water. The water then flows to the discharge canal approximately 29 m (95 ft) long and is returned to the river through the discharge structure. The water from the CWS is also used in the turbine system heat exchangers and the steam generator blowdown system.

The Mississippi River is the principal water source of all municipal, industrial, and agricultural use for towns and water districts downstream of Baton Rouge, Louisiana. All of the water required for plant operation, except potable water, will be withdrawn from the Mississippi River. The rate of withdrawal will not increase as a result of the EPU. As a result, operation of Waterford 3 will not affect the availability of water to downstream water users. Groundwater is not used in plant operations; therefore, there are no impacts to onsite groundwater use. The NRC staff concludes that the EPU would not have a significant impact on water usage as a result of hydrological alterations or changes in the plant water supply.

Discharge Impacts

The potential impacts to the Mississippi River from the plant discharge include turbidity, scouring, erosion, and sedimentation. These impacts can occur as a result of significant changes in the thermal discharge, sanitary waste discharge, and chemical discharge.

1. *Thermal Discharge:* Surface water and wastewater discharges at Waterford 3 are regulated by the State of Louisiana via a Louisiana Pollutant Discharge Elimination System (LPDES) Permit. This permit is periodically reviewed and renewed by the Louisiana Department of Environmental Quality (LDEQ). The EPU is expected to increase the temperature of the water discharged to the Mississippi River.

The LPDES Permit (1) restricts the temperature rise in the discharge water to five degrees Fahrenheit over the temperature of the river water and (2) limits the temperature of the discharge water to 118 degrees Fahrenheit. The licensee has calculated the increased heat load delivered to the CWS under EPU conditions and estimated an expected increase in the discharge water temperature of 2.2 degrees Fahrenheit. Based on this expected temperature increase from power uprate, the temperature limits defined in the LPDES Permit are adequate, and no changes to the LPDES Permit are necessary.

2. *Chemical Discharge:* Wastewater treatment chemicals that are currently regulated and approved by the State of Louisiana through the LPDES Permit for use in the once-through cooling water will not change as a result of the power uprate. The concentration of pollutants in the once-through effluent stream will remain the same and have insignificant impact.

3. *Sanitary Waste Discharge:* Sanitary wastes at the Waterford 3 facility are discharged at two different locations. Sanitary wastes from the training center are collected and discharged from an onsite sewage treatment plant that is regulated through LPDES Permit LA0007374. Sanitary wastes from all other site facilities are collected in one of seven sewage lift stations located around the plant site and then ultimately transferred to St. Charles Parish Killona sewage treatment facility. Since there will be no increase in the Waterford 3 staffing levels as a result of the power uprate, there will also be no increase in sanitary waste. The use of chemicals will not change as a result of the power uprate, and the power uprate will have no impact on current water chemical usage.

Therefore, the NRC staff concludes that the environmental impacts associated with the plant discharge will not be significant.

Impacts on Aquatic Biota

The potential impacts to aquatic biota from the proposed actions include impingement and entrainment, thermal discharge effects, and changes associated with the transmission line rights-of-way. Aquatic species found in the vicinity of Waterford 3 are associated with the Mississippi River. The river near the Waterford 3 site region supports aquatic biota ranging from microorganisms and various plankton to large commercial finfish. The more abundant fish near the site area include blue catfish, channel catfish, freshwater drum, and striped mullet. There are no unique fish habitats in the river near Waterford 3.

1. *Impingement and Entrainment:* Fish and other organisms removed from the cooling water by the traveling water screens are washed to a trough to a point downstream of the intake. The EPU will not increase the withdrawal rate or change current pumping

operations. Therefore, the water velocity through the traveling screens will not change as a result of the EPU. The flowrate of water being withdrawn from the intake canal at the intake structure would not increase and no change would be made in the design of the intake structure screens. Therefore, changes in the entrainment of aquatic organisms or in the impingement of fish are not anticipated as a result of the EPU.

2. *Thermal Discharge Effects (Heat Shock):* Entergy has conducted thermal studies in the Mississippi River in the vicinity of the Waterford 3 discharge for over 25 years and no adverse impacts on fish have been observed. The temperature of the water discharged to the river will remain within the limits of the LPDES Permit. The LPDES Permit states that the bounding thermal limit adequately regulates the amount of heat discharged to the Mississippi River from this facility such that it protects the balanced indigenous population.

3. *Transmission Line Rights-of-Way:* There will not be changes in transmission line right-of-way maintenance practices associated with the EPU. Therefore, no changes are expected in the amount of water or in the water quality of the water run-off to the streams or the river.

The EPU will not increase the flow of the water withdrawn from the river, and the amount of heat discharged to the Mississippi River will remain within the thermal limit specified by the LPDES Permit. There are no changes in transmission line right-of-way maintenance practices associated with the proposed action. Therefore, the NRC staff concludes that there are no significant impacts to aquatic biota for the proposed action.

Impacts on Terrestrial Biota

The potential impacts to terrestrial biota from the proposed action include construction activities and changes associated with the transmission line right-of-way maintenance. The power uprate will not disturb land, and no construction activities are planned for the EPU. The proposed EPU will not change the land use at Waterford 3, and no habitat of any terrestrial plant or animal species will be disturbed as a result of this power uprate. In addition, none of Entergy's transmission line rights-of-way maintenance practices will change. Therefore, the NRC staff concludes that there will be no significant impact to the habitat of any terrestrial plant or animal species as a result of the EPU.

Threatened and Endangered Species

Potential impacts to threatened and endangered species from the proposed action include the impacts assessed in the aquatic and terrestrial biota sections of this environmental assessment. These impacts include impingement and entrainment, thermal discharge effects, and impacts due to transmission line right-of-way maintenance for aquatic species, and impacts to terrestrial species from transmission line right-of-way maintenance and construction activities.

There are five species listed as threatened or endangered under the Federal Endangered Species Act within St. Charles Parish, Louisiana. These are the bald eagle (*Haliaeetus leucocephalus*), brown pelican (*Pelecanus occidentalis*), gulf sturgeon (*Acipenser oxyrinchus desotoi*), pallid sturgeon (*Scaphirhynchus albus*), and the West Indian manatee (*Trichechu manatus*). There have been reported sightings of the bald eagle (*H. leucocephalus*), gulf sturgeon (*A. oxyrinchus desotoi*), and the pallid sturgeon (*S. albus*) in St. Charles Parish. Thermal studies documented in the LPDES fact sheet found that no threatened or endangered species were present near Waterford 3.

In a letter dated March 15, 2004, the Louisiana Fish and Wildlife Service (LFWS) commented on the endangered species in the vicinity of the station. The pallid sturgeon was identified as an endangered fish found in both the Mississippi and Atchafalaya Rivers. The West Indian manatee (*T. manatus*) was also listed as a federally protected species known to inhabit Lakes Pontchartrain and Maurepas and associated coastal waters and stream during summer months. The LFWS did not identify any critical habitat in the vicinity of the site.

According to Entergy, the impacts from the Waterford 3 EPU to these species is insignificant because: (1) The EPU for Waterford 3 will not result in a decline of suitable habitat for these species; and (2) sightings of these species are rare and infrequent. Therefore, the NRC staff concludes that the proposed EPU would not affect threatened and endangered species significantly over the effects described in the FES.

Social and Economic Impacts

Potential social and economic impacts due to the proposed action include changes in tax revenue for St. Charles Parish and changes in the size of the workforce at Waterford 3. The NRC staff has reviewed information provided by the licensee regarding socioeconomic impacts. Waterford 3 is a major employer in the community with approximately 750 full-time employees. Entergy is also a major contributor to the local tax base. Entergy personnel also contribute to the tax base by paying sales taxes. Because the plant modifications needed to implement the EPU would be minor, any increase in sales tax and additional revenue to local and national business will be negligible relative to the large tax revenues generated by Waterford 3. It is expected that the proposed uprate will reduce incremental operating costs, enhance the value of Waterford 3 as a power-generating asset, and lower the probability of early plant retirement. Early plant retirement would be expected to have a significant negative impact on the local economy and the community as a whole by reducing tax revenues and limiting local employment opportunities, although these effects could be mitigated by decommissioning activities in the short term. The proposed EPU would not significantly affect the size of the Waterford 3 labor force and would have no material effect upon the labor force required for future outages after all stages of the modifications needed to support the EPU are completed.

Summary

In summary, the proposed EPU would not result in a significant change in non-radiological impacts in the areas of site, land use, transmission facility operation, water use, discharge, aquatic biota, terrestrial biota, threatened and endangered species, or social and economic factors. No other non-radiological impacts were identified or would be expected. Table 1 summarizes the non-radiological environmental impacts of the proposed EPU at Waterford 3.

TABLE 1.—SUMMARY OF NON-RADIOLOGICAL ENVIRONMENTAL IMPACTS

Land Use	No change in land use or aesthetics; will not impact lands with historic or archeological significance. No significant impact due to noise.
Transmission Facilities	No physical modifications to the transmission lines and facilities; no changes to rights-of-way; no significant change in electromagnetic field around the transmission lines; shock safety requirements will be met.
Water Use Surface Water	No increase in the water withdrawal rate from the river. Water withdrawal rate remains consistent with previous levels.
Groundwater	No change in groundwater use.
Discharge Thermal Discharge	No significant increase in temperature or heat load. Current LPDES Permit has adequate limits to accommodate any expected temperature and heat load increases.
Chemical and Sanitary Discharge	No expected change to chemical use and subsequent discharge, or sanitary waste systems; no change in pollutants to once-through cooling water effluent. No changes to sanitary waste discharges.
Aquatic Biota	No expected increased impact on aquatic biota.
Thermal Discharge (Heat Shock)	Historically not a problem. Additional heat is not expected to affect frequency of heat shock events or significantly increase the impact to aquatic biota.
Terrestrial Biota	No additional impact on terrestrial biota.
Threatened and Endangered Species	No expected increased impact on threatened and endangered species as a result of the EPU.
Social and Economic	No significant change in size of Waterford 3 workforce.

Radiological Impacts

Radioactive Waste Systems

Waterford 3 uses Waste Treatment Systems designed to collect, process, and dispose of radioactive gaseous, liquid, and solid wastes in accordance with the requirements of Title 10 of the Code of Federal Regulations (10 CFR) part 20 and 10 CFR part 50, Appendix I. The NRC staff concludes that the proposed power uprate will not result in changes to the operation or design of equipment used in the radioactive gaseous, liquid, or solid waste systems.

Gaseous Radioactive Waste

The Waterford 3 Gaseous Waste Treatment System is designed to collect, process, and dispose of radioactive gaseous waste in accordance with the requirements of 10 CFR part 20 and 10 CFR part 50, Appendix I.

The licensee calculated that the EPU will increase the potential doses to the public from gaseous effluents by less than 0.1 millirem per year over current doses, which are less than one millirem per year. These potential doses are well within the dose design objectives of 10 CFR part 50, Appendix I and the annual doses projected in the FES. Therefore, the estimated increase in the offsite dose from gaseous effluents due to the EPU will be small with no significant impact on human health.

Liquid Radioactive Waste

The Waterford 3 Liquid Waste Treatment System is designed to collect, process, and dispose of radioactive liquid waste in accordance with the requirements of 10 CFR part 20 and 10 CFR part 50, Appendix I.

The licensee calculated that the EPU will increase the potential doses to the public from liquid effluents by approximately 10 percent over the current doses, which are less than 0.01 millirem per year. These potential doses are well within the dose design objectives of 10 CFR part 50, Appendix I and the annual doses projected in the FES. Therefore, the estimated increase in the offsite dose from liquid effluents due to the EPU will be small with no significant impact on human health.

Solid Radioactive Waste

The Solid Radioactive Waste System collects, monitors, processes, packages, and provides temporary storage facilities for radioactive solid wastes prior to offsite shipment and permanent disposal. From 1998 through 2002, approximately 22,520 cubic feet of low level radioactive waste was generated, for an average of about 4,500 cubic feet per year.

There are three types of solid radioactive waste: wet waste, dry waste, and irradiated reactor components. The typical contributors to solid radioactive wet waste are secondary and primary resin, contaminated filters, oil, and sludge from various plant systems. The EPU will not change either reactor water cleanup flow rates or filter performance. However, the increased core inventory of radionuclides may lead to slightly more frequent replacement of filters and resins. Therefore, implementation of the EPU will not have a significant impact on the volume or activity of solid radioactive wet waste generated at Waterford 3.

Dry radioactive waste consists primarily of air filters, paper products, rags, clothing, tools, equipment parts that cannot be effectively decontaminated, and solid laboratory wastes. No significant change in the amount of dry waste is expected as a result of the EPU.

Irradiated reactor components such as in-core detectors and fuel assemblies must be replaced periodically. The volume and activity of waste generated from spent fuel assemblies and in-core detectors will increase slightly with the EPU conditions. The EPU would increase the number of fresh fuel bundles needed during each refueling cycle by four. This increase in the number of bundles will result in a slight increase in spent fuel discharge to the spent fuel pool.

The NRC staff concludes that any projected increases in solid waste generation under the EPU conditions will not be significant.

Direct Radiation Dose

The licensee evaluated the direct radiation dose to the unrestricted area and concluded that it is not a significant exposure pathway. Since the EPU will slightly increase the core inventory of radionuclides and the amount of solid radioactive wastes, the NRC staff concludes that direct radiation dose will not be significantly affected by the EPU and will continue to meet the limits in 10 CFR part 20.

Occupational Dose

Occupational exposures from in-plant radiation primarily occur during routine maintenance, special maintenance, and refueling operations. An increase in power at Waterford 3 could increase the radiation levels in the reactor coolant system. However, plant programs and administrative controls such as shielding, plant chemistry, and the radiation protection program will help compensate for these potential increases. The average collective worker dose at Waterford 3 over the five-year period from 1998 to 2002 was 80.3 person-rem/yr. Conservatively assuming

a linear increase in the occupational exposure due to the EPU, the projected in-plant occupational exposure would increase to approximately 88 person-rem/yr, which is well below the 1300 person-rem/yr estimated in the Waterford 3 FES. The increase is based on the power uprate ratio of .096 ((3716–3390) MWt/3390 MWt). Therefore, no significant occupational dose impacts will occur as a result of the EPU.

The EPU will not result in a significant increase in normal operational radioactive gaseous and liquid effluent levels, direct doses offsite, or occupational exposure. Potential doses to the public from effluents will continue to be well within the dose design objectives of 10 CFR part 50, Appendix I and the annual doses projected in the FES. Any increase in direct doses offsite will continue to be within the limits of 10 CFR part 20 and the slight potential increase in occupational exposure will be well within the FES estimate.

Postulated Accident Doses

As a result of implementation of the proposed EPU, there will be an increase in the source term used in the evaluation of some of the postulated accidents in the FES.

The inventory of radionuclides in the reactor core is dependent on power level; therefore, the core inventory of radionuclides could increase by as much as 9.6 percent. The concentration of radionuclides in the reactor coolant may also increase by as much as 9.6 percent; however, this concentration is limited by the Waterford 3 Technical Specifications and is more dependent on the degree of leakage occurring through the fuel cladding. The overall quality of fuel cladding has improved since the FES was published and Waterford 3 has been experiencing very little fuel cladding leakage in recent years. Therefore, the reactor coolant concentration of radionuclides would not be expected to increase significantly. This coolant concentration is part of the source term considered in some of the postulated accident analyses.

For those postulated accidents where the source term increased, the calculated potential radiation dose to individuals at the site boundary (the exclusion area) and in the low population zone would be increased over the values presented in the FES. However, the calculated doses would still be below the acceptance criteria of 10 CFR part 100, ''Reactor Site Criteria,'' and the Standard Review Plan (NUREG–0800). Therefore, the NRC staff concludes that the increased environmental impact in terms of potential increased doses from the postulated accidents are not significant.

Fuel Cycle and Transportation

The environmental impacts of the fuel cycle and transportation of fuels and wastes are described in Tables S–3 and S–4 of 10 CFR 51.51 and 10 CFR 51.52, respectively. An additional NRC generic environmental assessment (53 FR 30355, dated August 11, 1988, as corrected by 53 FR 32322, dated August 24, 1988) evaluated the applicability of Tables S–3 and S–4 to higher burnup cycle. The assessment concluded that there is no significant change in environmental impacts for fuel cycles with uranium enrichments up to 5.0 weight-percent U–235 and burnups less than 60 gigawatt-day per metric ton of uranium (GWd/MTU) from the parameters evaluated in Tables S–3 and S–4. In an amendment dated July 10, 1998, Waterford 3 was granted the ability to increase the fuel enrichment from 4.9 percent to 5.0 percent. Since the fuel enrichment for the power uprate will not exceed 5.0 weight-percent U–235 and the rod average discharge exposure will not exceed 60 GWd/MTU, the environmental impacts of the proposed power uprate will remain bounded by these conclusions and will not be significant.

Summary

The proposed EPU would not result in a significant increase in occupational or public radiation exposure, would not significantly increase the potential doses from postulated accidents, and would not result in significant additional fuel cycle environmental impacts. Accordingly, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed action. Table 2 summarizes the radiological environmental impacts of the proposed EPU at Waterford 3.

TABLE 2.—SUMMARY OF RADIOLOGICAL ENVIRONMENTAL IMPACTS

Radiological Waste Stream	No change in design or operation of waste streams.
Gaseous Waste	Slight increase in amount of radioactive material in gaseous effluents; within FES estimate; off-site doses would continue to be well within NRC criteria.
Liquid Waste	Slight increase in amount of radioactive material in liquid effluents; within FES estimate; offsite doses would continue to be well within NRC criteria.
Solid Waste	No significant change in radioactive resins; no significant changes in dry waste; no significant changes in irradiated components.
Dose Impacts Occupational Dose	Up to 9.6 percent increase in collective occupational dose possible; well within FES estimate.
Offsite Direct Dose	Slight increase possible; not significant; offsite doses would continue to be within NRC criteria.
Postulated Accidents	Up to 9.6 percent increase in calculated doses from some postulated accidents; calculated doses within NRC criteria.
Fuel Cycle and Transportation	Increase in bundle average enrichment. Fuel enrichment and burnup would continue to be within bounding assumptions for Tables S–3 and S–4 in 10 CFR Part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions;'' conclusions of tables regarding impact would remain valid.

Alternatives to Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed EPU (*i.e.*, the ''no-action alternative''). Denial of the application would result in no change in the current environmental impacts; however, other fossil-fuel generating facilities may need to be built in order to maintain sufficient power-generating capacity. As an alternative, the licensee could purchase power from power generating facilities outside the service area. The additional power would likely also be generated by fossil fuel facilities. Construction and operation of a fossil-fueled plant would create impacts in air quality, land use, and waste management significantly greater than those identified for the EPU at Waterford 3. Implementation of the proposed EPU would have less impact on the environment than the construction and operation of a new fossil-fueled generating facility or the operation of fossil facilities outside the

service area. Furthermore, the EPU does not involve environmental impacts that are significantly different from those presented in the 1981 FES for Waterford 3.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the 1981 FES for Waterford 3.

Agencies and Persons Consulted

In accordance with its stated policy, on December 21, 2004, the NRC staff consulted with the Louisiana State official, Ms. Nan Calhoun of the LDEQ, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the following: (1) The FES, dated September 1981 (NUREG–0779), (2) the EPU application dated November 13, 2003 (ADAMS Accession No. ML040260317), and (3) the April 15, 2004 (ML041110527), response to the request for additional information dated March 6, 2004. Documents may be examined and/or copied for a fee at the NRC's Public Document Room, at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Document Access and Management System (ADAMS) Public Electronic Reading Room on the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* 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 Reference staff by telephone at 1–800–397–4209, or 301–415–4737, or by e-mail at *pdr@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: N. Kalyanam, Office of Nuclear Reactor Regulation, Mail Stop O–7D1, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at (301) 415–1480, or by e-mail at *nxk@nrc.gov.*

Dated in Rockville, Maryland, this 28th day of March, 2005.

For the Nuclear Regulatory Commission.

Michael K. Webb,

Acting Chief, Section 1, Project Directorate IV, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. E5–1478 Filed 4–1–05; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Nuclear Waste Meeting on Planning and Procedures; Notice of Meeting

The Advisory Committee on Nuclear Waste (ACNW) will hold a Planning and Procedures meeting on April 18, 2005, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland. The entire meeting will be open to public attendance, with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACNW, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Monday, April 18, 2005—8:30 a.m.–10:30 a.m.

The Committee will discuss proposed ACNW activities and related matters. The purpose of this meeting is to gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official, Mr. Richard K. Major (Telephone: 301/415–7366) between 8 a.m. and 5:15 p.m. (e.t.) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Electronic recordings will be permitted only during those portions of the meeting that are open to the public.

Further information regarding this meeting can be obtained by contacting the Designated Federal Official between 8:30 a.m. and 5:15 p.m. (e.t.). Persons planning to attend this meeting are urged to contact the above named individual at least two working days prior to the meeting to be advised of any potential changes in the agenda.

March 29, 2005.

Michael L. Scott,

Branch Chief, ACRS/ACNW.

[FR Doc. E5–1477 Filed 4–1–05; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51441; File No. SR–FICC–2005–06]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Proposed Rule Change To Change the Minimum Margin Deficiency Call Amount for Participants in Its Mortgage-Backed Securities Division

March 28, 2005.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on March 11, 2005, the Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I, II, and III below, which items have been prepared primarily by FICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The purpose of this proposed rule change is to change the minimum margin deficiency call amount for participants in the Mortgage-Backed Securities Division (''MBSD'') of FICC.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FICC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to change the minimum margin deficiency call amount for MBSD participants to the lesser of $250,000 or 25 percent of the value of a participant's margin deposit. Currently, the MBSD's procedures establish a minimum margin deficiency

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by FICC.

call amount of $1,000. Upon review, FICC has determined that the minimum margin deficiency call amount creates unnecessary operational burdens and allocation of resources for a collection of margin calls that FICC believes is insubstantial from a risk perspective. On average, the MBSD makes 17 margin calls per day of which approximately five are for amounts under $250,000.

FICC seeks to harmonize the rules of its two divisions, the Government Securities Division (''GSD'') and Mortgage-Backed Securities Division (''MSBD''), wherever prudent and possible. The rules of the GSD provide for a minimum Clearing Fund deficiency call amount for margin requirement increases of the lesser of $250,000 or 25 percent of the value of the member's collateral deposits.[3] Under the proposed rule, the minimum margin deficiency call amount for MBSD participants would be the lesser of $250,000 or 25 percent of the value of a participant's margin deposit. FICC believes this would eliminate the operational burdens associated with the collection of *de minimis* margin amounts and would harmonize the rules of FICC's two divisions.[4]

FICC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act[5] and the rules and regulations thereunder applicable to FICC because it allows for a less burdensome application of its margin call process without presenting material risk to FICC or its participants. As such, FICC believes the proposed rule assures the safeguarding of securities and funds that are in the custody and control of FICC or for which it is responsible.

(B) Self-Regulatory Organization's Statement on Burden on Competition

FICC does not believe that the proposed rule change will have any impact or impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change have not yet been solicited or received. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period: (i) As the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding; or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

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–FICC–2005–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–FICC–2005–06. 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 Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filings also will be available for inspection and copying at the principal office of FICC and on FICC's Web site, *http://www.ficc.com*. 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–FICC–2005–06 and should be submitted on or before April 25, 2005.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1476 Filed 4–1–05; 8:45 am]

BILLING CODE 8010–01–P

[3] There is no minimum amount for deficiency calls where the subject member is subject to enhanced monitoring on what is known as the ''watch list.''

[4] As proposed and consistent with the applicable GSD rule, a minimum amount would not apply to deficiency calls where the subject participant is on the ''watch list.''

[5] 15 U.S.C. 78q–1.

[6] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51434; File No. SR–NASD–2005–033]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing of Proposed Rule Change Relating to Taping Rule ''Opt Out'' and Exemption Provisions

March 24, 2005.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 22, 2005, the National Association of Securities Dealers, Inc. (''NASD'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASD. 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

NASD is filing a proposed rule change to amend paragraph (L) of NASD Rule 3010(b)(2) (''Taping Rule'' or ''Rule'') to (1) require member firms that are seeking an exemption from the Rule to submit their exemption requests to NASD within 30 days of receiving notice from NASD or obtaining actual knowledge that they are subject to the provisions of the Rule and (2) clarify

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

that firms that trigger application of the Taping Rule for the first time can elect to either avail themselves of the one-time ''opt out provision'' or seek an exemption from the Rule, but they may not seek both options. Below is the text of the proposed rule change. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

3010. Supervision

(a) No Change.

(b) Written Procedures.

(1) No Change.

(2) Tape recording of conversations.

(A) Each member that either is notified by NASD [Regulation] or otherwise has actual knowledge that it meets one of the criteria in paragraph (b)(2)(H) relating to the employment history of its registered persons at a Disciplined Firm as defined in paragraph (b)(2)(J) shall establish, maintain, and enforce special written procedures for supervising the telemarketing activities of all of its registered persons.

(B) The member must establish and implement the supervisory procedures required by this paragraph within 60 days of receiving notice from NASD [Regulation] or obtaining actual knowledge that it is subject to the provisions of this paragraph.

A member that meets one of the criteria in paragraph (b)(2)(H) for the first time may reduce its staffing levels to fall below the threshold levels within 30 days after receiving notice from NASD [Regulation] pursuant to the provisions of paragraph (b)(2)(A) or obtaining actual knowledge that it is subject to the provisions of the paragraph, provided the firm promptly notifies the Department of Member Regulation, NASD [Regulation], in writing of its becoming subject to the Rule. Once the member has reduced its staffing levels to fall below the threshold levels, it shall not rehire a person terminated to accomplish the staff reduction for a period of 180 days. On or prior to reducing staffing levels pursuant to this paragraph, a member must provide the Department of Member Regulation, NASD [Regulation] with written notice, identifying the terminated person(s).

(C) No Change.

(D) The member shall establish reasonable procedures for reviewing the tape recordings made pursuant to the requirements of this paragraph to ensure compliance with applicable securities laws and regulations and applicable rules of [the Association] *NASD*. The procedures must be appropriate for the member's business, size, structure, and customers.

(E) through (F) No Change.

(G) By the 30th day of the month following the end of each calendar quarter, each member firm subject to the requirements of this paragraph shall submit to [the Association] *NASD* a report on the member's supervision of the telemarketing activities of its registered persons.

(H) No Change.

(I) For purposes of this Rule, the term ''registered person'' means any person registered with [the Association] *NASD* as a representative, principal, or assistant representative pursuant to the Rule 1020, 1030, 1040, and 1110 Series or pursuant to Municipal Securities Rulemaking Board (''MSRB'') Rule G–3.

(J) through (K) No Change.

(L) Pursuant to the Rule 9600 Series, [the Association] *NASD* may in exceptional circumstances, taking into consideration all relevant factors, exempt any member unconditionally or on specified terms and conditions from the requirements of this paragraph. *A member seeking an exemption must file a written application pursuant to the Rule 9600 Series within 30 days after receiving notice from NASD or obtaining actual knowledge that it meets one of the criteria in paragraph (b)(2)(H). A member that meets one of the criteria in paragraph (b)(2)(H) for the first time may elect to reduce its staffing levels pursuant to the provisions of paragraph (b)(2)(B) or, alternatively, to seek an exemption pursuant to paragraph (b)(2)(L), as appropriate; such a member may not seek relief from the Rule by both reducing its staffing levels pursuant to paragraph (b)(2)(B) and requesting an exemption.*

(3) through (4) No Change.

(c) through (g) No Change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASD 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

According to the NASD, the Taping Rule, which has been in effect since 1998, is designed to ensure that members with a significant number of registered persons that previously were employed by firms that have been expelled from membership or have had their registration revoked for sales practice violations (''Disciplined Firms'') have proper supervisory procedures in place relating to telemarketing activities to prevent fraudulent and improper sales practices or other customer harm.

Under the Rule, member firms that hire a specified number of registered persons from Disciplined Firms must establish, maintain, and enforce special written procedures for supervising the telemarketing activities of all their registered persons. Such procedures must include tape-recording all telephone conversations between such firms' registered persons and both existing and potential customers. The Rule provides firms up to 60 days from the date they receive notice from NASD or obtain actual knowledge that they are subject to the provisions of the Rule to establish and implement the required supervisory procedures, including installing taping systems. Such firms also are required to review the tape recordings, maintain appropriate records, and file quarterly reports with NASD.

The Taping Rule permits member firms that become subject to the Rule for the first time a one-time opportunity to adjust their staffing levels to fall below the prescribed threshold levels and thus avoid application of the Rule (often referred to as the ''opt out provision''). A firm that elects this one-time option must reduce its staffing levels to fall below the applicable threshold levels within 30 days after receiving notice from NASD or obtaining actual knowledge that it is subject to the provisions of the Rule. Once a firm has made the reductions, the firm is not permitted to rehire the terminated individuals for at least 180 days.

NASD also has the authority to grant exemptions from the Rule in ''exceptional circumstances.'' In reviewing exemption requests, NASD generally has required a firm to establish that it has alternative procedures to assure supervision at a level functionally equivalent to a taping system. The Rule currently is silent on the time frame for submitting an

exemption request. However, because a firm has a total of 60 days from the date it receives notice from NASD or obtains actual knowledge that it is subject to the provisions of the Rule to implement the required supervisory procedures, a firm implicitly has that 60-day period to submit an exemption request. A firm that submits an exemption request is not required to establish and implement the required supervisory procedures, including the taping system (*i.e.*, such requirements are ''tolled'') while the staff is reviewing the request and during the course of any subsequent appeals to NASD's National Adjudicatory Council (''NAC'').

NASD tolls the Taping Rule's requirements during the exemption appeal process primarily due to the significant costs involved with installing a taping system and the possibility that the staff or NAC will grant the exemption. At the same time, it has been NASD's experience that firms often wait until the 60th day (or shortly before) to request the exemption, which, assuming the exemption is not granted, only further prolongs the establishment and implementation of the required supervisory procedures.

To reduce these possible delays in implementation of the Taping Rule requirements, NASD is proposing to amend NASD Rule 3010(b)(2)(L) to require firms that are seeking an exemption from the provisions of the Rule to submit their exemption requests to NASD within 30 days of receiving notice from NASD or obtaining actual knowledge that they are subject to the provisions of the Rule. NASD believes that specifying a time frame for submitting an exemption request is consistent with the investor protection concerns that the Rule is intended to address, in particular given that the requirement to establish and implement the appropriate supervisory procedures is tolled upon the submission of an exemption request. Moreover, based on NASD's experience, 30 days would provide ample time for firms to decide whether to seek an exemption and to submit their requests to NASD.

Some firms also have inquired whether they could elect to use the ''opt out'' while simultaneously seeking an exemption, with the goal being that the firm would be granted an exemption and be able to immediately rehire the persons whose employment was terminated as part of the ''opt out'' (rather than waiting the requisite 180 days). It is NASD's belief, however, that firms should not be able to pursue these two alternatives simultaneously. NASD believes that a core purpose of the ''opt out provision'' is to provide relief to those firms that may have inadvertently or unintentionally become subject to the Taping Rule for the first time due, for example, to sudden turnover among registered persons or other events beyond the firm's control. In contrast, exemptions, which are granted only in ''exceptional circumstances,'' are for those situations where the firm has demonstrated that it has supervisory procedures that are equivalent to a taping system or is otherwise in a truly unique situation. NASD believes it would be inconsistent with the purposes of these two provisions to permit a firm to pursue both options with NASD, either simultaneously or one after the other. For instance, NASD believes that it would be inconsistent with the purposes of these provisions for a firm that chooses to submit an exemption request pursuant to NASD Rule 3010(b)(2)(L) and is denied the exemption to then employ the NASD Rule 3010(b)(2)(B) ''opt out'' as its second option.

Therefore, NASD also is proposing to amend NASD Rule 3010(b)(2)(L) to clarify that firms that trigger application of the Taping Rule for the first time must elect to either avail themselves of the one-time ''opt out provision'' (*i.e.*, make the staff adjustment to fall below the thresholds of the Rule) or seek an exemption from the Rule, but they may not elect to do both. Accordingly, under the proposed rule change, firms that become subject to the Taping Rule for the first time would have 30 days to decide on one option and may pursue only that option.

Finally, NASD no longer refers to itself or its subsidiary, NASD Regulation, Inc., using its full corporate name, ''the Association,'' ''the NASD,'' or ''NASD Regulation.'' Instead, NASD uses the name ''NASD'' unless otherwise appropriate for corporate or regulatory reasons. Accordingly, the proposed rule change replaces, as a technical change, several references to ''Association'' and ''NASD Regulation'' in NASD Rule 3010(b)(2) with the name ''NASD.''

NASD will announce the effective date of the proposed rule change in a Notice to Members (''*NtM*'') to be published no later than 60 days following Commission approval. The effective date will be 30 days following publication of the *NtM* announcing Commission approval.

2. Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[3] which requires, among other things, that NASD rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. NASD believes that the proposed rule change will ensure that members with a significant number of registered persons from Disciplined Firms have proper supervisory procedures over telemarketing activities to prevent fraudulent and improper sales practices or other customer harm, and will ensure that members use the ''opt out'' and exemption provisions in a manner that is consistent with the intent of the Rule.

[3] 15 U.S.C. 78o–3(b)(6).

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change; or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

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–NASD–2005–033 on the subject line.

Paper Comments

• Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number SR–NASD–2005–033. 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. Copies of such filing also will be available for inspection and copying at the principal office of NASD. 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 the File Number SR–NASD–2005–033 and should be submitted on or before April 25, 2005.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1479 Filed 4–1–05; 8:45 am]

BILLING CODE 8010–01–P

[4] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–51438; File No. SR–NYSE–2004–32]

Self-Regulatory Organizations; Order Approving a Proposed Rule Change and Amendment No. 1 Thereto by the New York Stock Exchange, Inc. Relating to NYSE Liquidity Quote℠

March 28, 2005.

I. Introduction

On June 24, 2004, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to include additional display requirements to the existing terms and conditions pursuant to which vendors may distribute to their customers NYSE Liquidity Quote℠ information. On July 16, 2004, the NYSE filed Amendment No. 1 to the proposed rule change.[3] The proposed rule change, as amended, was published for public comment in the **Federal Register** on July 27, 2004.[4] The Commission has received one comment letter on the proposed rule change[5] and two responses from the NYSE.[6] This order approves the proposed rule change, as amended.

II. Background

The NYSE Liquidity Quote represents aggregated Exchange trading interest at a specific price interval below the NYSE best bid (in the case of a liquidity bid) or at a specific price interval above the NYSE best offer (in the case of a liquidity offer). The specific price interval above or below the NYSE best bid and offer (''BBO''), as well as the minimum size of the liquidity bid or offer, is established by the specialist in the subject security. Liquidity bids and offers include orders on the limit order book, trading interest of brokers in the trading crowd, and the specialist's dealer interest, at prices ranging from the best bid (offer) to the liquidity bid (liquidity offer).

NYSE distributes Liquidity Quote data as part of its OpenBook data feed service[7] and requires recipients to execute existing NYSE vendor agreements and subscriber agreements. Specifically, in order for a vendor to receive NYSE Liquidity Quote data from the Exchange for redistribution to its customers or subscribers, the Exchange requires the vendor to enter into its standard form of ''Agreement for Receipt and Use of Market Data'' (*i.e.*, ''Consolidated Vendor Form''). According to the Exchange, the Consolidated Vendor Form is the same form that vendors must execute to receive market data under the Consolidated Tape Association (''CTA'') Plan and the Consolidated Quotation (''CQ'') Plan. The Exchange describes the Consolidated Vendor Form as a generic, one-size-fits-all agreement that consists of a standard set of basic provisions that apply to all data recipients and accommodates a number of different types of market data, a number of different means of receiving access to market data, and a number of different uses of market data. Because the Consolidated Vendor Form is not specific to types and uses of certain market data, paragraph 19(a) of the Consolidated Vendor Form provides that ''Exhibit C, if any, contains additional provisions applicable to any non-standard aspects of Customer's Receipt and Use of Market Data.'' Accordingly, NYSE has drafted a proposed Liquidity Quote Exhibit C to provide certain display requirements for Liquidity Quote data.

In the original approval order, the Commission conditionally approved NYSE Liquidity Quote[8] because the Commission had substantial concerns about the display restrictions NYSE had drafted in its Exhibit C to the Consolidated Vendor Form for Liquidity Quote.[9] Specifically, as originally

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Darla C. Stuckey, Corporate Secretary, NYSE, to Nancy J. Sanow, Assistant Director, Division of Market Regulation (''Division''), SEC, dated July 16, 2004 (''Amendment No. 1''). In Amendment No. 1, the NYSE clarified that the entire proposed Exhibit C represented new text.

[4] Securities Exchange Act Release No. 50040 (July 20, 2004), 69 FR 44701.

[5] *See* letters from Thomas F. Secunda, Bloomberg, L.P. (''Bloomberg'') to Annette L. Nazareth, Director, Division, SEC, (''Bloomberg Letter) dated July 7, 2004; and Jonathan G. Katz, Secretary, SEC, dated August 13, 2004. The letter dated August 13, 2004 merely resubmitted the July 7, 2004 Bloomberg Letter for Commission consideration.

[6] *See* letter from Mary Yeager, Assistant Secretary, NYSE, to Jonathan G. Katz, Secretary, SEC (''NYSE Response Letter'') dated November 11, 2004, and letter from Ronald Jordan, Senior Vice President, Market Data, NYSE, to Kelly Riley, SEC, dated January 26, 2005 (''NYSE 2nd Response Letter'').

[7] *See* Securities Exchange Act Release No. 45138 (December 7, 2001) 66 FR 66491 (December 14, 2001).

[8] *See* Securities Exchange Act Release No. 47614 (April 2, 2003), 68 FR 17140 (April 8, 2003) (SR–NYSE–2002–55) (''April Order'').

[9] The NYSE did not file the original Exhibit C to the Consolidated Vendor Form for Liquidity Quote with the Commission. However, as described above, the Commission did consider the terms of the original Liquidity Quote Exhibit C and the issues

Continued

drafted, the Liquidity Quote Exhibit C would have prohibited data feed recipients from enhancing, integrating, or consolidating NYSE Liquidity Quote data with data from other market centers for retransmission. In addition, pursuant to the terms of the original Liquidity Quote Exhibit C, NYSE would have imposed a ''window requirement,'' which would have required Liquidity Quote data to be displayed as a separate window or with a line drawn between Liquidity Quote data and other markets' data.

In the April Order, the Commission stated that it believed that the terms and conditions set forth in the original Liquidity Quote Exhibit C that prohibited data feed recipients from enhancing, integrating, or consolidating NYSE Liquidity Quote data with data from other market centers for retransmission to be inconsistent with sections 6(b)(5) [10] and 6(b)(8) [11] of the Act. Accordingly, the Commission approved the Liquidity Quote data product on the condition that the proposal would not be effective until NYSE removed from its contracts the prohibitions on the ability of data feed recipients, including vendors, to integrate Liquidity Quote data with the display of other markets' data. The Commission did, however, state that it ''believe[d] that it would be reasonable and consistent with the statute for the NYSE to require that data feed recipients who choose to provide a value-added [L]iquidity [Q]uote data package to: (i) Give NYSE attribution next to any integrated quote that includes NYSE data; and (ii) make available to customers NYSE [L]iquidity [Q]uote product as a separate branded package.'' [12]

Thereafter, on April 9, 2003, NYSE informed the Commission that it agreed to the conditions set forth in the April Order to remove the prohibitions on integration in the Liquidity Quote Exhibit C to the Consolidated Vendor Form. In their place, NYSE drafted a new Liquidity Quote Exhibit C that permitted integration but imposed new display requirements. These display requirements were challenged by Bloomberg LP as constituting a denial of access to services under Sections 19(d) [13] and 19(f) [14] of the Act.

In January 2004, the Commission held that the Exchange's actions of imposing the new display requirements on vendors' use of the Liquidity Quote data and its rejection of certain proposed displays of such data based on the display requirements were a denial of access. Therefore, the Commission set aside the Exchange's actions.[15] Specifically, the Commission held that the contractual display requirements were Exchange rules that were required to be filed and approved pursuant to section 19(b) of the Act [16] and because they were not so filed and approved, could not provide a basis for the Exchange's denial of access to Liquidity Quote data.

The Exchange filed this proposed rule change, pursuant to section 19(b) of the Act,[17] to adopt display requirements for Liquidity Quote data that will be set forth in the Liquidity Quote Exhibit C to the Consolidated Vendor Form.

III. Description of the NYSE's Proposal

The NYSE filed a proposed Liquidity Quote Exhibit C to the Consolidated Vendor Form to set forth additional display requirements pursuant to which vendors may distribute to their customers or subscribers NYSE Liquidity Quote data. Specifically, if a vendor wishes to provide Liquidity Quote data to its customers or subscribers, the vendor must execute and comply with the terms of the proposed Liquidity Quote Exhibit C to the Consolidated Vendor Form. The proposed Exhibit C defines what is considered ''Liquidity Quote information'' [18] and what is considered ''Other Bids and Offers.'' [19] The proposed Exhibit C provides that the vendor may only use and display Liquidity Quote information to the extent provided in the agreement and only for as long as the agreement is in effect.[20] Vendors also are required, pursuant to the terms of proposed Exhibit C, to provide its customers or subscribers with a notice or agreement specified by NYSE and to have its customers or subscribers either acknowledge receipt of such notice or assent to such agreement as directed by NYSE.[21]

The proposed Liquidity Quote Exhibit C contains display requirements for Liquidity Quote information. Specifically, proposed Exhibit C sets forth requirements regarding ''Aggregated Displays,'' ''Montages,'' ''Attribution,'' ''Liquidity Quote-Only Displays,'' and ''Screen Shots.'' For ''Aggregated Displays,'' NYSE proposes that if a vendor aggregates Liquidity Quote bids and offers with Other Bids and Offers in its displays (*i.e.*, an ''Aggregated Display''), then the vendor is required to indicate the number of shares attributable to the Liquidity Quote bids and offers.[22] For ''Montages,'' NYSE proposes that if a vendor includes a Liquidity Quote bid or offer in a montage that includes an NYSE BBO, then the vendor must exclude the size of the NYSE BBO from any calculation of cumulative size within the montage.[23] NYSE also proposes that vendors identify each element or line of Liquidity Quote information that it includes in an Aggregated Display, Montage, or other integrated display with either ''NYSE Liquidity Quote ''or ''NYLQ.'' [24]

Proposed Exhibit C also requires vendors to offer its customers or subscribers a non-integrated Liquidity Quote product, which would be a product separate and apart from information products that include other market centers' information.[25] Further, NYSE proposes that vendors provide it with sample screen shots of displays that include Liquidity Quote information at the time the vendor commences to provide the display to customers or subscribers.[26] Finally, proposed Exhibit C provides that the display requirements do not apply to vendors' internal Liquidity Quote displays.[27]

IV. Summary of Comments

The Commission received one comment letter on the proposal.[28] In its letter, Bloomberg argued that the Aggregated Display requirement, which requires vendors to indicate the number of shares attributable to NYSE Liquidity

raised by commenters to its terms in the April Order.

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78f(b)(8).

[12] *See* April Order footnote 53. The Commission later stated in the April Order that ''NYSE may require that vendors provide the NYSE attribution in any display that includes Liquidity Quote.''

[13] 15 U.S.C. 78s(d).

[14] 15 U.S.C. 78s(f).

[15] *See* In the Matter of the Application of Bloomberg L.P., For Review of Action taken by the New York Stock Exchange, Inc., Admin. Proc. File No 3–11129, Securities Exchange Act Release No. 49076 (January 14, 2004).

[16] 15 U.S.C. 78s(b).

[17] 15 U.S.C. 78s(b).

[18] ''Liquidity Quote information'' is proposed to be defined as ''any depth information and other information that NYSE makes available pursuant to the NYSE Liquidity Quote Service, including Liquidity Quote bids and offers, and any modified version of that information and any information derived from that information.'' *See* proposed Exhibit C 21(a)(i).

[19] ''Other Bids and Offers'' is proposed to be defined as ''bids and offers other than Liquidity Quote bids and offers. For example, Other Bids and Offers include the NYSE best bid or offer, another market center's best bid or offer and a national best bid or offer.'' *See* proposed Exhibit C 21(a)(ii).

[20] *See* proposed Exhibit C 21(b).

[21] *See* proposed Exhibit C 21(c).

[22] *See* proposed Exhibit C 21(d)(i).

[23] *See* proposed Exhibit C 21(d)(ii).

[24] *See* proposed Exhibit C 21(d)(iii).

[25] *See* proposed Exhibit C 21(d)(iv).

[26] *See* proposed Exhibit C 21(d)(v).

[27] *See* proposed Exhibit C 21(e).

[28] *See supra* note 5.

Quote, is not necessary to prevent investor confusion or to differentiate between NYSE Liquidity Quote data and other data it may wish to present in a quotation montage. Furthermore, Bloomberg noted that the Aggregated Display requirement would prevent Bloomberg from presenting a summary screen it currently provides to its customers. Bloomberg believes that its summary screen, which allows viewers to toggle to a detail screen that identifies Liquidity Quote data, has not caused any investor confusion.

Bloomberg also raised concerns regarding the NYSE's proposed Attribution requirement. Bloomberg stated that the NYSE's proposed Attribution requirement, if adopted, would require vendors to place the NYSE's identifier on analytics, including charts, graphs, and other derived presentations, regardless of whether the identifier would be necessary to prevent investor confusion. Bloomberg argued that the Attribution requirement would be unduly burdensome and anticompetitive and would provide NYSE with more attribution than what is given to other exchanges or market centers, therefore disadvantaging other market centers, and blocking entry of would-be competitors by denying them necessary screen space.

In its response, the Exhange argued that it believes that the proposed display requirements are minimal and comply with the Commission's orders on the display of Liquidity Quote.[29] NYSE believes that the display requirements assure that vendor displays identify the amount and source of liquidity so investors can make informed trading and order routing decisions.[30] The Exchange further argued that the display requirements afford market quality transparency, and enables markets to differentiate themselves on the basis of market quality and data products, which NYSE believes will invigorate inter-market competition.[31]

In response to Bloomberg's comment regarding attribution of analytics, NYSE confirmed that the proposed Exhibit C would require vendors to associate the identifier ''NYLQ'' or ''NYSE Liquidity Quote'' with information that a vendor may include in analytics, charts, graphs, and other derived data.[32] NYSE described the required attribution by way of example as follows: ''For example, if a user displays a line graph of information on the bid prices for all markets (including NYLQ), the page that displays the graph must delineate and identify the relevant contribution of NYSE to the graph.'' [33]

V. Discussion

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[34] In the April Order, the Commission conditioned approval of Liquidity Quote on the NYSE's agreement to remove from its contract those terms that strictly prohibited integration of Liquidity Quote data with other markets' data. The Commission found that the restrictions on integration were inconsistent with sections 6(b)(5) [35] and 6(b)(8) [36] of the Act. With this proposed rule change, NYSE has removed those terms that restricted integration. Accordingly, pursuant to the terms of the proposed Exhibit C, vendors will be permitted to enhance, integrate, or consolidate Liquidity Quote data with other markets' data. Therefore, the Commission finds that the removal of the terms that restricted integration of Liquidity Quote data with other markets' data to be consistent with the requirements of section 6(b)(5) of the Act,[37] which requires that an exchange's rules be designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest and Section 6(b)(8) of the Act,[38] which requires that an exchange's rules not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Commission also determined in the April Order that it would be reasonable and consistent with the Act for the NYSE to require those data feed recipients who choose to provide a value-added Liquidity Quote data package to: (i) Give the NYSE attribution next to any integrated quote that includes NYSE data; and (ii) make available to customers NYSE's Liquidity Quote product as a separate branded package.[39] The Commission believes that the proposed Exhibit C implements what the Commission has determined to be acceptable identification of NYSE Liquidity Quote data. Liquidity Quote bids and offers are not comparable to regular bids and offers.[40] Accordingly, the Commission determined that attribution next to an integrated quote would be permissible to alert investors that the quote they may be seeing reflects a quote that has been integrated with a Liquidity Quote and thus may include other price points. In proposed Exhibit C, NYSE requires vendors to provide it with attribution on each element or line that includes Liquidity Quote information and to indicate the number of shares attributable to Liquidity Quote in an Aggregated Display. The Commission believes that this attribution is consistent with the April Order.

The Commission notes that this order only approves the filing submitted by the Exchange for the proposed Exhibit C associated with the NYSE Liquidity Quote data. While Liquidity Quote data is distributed as part of the NYSE's OpenBook data service, the terms of the proposed Exhibit C for Liquidity Quote do not apply and have not been considered or approved by the Commission as acceptable for the distribution of NYSE OpenBook data.[41]

VI. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act [42] the proposed rule change (SR–NYSE–2004–32), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[43]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. E5–1475 Filed 4–1–05; 8:45 am]

BILLING CODE 8010–01–P

[29] *See* NYSE Response Letter, *supra* note 6.

[30] *Id.*

[31] *Id.*

[32] *See* NYSE 2nd Response Letter, *supra* note 6.

[33] *Id.*

[34] In approving this proposed rule change, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[35] 15 U.S.C. 78f(b)(5).

[36] 15 U.S.C. 78f(b)(8).

[37] 15 U.S.C. 78f(b)(5).

[38] 15 U.S.C. 78f(b)(8).

[39] *See supra* note 12 and accompanying text.

[40] NYSE has indicated that in some instances Liquidity Quotes and NYSE BBOs could be the same and that at such times both Liquidity Quotes and NYSE BBOs would be disseminated via the CTA/CQ Plan and via the NYSE Liquidity Quote data service.

[41] On December 7, 2001, the Commission approved a proposed rule change to establish fees for the NYSE OpenBook service. *See* Securities Exchange Act Release No. 44138 (December 7, 2004), 66 FR 64895 (December 14, 2004) (SR–NYSE–2001–42). On August 11, 2004, the NYSE filed a proposed rule change to establish fees for the NYSE OpenBook service on a real-time basis. *See* Securities Exchange Act Release No. 50275 (August 26, 2004), 69 FR 53760 (September 2, 2004) (SR–NYSE–2004–43). The NYSE has not filed the proposed restrictions on vendor redissemination of OpenBook data.

[42] 15 U.S.C. 78s(b)(2).

[43] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 10031]

Kentucky Disaster Number KY–00001

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 Kentucky (FEMA–1578–DR), dated 02/08/2005.

Incident: Severe Winter Storm and Record Snow.

Incident Period: 12/21/2004 through 12/23/2004.

DATES: *Effective Date:* 03/10/2005.

Physical Loan Application Deadline Date: 04/11/2005.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Disaster Area Office 1, 360 Rainbow Blvd. South 3rd Floor, Niagara Falls, NY 14303.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, 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 Kentucky dated 02/08/2005, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties:

Marshall
Todd
Trigg

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. 05–6574 Filed 4–1–05; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Interest Rates

The Small Business Administration publishes an interest rate called the optional ''peg'' rate (13 CFR 120.214) on a quarterly basis. This rate is a weighted average cost of money to the government for maturities similar to the average SBA direct loan. This rate may be used as a base rate for guaranteed fluctuating interest rate SBA loans. This rate will be 4.500 (4½) percent for the April–June quarter of FY 2005.

James E. Rivera,

Associate Administrator for Financial Assistance.

[FR Doc. 05–6575 Filed 4–1–05; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

National Small Business Development Center Advisory Board Public Meeting; Correction

The U.S. Small Business Administration National Small Business Development Center Advisory Board will be hosting a public meeting via conference call to discuss such matters that may be presented by members, and the staff of the U.S. Small Business Administration or interested others. Previously, the meeting date was incorrectly announced for Tuesday, April 29, 2005. The correct meeting date is Tuesday, April 19, 2005, at 1 p.m. eastern standard time.

Anyone wishing to make an oral presentation to the Board must contact Dionna Martin, Senior Program Manager, U.S. Small Business Administration, Office of Small Business Development Center, 409 3rd Street, SW., Washington, DC 20416, telephone (202) 205–7042; fax (202) 481–1671.

Matthew K. Becker,

Committee Manager Officer.

[FR Doc. 05–6572 Filed 4–1–05; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

National Advisory Council; Public Meeting

The U.S. Small Business Administration's National Advisory Council will be hosting a public meeting to discuss such matters that may be presented by members, and staff of the U.S. Small Business Administration, or others present. The meeting will be held on Tuesday, April 26, 2005, starting at 8 a.m. until 6:30 p.m. The meeting will be held at the Hilton Washington Hotel, 1919 Connecticut Avenue, NW., Washington, DC 20009.

Anyone wishing to attend must contact Balbina Caldwell in writing or fax. Balbina Caldwell, Director, National Advisory Council, 409 3rd Street, SW., Washington, DC 20416, telephone: (202) 205–6914, fax: (202) 481–4678.

Matthew K. Becker,

Committee Management Officer.

[FR Doc. 05–6573 Filed 4–1–05; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Aviation Administration (FAA), Dot.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for extension of the currently approved collection. The ICR describes the nature of the information collection and the expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on December 30, 2004 on page 78520.

DATES: Comments must be submitted on or before May 4, 2005. A comment to OMB is most effective if OMB receives it within 30 days of publication.

FOR FURTHER INFORMATION CONTACT: Judy Street on (202) 267–9895.

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: FAA Acquisition Management System (FAAAMS).

Type of Request: Extension of a currently approved collection.

OMB Control Number: 2120–0595.

Form(s) 79 Forms available online: *http://fast.faa.gov/docs/forms/form.html.*

Affected Public: A total of 15,298 respondents.

Abstract: Pursuant to section 348 of Public Law 104–50, the FAA implements an acquisition management system that addresses the unique needs of the agency. This document established the policies, guiding principles, and internal procedures for the FAA's acquisition system.

Estimated Annual Burden Hours: An estimated 1,701,099 hours annually.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention FAA Desk Officer.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimates of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on March 25, 2005.

Judith D. Street,

FAA Information Collection Clearance Officer, Standards and Information Division, APF–100.

[FR Doc. 05–6657 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for extension of the currently approved collection. The ICR describes the nature of the information collection and the expected burden. The **Federal Register** notice with a 60-day comment period soliciting comments on the following collection of information was published on December 30, 2004, page 78520.

DATES: Comments must be submitted on or before May 4, 2005. A comment to OMB is most effective if OMB receives it within 30 days of publication.

FOR FURTHER INFORMATION CONTACT: Judy Street on (202) 267–9895.

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: Commercial Space Transportation Reusable Launch Vehicle and Reentry Licensing Regulation.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 2120–9643.

Forms(s): NA.

Affected Public: A total of 3 commercial space operators.

Abstract: The required information will be used to determine whether applicants satisfy requirements for obtaining a launch license to protect the public from risks associated with reentry operations from a site not operated by or situated on a Federal launch range.

Estimated Annual Burden Hours: An estimated 10,000 hours annually.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: FAA Desk Officer.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimates of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on March 25, 2005.

Judith D. Street,

FAA Information Collection Clearance Officer, Standards and Information Division, APF–100.

[FR Doc. 05–6658 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2005–17]

Petitions for Exemption; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of disposition of prior petition.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption, part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains the disposition of certain petitions previously received. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

FOR FURTHER INFORMATION CONTACT: Susan Boylon (425–227–1152), Transport Airplane Directorate (ANM–113), Federal Aviation Administration, 1601 Lind Ave SW., Renton, WA 98055–4056; or John Linsenmeyer (202–267–5174), Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85 and 11.91.

Issued in Washington, DC, on March 25, 2005.

Brenda D. Courtney,

Acting Director, Office of Rulemaking.

Disposition of Petitions

Docket No.: FAA–2003–14908.

Petitioner: Airborne Express (ABX Air, Inc.).

Sections of 14 CFR Affected: 14 CFR part 21, SFAR No. 88.

Description of Relief Sought/Disposition: To permit McDonnell Douglas, as the supplemental type certificate (STC) holder of STC No. SA1411GL, relief from the requirements of SFAR No. 88 on McDonnell Douglas DC–9–31/32/32(VC–9)/32F/2F(C–9A)/32F(C–9B)/33F/34F /41/81/82/83/87 series airplanes. *Grant of Exemption, 03/14/2005, Exemption No. 8509.*

Docket No.: FAA–2004–15380.

Petitioner: The Boeing Company.

Sections of 14 CFR Affected: 14 CFR part 21, SFAR No. 88.

Description of Relief Sought/Disposition: To allow The Boeing Company, as the supplemental type certificate (STC) holder of STC No. ST00618WI–D, relief from the requirements of SFAR No. 88 on four Boeing Model 767–200 airplanes. *Grant of Exemption, 03/14/2005, Exemption No. 8510.*

Docket No.: FAA–2004–18020.

Petitioner: Omega Air.

Sections of 14 CFR Affected: 14 CFR part 21, SFAR No. 88.

Description of Relief Sought/Disposition: To allow Omega Air, as the holder of STC No. ST00888LA for the Boeing Model 707–300B airplane, to substantially meet the intent of SFAR No. 88 without conducting a complete safety review of the airplane fuel tank system, as required by SFAR No. 88. *Grant of Exemption, 03/14/2005, Exemption No. 8511.*

[FR Doc. 05–6648 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–13–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) has 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.

North County Transit District (Supplement to Waiver Petition Docket Number FRA–2002–11809)

As a supplement to North County Transit District's (NCTD) Petition for Approval of Shared Use and Waiver of Certain Federal Railroad Administration Regulations (the Waiver was granted by the FRA on June 24, 2003), NCTD seeks permanent waiver of compliance from additional sections of Title 49 of the CFR for operation of its SPRINTER rail line between Oceanside, CA and Escondido, CA. *See Statement of Agency Policy Concerning Jurisdiction Over the Safety of Railroad Passenger Operations and Waivers Related to Shared Use of the Tracks of the General Railroad System by Light Rail and Conventional Equipment,* 65 FR 42529 (July 10, 2000). *See also Joint Statement of Agency Policy Concerning Shared Use of the Tracks of the General Railroad System by Conventional Railroads and Light Rail Transit Systems,* 65 FR 42626 (July 10, 2000).

In this regard, NCTD has advanced the design and construction of the SPRINTER rail line towards implementation and in the process, has identified the following additional regulations from which it hereby seeks waivers: 49 CFR part 223 Safety Glazing Standards—Locomotives, Passenger Cars and Cabooses, Section 223.9(c); and part 229 Railroad Locomotive Safety Standards, Section 229.125(a).

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 2002–11809) and must be submitted to the Docket Clerk, DOT Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., Washington, DC 20590. 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://dms.dot.gov*.

Anyone is able to search the electronic form of all 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). The Statement may also be found at *http://dms.dot.gov*.

Issued in Washington, DC on March 29, 2005.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 05–6652 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–06–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–2005–20383

Applicant: Maine Eastern Railroad, Mr. Jonathan F. Shute, General Manager, 685 Sligo Road, North Yarmouth, Maine 04097.

The Maine Eastern Railroad (MERR) seeks relief from the requirements of the Rules, Standard and Instructions, Title 49 CFR, part 236, section 236.312, on the Carlton Bridge, at Bath, Maine, milepost 30.0, on the Rockland Branch, to the extent that MERR be permitted to detect displacement of the bridge locking members, when displaced more than two inches from their proper position, instead of the existing one inch requirement.

Applicant's justification for relief: The bridge and interlocking have recently been upgraded with new span lock rams, new rail seat detectors, and a new signal interlocking. It is not possible to maintain the one inch span lock retraction limit in cold temperature extremes, due to the contraction of the steel members in the span itself. The contraction of the steel affects the moveable span's west end span lock adjustment, which requires a maintainer to travel to the bridge piers to seasonally adjust both west end span lock circuit controller boxes to a setting of two inches to compensate for the contraction, and then again later in the season he must return the settings to one inch. This often places the maintainer at a safety risk due to icy conditions. The new power driven span lock rams are mechanically engaged for a distance of two feet to lock the moveable span down, and a change in the ram retraction limit from one to two inches clearly causes no safety risk.

Any interested party desiring to protest the granting of an application shall set forth specifically the grounds upon which the protest is made, and include 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 this proceeding should be identified by the docket number and must be submitted to the Docket Clerk, DOT Central Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., Washington, DC 20590–0001. Communications received within 45 days of the date of this notice will be considered by the 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://dms.dot.gov*.

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all

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) or you may visit *http://dms.dot.gov*.

FRA expects to be able to determine these matters without an oral hearing. However, if a specific request for an oral hearing is accompanied by a showing that the party is unable to adequately present his or her position by written statements, an application may be set for public hearing.

Issued in Washington, DC on March 29, 2005.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 05–6651 Filed 4–1–05; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Agency Information Collection Activities Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before May 4, 2005.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Records Management Service (005E3), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030, fax (202) 273–5981 or e-mail *denise.mclamb@mail.va.gov*. Please refer to ''OMB Control No. 2900–NEW.'' Send comments and recommendations concerning any aspect of the information collection to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503, (202) 395–7316. Please refer to ''OMB Control No. 2900–NEW'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Title: Request for Contact Information, VA Form 21–30.

OMB Control Number: 2900–NEW.

Type of Review: New collection.

Abstract: VA Form 21–30 is used to locate individuals when contact information cannot be obtained by other means or when travel funds may be significantly impacted in cases where the individual resides in a remote location and is not home during the day or when visited. VA uses the data collected to investigate and interview witnesses upon any matter within the jurisdiction of the Department, including determining whether a fiduciary of a beneficiary is properly executing his or her duties.

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 OMB control number. The **Federal Register** notice with a 60-day comment period soliciting comments on this collection of information was published on December 1, 2004, at page 69991.

Affected Public: Individuals or households.

Estimated Annual Burden: 1,250 hours.

Estimated Average Burden Per Respondent: 15 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 5,000.

Dated: March 17, 2005.

By direction of the Secretary.

Martin Hill,

Management Analyst, Records Management Service.

[FR Doc. 05–6661 Filed 4–1–05; 8:45 am]

BILLING CODE 8320–01–M

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0051]

Agency Information Collection Activities Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–21), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and includes the actual data collection instrument.

DATES: Comments must be submitted on or before May 4, 2005.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Records Management Service (005E3), Department of Veterans Affairs, 810 Vermont Avenue, NW., or e-mail *denise.mclamb@mail.va.gov*. Please refer to ''OMB Control No. 2900–0051.'' Send comments and recommendations concerning any aspect of the information collection to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0051'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501—3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Quarterly Report of State Approving Agency Activities.

OMB Control Number: 2900–0051.

Type of Review: Extension of a currently approved collection.

Abstract: VA makes reimbursement retrospectively on a monthly or quarterly basis after receiving a request from SAA. Since SAAs submit the information electronically to VA, VA Form 22–7398 is no longer required and will be discontinued; however, SAAs must submit other documents (such as reports of visits to schools and programs approved) to support the electronic request.

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 OMB control number. The **Federal Register** notice with a 60-day comment period soliciting comments on this collection of information was published on November 17, 2004, page 67388.

Affected Public: Federal government, and State, local or tribal government.

Estimated Annual Burden: 236 hours.

Estimated Average Burden Per Respondent: 1 hour.

Frequency of Response: Quarterly.

Estimated Number of Respondents: 59.

Estimated Number of Responses: 236.

Dated: March 23, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. E5–1494 Filed 4–1–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Agency Information Collection Activities Under OMB Review

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–21), this notice announces that the Veterans Health Administration (VHA), Department of Veterans Affairs, has submitted the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and includes the actual data collection instrument.

DATES: Comments must be submitted on or before May 4, 2005.

FOR FURTHER INFORMATION OR A COPY OF THE SUBMISSION CONTACT: Denise McLamb, Records Management Service (005E3), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8030, fax (202) 273–5981 or e-mail: *denise.mclamb@mail.va.gov.* Please refer to ''OMB Control No. 2900–NEW.''

Send comments and recommendations concerning any aspect of the information collection to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–NEW'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Titles: Forms and Regulations for Grants to States for Construction and Acquisition of State Home Facilities, VA Form 10–0388.

OMB Control Number: 2900–NEW.

Type of Review: New collection.

Abstract: State government use VA Form 10–0388 to apply for State Home Construction Grant Program and to certify compliance with VA requirements. VA uses this information, along with other documents submitted by the States to determine the feasibility of the projects for VA participation, to meet VA requirements for a grant award and to rank the projects in establishing the annual fiscal year priority list. The list is the basis for committing to State Home construction projects during the various fiscal years.

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 OMB control number. The **Federal Register** notice with a 60-day comment period soliciting comments on this collection of information was published on October 12, 2004, at pages 61912–61913.

Affected Public: State, local or tribal government.

Estimated Annual Burden: 360 hours.

Estimated Average Burden Per Respondent: 6 hours.

Frequency of Response: On occasion.

Estimated Number of Respondents: 60.

Dated: March 23, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. E5–1495 Filed 4–1–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0545]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection and allow 60 days for public comment in response to this notice. This notice solicits comments for information needed to determine a claimant's entitlement to income based benefits and the amount payable.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 3, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0545'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or fax (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501—3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Report of Medical, Legal, and Other Expenses Incident to Recovery for Injury or Death, VA Form 21–8416b.

OMB Control Number: 2900–0545.

Type of Review: Extension of a currently approved collection.

Abstract: Compensation awarded to claimants by another entity or government agency for personal injury or death is usually countable income. However, medical, legal or other

expenses may be deducted from the amount awarded. The claimant use VA Form 21–8416b to report these expenses. VA uses the information collected to determine the claimant's eligibility for income based benefits and the rate payable.

Affected Public: Individuals or households.

Estimated Annual Burden: 1,125 hours.

Estimated Average Burden Per Respondent: 45 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 1,500.

Dated: March 25, 2005.

By direction of the Secretary

Loise Russell,

Director, Records Management Service.

[FR Doc. E5–1496 Filed 4–1–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–New]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed new collection and allow 60 days for public comment in response to this notice. This notice solicits comments for information needed to determine a spouse and children entitlement to a portion of a veteran or beneficiary's compensation and pension benefits.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 3, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–New'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or fax (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501—3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Information Regarding Apportionment of Beneficiary's Award, VA Form 21–0788.

OMB Control Number: 2900–New.

Type of Review: New collection.

Abstract: The data collected on VA Form 21–0788 is used to determine whether a veteran's or beneficiary's compensation and pension benefits may be allocated to his or her dependents. The veteran and the claimant use the form to report their income information in order for VA to determine the amount of benefit that may be apportion to a spouse and children who do not reside with the veteran. A portion of the surviving spouse's benefits may be allocated to children of deceased veterans, who do not reside with the surviving spouse.

Affected Public: Individuals or households.

Estimated Annual Burden: 12,500 hours.

Estimated Average Burden Per Respondent: 30 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 25,000.

Dated: March 25, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. E5–1497 Filed 4–1–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0576]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to determine a claimant's date of enrollment in a correspondence course.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 3, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0049'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or fax (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Certificate of Affirmation of Enrollment Agreement—Correspondence Course (Under Chapters 20, 32, & 35, Title 38 U.S.C., Section 903 of PL 96–342, or Chapter 1606, Title 10, U.S.C.)

OMB Control Number: 2900–0576.

Type of Review: Extension of a currently approved collection.

Abstract: Claimants who enrolled in a correspondence training course completes VA Form 22–1999c and submit it to the correspondence school to affirm the enrollment agreement contract. The certifying official at the correspondent school submit VA Form 22–1999c and the enrollment certification to VA for processing. VA uses the information to determine if the claimant signed and dated the form during the ten-day reflection period deciding whether to enroll in the correspondence course and if such course is suitable to his or her abilities and interest. In addition, the claimant must sign VA Form 22–1999c on or after the twelfth day, the enrollment agreement was dated. VA will not pay educational benefits for correspondence training that was completed nor accept the affirmation agreement that was signed and dated on or before the enrollment agreement date.

Affected Public: Individuals or households.

Estimated Annual Burden: 135 hours.

Estimated Average Burden Per Respondent: 3 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 2,700.

Dated: March 25, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. E5–1498 Filed 4–1–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0049]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments for information necessary to determine entitlement to compensation and pension benefits for a child between the ages of 18 and 23 attending school.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 3, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *irmnkess@vba.va.gov.* Please refer to ''OMB Control No. 2900–0049'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or fax (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: a. Request for Approval of School Attendance, VA Form 21–674 and 21–674c.

b. School Attendance Report, VA Form 21–674b.

OMB Control Number: 2900–0049.

Type of Review: Revision of a currently approved collection.

Abstract: Recipients of disability compensation, dependency and indemnity compensation, disability pension, and death pension are entitled to benefits for eligible children between the ages of 18 and 23 who are attending school. VA Forms 21–674, 21–674c and 21–674b are used to confirm school attendance of children for whom VA compensation or pension benefits are being paid and to report any changes in entitlement factors, including marriages, a change in course of instruction and termination of school attendance.

Affected Public: Individuals or households.

Estimated Annual Burden: 37,792 hours.

Estimated Average Burden Per Respondent: 15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 177,500.

Dated: March 21, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. E5–1499 Filed 4–1–05; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0618]

Proposed Information Collection Activity: Proposed Collection; Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on the information needed to process accelerated death benefit payment.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 3, 2005.

ADDRESSES: Submit written comments on the collection of information to Nancy J. Kessinger, Veterans Benefits

Administration (20M35), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail *irmnkess@vba.va.gov*. Please refer to ''OMB Control No. 2900–0618'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 273–7079 or fax (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Application by Insured Terminally Ill Person for Accelerated Benefit (38 CFR 9.14(e).

OMB Control Number: 2900–0618.

Type of Review: Extension of a currently approved collection.

Abstract: An insured person who is terminally ill may request a portion of the face value of his or her Servicemembers' Group Life Insurance (SGLI) or Veterans' Group Life Insurance (VGLI) prior to death. If the insured wants to receive a portion of the SGLI or VGLI he or she must submit a Servicemembers' and Veterans' Group Life Insurance Accelerated Benefits Option application. The application must include a medical prognosis by a physician stating the life expectancy of the insured person and a statement by the insured on the amount of accelerated benefit he or she chooses to receive. The application is obtainable by writing to the Office of Servicemembers' Group Life Insurance ABO Claim Processing, 290 West Mt. Pleasant Avenue, Livingston, NJ 07039, or calling 1–800–419–1473 or downloading the application via the Internet at *http://www.insurance.va.gov.*

Affected Public: Individuals or households.

Estimated Annual Burden: 40 hours.

Estimated Average Burden Per Respondent: 12 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 200.

Dated: March 22, 2005.

By direction of the Secretary.

Loise Russell,

Director, Records Management Service.

[FR Doc. E5–1500 Filed 4–1–05; 8:45 am]

BILLING CODE 8320–01–P

Corrections

Federal Register

Vol. 70, No. 63

Monday, April 4, 2005

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Revision of an Information Collection; Comment Request

Correction

In notice document 05–6121 beginning on page 15857 in the issue of Tuesday, March 29, 2005, make the following correction:

On page 15857, in the third column, under the **DATES** section, in the second line, ''March 31, 2005'' should read ''May 31, 2005.''

[FR Doc. C5–6121 Filed 4–1–05; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4975–N–04]

Notice of Proposed Information Collection: Comment Request; Assisted Living Conversion Program (ALCP) and Emergency Capital Repair Program (ECRP)

Correction

In notice document 05–5825 beginning on page 15115 in the issue of Thursday, March 24, 2005, make the following correction:

On page 15115, in the third column, in the second line, under the title *OMB Control Number if applicable:* ''2502-0541'' should read ''2502-0542''.

[FR Doc. C5–5825 Filed 4–1–05; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Monday,
April 4, 2005

Part II

Department of Agriculture

Farm Service Agency
7 CFR Part 723
Commodity Credit Corporation
7 CFR Parts 1463 and 1464

Tobacco Transition Payment Program; Final Rule

DEPARTMENT OF AGRICULTURE

Farm Service Agency

7 CFR Part 723

Commodity Credit Corporation

7 CFR Parts 1463 and 1464

RIN 0560–AH30

Tobacco Transition Payment Program

AGENCY: Commodity Credit Corporation and Farm Service Agency, USDA.

ACTION: Final rule.

SUMMARY: This rule provides regulations for the Tobacco Transition Payment Program (TTPP), as required by Title VI of the American Jobs Creation Act of 2004 (the 2004 Act), ending the tobacco marketing quota and price support loan programs. The TTPP will provide payments over a ten-year period to quota holders and producers of quota tobacco to help them make the transition from the federally-regulated program. This rule also removes from the Code of Federal Regulations obsolete tobacco program provisions at 7 CFR parts 723 and 1464.

DATES: *Effective Date:* This rule will be effective March 30, 2005, except for the removal of 7 CFR parts 723 and 1464, which will be effective November 1, 2005.

FOR FURTHER INFORMATION CONTACT: Ann Wortham, Tobacco Division, Farm Service Agency (FSA), United States Department of Agriculture (USDA), Stop 0514, 1400 Independence Ave., SW., Washington, DC 20250–0514. Phone: (202) 720–2715; e-mail: *ann.wortham@wdc.usda.gov.* Persons with disabilities who require alternative means for communication (Braille, large print, audio tape, etc.) should contact the USDA Target Center at (202) 720–2600 (voice and TDD).

SUPPLEMENTARY INFORMATION:

Notice and Comment

Section 642(b) of the 2004 Act requires that these regulations be promulgated without regard to the notice and comment provisions of 5 U.S.C. 553 or the Statement of Policy of the Secretary of Agriculture effective July 24, 1971, (36 FR 13804) relating to notices of proposed rulemaking and public participation in rulemaking. These regulations are thus issued as final.

Background

General Overview

Sections 611 through 613 of the American Jobs Creation Act of 2004 (Pub. L. 108–357; the 2004 Act) repeal the tobacco marketing quota and related price support programs authorized by Title III of the Agricultural Adjustment Act of 1938 (the 1938 Act) and the Agricultural Act of 1949. This action is effective at the end of the 2004 marketing years established for the respective kinds of tobacco that are subject to such quotas. The regulations used to administer the marketing quota program are codified at 7 CFR part 723 and the price support loan program regulations are codified at 7 CFR part 1464.

Sections 621 through 624 of the 2004 Act provide for transitional payments to tobacco quota holders and producers. Eligible tobacco quota holders and producers will receive payments under this program in 10 installments in each of the 2005 through 2014 fiscal years (FYs). To the extent practical, the Commodity Credit Corporation (CCC) intends to make the FY 2005 payment between June and September of 2005, and subsequent payments during January of each FY.

Transition payments will be based on the Basic Quota Levels (BQLs) determined for each farm, and then for quota holders' ownership shares in the farm and producers' shares in the risk of producing quota tobacco on the farm during the years 2002, 2003 and 2004. For example, if a quota holder is the sole owner of a farm to which quota was assigned for the 2002 marketing year, the BQL established for that farm will also be the BQL for that quota holder. Similarly, if the quota holder has only a one-third ownership share in the farm, that quota holder's BQL will be one third of the BQL established for the farm.

Sections 625 through 627 of the 2004 Act provide for the establishment of assessments on certain domestic manufacturers and importers of tobacco products in order to fund the TTPP. The regulations relating to the manner in which the assessment provisions of the 2004 Act are to be administered are set forth in 7 CFR part 1463 subpart A.

TTPP contract payments are made by CCC and have the same contractual sanctity as other CCC payments. Accordingly, while the source of the funding is primarily derived from assessments levied upon manufacturers and importers of tobacco products, the obligation arising from these contracts that accrues to CCC is the same as for any other CCC contract.

Eligible Quota Holders

Payments

Generally, this rule provides for payments to be made to persons who owned farms on October 22, 2004 for which tobacco quota was assigned for the 2004 marketing year. Payments to such persons, or quota holders, are based on the marketing quota assigned to the farm for the 2002 marketing year, as provided by 7 CFR part 723. The payment rate is $7 per pound of eligible quota, to be paid in equal installments over 10 years.

Generally, this rule also provides for payments to producers of quota tobacco. Overmarketings and undermarketings play a part in calculating burley and flue-cured producer BQL. They are both conditions that are the result of an action in one year that cause temporary quota adjustments the following year.

Overmarketings are tobacco pounds sold during a marketing year in excess of a farm's effective marketing quota for that year. The excess pounds of tobacco sold in one year are deducted from the next year's marketing quota for that farm.

Undermarketings for burley or flue-cured tobacco are tobacco that could have been sold during a marketing year but were not. There are two categories of undermarketings: actual and effective. Actual undermarketings are the pounds of tobacco by which the effective quota is more than the pounds of tobacco marketed during a marketing year. Effective undermarketings are the smaller of the actual undermarketings or the sum of the previous year's basic quota on the farm plus pounds that were temporarily transferred to that farm for the previous year.

The BQL calculation must consider in what year these over/under pounds were originally assigned to a farm because under the former tobacco program marketing quotas were adjusted each year by a national factor determined by CCC to account for changes in supply and demand. Because payments are to be based on 2002 quota levels, the quotas for each year must be adjusted to the 2002 level. For example, undermarketings that are carried forward from 2002 to 2003 are pounds that were already at the 2002 level. Therefore, in calculating 2003 BQL these 2002 undermarketings are deducted from the 2003 marketings; the BQL factor is applied to the remaining 2003 marketings to bring them to the 2002 level; and then the 2002 undermarketings are added back into the process. The adjustment process is more fully described in the Eligible

Quota Producers section of this Preamble.

The 2004 Act specifically addresses the situation where permanent transfers of tobacco-marketing quota were initiated prior to October 22, 2004, but not completed as of that date. Accordingly, in the case of the incomplete transfer of an entire farm, where the quota distribution has not been agreed upon, CCC has determined that the eligible tobacco quota holder will be considered to be the person contractually bound to purchase the entire farm. Similarly, the 2004 Act provides that where there was in existence on October 21, 2004, an agreement for the permanent transfer of the tobacco quota, but the transfer was not completed by October 21, 2004, the owner of the farm to which the tobacco quota was to be transferred will be considered to be the eligible tobacco quota holder.

If a written agreement was initiated before October 22, 2004 for the purchase of all or a portion of a farm, the transition payment will be disbursed as specified in the agreement so long as the resulting distribution is consistent with the 2004 Act. If a written agreement was initiated before October 22, 2004 for the purchase of all or a portion of a farm and the agreement specified the distribution of the farm's tobacco quota and the parties to the agreement do not concur about the manner in which such quota would be assigned to the different portions of the farm, payments will be made in a fair and equitable manner as determined by CCC taking into account any incomplete permanent transfer of such quota. Where there was a sale of part of the farm not yet completed by October 22, 2004, CCC will divide the disputed quota taking into account the ratio of cropland on the unsold portion of the farm to the cropland on the portion of the farm subject to the purchase contract.

Disputes

In the event there is a dispute regarding the determination of which persons are eligible quota holders on a farm, no payment to any quota holder on that farm will be made until all parties have agreed or until all administrative appeals have been exhausted. Also, if a farm is determined eligible for a permanent tobacco quota and all or part of that farm is sold after October 22, 2004, the tobacco quota attributed to the owner of the farm as of October 22, 2004 cannot be transferred for purposes of determining a TTPP payment. In addition, consistent with the manner in which CCC administers other commodity programs, a person who holds a life-estate interest in a farm with a tobacco quota will be considered the owner of the farm in determining who is an eligible tobacco quota holder. A person with a remainder interest, any other contingent interest, or any equitable interest as a creditor or otherwise in such farm or marketing quota will not be considered to be an owner of the farm for purposes of determining a TTPP payment. If such a person believes that a private sales transaction did not take into account these statutory and regulatory provisions, a private resolution of such a dispute must be undertaken by the parties to the contract; neither FSA nor CCC will participate in the resolution of such matter.

There may have been transfers of farms that were not reported to FSA, or incomplete transfers of tobacco quotas and farms as of October 22, 2004. Accordingly, in order to ensure that only persons who meet the requirements of the 2004 Act receive a TTPP payment, and to reduce debt collection efforts with respect to persons who improperly represented their eligibility status to CCC, CCC will require program participants to make certain representations regarding whether the tobacco quota or their farm had been transferred to another person.

This rule provides that if a person who is not the tobacco quota holder for a farm, as identified in FSA records, submits a TTPP contract or other written claim to CCC before May 31, 2005, no payments will be made with respect to such farm until CCC has determined the eligibility status of each claimant and any other person who may be eligible to receive the payment. This 60-day period is intended to provide an opportunity for anyone who should have reported to FSA under 7 CFR part 723, but did not (1) claim ownership in a farm or tobacco quota or; (2) transfer ownership of a farm or tobacco quota. If a contract or written claim is submitted to CCC after May 31, 2005, and either, the first TTPP payment is made to the tobacco quota holder identified in FSA records, or collected by CCC of FSA by administrative offset or other action, additional payments will not be made on the subject TTPP contract until CCC can determine the status of the competing claimants. The rule also provides that if a contract or other written claim is provided to CCC by May 31, 2005 by two or more persons for the same tobacco quota used to calculate a TTPP payment, no payment will be issued until CCC determines the eligibility status of each claimant. Therefore, in anticipation of disputes concerning assignment of a farm marketing quota for purposes of determining the TTPP payment, any person who intends to enter into a TTPP contract is advised to visit the USDA service center in the county where the farm is located to make corrections or changes to records that relate to the farm.

Quota Holder Assignments and Successor in Interest Contracts

Any quota holder may assign the payment to another party, using the correct CCC form, so long as the consideration for the assignment is greater than or equal to the discounted value based on the discount rate established by CCC, except that special provision will be made for assignments between immediate family members and persons who purchased a tobacco marketing quota prior to October 22, 2004 and, in accordance with 7 CFR part 723, placed the quota on anther person's farm, prior to such date, with consent of the owner. The discount rate will be established by CCC at the prime rate plus two percentage points rounded to the nearest whole number.

Any quota holder may execute a successor in interest contract for their TTPP payments, except the 2005 payment, by using the correct CCC form, and subject to the following conditions: (1) The quota holder must not be subject to the payment offset provisions of the Debt Collection Improvement Act of 1996 as a result of a debt to any agency of the United States; (2) Consideration for the succession to TTPP payments must be greater than or equal to the discounted value of the remaining payment stream based on the discount rate established by CCC, except that special provision will be made for assignments between immediate family members and persons who purchased a tobacco marketing quota prior to October 22, 2004 and, in accordance with 7 CFR part 723, placed the quota on anther person's farm, prior to such date, with consent of the owner; and (3) For payments to be issued the following January for the 2006 and successive year payments, the successor must file a successor in interest contract no later than November 1 of the preceding year.

Once it has been determined that a tobacco quota holder is eligible for a payment under this rule, and CCC has executed a TTPP contract with such quota holder, the person may sell all or a portion of his farm and still receive the TTPP payments. CCC will not execute a TTPP contract with a person who was the buyer of the farm in a transaction that took place after October 22, 2004 unless the seller who had previously been determined by CCC to

be an eligible quota holder has executed a successor in interest contract, using the correct CCC form, in which the seller transfers all rights and obligations to the successor party, as approved by CCC.

Eligible Quota Producers

Generally, this rule provides for payments to persons who produced a crop or part of a crop of tobacco subject to a marketing quota in one or more of the 2002, 2003, and 2004-crop years. The Secretary will establish a base quota level (BQL) for each producer based on the 2002 marketing year effective quota produced on the farm each of the years 2002, 2003 and 2004. Marketing quota temporarily leased to a farm under disaster conditions will not be included in the receiving farm producer's BQL. The total payment of $3 per pound of eligible quota is to be paid at a rate of ⅓ that rate, or $1 per pound, for each of the years 2002, 2003 and 2004 in which the producer shared in the risk of producing the quota tobacco.

Where two or more persons shared in the risk of producing the same quota pound (for flue-cured and burley tobaccos only—effective undermarketings) the pound shall not be included in the producer's BQL for the year the effective undermarketing was suffered. Effective undermarketings are carried forward from the year suffered to the farm's next established marketing quota. These pounds were not factored when determining the national basic quota for the applicable year under 7 CFR part 723.

Actual undermarketings (flue-cured and burley tobacco only) that were not allowed to be carried forward to the farm's next established quota may be included in the producer's BQL where suffered to the extent the pounds were considered planted as defined under this subpart.

For burley tobacco, effective undermarketing pounds that were reduced under 7 CFR 723.206(c) in the 2004 marketing year will be included in the 2003 marketing year producer's BQL to the extent the quota was considered planted as defined under this subpart during the 2003 marketing year.

Overmarketings (flue-cured and burley only) exist when a farm markets in excess of the farm's effective quota established under 7 CFR part 723 and are deducted from the farm's next established marketing quota. To the extent the farm marketed penalty-free, these quota pounds will be included in the producer's BQL for the year in which the pounds were actually marketed, except in the 2004 marketing year. Overmarketings will be excluded from the 2004 marketing year producer's BQL because these pounds were not deducted from the farm's next established marketing quota.

For flue-cured and burley farms that temporarily leased quota pounds from the farm during the marketing year under disaster conditions these pounds will be included in the transferring farm's producer BQL and reduced from the receiving farm's producer BQL for the applicable year.

For tobaccos other than flue-cured and burley, marketing quotas were established under 7 CFR part 723 in acreage allotments. The acreage allotments will be converted to poundage quotas for purposes of determining the producer's BQL. In order to convert 2002 basic allotments established under 7 CFR part 723 to poundage quotas the allotment established will be multiplied by the farm's three-year average yield for the 2001, 2002 and 2003 crop years.

For all tobaccos for which temporary transfers of marketing quota were allowed under 7 CFR part 723 the producer's BQL will be adjusted to consider these pounds. An upward adjustment will be made to the receiving farm producer's BQL and a downward adjustment will be made to the transferring farm producer's BQL for each applicable year.

In order to calculate the producer's BQL for 2003 and 2004 marketing years, the BQL must be converted to the equivalent of the 2002 effective quota (flue-cured and burley) or the 2002 basic quota (tobaccos other than flue-cured and burley) level. This conversion will reverse the national marketing quota adjustments made by the Secretary for each applicable year. For this reason each producer's BQL for 2003 and 2004 will be broken down between basic quota pounds (adjusted annually by the Secretary) and effective undermarketing pounds (pounds for which two or more persons may have been at risk). Basic quota pounds will be adjusted using the BQL adjustment factor for the applicable kind of tobacco as shown in Table 1. The adjustment factor was determined for 2003 by dividing one by the national factor determined by FSA under 7 CFR part 723 for 2003 and, for 2004 by dividing one by the product of the national factor for 2003 times the national factor for 2004. The BQL factor, when applied to the 2003 or 2004 basic quota, will equate those years' basic quotas to the 2002 basic quota level. Effective undermarketings in the 2003 marketing year will not be adjusted because they were carried forward from the 2002 marketing year at the 2002 basic quota level. Effective undermarketings for the 2004 marketing year will be adjusted to the 2002 basic quota level using the 2003 adjustment factor shown in Table 1. These pounds were adjusted in 2003 from the 2002 level and will be factored to the 2002 basic quota level.

For burley farms where temporary transfers (not including disaster transfers) were approved, the receiving farm will be apportioned undermarketing pound history by dividing the transferring farm's prior year undermarketing pounds by the transferring farm's effective quota (before any temporary transfers) to determine a factor for apportionment of undermarketing pounds.

The receiving farm's share of undermarketing pounds will be determined by multiplying the transferring farm's apportionment factor by the receiving farms pounds leased from the transferring farm. The result will be subtracted from the total pounds leased into the receiving farm so the applicable BQL adjustment factor (Table 1) can be applied. The adjusted undermarketings leased to the receiving farm will be added to the receiving farm producer's BQL and subtracted from the transferring farm producer's BQL.

TABLE 1.—NATIONAL FACTORS AND BQL ADJUSTMENT FACTORS

Kind of Tobacco		2003	2004
Burley (type 31)	National Factor	.889	1.05
	BQL Adjustment Factor	[1] 1.124860	[2] 1.071295
Flue-Cured (types 11–14)	National Factor	.905	.895
	BQL Adjustment Factor	[1] 1.104970	[2] 1.234570
Fire-Cured (type 21)	National Factor	1.00	1.00
	BQL Adjustment Factor	[1] 1.00	[2] 1.00
Fire-Cured (types 22–23)	National Factor	1.02	1.03

TABLE 1.—NATIONAL FACTORS AND BQL ADJUSTMENT FACTORS—Continued

Kind of Tobacco		2003	2004
	BQL Adjustment Factor	[1].980392	[2].951837
Dark Air-Cured (types 35–36)	National Factor Factor	1.05	1.03
	BQL Adjustment	[1].952381	[2].924640
Va Sun-Cured (type 37)	National Factor	1.00	1.00
	BQL Adjustment Factor	[1] 1.00	[2] 1.00
Cigar Filler/Binder (types 42–44 and 54–55)	National Factor	1.12	.95
	BQL Adjustment Factor	[1].892900	[2].939800

[1] 2003 BQL adjustment factors were determined by dividing 1 by the 2003 national factor for the applicable kind of tobacco.
[2] 2004 BQL adjustment factors were determined by dividing 1 by the product of the 2003 national factor times the 2004 national factor for the applicable kind of tobacco.

Examples of BQL calculations are illustrated below.

Farm Example 1

Example 1 shows the BQL calculation for a single flue-cured producer for a farm that had no under-or over-marketings from a previous year, no temporary transfers (disaster), and marketed the entire effective quota for each of the years 2002, 2003 and 2004.

FARM EXAMPLE 1.—FLUE-CURED TOBACCO FARM

		2002	2003	2004
Basic Quota	+	1,000	905	810
Effective Undermarketings (previous year)	+	0	0	0
Overmarketings (previous year)	−	0	0	0
Lease Transfer To	+	0	0	0
Lease Transfer From	−	0	0	0
Effective Quota	=	1,000	905	810
Disaster Lease Transfer To	−	0	0	0
Disaster Lease Transfer From	+	0	0	0
TTPP Effective Quota (w/disaster leases)	=	1,000	905	810
Actual Marketings		1,000	905	810
Overmarketings		0	0	0
Actual Undermarketings		0	0	0
Effective Undermarketings		0	0	0
BQL Adjustment Factor	×	1.000000	1.104970	1.234570
Farm BQL	=	1,000	1,000	1,000
Producer Share	×	1.000	1.000	1.000
Total Payments	=	$1,000	$1,000	$1,000

Farm Example 2

Example 2 shows the BQL calculation for a single burley producer for a farm that had temporary transfers (not disaster) in 2002, 2003 and 2004. This farm did not have any under-or over-marketings from a previous year.

FARM EXAMPLE 2.—BURLEY TOBACCO FARM

		2002	2003	2004
Basic Quota	+	1,000	889	933
Effective Undermarketings (previous year)	+	0	0	0
Overmarketings (previous year)	−	0	0	0
Lease Transfer To	+	0	0	0
Lease Transfer From	−	500	500	500
Effective Quota	=	500	389	433
Disaster Lease Transfer To	−	0	0	0
Disaster Lease Transfer From	+	0	0	0
TTPP Effective Quota (w/disaster leases)	=	500	389	433
Actual Marketings		500	389	433
Overmarketings		0	0	0
Actual Undermarketings		0	0	0
Effective Undermarketings		0	0	0
BQL Adjustment Factor	×	1.000000	1.124860	1.071295
BQL	=	500	438	464
Producer share	×	1.000	1.000	1.000
Total Payments	=	$500	$438	$464

Farm Example 3:

Example 3 shows the BQL calculation for a single burley producer for a farm that had undermarketings from a previous year. In this example it is important to understand the separation of basic quota pounds from undermarketing pounds that are necessary in order to convert the 2003 or 2004 effective marketing quota to the applicable 2002 effective marketing quota level. As shown in this example the burley farm's basic quota for 2002 was 1,000 pounds and effective undermarketings (from 2001 marketing year) carried forward were 100 pounds. No temporary adjustments for leasing took place. The farm's 2002 effective quota was determined to be 1,100 pounds. The farm actually marketed 1,025 pounds which resulted in 75 pounds of actual undermarketings. Because the actual undermarketings are less than effective undermarketings brought forward from the 2001 marketing year all 75 pounds would be considered effective undermarketing in determining the farm's 2003 effective quota. Since the 75 pounds of effective undermarketings are included in both the 2002 and 2003 effective quota for the farm, the 75 pounds will be deducted from the producers BQL determined for 2002. In this case the producer's BQL for 2002 would be 1,025 pounds and the payment would be calculated as 1,025 pounds BQL multiplied by $1, or $1,025 for the producer with a 100-percent share in the 2002 crop.

In calculating the producer's BQL for the 2003 crop year the farm's marketing quota must be divided between basic quota pounds and undermarketings. This example shows the farm's basic quota was reduced from the 2002 marketing year (1,000 pounds) to the 2003 (889 pounds) marketing year. The farm has previous year effective undermarketings from 2002 (75 pounds). So that no pound is paid twice, the farm's actual marketings will be considered as the primary factor in determining the risk in production for the 2003 marketing year. Effective undermarketings will be deducted from the actual marketings so that the appropriate BQL adjustment factor from Table 1 can be applied to the basic quota. After adjusting the actual marketings to the 2002 effective quota level, the farm's adjusted marketing quota may, to the extent the quota was considered planted under this subpart, be adjusted upward to include the previous year effective undermarketing quota pounds in the producer's BQL.

The 2003 BQL calculation was performed as follows: 2002 effective undermarketings brought forward to 2003 marketing quota (75 pounds) are deducted from the farm's 2003 actual marketings (914 pounds). This is the necessary step to establish the farm's basic quota pounds so they can be adjusted to the 2002 basic quota level (839 pounds will be adjusted by the BQL adjustment factor of 1.12486 from Table 1). Once the 2002 basic quota level has been determined (944 pounds) the results must be adjusted to include the 2002 effective undermarketings (75 pounds). In this example the producer's BQL would be 1,019 pounds (944 pounds basic quota plus 75 pounds effective undermarketings) and the payment would be calculated as 1,019 pounds BQL multiplied by $1, or $1,019 for the producer with a 100-percent share in the 2003 crop.

In calculating the producer's BQL for the 2004 crop year the farm's marketing quota at the 2002 effective quota level the farm's effective quota must be divided between basic quota pounds and undermarketings. This example shows the farm's basic quota was increased from the 2003 marketing year (889 pounds) to the 2004 (993 pounds) marketing year, however the adjustment was still less than the 2002 marketing year (1,000 pounds) established for the farm. The farm's effective undermarketings from 2003 (50 pounds) will be deducted from the farm's basic quota (933 pounds) in order to convert the basic quota pounds to the 2002 basic quota level (933 pounds will be adjusted by the BQL adjustment factor of 1.071295 in Table 1). Once the 2002 basic quota level has been determined (1,000 pounds) the results must be adjusted to include the 2003 effective undermarketings (50 pounds will be adjusted by the BQL adjustment factor of 1.12486 from Table 1 or 56 pounds). The producer's 2004 BQL would be 1,056 pounds (1,000 pounds basic quota plus 56 pounds effective undermarketings) and the payment would be calculated as 1,056 pounds BQL multiplied by $1 or $1,056 for the producer with a 100 percent share in the 2004 crop. Since 2004 effective undermarketings and overmarketings will not be considered in establishing future year marketing quotas (program was repealed beginning with the 2005 crop year by the 2004 Act) the actual undermarketings suffered will be paid to the producer at risk during 2004 crop year on the farm. Similarly, had this farm overproduced and marketed in excess of the 2004 effective quota penalty-free, those pounds would not be considered in calculating the producer's BQL for 2004 because they could not be deducted from the next established marketing quota for the farm.

FARM EXAMPLE 3.—BURLEY TOBACCO FARM

		2002	2003	2004
Basic Quota	+	1,000	899	933
Effective Undermarketings (previous year)	+	100	75	50
Overmarketings (previous year)	−	0	0	0
Lease Transfer To	+	0	0	0
Lease Transfer From	−	0	0	0
Effective Quota	−	1100	964	983
Disaster Lease Transfer To	−	0	0	0
Disaster Lease Transfer From	+	0	0	0
TTPP Effective Quota	−	1100	964	983
Actual Marketings		1025	914	983
Overmarketings		0	0	0
Actual Undermarketings		75	50	0
Effective Undermarketings		75	50	0
BQL Adjustment Factor	×		1.124860	1.071295
Farm BQL	=	1,025	1,019	1,056
Producer share	×	1.000	1.000	1.000
Total Payments	=	$1,025	$1,019	$1,056

Farm Example 4

Example 4 shows the BQL calculation for a single flue-cured producer for a farm that had a temporary transfer (disaster) each of the years 2002, 2003 and 2004. This farm did not have any under- or over-marketings from a previous year.

FARM EXAMPLE 4.—FLUE-CURED TOBACCO FARM

		2002	2003	2004
Basic Quota	+	1,000	905	810
Effective Undermarketings (previous year)	+	0	0	0
Overmarketings (previous year)	−	0	0	0
Effective Quota	=	0	0	0
Disaster Lease to	−	0	0	0
Disaster Lease from	+	1,000	905	810
TTPP Effective Quota (w/disaster leases)	=	1,000	905	810
Actual Marketings		0	0	0
Overmarketings		0	0	0
Actual Undermarketings		0	0	0
Effective Undermarketings		0	0	0
BQL Adjustment Factor	×	1.0000	1.104970	1.234570
Farm BQL	=	1,000	1,000	1,000
Producer share	x	1.000	1.000	1.000
Total Payments		$1,000	$1,000	$1,000

Farm Example 5

Example 5 shows the BQL calculation for a single dark air-cured producer for a farm that had a temporary transfer to the farm each of the years 2002, 2003 and 2004.

FARM EXAMPLE 5.—DARK AIR-CURED TOBACCO FARM

		2002	2003	2004
Basic Allotment (acres)	+	3.52	3.70	3.81
Temporary Leased to	+	1.00	1.00	1.00
Temporary Leased from	−	0	0	0
Effective Allotment (acres)	=	4.52	4.70	4.81
BQL Adjustment Factor	×	1.0000	1.0497	1.23457
Effective Allotment at the 2002 Level	=	4.52	4.48	4.45
Farm's 2001–03 Average Yield (lbs./acre)	×	3,037	3,037	3,037
TTPP Effective Quota (Farm's Allotment Converted to Pounds)	=	13,727	13,606	13,515
Farm BQL	=	13,727	13,606	13,515
Producer Share	×	1.000	1.000	1.000
Total Payments	=	$13,727	$13,606	$13,515

Multiple Producers on a Farm

The 2004 Act provides that when more than one producer shared in the risk of producing tobacco on a farm in one or more of the 2002, 2003, and 2004 crop years, the producer may divide the payment on the farm in such manner as is fair and equitable. The producer must divide the payment in the same manner as all other CCC farm program payments are made by taking into consideration the degree to which a producer was at risk in the production of the crop in each of those three years. Subject to the preceding adjustment to reflect each producer's share in the production of each of the three crop years, a producer who produced tobacco in one of those years will receive ⅓ of the payment determined for the producers on the farm; a producer who produced tobacco in two of those years will receive ⅔ of the payment; and a producer who produced tobacco in all three years will receive all of the payment.

Disputes

In the event there is a dispute regarding the determination of which persons are eligible quota producers on a farm, no payment to a quota producer on such farm will be made until all parties have agreed or until all administrative appeals have been exhausted.

Producer share information on the TTPP contract shall be obtained from FSA–578 reported shares. Producers may change share percentages; however all producers on the farm for the applicable year must agree with the division of quota shares, not to exceed 100 percent. If producers are unable to agree with the share percentages, no payments to a quota producer on such farm will be made until all administrative appeals have been exhausted.

Producer Assignments and Successor in Interest Contracts

Any producer may assign the payment to another party, using the correct CCC form, so long as the consideration for the assignment is greater than or equal to the discounted value using the discount rate established by the CCC, except that special provision will be made for assignments between immediate family members, and persons who purchased a tobacco marketing quota prior to October 22, 2004 and, in accordance with 7 CFR part 723, placed the quota on another person's farm, prior to such date, with consent of the owner. The discount rate established by CCC will be equal to the prime rate plus two percentage points, rounded to the nearest whole number (for .5 and above, the rate will be rounded up).

Any producer may execute a successor in interest contract (except that the producer may not execute a successor in interest contract for the 2005 TTPP payment) using the correct CCC form, so long as the consideration for the successor in interest contract is greater than or equal to the discounted value using the discount rate

established by CCC, except that special provision will be made for successor in interest contracts between immediate family members and persons who purchased a tobacco marketing quota prior to October 22, 2004 and, in accordance with 7 CFR part 723, placed the quota on another person's farm, prior to such date, with consent of the owner. The discount rate established by USDA will be equal to the prime rate plus two percentage points, rounded to the nearest whole number (for .5 and above, round up). In order for a successor in interest contract to be effective for the successive year payments, the successor must file such contract no later than November 1 for such contract to be effective for the following year and successive year payments. In no case will CCC approve a successor in interest contract if the producer is indebted to any agency of the United States and would be subject to the offset of payment provisions of the Debt Collection Improvement Act of 1996.

Deadlines

In summary, this rule contains two important time periods: (1) The program enrollment period which begins on March 14, 2005 and ends on June 17, 2005; and (2) the 60-calendar-day period from March 30, 2005 to May 31, 2005, which is the time in which a person not identified in FSA records as a tobacco quota holder or tobacco producer on a specific farm may submit a written claim under the program.

Late-filed applications will be accepted. However, if a person makes application after June 17, 2005, that person will not receive the 2005 TTPP payment. For subsequent payments, late-filed applications must be filed by November 1 in order to receive payments January of the next year. Applicants will not be eligible to receive payments otherwise issued in previous years.

Refunds of Importer Assessments

This final rule also provides for a Subpart C—Miscellaneous Provisions, so that CCC may set forth regulations needed in the administration of tobacco-related activities. This subpart contains, at this time, one provision relating to the manner in which refunds relating to assessments paid in the 2004 and prior marketing years by importers of flue-cured and burley tobacco may be submitted. CCC has allowed refunds to be made under 7 CFR 1464.105. New 7 CFR 1463.201 provides that CCC will no longer accept requests for refunds after August 1, 2005 for flue-cured tobacco and November 1, 2005 for burley tobacco. This action is necessitated by the need to terminate the operation of the tobacco price support programs and to provide for the transfer of flue-cured and burley tobacco pledged as collateral for CCC price support loans to cooperative marketing associations as provided for in section 641 of the 2004 Act.

Removal of Previous Tobacco Program Regulations

Effective November 1, 2005, this rule also will remove 7 CFR parts 723 and 1464, which provide the regulations for the tobacco marketing quota and price support programs, because they will no longer be needed after the termination of the program, as required by the 2004 Act. Removal of the parts is delayed until November 1, 2005 to allow completion of program activities.

Clarification of Tobacco Transition Assessment Program Regulations

This rule makes several clarifications in the regulations governing the Tobacco Transition Assessments published February 10, 2005 (70 FR 7007). The definitions of *class of tobacco* and *market share* are revised for clarity; § 1463.7(c) is revised regarding the division of class assessment to individual entities; and § 1463.8(b) is revised regarding the notification of assessments.

As provided in § 1463.7(a), the amount of a quarterly assessment owed by a domestic manufacturer or importer of tobacco products that must be remitted to CCC by the end of such quarter is based upon the application of the manufacturer's or importer's adjusted market share (which is such entity's share of the market in the immediately preceding calendar year quarter) to the amount of the national assessment that has been allocated to one of the six specified tobacco product sectors under § 1463.5. The obligation of the manufacturer or importer to make the payment is determined by its actions in the quarter immediately preceding the quarter in which the payment is due. Accordingly, this amount must be remitted to CCC whether or not the manufacturer or importer is engaged in the removal of tobacco or tobacco products into commerce in the calendar year quarter in which it receives notification of the amount of assessment owed at the end of such quarter. Section 1463.7 has been revised by adding paragraph (f) to make this provision clearer.

Cost/Benefit Assessment

The 2004 Act addresses major changes in the market for tobacco and the structure of the tobacco industry in general. The 2004 Act repeals marketing quotas, acreage allotments and price support loan programs for tobacco.

Largely because of the CCC price support program, domestic tobacco is higher-priced than imported tobacco, and to maintain demand the domestic market has been isolated from cheaper imports. Over the past several years, import restrictions have been reduced and demand for domestic tobacco declined in favor of cheaper imports. Thus, to maintain a balance between supply and demand, formulas provided in the 1938 Act reduced the amount of tobacco that could be grown for the domestic market. Between 1997 and 2002 there was a 50-percent decline in marketing quotas. The continued decline of quotas cast doubt on the continued viability of the quota and price support system, and elicited nationwide support repeal of the statutory authority for the program and for compensation for the lost value of tobacco quotas.

The number of farms growing tobacco in the United States declined from 512,000 in 1954 to 56,977 in 2002. Besides quota reductions, the decline in farm numbers resulted from the lease and transfer of quota between farms, within counties and across county lines. Also, innovation and technology have reduced labor requirements and changed the economies of scale for tobacco farming in general.

CCC is required to dispose of accumulated tobacco loan stocks. Any losses associated with such disposition are to be covered through assessments against tobacco manufacturers and importers. While the total amount of CCC uncommitted stocks cannot be known with certainty before the conclusion of the marketing year, uncommitted stocks amounted to about 261 million pounds on December 31, 2004. The 2004 Act requires that a portion of the loan stocks of each kind of tobacco be disposed of by the associations, which have entered into loan agreements with the CCC, in an amount determined by dividing their no-net-cost accounts by the list price of the loan stocks. Any stocks not transferred to the associations will be sold by CCC. The total of payments to quota owners and producers is about $9.6 billion (discussed below), leaving approximately $540 million of the total $10.14 billion maximum allowed assessments available to cover CCC losses on loan stocks and other eligible expenses. CCC will determine the list price of the loan stocks based upon the approved grade loan rate for green weight tobacco. Then the amounts in

the no-net-cost accounts will be divided by this price to determine the quantities to distribute to the associations.

The expected impacts on tobacco quota holders, producers, and production as a result of these regulations are pervasive. Elimination of the tobacco program leaves remaining producers with no government price support for future production. In the absence of price support, tobacco producers will be subject to lower prices and increased price volatility. Although actual results cannot be determined, it is reasonable to assume that credit to finance production may be more difficult to obtain, and farmers will be reluctant to produce tobacco without written contracts from tobacco manufacturers that, in order to mitigate price risk, clearly establish the quantity of tobacco to be purchased and the price to be paid. Contract production, already representing a large portion of U.S. tobacco production, will likely increase. In the short run, tobacco prices should fall and the number of producers will decline. Income from quota rental, which was about $325 million in the flue-cured producing area in 1997, will be altogether eliminated. However, considering that quota values have declined in anticipation of additional reductions or program elimination, the $7-per-pound rate in the Act is in the range of quota values estimated by several research colleges. Payments to quota owners, based upon known payment rates and applicable quota levels, are estimated at about $6.7 billion.

Tobacco producers eligible for payments under the 2004 Act are estimated to receive about $2.9 billion, based upon the specified payment rate and known quota amounts. However, it is possible that, as a result of the transition payments, tobacco producers and quota owners may not receive the remaining Phase II payments of about $2.6 billion. Phase II payments were established in July 1999 in the National Tobacco Grower Settlement Trust Agreement, which provided for payments of $5.15 billion over 12 years to compensate tobacco growers and quota holders for reductions in tobacco production and sales resulting from the Master Tobacco Settlement reached in November 1998. The Fair and Equitable Tobacco Reform Act does not refer to Phase II, and the ongoing litigation regarding the agreements does not involve the Federal Government. However, the Phase II agreement provides that if future agreements provide compensation to producers for quota reductions or losses in production, then there is to be a dollar-for-dollar offset against Phase II payments.

Producers remaining in tobacco production are likely to experience increased efficiencies as a result of the 2004 Act. Removal of location restrictions will facilitate consolidation into larger and more efficient operations, while quota rents will be eliminated. While tobacco prices are expected to fall by 25 percent or more in the short run, over the longer term U.S. tobacco production is expected to recover from its recent downward trend. With domestically grown tobacco becoming available at lower prices, there will be reduced incentives to import foreign tobacco and U.S.-origin tobacco will be more competitive in the world market. U.S. tobacco prices should begin to recover after a few years and those producers remaining in the sector should see U.S. tobacco area and production increase well above levels of recent years.

The impact of the tobacco transition payment program on U.S. cigarette consumption is expected to be minimal, but cigarette consumption is expected to continue to decline as smokers find it increasingly difficult to smoke and more restrictions are imposed on places where they can smoke. The transition payments will result in the collection of approximately $10.14 billion from tobacco manufacturers and importers over a 10-year period, or about $1.014 billion annually. Manufacturers and importers are expected to pass these costs on to consumers of tobacco products and increase sales prices. Tobacco product demand is much more inelastic than supply. The price elasticity of demand for cigarettes is between -0.4 and -0.75, meaning that a 1-percent rise in the price of cigarettes reduces consumption by an estimated 0.4 percent to 0.75 percent. The average retail price of cigarettes is $3.8066 per pack and a 4.8-cent-per-pack increase in the price would equate to a 1.3-percent rise in the retail price. Thus, consumers are not expected to reduce consumption of tobacco products considerably due to the expected increases in tobacco prices attributable to the tobacco transition payments.

Executive Order 12866

This final rule has been determined to be economically significant under Executive Order 12866 and has been reviewed by the Office of Management and Budget (OMB). A cost-benefit assessment was completed and is summarized above.

Regulatory Flexibility Act

The Regulatory Flexibility Act is not applicable to this rule because neither the Secretary of Agriculture nor CCC is required by 5 U.S.C. 553 or any other law to publish a notice of proposed rulemaking for the subject matter of this rule.

Environmental Review

The environmental impacts of this rule have been considered under the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*, the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and FSA regulations for compliance with NEPA, 7 CFR part 799. An Environmental Evaluation was completed and it was determined that the proposed action does not have the potential to significantly impact the quality of the human environment and, therefore, the rule is categorically excluded from further review under NEPA. A copy of the environmental evaluation is available for inspection and review upon request.

Executive Order 12778

This final rule has been reviewed in accordance with Executive Order 12778. This final rule preempts State laws that are inconsistent with its provisions, but the rule is not retroactive. Before any judicial action may be brought concerning this rule, all administrative remedies must be exhausted.

Executive Order 12372

This program is not subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. See the notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

Federal Assistance Program

The title and number of the Federal assistance program as found in the Catalog of Federal Domestic Assistance, to which this rule applies, are: Commodity Loans and Purchases—10.051.

Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) does not apply to this rule because neither the Secretary of Agriculture nor CCC is required by 5 U.S.C. 553 or any other law to publish a notice of proposed rulemaking for the subject matter of this rule. Also, the rule imposes no mandates as defined in UMRA.

Small Business Regulatory Enforcement Fairness Act of 1996

Section 642(c) of the 2004 Act requires that the Secretary use the authority in section 808 of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121 (SBREFA), which allows an agency to forgo SBREFA's usual 60-day Congressional Review delay of the effective date of a major regulation if the agency finds that there is a good cause to do so. Accordingly, this rule is effective upon the date of filing for public inspection by the Office of the Federal Register.

Paperwork Reduction Act

Section 642(b) of the 2004 Act requires that these regulations be promulgated and the program administered without regard to the Paperwork Reduction Act. This means that the information to be collected from the public to implement these programs and the burden, in time and money, the collection of the information would have on the public do not have to be approved by the Office of Management and Budget or be subject to the normal requirement for a 60-day public comment period.

Government Paperwork Elimination Act

CCC is committed to compliance with the Government Paperwork Elimination Act and the Freedom to E-File Act, which require Government agencies in general, and the FSA in particular, to provide the public the option of either submitting information or transacting business electronically to the maximum extent possible. Because of the need to publish the regulations for this program quickly, the forms and other information collection activities required by participation in the TTPP are not yet fully implemented in a way that would allow the public to conduct business with FSA electronically. Accordingly, applications for this program may be submitted at the FSA county offices in person, by mail, or by facsimile.

List of Subjects

7 CFR Part 723

Acreage allotments, Cigarettes, Marketing quotas, Penalties, Reporting and recordkeeping requirements.

7 CFR Part 1463

Agriculture, Agricultural commodities, Acreage allotments, Marketing quotas, Price support programs, Tobacco, Tobacco transition payments.

7 CFR Part 1464

Loan programs—tobacco, Price support programs—tobacco, Reporting and recordkeeping requirements.

■ Accordingly, 7 CFR chapters VII and XIV are amended as follows:

CHAPTER VII—FARM SERVICE AGENCY, DEPARTMENT OF AGRICULTURE

PART 723—[REMOVED]

■ 1. Remove 7 CFR part 723.

CHAPTER XIV—COMMODITY CREDIT CORPORATION, DEPARTMENT OF AGRICULTURE

PART 1463—2005–2014—TOBACCO TRANSITION PROGRAM

■ 2. The authority citation for part 1463 continues to read as follows:

Authority: 7 U.S.C. 714b and 714c; and Title VI of Pub. L. 108–357.

Subpart A—Tobacco Transition Assessments

■ 3. In § 1463.3, revise the definitions for *class of tobacco* and *market share* to read as follows:

§ 1463.3 Definitions.

* * * * *

Class of tobacco means each of the following types of tobacco and tobacco products for which taxes are required to be paid for the removal of such into domestic commerce: cigarettes; cigars; snuff; roll-your-own tobacco; chewing tobacco; and pipe tobacco.

* * * * *

Market share means the share of each domestic manufacturer and importer of a class of tobacco product, to the fourth decimal place, of the total volume of domestic sales of the class of tobacco product in the base period. Such sales shall be determined by CCC by using the total volume of such class of tobacco product that is removed into domestic commerce in the base period.

* * * * *

■ 4. Amend § 1463.7 by revising paragraphs (b) and (c) and adding paragraph (d) to read as follows:

§ 1463.7 Division of class assessment to individual entities.

* * * * *

(b) For purposes of determining the volume of domestic sales of each class of tobacco products and for each entity, such sales shall be based upon the reports filed by domestic manufacturers and importers of tobacco with the Department of Treasury and the Department of Homeland Security and shall correspond to the quantity of the tobacco product that is removed into domestic commerce by each such entity:

(1) For cigarettes and cigars, on the number of cigarettes and cigars reported on such reports;

(2) For all other classes of tobacco, on the number of pounds of those products.

(c) In determining the adjusted market share of each manufacturer or importer of a class of tobacco products, except for cigars, CCC will determine to the fourth decimal place an entity's share of excise taxes paid of that class of tobacco product during the immediately prior calendar year quarter. With respect to cigars, CCC will determine the adjusted market share for each manufacturer or importer of a class of tobacco products based on the number of such products removed into domestic commerce.

(d) The amount of a quarterly assessment owed by a domestic manufacturer or importer of tobacco products that must be remitted to CCC by the end of a calendar year quarter is based upon the application of the manufacturer's or importer's adjusted market share to the amount of the national assessment that has been allocated to one of the six specified tobacco product sectors under § 1463.5. As provided in § 1463.3, this adjusted market share is determined by the actions of such manufacturer or importer in a prior calendar year quarter. Accordingly, this amount must be remitted to CCC whether or not the manufacturer or importer is engaged in the removal of tobacco or tobacco products into commerce in the calendar year quarter in which it receives notification of the amount of assessment owed to CCC.

■ 5. Revise § 1463.8(b)(5) and (b)(6) to read as follows:

§ 1463.8 Notification of assessments.

* * * * *

(b) * * *

(5) The volume of gross sales of each class of tobacco that CCC has allocated to the domestic manufacturer or importer of tobacco products for the purposes of determining such entity's adjusted market share. The volume of gross sales of each class of tobacco allocated to such an entity shall correspond to the quantity of the tobacco product that is removed into domestic commerce by each such entity;

(6) The total volume of gross sales of each class of tobacco that CCC has allocated to a class of tobacco, within the gross domestic volume determined for use in a fiscal year, that was used for the purpose of determining a tobacco manufacturer's or tobacco importer's adjusted market share. The total volume of gross sales of each such class of

tobacco shall correspond to the total quantity of the tobacco product that is removed into domestic commerce.

* * * * *

■ 6. Amend part 1463 by adding Subparts B and C, to read as follows:

Subpart B—Tobacco Transition Payment Program

Sec.
1463.100 General.
1463.101 Administration.
1463.102 Definitions.
1463.103 Eligible quota holder.
1463.104 Eligible tobacco producer.
1463.105 Base quota levels for eligible quota holders.
1463.106 Base quota levels for eligible tobacco producers.
1463.107 Payment to eligible quota holders.
1463.108 Payment to eligible tobacco producers.
1463.109 Contracts.
1463.110 Misrepresentation and scheme or device.
1463.111 Offsets and assignments.
1463.112 Successor in interest contracts.
1463.113 Issuance of payments in event of death.
1463.114 Appeals.

Subpart C—Miscellaneous Provisions

1463.201 Refunds of importer assessments.

Subpart B—Tobacco Transition Payment Program

§ 1463.100 General.

(a) The Commodity Credit Corporation (CCC) will make payments to tobacco quota holders and tobacco producers as provided in this subpart with respect to farms for which a tobacco marketing quota had been established by the Farm Service Agency (FSA). To be eligible for a payment, such person must meet all provisions of this part; submit to CCC an application provided by CCC to enter into a contract for payment; and submit other information as may be required by CCC. Payments will be made by CCC annually over a 10-year period.

(b) As provided in this part, a tobacco quota holder or tobacco producer who is not the subject of an outstanding claim established by the United States may, under the terms and conditions established by CCC and with the prior approval of CCC, enter into a successor in interest contract with another person or entity. Upon approval by CCC, all rights and obligations of the quota holder or producer, with respect to payments made by CCC under this part, will be terminated and transferred to the successor party.

(c) As provided in this part, a tobacco quota holder or tobacco producer who may, under the terms and conditions established by CCC, and with the prior approval of CCC, may assign the right to receive a payment to be made under this part by executing an assignment as provided in § 1463.111.

(d) Notwithstanding any other provision of this chapter, the provisions of 7 CFR parts 723 and 1464 shall not be applicable to the 2005 and subsequent crops and the 2005 and subsequent marketing years.

§ 1463.101 Administration.

(a) The program will be administered under the general supervision of the Executive Vice President, CCC, and shall be carried out by FSA State and county committees (State and county committees).

(b) State and county committees and their representatives and employees have no authority to modify or waive provisions of this subpart.

(c) The State committee shall take any action required by the regulations of this subpart that has not been taken by the county committee. The State committee shall also:

(1) Correct, or require a county committee to correct, any action taken by such county committee that is not in accordance with this subpart; or

(2) Require a county committee to withhold taking any action that is not in accordance with this subpart.

(d) No provision or delegation herein to a State or county committee shall preclude the Executive Vice President, CCC, or designee, from determining any question arising under the program or from reversing or modifying any determination made by a State or county committee. Further, the Executive Vice-President, CCC, or designee, may modify any deadline in this subpart to the extent doing so is determined to be appropriate and consistent with the purposes of the program.

(e) A representative of CCC may execute a contract for a transition payment only under the terms and conditions of this part, and as determined and announced by the Executive Vice President, CCC. Any contract that is not executed in accordance with such terms and conditions, including any purported execution prior to the date authorized by the Executive Vice President, CCC, is null and void and shall not be considered to be a contract between CCC and any person executing the contract.

§ 1463.102 Definitions.

The definitions in this section shall apply for all purposes of administering the Tobacco Transition Payment Program (TTPP) authorized by this subpart.

Act means the Fair and Equitable Tobacco Reform Act of 2004.

Actual marketings means tobacco that was disposed of in raw or processed form by voluntary or involuntary sale, barter, or exchange, or by gift between living persons.

Actual undermarketings means the amount by which the effective quota is more than the amount of tobacco marketed.

Assignee means the person designated by a tobacco quota holder or tobacco producer on the correct CCC form to receive a payment to be made by CCC under this subpart.

Assignor means the owner of a farm, or a producer on a farm, who has been determined by CCC to be eligible for a payment under this subpart and who has elected to assign to another person on the correct CCC form, the payment to be made by CCC under this subpart.

Average production yield means, for each kind of tobacco, other than burley (type 31) and flue-cured (types 11–14), the average of the production of a kind of tobacco in a county, on a per-acre basis, for the 2001, 2002, and 2003 crop years. For quota holders only, if no records are available to provide the average production of a kind of tobacco in a county, the average yield will be the production yield established by the National Agricultural Statistical Service of the Department of Agriculture (NASS) for the 2002 marketing year for the applicable kind of tobacco.

Basic allotment means the factored allotment plus and minus permanent adjustments.

Basic quota means the factored quota plus permanent adjustments.

Base Quota Level (BQL) means the payment pounds as determined under this subpart.

Calendar year means the twelve-months from January 1 through December 31.

Claim means any amount of money determined by any Federal agency to be owed by a tobacco quota holder or a tobacco producer to the United States, or any agency or instrumentality thereof, that has been the subject of a completed debt collection activity that is in compliance with the Debt Collection Improvement Act of 1996.

Considered planted means tobacco that was planted but failed to be produced as a result of a natural disaster, as determined by CCC.

Contract means a Tobacco Transition Payment Quota Holder Contract, a Tobacco Transition Payment Producer Contract, a Tobacco Transition Payment Quota Holder Successor In Interest Contract, or a Tobacco Transition

Payment Producer Successor In Interest Contract.

Contract payment means a payment made under a contract entered into under this subpart.

Dependent means an offspring child who is under 18 years of age.

Disaster lease means, as approved by FSA, a written transfer by lease under certain natural disaster conditions of flue-cured or burley tobacco when the transferring farm has suffered a loss of production due to drought, excessive rain, hail, wind, tornado, or other natural disasters. A disaster transfer of flue-cured tobacco must have occurred after June 30 and on or before November 15. A disaster transfer of burley tobacco must have occurred after July 1 and on or before February 16 of the following calendar year.

Effective allotment means the basic farm allotment plus or minus temporary adjustments.

Effective quota means the current year farm marketing quota plus or minus any temporary quota adjustments.

Effective undermarketings means the smaller of the actual undermarketings or the sum of the previous year's basic quota plus pounds of quota temporarily transferred to the farm for the previous year.

Eligible quota holder means only a person who, as of October 22, 2004, has either a fee simple interest or life estate interest in the farm for which FSA established a farm basic marketing quota for the 2004 marketing year. An eligible quota holder does not include any other person who: claims a lien, security interest or other similar equitable interest in the farm or in any personal asset of the owner of the farm or a producer on the farm; has a remainder interest or any other contingent interest in the farm or in any personal asset of the owner of the farm or a producer on the farm; or who may have caused any such marketing quota to have been transferred to the farm.

Eligible tobacco producer means an owner, operator, landlord, tenant, or sharecropper who shared in the risk of producing tobacco on a farm where tobacco was produced, or considered planted, pursuant to a tobacco poundage quota or acreage allotment assigned to the farm for the 2002, 2003 or 2004 marketing years and who otherwise meets the requirements in § 1463.104.

Experimental tobacco means tobacco grown by or under the direction of a publicly-owned agricultural experiment station for experimental purposes.

Factored allotment means allotment that has been factored to equate it to the 2002 basic allotment level.

Factored quota means quota that has been factored to equate it to the 2002 basic quota level.

Family member means a parent; grandparent or other direct lineal ancestor; child or other direct lineal descendent; spouse; or sibling of a tobacco quota holder or tobacco producer.

Farm means a farm as defined in part 718 of this title.

Fiscal year means the twelve-month period from October 1 through September 30.

Marketing year means, for flue-cured tobacco, the period beginning July 1 of the current year and ending June 30 of the following year. For kinds of tobacco other than flue-cured, the period beginning October 1 of the current year and ending September 30 of the following year.

NASS means the National Agricultural Statistics Service of USDA.

New farm means a farm for which a basic marketing quota was established for the 2003 or 2004 year from the national reserve that is set aside for such purposes from the national marketing quota established for the applicable year for the kind of tobacco.

Overmarketings means the pounds by which the pounds marketed exceed the effective farm marketing quota.

Permanent quota adjustments means adjustments made by FSA under part 723 of this title for:

(1) Old farm adjustments from reserve;

(2) Pounds of quota transferred to the farm from the eminent domain pool;

(3) Pounds of quota transferred to or from the farm by sale; or

(4) Pounds of forfeited quota.

Secretary means the Secretary of the United States Department of Agriculture.

Share in the risk of production means having a direct financial interest in the successful production of a crop of tobacco through ownership of a direct share in the actual proceeds derived from the marketing of the crop, which share is conditional upon the success of that marketing.

Successor party means the means the person who has assumed all rights and obligations of a quota holder or tobacco producer arising under this part by executing a TTPP contract.

Temporary quota adjustments means adjustments made by FSA under part 723 of this title for:

(1) Effective undermarketings;

(2) Overmarketings from any prior year;

(3) Reapportioned quota from quota released from farms in the eminent domain pool;

(4) Quota transferred by lease or by owner, for all kinds of tobacco except flue-cured and cigar tobacco; except for flue-cured disaster lease;

(5) Violations of the provisions of part 723 of this title and part 1464 of this chapter.

Tobacco means the following kinds of tobacco: Burley tobacco (type 31); cigar-filler and cigar binder tobacco (types 42, 43, 44, 53, 54, and 55); dark air-cured tobacco (types 35 and 36), fire-cured tobacco (types 21, 22 and 23); flue-cured tobacco (types 11, 12, 13 and 14); and Virginia sun-cured tobacco (type 37).

TTPP effective quota means effective quota plus or minus temporary adjustments because of disaster lease and transfer and before adjustment to the 2002 level for establishment of BQL.

United States includes any agency and instrumentality thereof.

§ 1463.103 Eligible quota holder.

(a) CCC will make a payment under this subpart to a person determined by CCC to be an eligible quota holder, as defined in § 1463.102.

(b) The wetlands and highly erodible land provisions of part 12 of this title, the controlled substance provisions of part 718 of this title, and the payment limitation provisions of part 1400 of this chapter shall not be applicable to payments made under this part to an eligible quota holder.

§ 1463.104 Eligible tobacco producer.

(a) CCC will make a payment under this subpart to a person determined by CCC to be an eligible tobacco producer, as defined in § 1463.102.

(b) The wetlands and highly erodible land provisions of part 12 of this title and the controlled substance provisions of part 718 of this title shall be applicable to payments made under this part to an eligible tobacco producer. However, the payment limitation provisions of part 1400 of this chapter shall not be applicable to payments made under this part to an eligible tobacco producer.

(c) For purposes of determining if an eligible tobacco producer has shared in the risk of producing a crop in the 2002, 2003, or 2004 crop years, CCC will consider evidence presented by a producer that includes, but is not limited to: written leases; contracts for the purchase of tobacco; crop insurance documents; or receipts for the purchase of items used in the production of tobacco.

§ 1463.105 Base quota levels for eligible quota holders.

(a) The BQL is determined separately for each kind of tobacco for each farm

for which a 2004 basic marketing year quota was established under part 723 of this title. Any marketing quota assigned by FSA to a new farm in 2003 or 2004, other than through transfer from another farm, shall not be considered when determining the BQL.

(b) For burley tobacco quota holders BQL is established according to the following table, except as adjusted under paragraph (e) of this section:

(1) Farm BQL. The 2004 basic quota, multiplied by the BQL adjustment factor 1.071295. (**Note:** The factor adjusts the 2004 basic quota to the 2002 basic quota level.)

(2) Quota holder BQL. The farm BQL multiplied by the quota holder's ownership share in the farm. (**Note:** In the case of undivided tract ownership, BQL must be distributed among the tract quota holders by the tract owners.)

(c) For flue-cured tobacco quota holders the BQL is established according to the following table, except as adjusted under paragraph (e) of this section:

(1) Farm BQL. The 2004 basic quota, multiplied by the BQL adjustment factor 1.23457. (**Note:** The factor adjusts the 2004 basic quota to the 2002 level.)

(2) Quota holder BQL. The farm BQL multiplied by the quota holder's ownership share in the farm. (**Note:** In the case of undivided tract ownership, BQL must be distributed among the tract quota holders by the tract owner.)

(d) For quota holders of all other kinds of tobacco the BQL is established according to the following table, except as adjusted under paragraph (e) of this section:

(1) Farm BQL. The basic allotment established for the farm in 2002 multiplied by the county average production yield. The following NASS yields are to be used for any county without production:

(i) Fire-cured (type 21)—1746 lbs.

(ii) Fire-cured (types 22–23)—2676 lbs.

(iii) Dark Air-cured (types 35–36)—2475 lbs.

(iv) Virginia Sun-cured (type 37)—1502 lbs.

(v) Cigar Filler/Binder (types 42–44, 54, 55)—2230 lbs.

(2) Quota holder BQL. The farm BQL multiplied by the quota holder's ownership share in the farm. (**Note:** In the case of undivided tract ownership, BQL must be distributed among the tract quota holders by the tract owner.)

(e)(1) CCC will divide the BQL for the farm between the parties to the agreement as CCC determines to be fair and equitable, taking into consideration the proportionate amounts of cropland sold, if:

(i) On or before October 22, 2004, the owner of a farm had entered into an agreement for the sale of all or a portion of a farm for which a farm marketing quota was established for the 2004 marketing year; and

(ii) Such agreement had not been fulfilled or terminated prior to that date; and

(iii) The parties to the agreement are unable to agree to the disposition of the contract payment to be made with respect to the farm.

(2) If, on or before October 22, 2004, the owner of a farm had entered into an agreement for the permanent transfer of all or a portion of a tobacco marketing quota and the transfer had not been completed by such date, the owner of the farm to which such quota was to be transferred shall be considered to be the owner of the marketing quota for the purposes of this subpart. The BQL's for the transferring farm and the receiving farm will be adjusted to reflect this transfer.

(f) Any tobacco marketing quota preserved under part 1410 of this chapter as the result of the enrollment of a farm in the Conservation Reserve Program shall be included in the determination of the BQL of the farm.

§ 1463.106 Base quota levels for eligible tobacco producers.

(a) BQL is determined separately, for each of the years 2002, 2003 and 2004, for each kind of tobacco and for each farm for which a 2002 farm marketing quota had been established under part 723 of this title.

(b) The BQL for producers of burley tobacco is established as follows:

(1) The 2002-crop year BQL for burley producers is the 2002 effective quota pounds actually marketed, adjusted for disaster lease and transfer, and considered-planted undermarketings and overmarketings. The BQL is then multiplied by the producer's share in the 2002 crop to determine the producer's 2002 BQL. The adjustments for disaster lease and transfer and considered-planted undermarketings and overmarketings are made as follows:

(i) Disaster-leased pounds are added to the marketings of the transferring farm and deducted from the marketings of the receiving farm;

(ii) Considered-planted pounds are added to the farm's actual marketings, and includes only undermarketings that were not part of the farm's 2003 effective quota.

(iii) Pounds actually marketed as overmarketings and sold penalty-free are added to the farm BQL after the BQL adjustment factor of 1.12486 has been applied to the overmarketed pounds.

(2) The 2003-crop year BQL for burley producers is the 2003 effective quota pounds actually marketed, adjusted for disaster lease and transfer and considered-planted undermarketings and overmarketings, as follows:

(i) Disaster leases are added to the marketings of the transferring farm and deducted from the marketings of receiving farm.

(ii) Considered-planted pounds are added to the farm's actual marketings, and includes only undermarketings that were not part of the farm's 2004 effective quota.

(iii) Pounds actually marketed as overmarketings and sold penalty-free are added to the farm BQL after the BQL adjustment factor of 1.071295 has been applied to the overmarketed pounds.

(iv) After these adjustments the BQL is calculated as follows:

Step	Calculation
1	Subtract all 2002 undermarketings from the 2003 marketings, including undermarketings from the parent farm in any special tobacco combinations. Leased pounds are apportioned undermarketing history by dividing the transferring farm's undermarketings by the transferring farm's effective quota, before any temporary transfers, resulting in the percentage of undermarketings that were leased.
2	Multiply the 2003 marketings remaining after Step 1 times 1.12486 (the 2003-BQL adjustment factor).
3	Add the undermarketings that were subtracted in Step 1 to the sum of Step 2 to determine the farm 2003 BQL.
4	Multiply the sum from Step 3 times the producer's share in the 2003 crop to determine the producer's 2003 BQL.

(3) The 2004-crop year BQL for burley producers is the 2004 effective quota before disaster lease and transfer is calculated as follows:

Step	Calculation
1	Subtract all 2003 undermarketings from the 2004 effective quota, including undermarketings from the parent farm in any special tobacco combinations. Leased pounds are apportioned undermarketing history by dividing the transferring farm's undermarketings by the transferring farm's effective quota, before any temporary transfers, resulting in the percentage of undermarketings that were leased.
2	Multiply the 2004 effective quota remaining after Step 1 times 1.071295 (the 2004 BQL adjustment factor).
3	Multiply the undermarketings that were subtracted in Step 1 times 1.12486 (the 2003 BQL adjustment factor).
4	Add the effective quota from Step 2 to the undermarketings in Step 3 to determine the farm 2004 BQL.
5	Multiply the sum from Step 4 times the producer's share in the 2004 crop to determine the producer's 2004 BQL.

(c) The BQL for producers of flue-cured tobacco is established by year, as follows:

(1) The 2002-crop year BQL for flue-cured producers is the effective 2002 quota actually marketed, adjusted for disaster lease and transfer and considered-planted undermarketings and overmarketings. The BQL is then multiplied by the producer's share in the 2002 crop to determine the producer's 2002 BQL. Adjustments for disaster lease and transfer and considered-planted undermarketings and overmarketings are calculated as follows:

(i) Disaster-leased pounds are added to the marketings of the transferring farm and deducted from the marketings of the receiving farm;

(ii) Considered-planted pounds are added to the farm's actual marketings, and include only undermarketings that were not part of the farm's 2003 effective quota.

(iii) Pounds actually marketed as overmarketings and sold penalty-free are added to the farm BQL after the BQL adjustment factor of 1.10497 has been applied to the overmarketed pounds.

(2) The 2003-crop year BQL for flue-cured producers is the 2003 effective quota actually marketed, adjusted for disaster lease and transfer and considered-planted undermarketings and overmarketings, as follows:

(i) Disaster leases are added to the marketings of the transferring farm and deducted from the marketings of the receiving farm.

(ii) Considered-planted pounds are added to the farm's actual marketings, and includes only undermarketings that were in not part of the farm's 2004 effective quota.

(iii) Pounds actually marketed as overmarketings and sold penalty-free are added to the farm BQL after the BQL adjustment factor of 1.23457 has been applied to the overmarketed pounds.

(iv) After these adjustments the BQL is calculated as follows:

Step	Calculation
1	Subtract all 2002 undermarketings from the 2003 marketings, including undermarketings from the parent farm in any special tobacco combinations.
2	Multiply the 2003 marketings remaining after Step 1 times 1.10497 (the 2003 BQL adjustment factor).
3	Add the undermarketings that were subtracted in Step 1 to the sum of Step 2 to determine the farm 2003 BQL.
4	Multiply the sum from step 3 times the producer's share in the 2003 crop to determine the producer's 2003 BQL.

(3) The 2004-crop year BQL for flue-cured producers is the 2004 effective quota before disaster lease and transfer. The 2004 BQL is calculated as follows:

Step	Calculation
1	Subtract all 2003 undermarketings from the 2004 effective quota, including undermarketings from the parent farm in any special tobacco combinations.
2	Multiply the 2004 effective quota remaining after Step 1 times 1.23457 (the 2004 BQL adjustment factor).
3	Multiply the undermarketings that were subtracted in Step 1 times 1.10497 (the 2003 BQL adjustment factor).
4	Add the effective quota from Step 2 to the undermarketings in Step 3 to determine the farm 2004 BQL.
5	Multiply the sum from Step 4 times the producer's share in the 2004 crop to determine the producer's 2004 BQL.

(d) The BQL for producers of cigar filler and binder tobacco is established by years, as follows:

(1) The 2002-crop year BQL for cigar filler and binder tobaccos is calculated as follows:

Step	Calculation
1	Multiply the 2002 farm's basic allotment times the farm's average yield for 2001, 2002, and 2003 to get the 2004 farm base pounds total.
2	Multiply any 2002 special tobacco combination acres times the 2002-equivalence factor of 1.000.
3	Multiply the sum from Step 2 times the farm's average yield for 2001, 2002, and 2003 to get the 2002 farm special tobacco combination pounds total.
4	Add the sum from Step 1 to the sum from Step 3 to get the 2004 farm BQL total.
5	Multiply the sum from Step 4 times the producer's share in the 2002 crop to get the producer 2002 BQL.

(2) The 2003-crop year BQL for cigar filler and binder tobaccos is calculated as follows:

Step	Calculation
1	Multiply the 2002 farm's basic allotment times the farm's average yield for 2001, 2002, and 2003 to get the 2003 farm base pounds total.
2	Multiply any 2003 special tobacco combination acres times the 2003 BQL adjustment factor of 0.8929.
3	Multiply the sum from Step 2 times the farm's average yield for 2001, 2002, and 2003 to get the 2003 farm special tobacco combination pounds total.
4	Add the sum from Step 1 to the sum from Step 3 to get the 2003 farm BQL total.
5	Multiply the sum from Step 4 times the producer's share in the 2003 crop to get the producer 2003 BQL.

(3) The 2004-crop year BQL for cigar-filler and binder tobaccos is calculated as follows:

Step	Calculation
1	Multiply the 2002 farm's basic allotment times the farm's average yield for 2001, 2002, and 2003 to get the 2004 farm base pounds total.
2	Multiply any 2004 special tobacco combination acres times the 2004 BQL adjustment factor of 0.9398.
3	Multiply the sum from Step 2 times the farm's average yield for 2001, 2002, and 2004 to get the 2003 farm special tobacco combination pounds total.
4	Add the sum from Step 1 to the sum from Step 3 to get the 2004 farm BQL total.
5	Multiply the sum from Step 4 times the producer's share in the 2004 crop to get the producer 2004 BQL.

(e) The BQL's for producers of all kinds of tobacco other than burley, flue-cured and cigar filler and binder, are established by year, as follows.

(1) The 2002-crop year BQL's for these kinds of tobaccos are calculated as follows:

Step	Calculation
1	Multiply the 2002 farm's basic allotment times the farm's average yield for 2001, 2002, and 2003 to get the 2002 farm base pounds total.
2	Multiply any 2002 special tobacco combination acres times the farm's average yield for 2001, 2002, and 2003 to get the 2002 special tobacco combinations pounds total.
3	Add the sum from Step 1 to the sum from Step 2.
4	Multiply any 2002 acres leased to or from the farm times the farm's average yield for 2001, 2002, and 2003 to get the 2002 lease pounds total. Then, to the sum from either: (i) Step 3, add pounds leased to the farm to get the farm 2002 BQL total (ii)Step 3, subtract pounds leased from the farm to get the farm 2002 BQL total.
5	Multiply the result from Step 4 times the producer's share in the 2002 crop to get the producer 2002 BQL.

(2) The 2003-crop year BQL's for these kinds of tobaccos are calculated as follows:

Step	Calculation
1	Multiply the 2002 farm's basic allotment times the farm's average yield for 2001, 2002, and 2003 to get the 2003 farm base pounds total.
2	Multiply any 2003 special tobacco combinations acres times the applicable 2003 BQL adjustment factor: (i) Fire-cured (type 21)—1.0000 (ii) Fire-cured (types 22–23)—.980392 (iii) Dark Air-cured (35–36)—.952381 (iv) Virginia Sun-cured (type 37) 1.0000
3	Multiply the sum from Step 2 times the farm's average yield for 2001, 2002, and 2003 to get the 2003 farm special tobacco combination pounds total.
4	Add the sum from Step 1 to the sum from Step 3.
5	Multiply any 2003 acres leased times the applicable 2003 BQL adjustment factor: (i) Fire-cured (type 21) 1.0000 (ii) Fire-cured (types 22–23)—.980392 (iii) Dark Air-cured (35–36)—.952381 (iv) Virginia Sun-cured (type 37) 1.0000
6	Multiply the sum from Step 5 times the farm's average yield for 2001, 2002, and 2003 to get the 2003 lease pounds total.
7	To the sum from Step 4 either: (i) Add pounds from Step 6 leased to the farm to get the farm 2003 BQL total (ii) Subtract pounds from Step 6 leased from the farm to get the farm 2003 BQL total.

Step	Calculation
8	Multiply the sum from Step 7 times the producer's share in the 2003 crop to get the producer 2003 BQL total.

(3) The 2004-crop year BQL's for these kinds of tobaccos are calculated as follows:

Step	Calculation
1	Multiply the 2002 farm's basic allotment times the farm's average yield for 2001, 2002, and 2003 to get the 2004 farm base pounds total.
2	Multiply any 2004 special tobacco combinations acres times the applicable 2004 BQL adjustment factor: (i) Fire-cured (type 21) 1.0000 (ii) Fire-cured (types 22–23)—.951837 (iii) Dark Air-cured (35–36)—.94264 (iv) Virginia Sun-cured (type 37) 1.0000
3	Multiply the sum from Step 2 times the farm's average yield for 2001, 2002, and 2003 to get the 2004 farm special tobacco combination pounds total.
4	Add the sum from Step 1 to the sum from Step 3.
5	Multiply any 2004 acres leased times the applicable 2004 BQL adjustment factor: (i) Fire-cured (type 21) 1.0000 (ii) Fire-cured (types 22–23)—.951837 (iii) Dark Air-cured (35–36)—.92464 (iv) Virginia Sun-cured (type 37) 1.0000
6	Multiply the sum from Step 5 times the farm's average yield for 2001, 2002, and 2003 to get the 2004 lease pounds total.
7	To the sum from Step 4 either: (i) Add pounds from Step 6 leased to the farm to get the farm 2004 BQL total (ii) Subtract pounds from Step 6 leased from the farm to get the farm 2004 BQL total.
8	Multiply the sum from Step 7 times the producer's share in the 2004 crop to get the producer 2004 BQL total.

§ 1463.107 Payment to eligible quota holders.

(a) The total amount of contract payments that may be made to an eligible quota holder shall be the product obtained by multiplying:

$7.00 per pound × the BQL for the quota holder as determined under § 1463.105 for each kind of tobacco

(b) During each of the fiscal years 2005 through 2014, CCC will make a payment to each eligible quota holder in an amount equal to 10 percent of the total amount due under a contract entered into under this subpart, except that in the case an application was filed after June 17, 2005, the applicant will receive only the TTPP payments that have not been made as of the date the contract is approved. However, in order for the contract participant to receive the 2005 TTPP payment an application to enter into a TTPP contract must be filed no later than June 17, 2005. CCC may, in its discretion, extend any deadline set forth in this paragraph. However, CCC will make the FY 2005 payment between June and September of 2005, and subsequent payments will be made in January, to the extent practicable, of each FY.

§ 1463.108 Payment to eligible tobacco producers.

(a) Subject to paragraph (b) of this section, the total amount of contract payments that may be made to an eligible tobacco producer shall be the product obtained by multiplying:

$3.00 per pound × the BQL for the producer determined under § 1463.106 for each kind of tobacco

(b) Payments to an eligible producer shall be equal to:

(1) For an eligible producer that produced tobacco that was marketed or considered by CCC as planted under a marketing quota in all of the 2002, 2003, and 2004 marketing years, 100 percent of the rate specified in paragraph (a) of this section;

(2) For an eligible producer that produced tobacco that was marketed or considered by CCC as planted under a marketing quota in any two of the 2002, 2003, and 2004 marketing years, 2/3 of the rate specified in paragraph (a) of this section; and

(3) For an eligible producer that produced tobacco that was marketed, or considered by CCC as planted under a marketing quota in any one of the 2002, 2003, and 2004 marketing years, 1/3 of the rate specified in paragraph (a) of this section.

(c) During each of the fiscal years 2005 through 2014, CCC will make a payment to each eligible producer in an amount equal to 10 percent of the total amount due under a contract entered into under this subpart except that in the case an application was filed after June 17, 2005, the applicant will receive only the TTPP payments that have not been made as of the date the contract is approved. However, in order for the contract participant to receive the 2005 TTPP payment, an application to enter into a TTPP contract must be filed no later than June 17, 2005. CCC may, in its discretion, extend any deadline set forth in this paragraph. However, CCC will make the FY 2005 payment between June and September of 2005, and subsequent payments will be made in January, to the extent practical, of each FY.

§ 1463.109 Contracts.

(a) CCC will enter into a contract with eligible tobacco quota holders and producers. To the extent a person has filed such a contract with CCC, but a final administrative decision has not been made with respect to such person's status as an eligible quota holder or tobacco producer prior to the final enrollment date, CCC will enter into such a contract only upon the issuance of a final determination of eligibility and the passing of any deadline for any administrative appeal under parts 780 and 11 of this title.

(b)(1) If contracts or other written claims are provided to CCC by June 3, 2005, by two or more persons with respect to the same tobacco BQL used to calculate a program payment, CCC will not issue such payment until CCC has determined the eligibility status of each claimant.

(2) If CCC has made a payment to a person after June 3, 2005, a person who is not an eligible holder or producer, as identified on FSA records, for such farm, or claims to be an eligible tobacco holder or producer and submits a contract or other written claim with CCC for the same quota used to issue the initial payment, CCC will issue no further payments for such farm until CCC has determined the eligibility status of each person who has submitted a contract or other written claim for such farm and the occurrence of the repayment of the initial payment made by CCC.

§ 1463.110 Misrepresentation and scheme or device.

A person must refund all payments received on all contracts entered into under this subpart, plus interest as determined in accordance with part 1403 of this chapter, and pay to CCC liquidated damages as specified in the contract, if CCC determines the person has:

(a) Erroneously represented any fact affecting a program determination made in accordance with this subpart;

(b) Adopted any scheme or device that tends to defeat the purpose of the program; or

(c) Made any fraudulent representation affecting a program determination made in accordance with this subpart.

§ 1463.111 Offsets and assignments.

(a) TTPP payments made to any person under this subpart shall be made without regard to questions of title under State law and without regard to any claim or lien against the tobacco quota, tobacco marketing allotment, or the farm for which a tobacco quota had been established under part 723 of this title by any creditor or any other person.

(b) The provisions of part 1404 of this title shall not apply to this part.

(c) A quota holder or tobacco producer who is eligible to receive a payment under this part may assign a payment, or a portion thereof, to be made under this part to another person using the correct CCC form. Such an assignment will become effective upon approval by CCC. In order to provide for the orderly issuance of payments under this part, CCC may limit, in its sole discretion, the number of assignments that may be made with respect to a contract.

(d)(1) CCC will establish, after consultation with the Department of the Treasury, a discount rate that reflects the value of any remaining payments due under this part if such payments were to be made as a lump sum payment in the current year. Unless there is consideration for such contract in an amount equal to or greater than the discounted value of the payments, subject to the assignment, based on the discount rate established for such payments by CCC, CCC will not approve any assignment other than to:

(i) A family member; or

(ii) A party who had purchased a tobacco marketing quota prior to October 22, 2004 and had placed the quota on a farm with the owner's consent prior to that date in the manner that had been prescribed by FSA under part 723 of this chapter.

(2) The discount rate established by CCC will be determined by adding 200 basis points to the prime lending rate, as determined by CCC. If this sum is a fraction of a number, CCC will round the discount rate to the nearest whole number. Rounding of a half percent will be to the next higher whole number.

(e) CCC will issue a payment to an assignee only to the extent and amount of payment that CCC would otherwise have issued to the quota holder or producer in the absence of the assignment. In accordance with part 1403 of this title, any claim owed by the assignor to the United States will be deducted from any payment made under this part prior to the issuance of the payment to the assignee.

(f) CCC will report to the Internal Revenue Service any payment assigned under this section as income earned by the assignor.

§ 1463.112 Successor in interest contracts.

(a) A quota holder or tobacco producer who is eligible to receive a payment under this part, and for whom a claim has not been established by the United States, may enter into a successor in interest contract with another party using the correct CCC form. Such successor in interest contract will become effective upon approval by CCC, and will not include the 2005 payment. Only one such successor in interest contract may be entered into by a quota holder or tobacco producer with respect to a farm for each kind of tobacco.

(b) Annually, CCC will establish, after consultation with the Department of the Treasury, a discount rate that reflects the value of any remaining payments due under this part if such payments were to be made as a lump sum payment in the current year. This discount rate will be determined as provided in § 1463.111(d)(2). Unless there is consideration for such contract in an amount equal to or greater than the discounted value of the payments, subject to the successor in interest or contract, based on the discount rate established for such payments by CCC, CCC will not approve any succession in interest contract other than to:

(1) A family member; or

(2) A party who had purchased a tobacco marketing quota prior to October 22, 2004 and had placed the quota on a farm with the owner's consent prior to that date in the manner that had been prescribed by FSA under part 723 of this chapter.

(c) CCC will issue a payment, except the 2005 payment, to a successor party only if such party is otherwise in compliance with all other applicable regulations, which includes for successors to producer contracts only the wetlands and highly erodible land provisions of part 12 of this chapter. In accordance with part 1403 of this title, any claim owed by the successor party to the United States will be deducted from any payment made under this part prior to the issuance of the payment to the successor party.

(d) CCC will report to the Internal Revenue Service any payment made under a successor in interest contract as income earned by the successor party.

§ 1463.113 Issuance of payments in event of death.

If a quota holder or tobacco producer who is eligible to receive a payment under this subpart dies, the right to receive payments shall be transferred to the estate of the quota holder or tobacco producer unless such person is survived by a spouse or one or more dependents, in which case the right to receive the payments shall be transferred to the surviving spouse.

§ 1463.114 Appeals.

A person may obtain reconsideration and review of any adverse determination made under this subpart in accordance with the appeal regulations found at parts 11 and 780 of this title.

Subpart C—Miscellaneous Provisions

§ 1463.201 Refunds of importer assessments.

Assessments paid on imported flue-cured or burley tobacco under sections 106A and 106B of the Agricultural Act of 1949 with respect to imports in the 2004 and prior marketing years may be refunded by CCC in accordance with the provisions of 7 CFR 1464.105 that were in effect prior to March 30, 2005, so long as such request for refunds are filed in accordance with such part no later than:

(a) August 1, 2005 for flue-cured tobacco; and

(b) November 1, 2005 for burley tobacco.

PART 1464—[REMOVED]

■ 7. Remove part 1464.

Signed at Washington, DC, March 29, 2005.

James R. Little,

Administrator, Farm Service Agency, and Executive Vice-President, Commodity Credit Corporation.

[FR Doc. 05–6455 Filed 3–30–05; 12:10 pm]

BILLING CODE 3410–05–U

Federal Register

Monday,
April 4, 2005

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 2

Use of Ozone-Depleting Substances; Removal of Essential-Use Designations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 2003P–0029]

RIN 0910–AF18

Use of Ozone-Depleting Substances; Removal of Essential-Use Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulation on the use of ozone-depleting substances (ODSs) in self-pressurized containers to remove the essential-use designations for albuterol used in oral pressurized metered-dose inhalers (MDIs). Under the Clean Air Act, FDA, in consultation with the Environmental Protection Agency (EPA), is required to determine whether an FDA-regulated product that releases an ODS is an essential use of the ODS. Two albuterol MDIs that do not use an ODS have been marketed for more than 3 years. FDA has determined that the two non-ODS MDIs will be satisfactory alternatives to albuterol MDIs containing ODSs and is removing the essential-use designation for albuterol MDIs as of December 31, 2008. Albuterol MDIs containing an ODS cannot be marketed after this date.

DATES: This rule is effective December 31, 2008.

ADDRESSES: Received comments, a transcript of, and material submitted for, the Pulmonary-Allergy Advisory Committee meeting held on June 10, 2004, the environmental assessment, and the finding of no significant impact may be seen in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–594–2041.

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I. Introduction and Highlights of the Rule

We published a proposed rule in the **Federal Register** of June 16, 2004 (69 FR 33602) (the 2004 proposed rule), proposing to remove the essential-use designation for albuterol MDIs. Albuterol MDIs containing chlorofluorocarbons (CFCs) or other ODSs cannot be marketed without an essential-use designation. We have determined that the following four criteria for removing an essential use have been met or will be met by the effective date of the final rule:

- More than one non-ODS product with the same active moiety is marketed with the same route of administration, for the same indication, and with approximately the same level of convenience of use as the ODS product containing that active moiety;
- Supplies and production capacity for the non-ODS products will exist at levels sufficient to meet patient need;
- Adequate U.S. postmarketing use data is available for the non-ODS products; and
- Patients who medically required the ODS product will be adequately served by the non-ODS products containing that active moiety and other available products.

We have also determined that the appropriate effective date for the removal of the essential-use designation for albuterol MDIs is December 31, 2008.

We will discuss our determinations on the criteria and the effective date in section V of this document ''Comments on the 2004 Proposed Rule.''

II. Background

A. Albuterol

Albuterol is a relatively selective $beta_2$–adrenergic agonist used in the treatment of bronchospasm associated with asthma and chronic obstructive pulmonary disease (COPD). Albuterol has the molecular formula $C_{13}H_{21}NO_3$. Albuterol is the name established for the drug by the U.S. Pharmacopeia and the U.S. Adopted Names Council. FDA uses the name albuterol, and it is the name commonly used in the United States. In most of the rest of the world, the drug is called salbutamol, which is the International Nonproprietary Name for the drug (the name recommended by the World Health Organization). Albuterol is widely used in its sulfate salt form, which has the molecular formula $(C_{13}H_{21}NO_3)_2H_2SO_4$. We will use ''albuterol'' to refer to both albuterol base and albuterol sulfate, unless otherwise indicated.

Albuterol is available in many dosage forms for the treatment of asthma and COPD. Syrups and tablets may be taken by mouth to be absorbed into the blood through the digestive tract. Albuterol drug products are marketed in various forms for inhalational use. Albuterol is available in inhalation solutions for use

in nebulizers, and was previously marketed in the United States in a compact dry-powder inhaler. Most important for purposes of this document, albuterol is marketed in MDIs, which are small, pressurized aerosol devices that deliver a measured dose of an aerosolized drug into a patient's mouth for inhalation into the lungs.

Albuterol MDIs were first approved for use in the United States in 1981, when the new drug applications (NDAs) for VENTOLIN (NDA 18–473) and PROVENTIL (NDA 17–559) albuterol MDIs were approved by FDA. The first generic albuterol MDI was approved in 1995. Albuterol MDIs have historically used the CFCs trichlorofluoromethane (CFC–11) and dichlorodifluoromethane (CFC–12) as propellants.

Albuterol MDIs are among the most widely used drug products for the treatment of asthma and COPD. Because of albuterol's relatively rapid onset of action, albuterol MDIs are frequently used as ''rescue'' inhalers for treatment of bronchospasm during acute episodes. Albuterol MDIs can be considered lifesaving for some patients at certain times; they are very important for controlling symptoms in many more patients who suffer from asthma or COPD. We recognize and take very seriously our obligation to examine with particular care any action that could affect the availability of these important drugs.

B. CFCs

CFCs are organic compounds that contain carbon, chlorine, and fluorine atoms. CFCs were first used commercially in the early 1930s as a replacement for hazardous materials then used in refrigeration, such as sulfur dioxide and ammonia. Subsequently, CFCs were found to have a large number of uses, including as solvents and as propellants in self-pressurized aerosol products, such as MDIs.

CFCs are very stable in the troposphere, the lowest part of the atmosphere. They move to the stratosphere, a region that begins about 10 to 16 kilometers (km) (6 to 10 miles) above Earth's surface and extends up to about 50 km (31 miles) altitude. Within the stratosphere, there is a zone about 15 to 40 km (10 to 25 miles) above the Earth's surface in which ozone is relatively highly concentrated. This zone in the stratosphere is generally called the ozone layer. Once in the stratosphere, CFCs are gradually broken down by strong ultraviolet light, where they release chlorine atoms that then deplete stratospheric ozone. Depletion of stratospheric ozone by CFCs and other ODSs allows more ultraviolet-B (UV–B) radiation to reach the Earth's surface, where it increases skin cancers and cataracts, and damages some marine organisms, plants, and plastics.

C. Regulation of ODSs

The link between CFCs and the depletion of stratospheric ozone was discovered in the mid-1970s. Since 1978, the U.S. Government has pursued a vigorous and consistent policy, through the enactment of laws and regulations, of limiting the production, use, and importation of ODSs, including CFCs.

1. The 1978 Rules

In the **Federal Register** of March 17, 1978 (43 FR 11301 at 11318), FDA and EPA published rules banning, with a few exceptions, the use of CFCs as propellants in aerosol containers. These rules were issued under authority of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*) and the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*), respectively. FDA's rule (the 1978 rule) was codified as § 2.125 (21 CFR 2.125). The rules issued by FDA and EPA had been preceded by rules issued by FDA and the Consumer Product Safety Commission requiring products that contain CFC propellants to bear warning statements on their labeling (42 FR 22018, April 29, 1977; 42 FR 42780, August 24, 1977).

The 1978 rule prohibited the use of CFCs as propellants in self-pressurized containers in any food, drug, medical device, or cosmetic. As originally published, the rule listed five essential uses that were exempt from the ban. The third listed essential use was for ''[m]etered-dose adrenergic bronchodilator human drugs for oral inhalation.'' This language describes albuterol MDIs, so the list of essential uses did not have to be amended in 1981 when VENTOLIN and PROVENTIL albuterol MDIs were approved by FDA.

The 1978 rule provided criteria for adding new essential uses, and several uses were added to the list, the last one in 1996. The 1978 rule did not provide any mechanism for removing essential uses from the list as alternative products were developed or CFC-containing products were removed from the market. The absence of a removal procedure came to be viewed as a deficiency in the 1978 rule, and was addressed in a later rulemaking, discussed in section II.C.5 of this document.

2. The Montreal Protocol

On January 1, 1989, the United States became a party to the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol) (September 16, 1987, 26 I.L.M. 1541 (1987)), available at *http://www.unep.org/ozone/pdfs/Montreal-Protocol2000.pdf*.[1] The United States played a leading role in the negotiations of the Montreal Protocol, believing that internationally coordinated control of ozone-depleting substances would best protect both the U.S. and global public health and the environment from potential adverse effects of depletion of stratospheric ozone. Currently, there are 188 parties to this treaty.[2] When it joined the treaty, the United States committed to reducing production and consumption of certain CFCs to 50 percent of 1986 levels by 1998 (Article 2(4) of the Montreal Protocol). It also agreed to accept an ''adjustment'' procedure, whereby, following assessment of the existing control measures, the Parties could adjust the scope, amount, and timing of those control measures for substances already subject to the Montreal Protocol. As the evidence regarding the impact of ODSs on the ozone layer became stronger, the Parties used this adjustment procedure to accelerate the phaseout of ODSs. At the fourth meeting of the Parties to the Montreal Protocol, held at Copenhagen in November 1992, the Parties adjusted Article 2 of the Montreal Protocol to eliminate the production and importation of CFCs by Parties that are developed countries by January 1, 1996 (Decision IV/2).[3] The adjustment also indicated that it would apply ''save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be essential'' (Article 2A(4)). Under the treaty's rules of procedure, the Parties may make such an essential-use decision by a two-thirds majority vote,

[1] FDA has verified all Web site addresses cited in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document has published in the **Federal Register**.

[2] The summary descriptions of the Montreal Protocol and decisions of parties to the Montreal Protocol contained in this document are presented here to help you understand the background of the action we are taking. These descriptions are not intended to be formal statements of policy regarding the Montreal Protocol. Decisions by the parties to the Montreal Protocol are cited in this document in the conventional format of ''Decision IV/2,'' which refers to the second decision recorded in the Report of the Fourth Meeting of the parties to the Montreal Protocol on Substances That Deplete the Ozone Layer. Reports of meetings of the parties to the Montreal Protocol may be found on the United Nations Environment Programme's Web site at *http://www.unep.org/ozone/mop/mop-reports.shtml*.

[3] Production of CFCs in economically less-developed countries is being phased out and is scheduled to end by January 1, 2010. See Article 2a of the Montreal Protocol.

although, to date, all such decisions have been made by consensus.

To produce or import CFCs for an essential use under the Montreal Protocol, a Party must request and obtain approval for an exemption at a meeting of the Parties. One of the most important essential uses of CFCs under the Montreal Protocol is their use in MDIs for the treatment of asthma and COPD. The decision on whether the use of CFCs in MDIs is ''essential'' for purposes of the Montreal Protocol turns on whether: ''(1) It is necessary for the health, safety, or is critical for the functioning of society (encompassing cultural and intellectual aspects) and (2) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health'' (Decision IV/25). Each request and any subsequent exemption is for only 1 year's duration (Decision V/18). Since 1994 the United States and some other Parties to the Montreal Protocol have annually requested, and been granted, essential-use exemptions for the production or importation of CFCs for their use in MDIs for the treatment of asthma and COPD (see, among others, Decisions VI/9 and VII/28). The exemptions have been consistent with the criteria established by the Parties, which make the grant of an exemption contingent on a finding that the use for which the exemption is being requested is essential for health, safety, or the functioning of society, and that there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of health or the environment (Decision IV/25).

Phasing out the use of CFCs in MDIs for the treatment of asthma and COPD has been an issue of particular interest to the Parties to the Montreal Protocol. Several decisions of the Parties have dealt with the transition to CFC-free MDIs, including the following decisions:

- Decision VIII/10 stated that the Parties that are developed countries would take various actions to promote industry's participation in a smooth and efficient transition away from CFC-based MDIs (San Jose, Costa Rica, 1996).
- Decision IX/19 required the Parties that are developed countries to present an initial national or regional transition strategy by January 31, 1999 (Montreal, Canada, 1997).
- Decision XII/2 elaborated on the content of national or regional transition strategies required under Decision IX/19 and indicated that any MDI for the treatment of asthma or COPD approved for marketing after 2000 would not be an ''essential use'' unless it met the criteria laid out by the Parties for essential uses (Ouagadougou, Burkina Faso, 2000).
- Decision XIV/5 requested that each Party report annually the quantities of CFC and non-CFC MDIs and dry-powder inhalers sold or distributed within that country and the approval and marketing status of non-CFC MDIs and dry-powder inhalers. Decision XIV/5 also noted ''with concern the slow transition to CFC-free metered-dose inhalers in some Parties'' (Rome, Italy, 2002).
- Decision XV/5 states that no essential uses of CFCs will be authorized for Parties that are developed countries at the 17th meeting of the Parties (in autumn 2005), or thereafter, unless the Party requesting the essential-use allocation has submitted an action plan. Among other items, the action plan should include a specific date by which the Party plans to cease requesting essential-use allocations of CFCs for albuterol MDIs to be sold or distributed in developed countries. The action plan must be submitted before the 25th meeting of the Open-Ended Working Group[4] in the summer of 2005 (Nairobi, Kenya, 2003).

In addition to fulfilling our obligations under the Clean Air Act and other provisions of the Montreal Protocol, this rule is intended to provide, for purposes of Decision XV/5, the specific date after which the United States will not request essential-use allocations of CFCs for albuterol MDIs.

3. The 1990 Amendments to the Clean Air Act

In 1990, Congress amended the Clean Air Act to, among other things, better protect stratospheric ozone (Public Law 101–549, November 15, 1990) (the 1990 amendments). The 1990 amendments were drafted to complement, and be consistent with, our obligations under the Montreal Protocol (see section 614 of the Clean Air Act (42 U.S.C. 7671m)). Section 614(b) of the Clean Air Act provides that in the case of a conflict between any provision of the Clean Air Act and any provision of the Montreal Protocol, the more stringent provision will govern. Section 604 of the Clean Air Act requires the phaseout of the production of CFCs by 2000 (42 U.S.C. 7671c),[5] while section 610 of the Clean Air Act (42 U.S.C. 7671i) required EPA to issue regulations banning the sale or distribution in interstate commerce of nonessential products containing CFCs. Sections 604 and 610 provide exceptions for ''medical devices.'' Section 601(8) (42 U.S.C. 7671(8)) of the Clean Air Act defines ''medical device'' as

> any device (as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)), diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), or drug delivery system-
>
> (A) if such device, product, drug, or drug delivery system utilizes a class I or class II substance for which no safe and effective alternative has been developed, and where necessary, approved by the Commissioner [of Food and Drugs]; and
>
> (B) if such device, product, drug, or drug delivery system, has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner [of Food and Drugs] in consultation with the Administrator [of EPA].''

4. EPA's Implementing Regulations

EPA regulations implementing the Montreal Protocol and the stratospheric ozone protection provisions of the 1990 amendments are codified in part 82 of title 40 of the Code of Federal Regulations (40 CFR part 82). (See 40 CFR 82.1 for a statement of intent.) Like the 1990 amendments, EPA's implementing regulations contain two separate prohibitions, one on the production and import of CFCs (subpart A of 40 CFR part 82) and the other on the sale or distribution of products containing CFCs (40 CFR 82.66).

The prohibition on production and import of CFCs contains an exception for essential uses and, more specifically, for essential MDIs. The definition of essential MDI at 40 CFR 82.3 requires that the MDI be intended for the treatment of asthma or COPD, be essential under the Montreal Protocol, and if the MDI is for sale in the United States, be approved by FDA and listed as essential in FDA's regulations at § 2.125.

The prohibition on the sale of products containing CFCs includes a specific prohibition on aerosol products and other pressurized dispensers. The aerosol product ban contains an exception for medical devices listed in § 2.125(e). The term ''medical device'' is used with the same meaning it was given in the 1990 amendments and

[4] The Open-Ended Working Group (OEWG) was established in 1989 at the first meeting of the Parties to the Montreal Protocol held in Helsinki. The OEWG, among other duties, considers proposals for amendments and adjustments to the Montreal Protocol and prepares consolidated reports based on the reports of various scientific, technical, and economic panels. These proposals and reports may subsequently be acted on by a meeting of the Parties to the Montreal Protocol.

[5] In conformance with Decision IV/2, EPA issued regulations accelerating the complete phaseout of CFCs, with exceptions for essential uses, to January 1, 1996 (58 FR 65018, December 10, 1993).

includes drugs as well as medical devices.

5. FDA's 2002 Regulation

In the 1990s, we decided that § 2.125 required revision to better reflect our obligations under the Montreal Protocol, the 1990 amendments, and EPA's regulations, and to encourage the development of ozone-friendly alternatives to medical products containing CFCs. In particular, as acceptable alternatives that did not contain CFCs or other ODSs came on the market, there was a need to provide a mechanism for removing essential uses from the list in § 2.125(e). In the **Federal Register** of March 6, 1997 (62 FR 10242), we published an advance notice of proposed rulemaking (the 1997 ANPRM) in which we outlined our then-current thinking on the content of an appropriate rule regarding ODSs in products FDA regulates. We received almost 10,000 comments on the 1997 ANPRM. In response to the comments, we revised our approach and drafted a proposed rule published in the **Federal Register** of September 1, 1999 (64 FR 47719) (the 1999 proposed rule). We received 22 comments on the 1999 proposed rule. After minor revisions in response to these comments, we published a final rule in the **Federal Register** of July 24, 2002 (67 FR 48370) (the 2002 final rule) (corrected in 67 FR 49396, July 30, 2002, and 67 FR 58678, September 17, 2002).

Among other changes, the 2002 final rule, in revised § 2.125(g)(3), set standards that FDA would use for determining whether the use of an ODS in a medical product is no longer essential. The 2002 final rule provided that to remove an essential-use designation, FDA must find that:

- At least one non-ODS product with the same active moiety is marketed with the same route of administration, for the same indication, and with approximately the same level of convenience of use as the ODS product containing that active moiety;
- Supplies and production capacity for the non-ODS product(s) exist or will exist at levels sufficient to meet patient need;
- Adequate U.S. postmarketing use data is available for the non-ODS product(s); and
- Patients who medically required the ODS product are adequately served by the non-ODS product(s) containing that active moiety and other available products.

To remove the essential-use designation of an active moiety marketed in an ODS product represented by one NDA, there must be at least one acceptable alternative, while for an active moiety marketed in ODS products and represented by two or more NDAs, there must be at least two acceptable alternatives.

Because there are multiple NDAs for albuterol MDIs containing an ODS, the rule requires that there must be at least two acceptable alternatives available for us to remove the essential-use designation for albuterol. We have determined that there are two acceptable alternatives for albuterol MDIs containing an ODS.

FDA approved the NDA for PROVENTIL HFA, albuterol sulfate MDI, on August 15, 1996 (NDA 20–503), and the product was introduced into the U.S. market later that year. PROVENTIL HFA is manufactured by 3M Co. (3M) and marketed by Schering-Plough Corp. (Schering). VENTOLIN HFA, albuterol sulfate MDI, was approved on April 19, 2001 (NDA 20–983), and it was introduced into the U.S. market in February 2002. VENTOLIN HFA is manufactured and marketed by GlaxoSmithKline (GSK). Both of these products use the hydrofluoroalkane HFA–134a as a replacement for ODSs. HFA–134a does not affect stratospheric ozone. We will use the phrase ''albuterol HFA MDIs'' to refer to both of these products in this document. IVAX Corp. (IVAX) has recently begun marketing an albuterol HFA MDI, but the short period of time that the IVAX MDI has been on the market prevents us from considering the drug an alternative to albuterol CFC MDIs for purposes of this rulemaking (see our response to comment 14 of this document). Albuterol HFA MDIs are the subject of patents, listed in our publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book), which will, presumably, block the marketing of generic albuterol HFA MDIs until they expire. See our response to comment 36 of this document for a discussion of the patent issues that were raised in this rulemaking.

There is a separate essential-use designation for metered-dose ipratropium bromide and albuterol sulfate, in combination, administered by oral inhalation for human use, § 2.125(e)(2)(viii). This essential use was added to the list of essential uses (§ 2.125(e)), even though albuterol and ipratropium bromide were already separately included in the list of essential uses. (See 60 FR 53725, October 17, 1995, and 61 FR 15699, April 9, 1996.) The only drug product marketed under the essential-use designation for metered-dose ipratropium bromide and albuterol sulfate, in combination, is Boehringer Ingelheim Phamaceuticals' product COMBIVENT. Because COMBIVENT has two active ingredients, it is not subject to Decision XV/5, which concerns MDIs with albuterol as the sole active ingredient. This rule will not affect the essential-use status of COMBIVENT.

III. Comments on the 2004 Proposed Rule

On June 10, 2004, we held a meeting of the Pulmonary-Allergy Drug Advisory Committee (the PADAC meeting) to discuss the issues involved in removing the essential-use designation for albuterol MDIs (see the **Federal Registers** of May 11, 2004 (69 FR 26169), and June 2, 2004 (69 FR 31126)). Presentations were made by 13 speakers representing patient advocacy groups, medical professional organizations, an industry organization, an environmental advocacy group, an economics consulting firm, GSK, Schering, Honeywell Chemicals (Honeywell), and IVAX. We address the comments made in written material submitted to the committee and oral comments made during the open public hearing and committee discussion portions of the meeting in addition to the written and electronic comments submitted to the docket in response to the 2004 proposed rule.[6]

We received over 75 written and electronic comments in response to the 2004 proposed rule. They were submitted by patients, health care providers, patient advocacy groups, professional groups, manufacturers, a law firm, an economics consulting firm, and industry organizations. Most of the parties who spoke at the PADAC meeting also submitted written comments.

A. General Comments

(Comment 1) We received several comments that expressed general approval for the 2004 proposed rule.

[6] Fran Du Melle, Executive Vice President of the American Lung Association, submitted a citizen petition on behalf of the U.S. Stakeholders Group on MDI Transition on January 29, 2003 (Docket No. 2003P–0029/CP1) (Stakeholders' petition). The Stakeholders' petition requested that we initiate rulemaking to remove the essential-use designation of albuterol MDIs. Several comments were submitted in response to the petition. All of the opinions and information in those comments, with one exception (see comment 39 of this document), were also contained in testimony at the PADAC meeting or in comments on the proposed rule. In nearly every case, parties submitting comments on the petition also testified at the PADAC meeting, submitted comments on the proposed rule, or both. Accordingly, with the exception of comment 39 of this document, we will not be directly responding in this document to the Stakeholders' petition or the comments on the petition.

We appreciate the effort that the people who submitted these comments, and all other comments, made in expressing their opinions on this important rulemaking.

(Comment 2) We received several comments that expressed a general opposition to the phaseout of albuterol CFC MDIs, without giving any reasons for the opposition.

We cannot address these general comments. Comments that gave specific reasons why the person submitting the comment opposes the elimination of the essential-use designation for albuterol CFC MDIs will be discussed in the appropriate sections of this document.

(Comment 3) A few comments seemed to be based on a perception that this rulemaking would remove all albuterol MDIs from the market.

The perception is inaccurate. This rulemaking is based on the fact that there will be at least two different albuterol MDIs that are acceptable alternatives under § 2.125(g) available after the rule goes into effect.

(Comment 4) Several comments were made advocating an expeditious phaseout of albuterol CFC MDIs. A few comments recommended we proceed slowly and cautiously.

We believe this final rule provides for the phaseout of albuterol CFC MDIs with a speed that is consistent with our duty to protect the public health and our legal obligations.

(Comment 5) One comment requested we publish this rule by December 31, 2004.

We did not publish this rule by December 31, 2004, because it involves complicated and sensitive issues that required extensive consultation and deliberation within FDA and the Department of Health and Human Services (HHS), and with EPA and other Federal agencies. We have issued this rule in the most expeditious manner, consistent with the complexities and sensitivity of the issues involved.

(Comment 6) One comment asked that we consider in this rulemaking the availability of CFC drug products that do not have a non-CFC substitute, the availability of generic albuterol MDIs, and the impact that higher priced drugs may have on the public health.

As we discuss in several places in the 2004 proposed rule and this document, issues of price and generic competition were major concerns to us. However, because this rulemaking deals exclusively with the essential-use designation for albuterol MDIs, we did not examine the availability of non-CFC substitutes for drug products other than albuterol CFC MDIs.

(Comment 7) One comment stated we did not adequately communicate to the medical community the details of our policy regarding CFC MDIs. The comment expressed concern that we did not give a timeframe for the phaseout of albuterol CFC MDIs.

We believe we have done a good job of keeping the public and the medical community informed on our policy regarding the elimination of essential-use designations for medical products. We first discussed our general policy on the issue in the 1997 ANPRM. We received nearly 10,000 comments in response to the 1997 ANPRM, which demonstrates that this document received wide publicity. We received additional comments in response to the 1999 proposed rule, which proposed changes in § 2.125 to provide a mechanism for eliminating essential uses. A citizen petition was submitted on behalf of the U.S. Stakeholders Group on MDI Transition (stakeholders group) on January 29, 2003 (Docket No. 2003P–0029/CP1), essentially requesting that we initiate this rulemaking. This stakeholders group consists of both patient advocacy and professional organizations. These groups were aware of our policies. FDA staff has spoken several times before professional medical organizations, patient advocacy groups, and the National Asthma Education and Prevention Program Coordinating Committee of the National Institutes of Health. FDA staff have also answered countless telephone calls and correspondence on the subject. We have provided press releases and opportunities for interviews to the general, trade, and professional media. We believe we have done what can be reasonably expected to inform the public and the medical profession. However, we were not able to provide a timeframe for eliminating the essential-use designation for albuterol MDIs. We specifically solicited comments on an appropriate effective date for the elimination of the essential-use designation for albuterol MDIs. The effective date could not be established until we had finished our evaluation of the comments submitted in response to the 2004 proposed rule, prepared a draft of this document, and consulted with EPA and other Federal agencies.

B. The Same Active Moiety with the Same Route of Administration, for the Same Indication, and With Approximately the Same Level of Convenience of Use

1. The Same Active Moiety with the Same Route of Administration, for the Same Indication

We did not receive any comments disagreeing with our tentative conclusions stated in the 2004 proposed rule, or addressing the conclusions in any substantive way, that albuterol HFA MDIs have the same active moiety with the same route of administration for the same indications as albuterol CFC MDIs. We therefore finalize our tentative conclusion that albuterol HFA MDIs have the same active moiety with the same route of administration for the same indications as albuterol CFC MDIs.

2. Approximately the Same Level of Convenience of Use

(Comment 8) One comment asserted that the VENTOLIN HFA MDIs were not an adequate alternative for albuterol CFC MDIs because the VENTOLIN HFA MDI requires more force to operate.

Although we do have some data on the force needed to operate the various albuterol MDIs, because that information comes from different sources using different measuring techniques and apparatus, we are not able to meaningfully compare the amounts of force needed to operate albuterol HFA MDIs compared to the force needed for albuterol CFC MDIs. However, of the approximately 20 comments we received that indicated that the person submitting the comment had some experience using albuterol HFA MDIs, only one complained that the albuterol HFA MDIs required excessive effort to operate. None of the thirteen comments from health care providers indicated that their patients had problems operating the albuterol HFA MDIs. The PROVENTIL HFA MDI is somewhat shorter and wider than the VENTOLIN HFA MDI. Patients who find it difficult to apply adequate pressure to the VENTOLIN HFA MDI may wish to try the shorter PROVENTIL HFA MDI or other albuterol HFA MDIs that may come onto the market.

(Comment 9) One comment said that the VENTOLIN HFA MDIs were not an adequate alternative for albuterol CFC MDIs because the VENTOLIN HFA MDI needs to be primed before use.

The approved labeling for both PROVENTIL HFA and VENTOLIN HFA recommend that patients prime the MDI before using it for the first time and in cases where the MDI has not been used for more than 2 weeks by releasing four

test sprays into the air, away from the face. The approved labeling for PROVENTIL CFC MDIs and Warwick brand albuterol CFC MDIs contain a similar instruction about priming, but recommend priming if the MDI has not been used for 4 days, as opposed to the more convenient 2 weeks for the albuterol HFA MDIs. The approved labeling for VENTOLIN CFC MDIs, and for the generic albuterol CFC MDIs which refer to the VENTOLIN CFC MDI, contain an essentially identical recommendation, but refer to the operation as ''test sprays'' rather than priming. These test sprays are recommended if these albuterol CFC MDIs have not been used for more than 4 weeks. Therefore, priming is recommended for all of the albuterol CFC MDI products affected by this rulemaking. The only difference between albuterol CFC MDIs and albuterol HFA MDIs that would inconvenience patients is the shorter period of non-use before priming is recommended for the albuterol HFA MDIs compared to VENTOLIN CFC MDIs and the generic albuterol CFC MDIs which refer to the VENTOLIN CFC MDI. We consider this difference to be at most a minor inconvenience, and not a ''significant [variation] in convenience that materially impede[s] patient compliance.'' (See the 2002 final rule (67 FR 48370 at 48377).) When we compare the albuterol HFA MDIs to PROVENTIL CFC MDIs and Warwick brand albuterol CFC MDIs, the albuterol HFA MDIs are actually more convenient, because of the longer period of non-use before priming is recommended.

(Comment 10) One comment stated that the VENTOLIN HFA MDIs were not an adequate alternative for albuterol CFC MDIs because the float test cannot be used to determine whether the VENTOLIN HFA MDI is empty.

The float test is a widely described, but inaccurate, method of ascertaining whether an MDI is empty by seeing if it floats. In addition to being an inaccurate method to ascertain whether an MDI still contains usable quantities of the drug, the float test can damage the MDI (See Refs. 1 and 2). The float test is not recommended in the approved labeling of any albuterol CFC MDI. The only accurate way to determine whether an MDI still contains usable quantities of the drug is to keep track of the number of actuations. This is true for both albuterol CFC and HFA MDIs. Therefore we cannot view the inability to perform the float test on the albuterol HFA MDIs as a ''significant [variation] in convenience that materially impede patient compliance.'' (See the 2002 final rule (67 FR 48370 at 48377).)

We find that albuterol HFA MDIs have approximately the same level of convenience of use as albuterol CFC MDIs.

C. Supplies and Production Capacity for the Non-ODS Products Will Exist at Levels Sufficient to Meet Patient Need

(Comment 11) At the PADAC meeting a representative of GSK stated GSK was currently producing approximately 300,000 albuterol HFA MDIs annually at their Zebulon, NC, plant. She further stated the current installed capacity at Zebulon is 15 million albuterol HFA MDIs annually, but that it would take GSK 6 to 12 months after a final decision on an effective date in this rulemaking to hire staff and reconfigure existing space to take full advantage of the installed capacity. She stated it would take GSK 12 to 18 months after a final decision on an effective date in this rulemaking to install additional manufacturing equipment and secure required component supplies to enable GSK to manufacture 30 to 33 million albuterol MDIs.

A representative of Schering stated at the PADAC meeting that 3M would be able to manufacture enough albuterol MDIs to meet Schering's ''share of the expected demand'' for approximately 50 million albuterol HFA MDIs (transcript of PADAC meeting at p. 130). Answering a question from a committee member, the Schering representative clarified that his statement regarding Schering's and 3M's share of the manufacturing capacity was consistent with the earlier statements made on behalf of GSK.

In a subsequent written comment (2003P–0029/C20), GSK revised its production estimates and stated they would begin increasing production before the publication of this rule, and that they currently anticipated having the capacity to produce 30 million albuterol HFA MDIs annually by December 31, 2005. GSK further said they will also begin building up their inventory at least 3 months before the effective date of this rule. GSK also said they would reevaluate their expansion plans if the effective date of this rule were substantially beyond December 31, 2005.

Schering also revised their projections on increasing production capacity in a written comment submitted after the PADAC meeting (2003P–0029/C31). Schering said they will have adequate production available to meet demand for albuterol HFA MDIs by December 2005. Schering also said they would reevaluate their expansion plans if the effective date of this rule were substantially beyond December 2005. 3M, which produces the albuterol HFA MDIs Schering markets, confirmed Schering's comment by stating that they will have the capacity to manufacture 30 million albuterol HFA MDIs annually by December 31, 2005.

These projections were major considerations we took into account in establishing the effective date for this rule. We discuss our rationale for setting a December 31, 2008, effective date in our response to comment 32 of this document.

(Comment 12) A comment from a manufacturer of HFA–134a stated there would be more than adequate supplies of HFA–134a for albuterol MDIs if the essential-use designation is removed.

We appreciate this confirmation that adequate supplies of HFA–134a will exist to meet the increased demand for the propellant.

(Comment 13) A few comments from patients expressed concerns that shortages of albuterol MDIs may result from the elimination of the essential-use status of albuterol MDIs. Comments from a trade organization and a chain drug store expressed concerns about whether production capacity for albuterol HFA MDIs would be in place as quickly as had been discussed in the 2004 proposed rule.

The issue of adequate supply and production capacity has been key to this rulemaking. We regard the statements by GSK, Schering, and 3M that they will have adequate production in place as the best evidence on the availability of production capacity. When we chose December 31, 2008, as the effective date of this rule, we did so with every reasonable expectation that adequate supplies and production capacity would be in place by December 31, 2008.

(Comment 14) A representative of IVAX stated at the PADAC meeting that IVAX had submitted an NDA for an albuterol HFA MDI in January 2003, and received an approvable letter[7] from FDA for the NDA on November 28, 2003. He also said IVAX had submitted a separate NDA for an albuterol HFA breath-actuated inhaler in August 2003. He said he expected the products to be on the market in the near future. He stated that IVAX would soon have the capacity to manufacture 50 to 60 million HFA MDIs a year at IVAX's Waterford,

[7] An ''approvable letter'' is a written communication to an applicant from FDA stating that we will approve the NDA if specific additional information or material is submitted or specific conditions are met. An approvable letter does not constitute approval of any part of an NDA and does not permit marketing of the drug that is the subject of the NDA (21 CFR 314.3).

Ireland, plant, although he did not specify what proportion of that capacity would be allocated to albuterol HFA products or to products for the U.S. market.

We did not consider this information in making our decision on the essential-use designation for albuterol MDIs. The IVAX albuterol HFA MDI was approved on October 29, 2004, and introduced into the market in December 2004. Because this product has been on the market for such a short time, the available U.S. postmarketing use data is inadequate for purposes of § 2.125(g)(3)(iii). IVAX's albuterol HFA breath-actuated inhaler has not been approved or marketed. Section 2.125(g)(4)(i) requires alternative products to be marketed. In addition, because the product has not been marketed, there can be no U.S. postmarketing use data available to allow us to evaluate whether the breath-actuated inhaler will be an acceptable alternative to albuterol CFC MDIs.

(Comment 15) One comment asserted the entire supply of albuterol HFA MDIs for the United States would be produced at one GSK facility and one 3M facility. The comment concluded that adequate supplies of albuterol HFA MDIs were insufficient because it was unclear whether one facility could supply the entire market if the other facility were forced to close.

We appreciate the concerns expressed in this comment; however, the factual premise for the comment is misstated. We believe that a switch to albuterol HFA MDIs will improve the security of the U.S. supply of albuterol MDIs. Immediately after the phaseout of albuterol CFC MDIs, we will have one GSK facility and two 3M/Schering facilities supplying the U.S. market for albuterol MDIs. This compares favorably to the current situation with albuterol MDIs, where one Schering facility and one IVAX facility supply 95 percent of the U.S. market for albuterol CFC MDIs (comment from NERA dated August 13, 2004 (2003P–0029/C25)), exhibit 4; and corrected comment from GSK, dated August 25, 2004 (2003P–0029/CR1). IVAX's recently approved albuterol HFA MDI, although not considered an alternative product for purposes of this rule (see our response to comment 14 of this document), gives additional assurance that there will be adequate supplies of albuterol HFA MDIs if there is an interruption of production at one of the GSK or 3M approved manufacturing sites. We also would like to point out that GSK and 3M have overseas production facilities that are not listed as authorized manufacturing facilities in the approved NDAs for PROVENTIL HFA and Ventolin HFA. These facilities may be able to export albuterol HFA MDIs to the United States in an emergency shortage situation.

In our rulemaking establishing the criteria for eliminating an essential-use designation, we considered requiring multiple production sites to ensure a secure supply of non-ODS drug products (see the 1997 ANPRM (69 FR 10242 at 10245), the 1999 proposed rule (64 FR 47719 at 47723), and the 2002 final rule (67 FR 48370 at 48377)). We chose not to require multiple production sites for the alternative products as a criterion for eliminating the essential-use designation. In any case, albuterol HFA MDIs can be manufactured at three or more sites, which will provide a high degree of security for continued supplies of albuterol HFA MDIs, compared to the supply of other drugs intended for treatment of serious or life-threatening diseases, many of which are only manufactured in one facility.

(Comment 16) One comment recommended we delay the effective date for this rule until albuterol MDIs from IVAX and Sepracor Inc. (Sepracor) are on the market to ensure adequate supplies and provide price competition. Another comment recommended we establish an earlier effective date if the albuterol MDIs from IVAX and Sepracor Inc., are approved.

The IVAX albuterol HFA MDI is already approved (see our response to comment 14 of this document). Sepracor's levalbuterol tartrate[8] MDI XOPENEX HFA was approved on March 11, 2005, but has not been marketed by the time this document was published. Because XOPENEX HFA has not been marketed, we cannot consider it an alternative to albuterol CFC MDIs (see our response to comment 14 of this document). While we believe that the presence of additional suppliers of non-ODS albuterol products would be desirable for the reasons given in the comment, we do not believe they are necessary for the purposes of this rulemaking. Based on statements from GSK, Schering, and 3M, we expect that adequate production capacity for alternative products evaluated under § 2.125(g) will exist by the effective date of this rule. As we discuss in our responses to comment 18 and in section V of this document, we also believe that anticipated prices for albuterol HFA MDIs will not prevent patients from being adequately served by the albuterol HFA MDIs, even without the downward price pressure of additional competition.

We find that supplies and production capacity for albuterol HFA MDIs will exist at levels sufficient to meet patient needs by December 31, 2008.

D. Adequate U.S. Postmarketing Use Data is Available for the Non-ODS Products

We did not receive any substantive comments about whether adequate U.S. postmarketing use data is available for the albuterol HFA MDIs. We therefore finalize our tentative conclusion that adequate U.S. postmarketing use data is available for PROVENTIL HFA and VENTOLIN HFA, the albuterol HFA MDIs that we considered as alternatives in this rulemaking.

E. Patients Are Adequately Served by the Non-ODS Products

(Comment 17) A representative of GSK speaking at the PADAC meeting described GSK's Bridges to Access program. Bridges to Access provides GSK drugs at very low cost to lower-income individuals and families. She also mentioned GSK's Orange Card Program and the Together Rx program in which GSK participates. Both of these programs allow eligible Medicare patients to purchase drugs at significantly reduced prices. She added that GSK intended to annually distribute 2 million VENTOLIN HFA MDIs to physicians as samples. She also said GSK expected that many physicians would primarily provide these samples to their lower-income patients.

A subsequent written comment from GSK provided additional information on the Bridges to Access, Orange Card, and Together Rx programs. The comment also describes a Ventolin HFA Savings Check program which will distribute at least 3 million $10 coupons for use in purchasing VENTOLIN HFA MDIs.

A representative of Schering speaking at the PADAC meeting said Schering's SP Cares program, which is similar to GSK's Bridges to Access program, distributes free drugs, including PROVENTIL HFA, to low-income uninsured patients.

A written comment asserted that the Bridges to Access program provided albuterol HFA MDIs to only approximately 1.4 percent of the uninsured patients who need albuterol MDIs, and that the program would have to be expanded to an extreme degree to

[8] Levalbuterol tartrate is the tartrate salt of levalbuterol, the single R-enantiomer of albuterol, which is the active ingredient in both CFC and HFA MDIs as a racemic mixture of the two stereoisomers (R and S) at a 1:1 ratio. We have not determined whether we will, in the future, consider products whose active ingredient is a stereoisomer to be alternatives to drug products whose active ingredient is the corresponding racemic mixture.

provide meaningful supplies of albuterol MDIs to all uninsured patients. This comment also asserted that GSK's commitment to annually provide 2 million free albuterol HFA MDIs would have a limited benefit to the uninsured population because large numbers of uninsured patients receive medical care in the emergency departments of hospitals rather than in a physician's office, and it is unlikely that the free albuterol HFA MDIs will be distributed to the emergency departments. This comment was submitted before GSK's comment describing the Ventolin HFA Savings Check program.

Another comment stated that any patient assistance program must be targeted to those most in need, particularly low-income children and minority populations, while yet another comment stressed the importance of patient assistance programs in the transition to albuterol HFA MDIs.

We took these comments into consideration in determining that patients would be adequately served by albuterol HFA MDIs. These patient assistance programs have the potential to alleviate difficulties that lower income patients may have in obtaining the higher-priced albuterol HFA MDIs.

We agree with the comment that stated that these programs must carefully target the populations most in need of financial assistance in procuring needed albuterol MDIs, and we strongly recommend that GSK and Schering take all reasonable steps to ensure that their programs serve patients with the greatest needs, regardless of whether those patients are treated in a physician's office, clinic, or hospital emergency department. This targeting is particularly important in distributing free albuterol HFA MDIs.

We believe that many of the concerns expressed by the comment critical of GSK's Bridges to Access are valid, but that the comment underestimates the positive effect that Bridges to Access and other patient assistance programs can have. The estimate in the comment did not factor in the 2 million free albuterol HFA MDIs GSK has committed to distribute to physicians as samples and whatever free albuterol HFA MDIs Schering may distribute. The comment also could not factor in the effect of GSK's Ventolin HFA Savings Check program. With successful targeting, these free albuterol HFA MDIs and $10 coupons should have a beneficial impact; with less successful targeting the impact could be very limited (see section VII.D.2 of this document). The comment also ignores the potential impact of Schering's SP Cares program, which is similar to GSK's Bridges to Access program. We recognize that the Bridges to Access and SP Cares programs will have to expand to reach all uninsured low and moderate income patients who will need albuterol HFA MDIs, but the degree of expansion required would be smaller than that described in the comment critical of the Bridges to Access program. We also believe that GSK and Schering understand the need to expand these programs, and that this understanding was implicit in their testimony at the PADAC meeting and written comments (see pp. 5–6 of GSK's corrected comment of August 25, 2004 (2003P–0029/CR1) and p. 4 of Schering's comment of August 13, 2004 (2003P–0029/C31)).

(Comment 18) A speaker at the PADAC meeting said because albuterol HFA inhalers retail for $20 more than generic albuterol CFC MDIs, an early phaseout of albuterol HFA MDIs could result in a total $5 billion in additional treatment costs until HFA inhalers come off patent. The speaker also said the economic burden would fall most heavily on those Americans least able to pay the price, with a disproportionate effect on minorities, inner-city children, elderly patients on fixed incomes, and the rural poor. The speaker asserted that eliminating the essential-use designation before lower-priced generic albuterol HFA MDIs are on the market would force many lower-income patients to discontinue use of albuterol MDIs. The speaker also referred to a recent study in *JAMA: The Journal of the American Medical Association* indicating that increasing copayments can reduce prescription drug use up to 32 percent. She further stated this would result in a cascading increase in total health care costs, as patients who discontinue their albuterol are admitted to emergency rooms and hospital wards.

A speaker representing an economics consulting firm under contract to GSK stated at the PADAC meeting that patients would be adequately served by albuterol HFA MDIs. He projected the average price per MDI would increase by $9.87 and the yearly average cost per patient would rise by $16.02. He also said adequate programs were in place to minimize the adverse impact on lower-income patients.

Several comments from patients, health care professionals, and other parties stated the elimination of lower-priced generic albuterol MDIs that would result from this rule would force many patients to discontinue the use of albuterol MDIs, with significant adverse impact on their health, increased hospitalizations, loss of time at work, and a worsening quality of life. Many of these comments recommended the essential-use status of albuterol MDIs not be removed until after generic albuterol HFA MDIs are approved and marketed.

Other comments agreed with our tentative conclusion stated in the 2004 proposed rule that patients will be adequately served by albuterol HFA MDIs.

While we do not agree with the statement from the speaker from the contract economic consulting firm that the average price per MDI would only increase by $9.87 and that the yearly average cost per patient would only rise by $16.02, we do agree with the conclusion of the speaker that the price of albuterol HFA MDIs will not prevent patients from being adequately served. As discussed in more detail in section V of this document, we estimate that the retail cash price per MDI would increase by $27 and the average yearly cost to uninsured patients would rise $95. While higher drug prices are undesirable, we do not believe that asthma and COPD patients will be forced to stop using albuterol MDIs because of price increases. We believe that the programs discussed in comment 17 of this document can, if properly utilized, provide a safety net for lower-income patients who otherwise could not afford this very important drug. Section V of this document contains a fuller discussion of the economic issues presented by this rulemaking. While we recognize that sales of albuterol MDIs may decline by approximately 1 or 2 percent as a result of this rulemaking, this decline in sales does not necessarily equate to patients having to forgo appropriate treatment of their asthma or COPD because of price increases. There are many ways patients may modify their behavior in order to minimize the impact of elimination of generic albuterol MDIs, including: increasing their use of other asthma and COPD drugs, including non-albuterol bronchodilators (and thereby decreasing their need for albuterol); buying fewer MDIs to keep in different locations because they have chosen to limit the number of MDIs they have beyond the one patients generally carry on their person. Patients with infrequent bouts of bronchospasm may also choose not to purchase albuterol HFA MDIs that the patients believe they might not use, even though the patients are financially able to do so.

(Comment 19) A speaker at the PADAC meeting said an FDA policy that removed lower priced generic drugs from the market was contrary to the intent of the Drug Price Competition and Patent Term Restoration Act of 1984

(Public Law 98–417) (Hatch-Waxman amendments). A written comment asserted the real intent of this rulemaking was to remove generic albuterol MDIs from the market.

We recognize that one of the consequences, although not one we desire, of this rulemaking will be the removal, for a period of time, of generic albuterol MDIs from the market. We agree with the speaker at the PADAC meeting that one of the general intentions of the Hatch-Waxman amendments is to encourage the entry of lower-priced generic drug products into the market. However, another key purpose of the Hatch-Waxman amendments is to encourage significant innovations in human drugs (*see generally* 130 Cong. Rec. H9113–14 and H9121–22 (Sept. 6, 1984) (statements of Rep. Waxman)). The development of HFA inhalers represents large investments of time and money by innovator firms. This investment resulted in innovative products that significantly serve the public health by protecting the stratospheric ozone. While the provisions of the Hatch-Waxman amendments do not directly apply to this rulemaking, the underlying general policy of encouraging innovation and protecting investment in research and development does apply as much as the policy of encouraging the availability of lower-priced generic drugs. Most importantly, there is no specific provision in the Hatch-Waxman amendments that prohibits us from removing generic albuterol MDIs from the market. There is, however, specific language in the Clean Air Act (42 U.S.C. 7671) that requires us to evaluate whether a use of an ozone-depleting substance in a drug product is, or remains, an essential use. We are obligated to follow the specific mandate Congress gave us in the Clean Air Act, rather than one of two general policies underlying another piece of legislation.

(Comment 20) One comment suggested we approve generic albuterol HFA MDIs immediately, to lower expenses incurred by asthma patients.

Albuterol HFA MDIs are the subject of patents that may affect the availability of generic albuterol HFA MDIs until they expire. FDA's ability to approve generics is constrained by the patent and exclusivity protections afforded by the Hatch-Waxman amendments. FDA may not approve generic albuterol HFA MDIs before permitted by law.

(Comment 21) One comment expressed concern that the removal of the essential-use designation for albuterol MDIs would lead to higher costs to the Federal Government as a result of the Medicare prescription drug benefits that will go into effect on January 1, 2006 (see Title I of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (Public Law 108–173, December 8, 2003)). The comment recommended that the essential-use designation for albuterol not be removed until generic albuterol HFA MDIs come on the market, to minimize spending by the Federal Government.

Although cost to the Federal Government is not a criterion under § 2.125(g), the availability of prescription drug benefits under Medicare does affect whether patients are adequately served by the non-ODS products. In fact, the prescription drug benefits will reduce the impact of higher prices for albuterol MDIs on Medicare-eligible patients, who would not otherwise have prescription drug insurance benefits. This will help ensure that patients are adequately served by albuterol HFA MDIs.

(Comment 22) A few comments suggested that prices for albuterol HFA MDIs would increase after the rulemaking. A GSK spokesperson at the PADAC meeting stated that GSK had committed to a price freeze on VENTOLIN HFA until December 31, 2007. The commitment was repeated in GSK's subsequent written comments.

We believe that GSK's price freeze will be effective in keeping prices at the current level through much of the transition period before the effective date of this rule. Although Schering has not made a similar commitment, it seems unlikely that they will raise their prices knowing that one of their two competitors is committed to a price freeze. The presence of both GSK and Schering in the market should provide downward pressure on prices for albuterol HFA MDIs that will continue after the effective date of this rule (see pp. 13–20 of the National Economic Associates' comment of August 13, 2004 (2003P–0029/C25), and section V.D.1 of this document). Even if this pressure does not result in price decreases, it may prevent price increases. A representative of IVAX indicated at the PADAC meeting that IVAX's albuterol HFA MDI would be priced lower than PROVENTIL HFA and VENTOLIN HFA. IVAX's entry into the albuterol HFA MDI market and the potential market entry of additional albuterol HFA MDIs will provide additional downward pressure on prices even before the entry of generic albuterol HFA MDIs.

(Comment 23) One comment objected to the elimination of the essential-use designation for albuterol MDIs, saying the price of albuterol HFA MDIs is more than $100 per MDI compared to generic albuterol CFC MDIs, which cost less than $10 per MDI.

The issue of the impact of higher prices for albuterol HFA MDIs is one that we have given a great deal of thought, but the difference is not nearly as great as this comment states. The weighted average (across all payer types) of retail prescription price for generic albuterol CFC MDIs during the first half of 2004 was about $13.50 per MDI and the weighted average retail prescription price for albuterol HFA MDIs was about $39.50 per MDI (see section V.C.6 of this document). As we discuss in our response to comment 18 and section V of this document, we do not believe that this price difference prevents patients from using albuterol HFA MDIs.

(Comment 24) One comment recommended that we perform a cost-benefit analysis using Medical Expenditure Panel Survey (MEPS) data from the Agency for Healthcare Research and Quality (AHRQ).

The analysis of impacts described in section V of this document uses the MEPS data. While the analysis does look at both the costs and benefits of this rulemaking, we would not characterize the analysis as a full cost-benefit analysis because we are unable to fully quantify the public health costs and environmental benefits in dollar terms; however, we do quantify these costs and benefits to the extent we are able.

(Comment 25) One comment asserted that, while our analysis in the 2004 proposed rule of the economic impact of this rulemaking on patients was appropriate to the extent the analysis focused on whether higher prices would deter patients from using albuterol MDIs, those portions of the economic analysis that dealt with more general societal costs were inappropriate and contrary to the provisions of § 2.125.

We are required to examine the broader societal costs and benefits of any rulemaking. Executive Order 12866 directs us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement that includes an assessment of anticipated costs and benefits before proposing any rule that includes any Federal mandate that may result in significant expenditure by State, local,

and tribal governments, or the private sector.

(Comment 26) A few comments stated albuterol HFA MDIs were unacceptable alternatives because they did not propel the drug with adequate force into the lungs. Other comments stated that they had to use an albuterol HFA MDI several times to get the same effect they had received from significantly fewer uses of an albuterol CFC MDI. Several comments from patients stated that their experience indicated albuterol HFA MDIs were less effective than albuterol CFC MDIs, while other comments from patients stated that they had found albuterol HFA MDIs to be more effective than albuterol CFC MDIs. One physician commented that she believed HFA MDIs were better drug delivery systems than CFC MDIs.

The wording of certain comments leads us to believe that at least some of people submitting these comments may be confusing dry powder inhalers (DPIs) or aqueous (AQ) pumps with HFA MDIs. There are currently no albuterol DPIs or AQ pumps being marketed. We did not consider any DPI or AQ pump as a potential alternative to albuterol CFC MDIs. Other comments may reflect the common misperception that MDIs propel drugs into the lungs. MDIs do not in fact propel any significant amount of drug into the lungs. MDIs propel the drug into the mouth and the drug is then inhaled into the lungs. Albuterol CFC MDIs and albuterol HFA MDIs work in same way; both contain the active ingredient as a very fine powder which is delivered in a suspension into the patient's mouth. MDIs that forcefully deliver the drug suspension may actually be less effective at delivering the drug into the lungs. In these instances, a significant portion of the drug may be sprayed onto the surfaces in the back of the mouth, from which they will be swallowed rather than inhaled into the lungs. An explanation that we believe likely for some of these perceived differences is the possibility that the albuterol HFA MDIs that were being used had clogged mouthpieces. Cleaning the mouthpieces as described in the labeling for PROVENTIL HFA and VENTOLIN HFA should alleviate these problems.

Whatever the perceived differences between albuterol CFC MDIs and albuterol HFA MDIs may be, clinical studies have shown the albuterol HFA MDIs are as effective as the albuterol CFC MDIs in treating asthma and COPD.

(Comment 27) One comment stated we should not remove the essential-use designation for albuterol MDIs because members of the person submitting the comment's family are allergic to the lactose contained in alternative products.

Neither VENTOLIN HFA nor PROVENTIL HFA contains lactose. While other inhaled drug products for the treatment of asthma and COPD do contain small amounts of lactose, our determination on the essential-use designation for albuterol MDIs is based exclusively on the suitability of VENTOLIN HFA and PROVENTIL HFA as alternatives.

(Comment 28) One person said in his comment he had an adverse reaction that included tachycardia (elevated heart rate) after taking PROVENTIL HFA. He attributed the adverse event to ethanol, which is an inactive ingredient in PROVENTIL HFA and to which he is sensitive.

Reports of an allergic reaction attributed to the very small amounts of ethanol contained in PROVENTIL HFA are extremely rare.[9] VENTOLIN HFA, which does not contain ethanol, should be considered for asthma and COPD patients who may be sensitive to ethanol. Unlike the albuterol CFC MDIs, VENTOLIN HFA and PROVENTIL HFA do not contain identical active ingredients, and patients having difficulties with one product should discuss with their physicians switching to the other.

(Comment 29) One person said in his comment he had an asthma attack after his first use of a QVAR (beclomethasone dipropionate) HFA MDI. He attributed the adverse event to the HFA propellant in the QVAR MDI and concluded that HFA MDIs would not serve patients who were sensitive to HFA.

Another person said in her comment her use of an albuterol HFA MDI caused irritation and triggered an asthma attack.

A third comment suggested HFA MDIs could be less likely to cause paradoxical bronchospasm because of tighter specifications for the various compounds in the MDIs.

Bronchospasm may occur after using any inhaled asthma drug, including both albuterol CFC and HFA MDIs. The approved labeling for both albuterol CFC and HFA MDIs, as well as QVAR and most other approved inhaled drugs, describe paradoxical bronchospasm as an adverse event that can be expected in a small number of patients. Paradoxical bronchospasm seems to be associated with the first use of an MDI or vial of an inhaled drug. The warnings about paradoxical bronchospasm represent a general concern with inhaled drugs, and do not represent a special concern for albuterol CFC and HFA MDIs or QVAR. Paradoxical bronchospasm is very rare; a study conducted in the United Kingdom of 10,472 patients regularly using VENTOLIN EVOHALER (an albuterol HFA MDI marketed in the United Kingdom that is substantially similar to VENTOLIN HFA) over five 3-month observation periods, did not show any incidents of paradoxical bronchospasm (Ref. 3). We have not seen any evidence from the clinical studies of various HFA MDIs that this type of adverse event is more or less common with HFA MDIs than with CFC MDIs. Absent other data, we cannot assume that the adverse events described in the comments were caused by the HFA propellant in the MDIs.

(Comment 30) A few comments stated albuterol HFA MDIs left a powdery residue at the back of the throat. One person said in her comment that after using an albuterol HFA MDI she felt the need to rinse her mouth out. One comment said this tendency to leave a powdery residue could lead to thrush and other infections.

A very small number of patients have reported an unpleasant powdery residue in the oral cavity after use of an albuterol HFA MDI. Any MDI can leave a residue in the oral cavity. Use of a spacer can minimize the amount of residue left in the mouth. Patients who experience this problem may wish to speak to their physicians about using a spacer with the MDI. We do not consider problems with a powdery residue to be either prevalent enough or serious enough to prevent patients from being adequately served by albuterol HFA MDIs.

Thrush, also known as candidiasis, is occasionally seen with the use of inhaled corticosteroids. Although thrush may be seen in patients who are taking both inhaled corticosteroids and inhaled albuterol, there is no evidence to suggest that use of albuterol or HFA contributes to the development of thrush. Accordingly, we do not believe thrush to be a problem with use of albuterol HFA MDIs.

(Comment 31) One comment stated albuterol HFA MDIs are not an adequate substitute because they cannot be used with spacers.

Commercially available spacers can be used with both albuterol HFA MDIs. Patients who are having difficulties with any MDI may wish to speak to their

[9] We are only aware of one report in our MedWatch system of an allergic reaction attributed to the very small amounts of ethanol contained in PROVENTIL HFA. VENTOLIN HFA, which does not contain ethanol, should be considered for asthma and COPD patients who may be sensitive to ethanol. MedWatch is the FDA safety information and adverse event reporting program, which allows health care professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.

physicians about using a spacer in conjunction with the MDI.

We find that patients who medically require albuterol CFC MDIs are adequately served by albuterol HFA MDIs.

F. Effective Date

(Comment 32) Several speakers at the PADAC meeting and comments, including comments from Schering, 3M, and GSK, recommended an effective date of December 31, 2005.

Schering, 3M, and GSK have all stated that adequate production capacity and supplies would be in place by December 31, 2005. However, the December 31, 2005, date is merely a projected date, and neither Schering, 3M, nor GSK provided the basis for their projections. No timelines, construction and installation schedules, or training goals were provided to us. We have no descriptions of what new machinery must be procured, nor any idea when that machinery can be up and running. While we believe that the projections were made in good faith, unanticipated delays and shortages could push the date on which adequate production capacity and supplies are in place significantly beyond December 31, 2005. Due to the lack of underlying information, we are unable to evaluate the likelihood or length of any possible delays.

If this rule were to go into effect before adequate production capacity and supplies were in place, there would not be a smooth transition from albuterol CFC MDIs to albuterol HFA MDIs. We could be forced to publish a document postponing the effective date. We could see resumption of production at albuterol CFC MDI lines that had been closed and increased production to restock supplies of albuterol CFC MDIs that had been allowed to dwindle in anticipation of the effective date of this rule. If needed CFCs, MDI components, or production facilities were unavailable, shortages of albuterol MDIs could exist.

Furthermore, if we were forced to push the effective date of this rule back because of the failure of manufacturers to have adequate production capacity and supplies in place, it would be very harmful to any transition education program. Patients and health care providers would be provided with different dates by which the transition from albuterol CFC MDIs to albuterol HFA MDIs would be completed. This could lead to confusion, lack of trust, and the belief that people would not have to think about the transition because it would probably be postponed again.

When we consider how serious and life threatening asthma and COPD are, and how important albuterol MDIs are in treating asthma and COPD, it becomes apparent that a conservative estimate of when sufficient supplies and production capacity will exist and a later effective date will better ensure that shortages do not happen and a smoother transition will be made. For these reasons we believe that a December 31, 2005, effective date does not provide an adequate safety margin to ensure that adequate production capacity and supplies will be in place. Accordingly, we have determined that December 31, 2008, is a more appropriate effective date for this rule.

We arrived at a December 31, 2008, effective date with the expectation that an orderly transition to albuterol HFA MDIs would be completed by that date. Although significant production and supplies may be in place prior to this date, in light of the serious consequences of inadequate supplies and the need to ensure that vulnerable patients have adequate access, the date of December 31, 2008, ensures that the criteria in § 2.125(g) will be met and that the transition to albuterol HFA MDIs can be accomplished smoothly. This transition period between the publication of the final rule and the effective date ensures that new facilities will be on line, that manufacturers will have successfully demonstrated their ability to produce necessary supplies of albuterol HFA MDIs, and patients and health care providers will be adequately educated about the transition to albuterol HFA MDIs. After the effective date, section 610 of the Clean Air Act would prohibit the sales of albuterol CFC MDIs in interstate commerce. As discussed in response to comment 42 of this document, the transition time under this rule should allow for retailers and their suppliers to deplete their stock.

(Comment 33) One comment suggested a 2007 effective date without giving reasons why this date would be more appropriate than others.

This comment did not provide any information or rationale for the date, and our rationale for the December 31, 2008, effective date is set out in our response to comment 32 of this document.

(Comment 34) A few comments asked that we set an effective date that will allow patients to try different albuterol HFA MDIs to see if they perform adequately for individual patients.

We believe the December 31, 2008, effective date provides ample opportunity for patients to work with their healthcare providers to determine the best substitute.

(Comment 35) Several comments urged us to set the effective date for this rule late enough to allow lower-priced generic albuterol HFA MDIs onto the market before the essential-use status of albuterol MDIs is removed.

As we discussed in our responses to comment 18 and in section V of this document, we do not believe that presence of generic albuterol HFA MDIs is necessary to ensure that patients are adequately served by albuterol HFA MDIs.

(Comment 36) In the 2004 proposed rule we asked for comments ''on when patents may cease to bar the marketing of generic albuterol HFA MDIs'' (69 FR 33602 at 33608). We did not receive any substantive comments on this issue. One comment, while agreeing with us that we do not have the institutional expertise to evaluate patents, criticized our statement that ''it seems at least possible that key patents could be successfully challenged well before 2015 or perhaps even 2010, allowing generic drugs to enter the market much earlier than anticipated'' (69 FR 33602 at 33608). The comment asserted it would be irresponsible to base any decision on the mere possibility that patents may be successfully challenged. The comment also stated competition would not be blocked because of the ability of firms to license HFA MDI technology from 3M. It also pointed to IVAX as a potential source of competition.

We did not receive any substantive comments on the validity of the patents listed in the Orange Book for albuterol HFA MDIs. Because we have determined that, as we discussed in our response to comment 18 and in section V of this document, the presence of generic albuterol HFA MDIs in the market is not necessary to ensure that patients are adequately served by albuterol HFA MDIs, it is not necessary for us to reach a conclusion on the validity of those patents. We do not believe that IVAX or entrants into the albuterol HFA MDI market that license HFA MDI technology from 3M will be priced as low as current generic albuterol CFC MDIs. We base this belief on the added expense that licenses will entail for manufacturers and the past history of drug pricing. However, we do believe that IVAX and other, potential, entrants can exert downward pressure on prices that could result in lower prices than we currently see for albuterol HFA MDIs.

(Comment 37) A representative of Honeywell, speaking at the PADAC meeting, said Honeywell planned to resume production of CFC propellants at a Louisiana plant, and gave

assurances that Honeywell Chemicals could supply CFC propellants for years to come, if needed. He also said FDA should not consider a shortage of CFC propellants in establishing a transition strategy. Honeywell later provided more details on the subject in a written comment.

Another speaker at the PADAC meeting said Honeywell's resumption of production at their Baton Rouge plant would violate U.S. law and the Montreal Protocol. He further said that according to statements made by Honeywell, current stockpiles of CFCs coupled with production of CFCs at Honeywell's Netherlands facility, which is scheduled to close at the end of 2005, should meet U.S. demand for CFCs for use in MDIs until 2008.

Another comment stated it was appropriate for us to take into account the disruptions in the supply of CFCs caused by Honeywell ending production of CFCs at their Netherlands facility and the equivocal legal status of Honeywell's resumption of production of CFCs at their Baton Rouge facility. It also said we should carefully scrutinize Honeywell's ability to manufacture pharmaceutical grade CFCs at the Baton Rouge facility.

Although we discussed Honeywell's continued production of CFCs in the 2004 proposed rule (69 FR 33602 at 33607–33608), this issue does not address any of the criteria under which we are making a determination on the essential-use status of albuterol MDIs. The criteria in § 2.125(g) direct us to examine the adequacy of supplies and capacity for the non-ODS substitutes, but not the supplies and capacity for the ODS product.

(Comment 38) Speakers at the PADAC meeting and written comments stated that the Parties to the Montreal Protocol were unlikely to continue to approve the United States' future nominations for allocations of CFCs for use in MDIs. One comment asked that we carefully consider the future supply of CFCs in setting an effective date for this rule. Another comment pointed out that a key raw material in the production of CFCs is carbon tetrachloride, an ODS that is being phased out under the provisions of the Montreal Protocol. The comment asserted that this could lead to a situation where it could be very difficult to obtain the needed raw materials for the manufacture of CFCs, even if the manufacture itself was allowed under the Montreal Protocol. Another comment urged us to not allow the fact that other Parties to the Montreal Protocol have initiated phaseouts of albuterol CFC MDIs pressure us into a premature action, pointing out that prices for albuterol HFA MDIs are lower in other countries.

We are obligated to follow the procedures and criteria in § 2.125 in this rulemaking, and the continued supply of CFCs under the Montreal Protocol or the phaseout strategies in other countries are not criteria listed in § 2.125(g) and these issues were not considered in this rulemaking.

(Comment 39) Prior to publication of the 2004 proposed rule, we received a comment from a manufacturer of MDI components submitted in response to the Stakeholders' petition. The manufacturer said it has the ongoing capacity to supply MDI components necessary for ongoing use of CFC MDIs, including albuterol CFC MDIs, and it will continue production as long as there is sufficient demand.

While we appreciate the information contained in this comment, the continued availability of MDI components necessary for continuing use of CFC MDIs is also not a criterion under § 2.125(g) upon which we may base our decision.

(Comment 40) One speaker at the PADAC meeting suggested that FDA monitor patient compliance and access to albuterol HFA MDIs and reserve the right to allow a certain number of albuterol CFC MDIs to be sold in case of a real emergency.

Under the Clean Air Act, a use of an ODS is either essential or it is not. We are currently unaware of any interpretation of the provisions of the Clean Air Act that would give us the flexibility to allow emergency sale or distribution of a CFC MDI once its use is determined to be non-essential.

(Comment 41) One comment recommended that we not set an effective date until we are certain that adequate production capacity will exist.

In choosing December 31, 2008, as the effective date of this rule, we did so with every reasonable expectation that adequate supplies and production capacity will exist by that time.

(Comment 42) A comment recommended that we not establish a date beyond which retail pharmacies are barred from selling albuterol CFC MDIs, even if we did establish a date beyond which albuterol CFC MDIs could not be manufactured.

The sale of remaining stocks of albuterol CFC MDIs was one of the factors we considered in establishing an effective date that is well after the date we expect the transition to HFA MDIs to be substantially completed by manufacturers of albuterol MDIs. This additional buffer period should give wholesalers and retailers adequate time to dispose of stocks of albuterol CFC MDIs. That being said, we do not have the authority to establish an effective dates for wholesalers and retailers that differs from an effective date for manufacturers. We can only make a determination on the date by which the criteria set out in § 2.125(g) will be met and the use of ODSs in albuterol MDIs is no longer essential. Once a product is no longer an essential use, the prohibitions in section 610 of the Clean Air Act automatically come into play. However, section 610 of the Clean Air Act only applies to sales in interstate commerce. If shipments of albuterol CFC MDIs by producers have stopped by December 31, 2007, or shortly thereafter, wholesalers and retailers should not find it difficult to distribute their stocks by December 31, 2008.

G. CFCs and the Environment

(Comment 43) A few comments asserted that CFCs used in MDIs do not have an adverse impact on the environment because the CFCs are inhaled rather than being released into the environment.

Nearly all of the CFCs inhaled into the lungs from an MDI are almost immediately exhaled into the environment. The small amounts of CFCs absorbed into the body are later excreted and exhaled without being broken down. Essentially all of the CFCs released from an MDI end up in the atmosphere with resulting harm to the stratospheric ozone layer.

(Comment 44) A few comments asserted that the amount of ODSs released from albuterol CFC MDIs is insignificant, and eliminating their use would not provide any environmental benefit.

The United States evaluated the environmental effect of eliminating the use of all CFCs in an environmental impact statement (EIS) in the 1970s (see 43 FR 11301, March 17, 1978) (the 1978 rule). As part of that evaluation, FDA concluded that the continued use of CFCs in medical products posed an unreasonable risk of long-term biological and climatic impacts (see Docket No. 96N–0057). In 1990, Congress enacted Title VI of the Clean Air Act, which codified the decision to fully phase out the use of CFCs over time. Congress did not assign us the task of determining what amount of environmental benefit would result from the removal of CFC-containing medical devices, diagnostic products, drugs, and drug delivery systems from the market. Congress did instruct us to determine whether such products are essential. This rulemaking fulfills that obligation.

(Comment 45) A comment asserted that the Montreal Protocol is working well and that according to the Executive Summary of the ''World Meteorological Organization Global Ozone and Research Project—Report No. 47: Scientific Assessment of Ozone Depletion: 2002'' (Executive Summary) (available at *http://www.unep.org/ozone/Publications/6v_science%20assess%20panel.asp*), the continuing use of CFCs in albuterol MDIs would delay restoration of the Earth's ozone layer to its 1980 condition by an insignificant time past the currently projected date of 2050. The comment quoted the following passage from page xvii of the Executive Summary:

> The updated, best-estimate scenario for future halocarbon mixing ratios suggests that the atmospheric burden of halogens will return to the 1980 pre-Antarctic-ozone-hole levels around the middle of the 21st century, provided continued adherence to the fully amended and adjusted Montreal Protocol. Only small improvements would arise from further reduced production allowances in the future.

The size of the delay in the date the ozone layer will be restored to its 1980 condition is not a criterion in determining which medical devices, diagnostic products, drugs, and drug delivery systems are essential under the Clean Air Act. These criteria are set out in § 2.125 and are discussed previously in this document. However, we note that the estimate described in the quoted paragraph assumes ''continued adherence to the fully amended and adjusted Montreal Protocol.'' As we discussed in section II.C.2 of this document, Decision IV/2 envisioned elimination of the production and importation of CFCs by January 1, 1996, by Parties that are developed countries. Although production and importation of CFCs for use in albuterol MDIs are permitted, year to year, as an essential use under the Montreal Protocol, we fail to see how a rule that permits sale and distribution of albuterol CFC MDIs into 2008 can be characterized as a reduction in production allowances. The Montreal Protocol is frequently called the most successful environmental treaty in history, yet its success is based primarily on voluntary compliance by all of the Parties to the treaty. If the United States were to continue sale and distribution of ODS products after adequate alternative products were available, this could lead other Parties to do the same, eventually threatening the integrity of the Montreal Protocol. In the words of the Executive Summary cited in the comment, ''Failure to comply with the Montreal Protocol would delay or could even prevent recovery of the ozone layer.'' (Executive Summary at xxv.) The continued existence of a strong Montreal Protocol is in the best interest of the public health of the United States, and our failure to take timely action on albuterol MDIs could potentially weaken the Montreal Protocol.

(Comment 46) One comment criticized our attempts in the 2004 proposed rule to quantify the environmental benefits of this rulemaking.

We agree with the comment that accurately quantifying the direct environmental benefits of this rule is very difficult and that quantifying the indirect environmental benefits may be impossible. However, as we discussed in our response to comment 25 of this document, we are under separate legal obligation to examine the broader societal costs and benefits of any rulemaking, including the environmental costs and benefits. Accordingly, the discussion of the environmental costs and benefits of this rule is separate from the determination as to whether the criteria in § 2.125 have been met.

(Comment 47) One comment stated the amount of CFCs released by MDIs is negligible compared to naturally occurring CFCs.

There are no naturally occurring CFCs.

(Comment 48) A few comments seemed to confuse CFCs with other greenhouse gases, such as carbon dioxide and nitrous oxide, when stating that MDIs were a minor source of CFCs compared to sources such as power plant and automobile emissions.

While CFCs are considered to be greenhouse gases, we are publishing this rule because the criteria in § 2.125 have been met, rather than any contribution CFCs may be making towards global warming.

(Comment 49) A few comments stated that MDIs were a minor source of CFCs compared to hair spray and deodorants.

CFCs were banned from deodorants, hair spray, and other cosmetics by the 1978 rule. Cosmetics containing CFCs have not been legally marketed in the United States since April 15, 1979, the effective date of the 1978 rule.

H. Comments on the Analysis of Impacts

(Comment 50) We received several comments about our estimates of the price increases that might result from the proposed rule.

One comment objected to FDA estimates of expected price increases based on the price gap between albuterol CFC MDIs and albuterol HFA MDIs from drugstore.com, because the Web site's market share is small and therefore does not accurately represent market prices. This comment recommended that we use retail cash albuterol MDI prices from IMS Health Inc. (IMS). Another comment took average wholesale prices of albuterol MDIs and inflated them according to average retail markups on albuterol for cash payers of 28.8 percent for branded MDIs and 363.3 percent for generic MDIs. From this, the comment calculated cash payers will pay on average $8.61 more per MDI.

Another comment contended that price increases are of limited importance, because insurers have an incentive to maintain lower copayments for albuterol. Lower copayments would minimize the costs to insurers for emergency department visits, hospitalizations, etc. that result from poorer compliance with albuterol therapy.

A few comments said individuals eligible for Medicare or Medicaid are unlikely to face higher costs for albuterol as a result of this rule.

We believe that cash albuterol MDI prices best reflect prices paid by the uninsured, and, consistent with the comment, have considered data on retail cash albuterol MDI prices from IMS, which are generally considered to be the best price data available. Although we did use prices from drugstore.com in the 2004 proposed rule,[10] this was done primarily because we did not have rights to use the IMS data when the 2004 proposed rule was being prepared. IMS retail price data reflect the impact on consumers better than other measures such as estimates derived from average wholesale cash prices inflated by average retail markups for cash payers.

After reviewing these comments, we continue to believe that the likely price increase will be approximately the current difference in price between generic albuterol CFC MDIs and albuterol HFA MDIs, although competition from IVAX's approved albuterol HFA MDI and other albuterol

[10] Although the prices derived from IMS data give us much greater assurance than the prices found on drugstore.com that the numbers we use accurately reflect market prices, in the case of albuterol MDIs the differences in prices are not very significant. The drugstore.com price for generic albuterol CFC MDIs is $13.99, while the weighted average retail price derived from IMS data is approximately $13.50. The drugstore.com prices for VENTOLIN HFA and PROVENTIL HFA are $39.61 and $38.99 respectively, while the weighted average retail price derived from IMS data for albuterol HFA MDIs is $39.50. The drugstore.com prices are those posted on February 10, 2005. See section V.C.6 of this document for more information on the prices derived from IMS data.

HFA MDIs that enter the market may lower prices somewhat.

We believe that price increases are an important determinant of access for individuals without insurance, who are likely to pay the full amount of price increases out of their own pockets. Copayments for albuterol MDIs for privately insured individuals may change when this rule goes into effect, but such changes will be determined by their insurers. While copayments are generally higher for branded drugs, they are not necessarily higher for branded drugs that lack a generic alternative. We are unable to predict how average copayments may change as a result of the rule.

We agree with the comments suggesting that individuals eligible for Medicare or Medicaid are unlikely to face higher out-of-pocket costs for albuterol as a result of this rule.

(Comment 51) Comments were submitted about our use of estimates of consumers' response to drug price increases taken from the Goldman article (Ref. 4). One comment noted that elasticity estimates in the Goldman article were based on a broad range of asthma drugs, many of which differ from albuterol MDIs in important ways. The comment contended that these differences prevent us from drawing meaningful conclusions about how demand for albuterol MDIs will respond to price increases.

A second comment noted that the proposed rule failed to make use of estimates in the Goldman article indicating a price elasticity of demand for asthma drugs as large as -.32.

We recognize the limitations of applying results from the Goldman article to the market for albuterol MDIs, and have sought to characterize fully the associated uncertainty. We believe, however, that focusing on a range of elasticity estimates from -.05 to -.15 is reasonable and appropriate given available information.

We used the Goldman article because it provides recent estimates of how consumer demand for asthma drugs responds to price increases. The article finds that among all users of asthma drugs, a doubling of copayments for asthma drugs reduced drug use by 32 percent. Among chronic asthma sufferers, use of asthma drugs decreased only 22 percent. To the extent that asthmatics are more willing to reduce their use of maintenance drugs, such as steroid inhalers, than to reduce their use of rescue drugs, such as albuterol MDIs, the true consumer response to albuterol MDI price increases may be less than the Goldman article suggests.

We acknowledge the potential shortcomings of applying estimates from the Goldman article to the market for albuterol MDIs but, lacking better information upon which to base our estimates, focus on the range of elasticity estimates from -.05 to -.15, the same range focused upon in the proposed rule.

(Comment 52) Several comments sought to place our analysis of impacts in proper historical context by suggesting that the reductions in use that we estimate are small compared with historical variations. One comment noted that introduction of generic albuterol MDIs to the market for albuterol MDIs in the mid-1990s, and the associated decline in prices, was not associated with any decrease in asthma morbidity.

A second comment noted that the introduction of cheaper generic albuterol MDIs did not result in an increase in consumption of albuterol MDIs, implying that removal of generic albuterol MDIs should not result in a decrease in consumption.

A third comment pointed out that the introduction of generic albuterol MDIs to the market coincided roughly with the entry of therapeutic alternatives such as salmeterol xinafoate, ipatropium bromide, fluticasone propionate, and COMBIVENT, which would have decreased demand for albuterol MDIs at the time lower priced generics became available.

A fourth comment noted that year-to-year fluctuations in demand for albuterol MDIs exceed 1 million units, implying that estimated decreases in albuterol demand are small relative to the market.

We believe it is difficult to draw conclusions about the future albuterol MDI market based on characteristics of the market from the 1990s. Our projected decrease in albuterol MDI sales assumes that, apart from price increases, other determinants of albuterol demand are held constant. In the mid–1990s, several factors that influence albuterol MDI demand changed including the prevalence and incidence of asthma and COPD and patterns of medical practice. However, the effects of these changes cannot easily be estimated with existing data. For example, changes in asthma prevalence before and after 1997 are complicated by changes in the design of the National Health Interview Survey in 1997. We believe the comment stating that introduction of new asthma drugs at this time decreased demand for albuterol MDIs is probably correct, but we lack the data needed to quantify any decrease in demand caused by introduction of new asthma drugs. Because important determinants of albuterol MDI demand are not held constant, the lack of a clear relationship between aggregate albuterol MDI sales and average prices in the 1990s does not undermine the projection that, all other factors remaining the same, use of albuterol MDIs will fall as prices rise.

We agree that a reduction in albuterol MDI use of several hundred thousand annually is a small percentage of the total number of albuterol MDIs used in the United States.

I. Other Comments

(Comment 53) Speakers at the PADAC meeting and written comments said albuterol MDIs were overused and the phaseout of albuterol CFC MDIs would be an appropriate time for physicians and patients to reevaluate the patients' use of asthma medication. The reevaluation would optimize drug regimens used by asthma patients by emphasizing use of maintenance drugs and deemphasizing the use of albuterol MDIs as a rescue medication. One comment suggested we incorporate strategies to encourage these interchanges into this final rule. Another written comment disagreed with these comments, and asserted that the elimination of the essential-use designation for albuterol MDIs should not be viewed as a teachable moment and it would be inappropriate to force patients to use other longer acting but more expensive drugs by effectively raising the price of albuterol MDIs.

While recognizing that many experts believe that albuterol MDIs are being overused, we do not have any reliable data that show that there is a significant pattern of overuse. In any case, the overuse or underuse of a drug product is not a factor that we consider under § 2.125(g). We do, however, welcome any opportunity for physicians and patients to reexamine the patients' drug use and to try to optimize the patients' treatment regimens. It is also important to remember that we do not regulate the practice of medicine and, depending on how the strategies are expressed, an effort on our part to incorporate into our regulation strategies to encourage these consultations might be construed as the regulation of the practice of medicine.

(Comment 54) A comment from an industry organization stated that educating patients and health care providers about the transition from albuterol CFC MDIs to albuterol HFA MDIs is very important, and offered to participate in cooperative education programs with FDA and other interested parties. GSK has outlined their education plans in their comments.

Other comments stated the importance of transition education.

We agree that educating patients and health care providers about the transition is very important. Anyone who wishes to discuss a cooperative educational effort with HHS and FDA should contact FDA or the Office of the Secretary of HHS.

(Comment 55) One comment recommended that, in setting an effective date, we take into consideration the time necessary to educate patients and health care providers about the transition to albuterol HFA MDIs, and one comment recommended more time for this education.

We believe that educating patients and health care providers about the transition to albuterol HFA MDIs is very important. From most patients' perspective, albuterol HFA MDIs are essentially identical[11] to the albuterol CFC MDIs they will be replacing. An explanation that an albuterol HFA MDI is being substituted for the albuterol CFC MDI the patient had been receiving and a explanation of the differences in using the new MDI should be adequate for the vast majority of patients. This explanation can be given by the patient's physician, pharmacist, or other health care provider. While we realize it will take some time to prepare and distribute educational material, we believe that adequate education can easily be provided before the final transition to albuterol HFA MDIs.

(Comment 56) One comment asserted that ''a premature phaseout would compromise the reward structure for innovation.'' The comment also asserted that firms that had made substantial investments in developing albuterol HFA MDIs would be adequately rewarded for the innovation even if this rule were made effective at a date that would allow generic albuterol HFA MDIs to enter the market before the removal of the essential-use designation for albuterol MDIs. The comment stated that GSK had profited handsomely from sales of its combination fluticasone and salmeterol DPI products in the United States and abroad.

We do not see, nor does the comment explain, how profits from the sale of combination fluticasone and salmeterol DPIs could be seen as a reward for GSK's albuterol HFA MDI research and development. Even if we assume that GSK's sales of other products somehow provide adequate incentives for its innovation, the comment does not assert how the research and development efforts of 3M, the manufacturer of the first albuterol HFA MDI marketed in the United States, have been rewarded.

The development of ozone-friendly products is important to achieving the goal of protection of the Earth's ozone layer. Accordingly, it is a factor we considered in our analyses of impacts (see 69 FR 33602 at 33614–33615 and section V of this document).

(Comment 57) One comment emphasized the importance of encouraging the development of ozone-friendly products and stated that, in consideration of the pharmaceutical firms developing ODS free alternatives, the U.S. Government had committed itself ''to ensure prompt removal of nonessential CFC MDIs as soon as new and reformulated products became available.''

As we said previously in this document, the development of ozone-friendly products is important to achieving the goal of protection of the Earth's ozone layer. However, we are unaware of the commitment described in this comment. The 2002 final rule and this rulemaking have been undertaken under our obligations under the Clean Air Act and the Montreal Protocol.

(Comment 58) A few comments expressed unfavorable opinions on salmeterol DPIs and combination fluticasone and salmeterol DPIs. Another comment complained about the high prices of levalbuterol hydrochloride (HCl) inhalation solution.

We have not considered salmeterol DPIs, combination fluticasone and salmeterol DPIs, or levalbuterol HCl inhalation solution to be alternatives to albuterol CFC MDIs. Comments about salmeterol DPIs, combination fluticasone and salmeterol DPIs, and levalbuterol HCl inhalation solution are not relevant to this rulemaking.

IV. Environmental Impact

We have carefully considered the potential environmental effects of this action. We have concluded that the action will not have a significant adverse impact on the human environment, and that an environmental impact statement is not required. Our finding of no significant impact, and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

V. Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), and the Congressional Review Act. 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). We believe that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. This final rule is considered an economically significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We lack the data to certify that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, we have prepared a Regulatory Flexibility Analysis.

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 issuing ''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 $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. This rule, however, does not contain such a mandate.

The Congressional Review Act requires that regulations that have been identified as being major must be submitted to Congress before taking effect. This rule is major under the Congressional Review Act.

Limitations in the available data prevent us from estimating quantitatively the anticipated costs and benefits to society, so we focus instead on proxy measures. The costs of this final rule include the benefits lost by consumers who would have bought albuterol MDIs at the current price but are unwilling or unable to buy them at

[11] While PROVENTIL HFA and VENTOLIN HFA can be substituted for albuterol CFC MDIs, they are not therapeutic equivalents to albuterol CFC MDIs, or to each other, as that term is defined in the Orange Book. There are minor differences between the formulations of VENTOLIN HFA and PROVENTIL HFA that might be significant for some small patient subpopulations (see our response to comment 28 of this document), but for the vast majority of patients these differences should not be significant.

a higher price. The price of albuterol MDIs will rise because this rule, by ending the essential-use designation for albuterol MDIs, will effectively remove less expensive generic versions of albuterol MDIs from the market. Consumers and third-party payers, including Federal and State Governments, will spend more for albuterol MDIs as a result of the price increase. But this increased spending is not part of social cost as conventionally defined, because it represents resources that are transferred from drug buyers (consumers and third-party payers) to drug sellers (drug manufacturers, wholesalers, pharmacies, etc.). The benefits of this rule include the value of improvements in the environment and public health that may result from reduced emissions of ODSs (for example, the reduced future incidence of skin cancers and cataracts). The benefits also include improved expected returns on investments in environmental technologies and greater international cooperation to comply with the Montreal Protocol. As we are unable to estimate the costs and benefits in dollar terms, we instead focus on the cumulative number of albuterol MDIs that might not be sold and the changes in CFC emissions as a result of the rule.

As a result of this rule, approximately 96 million to 430 million albuterol CFC MDIs will be removed from the market, depending on whether generic albuterol MDIs become available in 2010 or 2017. If generic albuterol HFA MDIs enter the market at the end of 2010 (when one of the earlier listed patents for albuterol HFA MDIs expires) then 96 million albuterol CFC MDIs would have been sold between the effective date of this rule (December 31, 2008) and the end of 2010, without the rule. If generic albuterol HFA MDIs enter the market at the end of 2017 (when the last listed patent for albuterol HFA MDIs expires)[12] 430 million albuterol CFC MDIs would otherwise have been sold between the effective date of this rule, and December 2017, without the rule. After generic albuterol HFA MDIs enter the albuterol MDI market and competition among albuterol HFA MDI producers determines the price, there would be no rationale related to patient access to albuterol MDIs for maintaining an essential-use designation for ODSs for albuterol.

Assuming generic albuterol HFA MDIs enter the market at the end of 2010, the removal of albuterol CFC MDIs will eliminate competition from low-cost generic drugs during the period between December 2008 and December 2010, thereby raising prices and increasing spending on albuterol MDIs by about $2.1 billion, assuming a 3-percent discount rate, or $1.7 billion, assuming a 7-percent discount rate (present value in 2005).

Assuming generic albuterol HFA MDIs enter the market at the end of 2017, the removal of albuterol CFC MDIs will eliminate competition from low-cost generic drugs during the period between December 2008 and December 2017, thereby raising prices and increasing spending on albuterol MDIs by about $8.3 billion, assuming a 3-percent discount rate, or $6.2 billion, assuming a 7-percent discount rate (present value in 2005).

Taking into account GSK's commitment to provide free samples and coupons, we estimate that higher prices due to the elimination of generic competition will reduce the number of albuterol MDIs sold by between 300,000 and 900,000 per year. This will induce U.S. consumers to use between 600,000 and 1.8 million fewer albuterol MDIs between the removal of albuterol CFC MDIs on December 31, 2008, and December 2010, or to use 2.7 million and 8.1 million fewer albuterol MDIs during the years between December 31, 2008, and December 2017. These estimates do not take into account the GSK and Schering patient assistance programs designed to provide free or low cost drugs to low-income patients. Should generic albuterol MDIs become available at the end of 2010, consumers will substitute 96 million albuterol HFA MDIs for albuterol CFC MDIs between 2008 and December 2010, reducing atmospheric CFC emissions by 2,400 tons in total. If generic albuterol MDIs become available at the end of 2017, substitution of albuterol HFA MDIs for the 430 million albuterol CFC MDIs that would have been consumed between 2008 and December 2017 will reduce atmospheric emissions of CFCs by about 10,800 tons in total. These quantitative estimates of the effects of this rule are summarized in tables 1 and 2 of this document.

TABLE 1.—SUMMARY OF QUANTIFIABLE EFFECTS OF THE FINAL RULE RELATIVE TO HFA PATENT EXPIRATION IN 2010

Number of Affected Albuterol MDIs (millions)	Increased Expenditures for Albuterol MDIs Present Value in 2005 (billions)		Possible Reduction in MDI Use (millions)	Reduced Aggregate Emissions Related to Phaseout (metric tons)
	3–percent discount rate	7–percent discount rate		
96 million	$2.1	$1.7	0.6 to 1.8	2,400

TABLE 2.—SUMMARY OF QUANTIFIABLE EFFECTS OF THE FINAL RULE RELATIVE TO HFA PATENT EXPIRATION IN 2017

Number of CFC Albuterol MDIs Removed From the Market	Increased Expenditures for Albuterol MDIs Present Value in 2005 (billions)		Possible Reduction in MDI Use (millions)	Reduced Aggregate Emissions Related to Phaseout (metric tons)
	3–percent discount rate	7–percent discount rate		
430 million	$8.3	$6.2	2.7 to 8.1	10,800

While the agency believes that the benefits of this regulation justify its costs, we cannot estimate quantitatively the public health effects of the phaseout. The decreased use of albuterol MDIs may adversely affect some patients, but we lack an ability to characterize such effects quantitatively. We also are unable to estimate quantitatively the reductions in skin cancers, cataracts, and environmental harm that may result from the reduction in CFC emissions by 10,800 metric tons during these years.

We state the need for the regulation and its objective in section V.B of this

[12] Since publication of the 2004 proposed rule, two patents that expire in 2017 have been listed in the Orange Book for VENTOLIN HFA.

document. Section V.C of this document provides background on CFC depletion of stratospheric ozone, the Montreal Protocol, the albuterol MDI market, and the health conditions that albuterol is used to treat. We analyze the benefits and costs of the rule, including effects on government outlays, in section V.D of this document. We assess alternative phaseout dates in section V.E of this document, and conduct a sensitivity analysis on entry dates of generic competition in section V.F of this document. We present an analysis of the effects on small business in a regulatory flexibility analysis in section V.G of this document. We discuss our conclusions in section V.H of this document.

B. Need for Regulation and the Objective of this Rule

This regulation is necessary because private markets are very unlikely to preserve levels of stratospheric ozone sufficient to protect the public health. Individual users of albuterol MDIs have no significant private incentive to switch to non-ozone depleting albuterol HFA MDIs. In fact, each user would bear all of the costs and virtually none of the benefits of such a switch, as the environmental and health benefits would tend to be distributed globally and occur decades in the future. Thus, the outcome of a private market would be continued use of the albuterol MDI available at the lowest price, even if the social value of reducing emissions were clearly much greater than the price premium for non-ozone depleting albuterol HFA MDIs.

The objective of this final rule is to reduce atmospheric emissions of ODSs, specifically CFCs. CFCs and other ODSs deplete the stratospheric ozone that protects the Earth from ultraviolet solar radiation. We are ending the essential-use designation for ODSs used in albuterol MDIs because two acceptable ODS-free albuterol formulations have been successfully marketed in the United States for more than 2 years. Removing this essential-use designation will comply with obligations under the Montreal Protocol and the Clean Air Act, thereby reducing emissions that deplete stratospheric ozone, while preserving access to essential drugs by minimizing adverse effects on affected patient populations.

C. Background

1. CFCs and Stratospheric Ozone

During the 1970s, scientists became aware of a relationship between the level of stratospheric ozone and industrial use of CFCs. Ozone (O_3), which causes respiratory problems when it occurs in elevated concentrations near the ground, shields the Earth from potentially harmful solar radiation when in the stratosphere. Excessive exposure to solar radiation is associated with adverse health effects such as skin cancer and cataracts, as well as other adverse environmental effects. Emissions of CFCs and other ODSs reduce stratospheric ozone concentrations through a catalytic reaction, thereby allowing more solar radiation to reach the Earth's surface. Because of this, environmental scientists from the United States and other countries advocated ending all uses of these chemicals.

2. The Montreal Protocol

The international effort to craft a coordinated response to the global environmental problem of stratospheric ozone depletion culminated in the Montreal Protocol, an international agreement to regulate and reduce production of ODSs. The Montreal Protocol is described in section III.B of this document. One hundred and eighty-six countries have now ratified the Montreal Protocol, and the overall usage of CFCs has been dramatically reduced. In 1986, global consumption of CFCs totaled about 1.1 million metric tons annually, and by 2000, total annual consumption had been reduced to fewer than 0.1 million metric tons (Ref. 5). This decline amounts to about a 90-percent decrease in consumption and is a key measure of the success of the Montreal Protocol. Within the United States, consumption of ODSs, and CFCs in particular, has fallen sharply—consumption of CFC–11 and CFC–12 is about 20 percent of 1990 consumption.[13]

A relevant aspect of the Montreal Protocol is that production of CFCs in any year by any country is banned after the phase-out date unless the Parties to the Montreal Protocol agree to designate the use as ''essential'' and approve a quantity of new production for that use. Each year, each Party nominates the amount of CFCs needed for each essential use and provides the reason why such use is essential. Agreement on both the essentiality and the amount of CFCs needed for each nominated use has been reached by consensus at the annual Meeting of the Parties.

3. Benefits of the Montreal Protocol

EPA has generated a series of estimates of the environmental and public health benefits of the Montreal Protocol (Ref. 6). The benefits include reductions of hundreds of millions of nonfatal skin cancers, 6 million fewer fatalities due to skin cancer, and 27.5 million cataracts avoided between 1990 and 2165 if the Montreal Protocol were fully implemented. EPA estimates the value of these and related benefits to equal $4.3 trillion in present value when discounted at 2 percent over the period of 175 years. This amount is equivalent to about $6 trillion after adjusting for inflation between 1990 and 2004. This estimate includes all benefits of total global ODS emission reductions expected from the Montreal Protocol and is based on reductions from a baseline scenario in which ODS emissions would continue to grow for decades but for the Montreal Protocol.

4. Characteristics of COPD

Albuterol MDIs are used to treat COPD. While there is some overlap between asthma patients and COPD patients, COPD encompasses a group of diseases characterized by relatively fixed airway obstruction associated with breathing-related symptoms (for example, chronic coughing, expectoration, and wheezing). COPD is generally associated with cigarette smoking and is extremely rare in persons younger than 25.

According to the Centers for Disease Control (CDC), an estimated 10 million U.S. adults carried the diagnosis of COPD in 2000 (Ref. 7). Because the underlying surveys depend on patient-reported diagnoses and many affected individuals have not been formally diagnosed, the National Health Interview Survey (NHIS) suggests that as many as 24 million Americans may actually be affected by the disease. The proportion of the U.S. population with mild or moderate COPD has declined over the last quarter century, although the rate of COPD in females increased relative to males between 1980 and 2000. The most effective intervention in modifying the course of COPD is smoking cessation. Symptoms such as coughing, wheezing, and sputum production are treated with medication.

5. Characteristics of Asthma

Albuterol MDIs are also used to treat asthma, a chronic respiratory disease characterized by episodes or attacks of bronchospasm on top of chronic airway inflammation. These attacks can vary from mild to life-threatening and involve shortness of breath, wheezing, cough, or a combination of symptoms. Many factors, including allergens, exercise, viral infections, and others, may trigger an asthma attack.

[13] The ozone depleting potentials of CFC–11 and CFC–12 are equal. See *http://www.epa.gov/ozone/ods.html.*

According to the 2002 NHIS, approximately 20 million patients in the United States reported they had asthma (Ref. 8). The prevalence of asthma decreases with age, with the prevalence being 92 per 1,000 children ages 0–17 (6.1 million children) compared to 83 per 1,000 among adults ages 18–44 (7.4 million), 71 per 1,000 among adults ages 45–64 (4.6 million), and 59 per 1,000 among adults age 65 and over (1.9 million) (Ref. 8).

The NHIS reported that during 2002, about 12 million patients reported experiencing an asthma attack during the previous year (Ref. 8, table 10). According to the National Ambulatory Medical Care Survey, in 2001 there were 1.3 million outpatient asthma visits to physician offices and hospital clinics and 1.9 million emergency room visits (Ref. 8, table 16). According to the National Center for Health Statistics, there were 454,000 hospital admissions for asthma in 2001 (Ref. 8, table 12), and 4,269 mortalities (Ref. 8, table 1). The estimated direct medical cost of asthma (hospital services, physician care, and medications) was $9.4 billion (Ref. 8, table 17).

While the prevalence of asthma has been increasing in recent years, CDC reports that the incidence of asthma (or the rate of new diagnoses) has remained fairly constant since 1997 (Ref. 9). Non-Hispanic blacks, children under 17 years old, and females have higher incidence rates than the general population and also have higher attack prevalence. The CDC notes that although numeric increases have occurred in the numbers and rates of physician office visits, hospital outpatient visits, and emergency room visits, these increases are accounted for by the increase in prevalence. This phenomenon might indicate early successes by asthma intervention programs that include access to medications.

6. Current U.S. Albuterol MDI Market

Albuterol is the preferred, and most commonly prescribed, short-acting relief medication for asthma and is also important in the treatment of COPD. For reasons of cost, convenience, and effectiveness, MDIs are the preferred, and most commonly prescribed, route of administration for albuterol.

We estimate that, in the first two quarters of 2004, U.S. consumers bought about 22.7 million generic albuterol MDIs through retail channels. This estimate is based on our analysis of IMS data (Ref. 10). Total consumption of albuterol MDIs has fluctuated around approximately 50 million MDIs annually over the last several years (Ref. 11). Based on retail sales, we estimate approximately 96 percent of albuterol MDIs sold were generic MDIs or branded MDIs relabeled and sold as generic (Ref. 10) (all containing CFCs), suggesting a total market for generic albuterol MDIs of approximately 48 million MDIs.

IMS provides data on average retail prices for marketers of albuterol MDIs for each of three payer types (cash customers, Medicaid recipients, and patients covered by other third-party payers), and the proportion of each marketer's sales to each payer type. As described in table 3 of this document, the weighted average (across all payer types) of retail prescription price for generic albuterol CFC MDIs during the first half of 2004 was about $13.50 per MDI, the weighted average retail prescription price for branded versions of albuterol CFC MDIs was about $38.90 per MDI, and the weighted average retail prescription price for albuterol HFA MDIs was about $39.50 per MDI.

TABLE 3.—SUMMARY OF CURRENT RETAIL PRICES FOR ALBUTEROL CFC AND HFA MDIS[1]

Payer Type	Generic Market Share (percent)	Albuterol CFC MDI Prices		Albuterol HFA MDI Prices	Price Premium: HFA MDI Price Relative to Generic Price		Estimated Units (millions)[2]
		Generics	Weighted Average Branded Products	Weighted Average	Dollars per MDI	Percent	
Cash	97.0	$19.13	$45.90	$46.32	$27.19	142	5.2
Medicaid[3]	97.3	$15.61	$37.10	$41.14	$25.53	164	8.7
Third-party	95.4	$12.03	$37.75	$38.60	$26.57	221	31.4
Total Market	96.0	$13.53	$38.87	$39.47	$25.94	192	45.3

[1] Source: (Ref. 10)
[2] These estimates reflect retail sales of generic albuterol MDIs, excluding sales at Internet and mail-order pharmacies.
[3] Medicaid prices do not reflect rebates given directly to States by drug companies.

We estimate albuterol CFC MDIs are responsible for roughly 1,200 metric tons of CFC emissions annually. Each albuterol CFC MDI contains about 21 grams of CFCs.[14] The estimated 48 million albuterol CFC MDIs sold annually therefore contain about 1,000 metric tons of CFCs. Adding an additional 20 percent to account for use in production, unusable batches, and other factors (as manufacturers typically do in the process of requesting essential-use allocations of CFCs for manufacturing) brings the total emissions to about 1,200 metric tons. To the extent that CFCs used in the production process are reclaimed and destroyed, this estimate overstates expected emissions reductions.

D. Benefits and Costs of the Final Rule

The benefits and costs of a government action are conventionally estimated relative to a baseline scenario that in this case is a description of the production, use, and access to albuterol MDIs in the absence of this rule. In this section we first describe such a baseline and then present our analysis of the benefits of the final rule. Next we turn to the costs of the rule and to an analysis of the effects on the Medicare and Medicaid programs.

1. Baseline Conditions

We developed baseline estimates of future conditions to estimate the economic effects of prohibiting marketing of albuterol CFC MDIs after December 31, 2008. It is standard practice to use, as a baseline, the state of the world absent the rulemaking in question, or where this implements a legislative requirement, the world absent the statute.

[14] CFC MDI manufacturers disclose the CFC content of their MDIs to EPA as part of the process of requesting essential-use allocations; however, the CFC content of any particular MDI is considered confidential business information and may not be disclosed without the manufacturer's consent.

For the baseline in this analysis, we assume that access to CFC propellants, and therefore to albuterol CFC MDIs, continues indefinitely. This assumption focuses our analysis on the impact of removing less expensive generic albuterol CFC MDIs from the market, until the date that competition from generic albuterol HFA MDIs lowers prices. As stated previously in this document, we have identified listed patents on the HFA technology with expiration dates of 2009, 2010, 2014, 2015, and December 2017. In performing our analysis, we make two different sets of assumptions. First, we perform an evaluation based on the assumption that generic versions of albuterol HFA MDIS will come on the market after patents expire in 2010. Second, we perform an evaluation based on the assumption that generic albuterol HFA MDIs will come on the market after the last listed patent expires in 2017. Without this rule, U.S. commitments to the Montreal Protocol could limit future access to CFCs and, therefore, inexpensive generic albuterol CFC MDIs. This observation suggests an alternative baseline where Parties to the Montreal Protocol stop approving nominations for the use of CFCs in albuterol MDIs at a particular date. While the Parties could theoretically take such action for calendar year 2008, it would be speculative on our part to assume that they would take such action for that specific date or any other. As a result, we do not pursue a quantitative analysis with such alternative baselines.

Throughout our analysis, we assume that future prices for albuterol CFC and HFA MDIs do not change from current levels. This assumption overstates prices to the extent that competition from new entrants reduces future albuterol HFA MDI prices. We assume, however, that competition among the albuterol HFA MDI manufacturers will leave prices roughly stable and note that one manufacturer has pledged to freeze prices until at least the beginning of 2008.

Throughout this analysis, we assume that sufficient inventories of CFCs are available to meet demand up to December 31, 2008, and that albuterol HFA MDIs available on and after December 31, 2008, will be adequate to meet demand. In calculating the present value of increased expenditures, we discount expected future increases in expenditures by both 7 percent and 3 percent annually for each year after 2005.

2. Benefits of the Final Rule

The benefits of the final rule include environmental and public health improvements from protecting stratospheric ozone by reducing CFC emissions. Benefits also include expectations of increased returns on investments in environmentally friendly technology, reduced risk of unexpected disruption of supply of albuterol MDIs, and continued international cooperation to comply with the spirit of the Montreal Protocol, thereby potentially reducing future emissions of ODS throughout the world.

a. *Reduced CFC emissions.* Market withdrawal of albuterol CFC MDIs will reduce emissions by approximately 1,200 metric tons of CFCs per year. We have reviewed current CFC inventories and believe currently available quantities are likely to be sufficient to supply the albuterol CFC MDI market for approximately 12 months. Nominations for new CFC production are generally approved by the Parties to the Montreal Protocol 2 years in advance. The final rule bans marketing of albuterol CFCs after December 31, 2008. There is considerable uncertainty with respect to the amount of inventories that will be available in the future, but we anticipate that utilization of existing inventory will allow the United States to avoid requesting a 2008 exemption, or to significantly reduce the amount requested. Therefore, we estimate the final regulation will reduce CFC use by 1,200 metric tons per year after the end of 2008, a benefit that will continue beyond the evaluation period.

In an evaluation of its program to administer the Clean Air Act, EPA has estimated that the benefits of controlling ODSs under the Montreal Protocol are the equivalent of $6 trillion in current dollars. However, EPA's report provides no information on the total tons of reduced emissions or the incremental value per ton of reduced emissions. EPA derived its benefits estimates from a baseline that included continued increases in emissions in the absence of the Montreal Protocol. We have searched for authoritative scientific research that quantifies the marginal economic benefit of incremental emission reductions under the Montreal Protocol, but have found none conducted during the last 10 years. As a result, we are unable to quantify the environmental and human health benefits of reduced ODS emissions from this regulation. Such benefits, in any event, were apparently included in EPA's earlier estimate of benefits.

As a share of total global emissions, the reduction associated with the elimination of albuterol CFC MDIs represents only a small fraction of 1 percent. Current allocations of CFCs for albuterol MDIs account for about 0.1 percent of the total 1986 global consumption of CFCs (Ref. 5). Furthermore, current U.S. CFC emissions from MDIs represent a much smaller, but unknown share of the total emissions reduction associated with EPA's estimate of $6 trillion in benefits because that estimate reflects future emissions growth that has not occurred.

Although the direct benefits of this regulation are small relative to the overall benefits of the Montreal Protocol, we believe the reduced exposure to UV–B radiation that will result from these reduced emissions will help protect public health. However, we are unable to assess or quantify specific reductions in future skin cancers and cataracts associated with these reduced emissions.

b. *Returns on investment for environmental technology.* Establishing a phaseout date prior to the expiration of patents on albuterol HFA MDIs not only rewards the developers of the HFA technology, but also serves as a signal to other potential developers of ozone-safe technologies. In particular, such a phaseout date would preserve expectations that the government protects incentives to research and develop ozone-safe technologies.

Newly developed technologies to avoid ODS emissions have resulted in more environmentally ''friendly'' air conditioners, refrigerants, solvents, and propellants, but only after significant investments. Several manufacturers have claimed development costs that total between $250 million and $400 million to develop HFA MDIs and new propellant-free devices for the global market (Ref. 11).

These investments have resulted in several innovative products in addition to albuterol HFA MDIs. For example, breath-activated delivery systems, dose counters, dry powder inhalers, and mini-nebulizers have also been successfully marketed. This technology could also affect other drugs used for the treatment of asthma and COPD because of the likelihood that, eventually, CFCs will not be available for any drug use. To compare the effect of alternative phaseout dates on these returns to investment, we compare the ratio of the present value of increased revenues expected to accrue to innovative firms from a December 31, 2008, phaseout date and the present value of the future revenue stream of alternative phaseout dates, using both 7 percent and 3 percent annual discount rates. This ratio can provide a basis for relative assessments of the returns to investors for alternative phaseout dates. We present estimates of this ratio in a later discussion of alternatives.

Returns on investment are very sensitive to the current market prices in the United States. The pharmaceutical markets of other Parties to the Montreal Protocol operate with implicit or explicit price controls. These controls have depressed the potential returns to technological innovation. For example, in 2003, the ex-manufacturer prices (the prices of the drugs when they leave the production facilities) of the albuterol HFA MDIs most widely sold in France, Germany, and the United Kingdom ranged between roughly $3.30 and $6.40; in the United States these prices were in the neighborhood of $29 to $30.[15]

c. *International cooperation*. The advantages of selecting a date that maintains international cooperation are substantial because the Montreal Protocol, like most international environmental treaties, relies primarily on a system of national self-enforcement, although it also includes a mechanism to address noncompliance. In addition, compliance with its directives is subject to differences in national implementation procedures. Economically less-developed nations, which have slower phaseout schedules than developed nations, have emphasized that progress in eliminating ODSs in developing nations is affected by observed progress by developed nations, such as the United States. If we had adopted a later phaseout date, other Parties could attempt to delay their own control measures.

3. Costs of the Final Rule

The effects of the final rule include increased spending for needed albuterol medication. The social costs of the final rule include the lost benefits of albuterol use that may result from the price increase. We discuss the increased spending and then the social costs in turn.

In the absence of this regulation, we would expect 430 million generic albuterol MDIs to be sold during the entire period between December 31, 2008, and December 2017, when the last patent listed in the Orange Book for an albuterol HFA MDI will expire. Of these, 96 million would be sold before 2010, an earlier date when generics might arrive. These figures are based on the estimate that approximately 96 percent (Ref. 10) of the approximately 50 million albuterol MDIs sold per year (Ref. 11) are generic, suggesting that about 48 million generic albuterol MDIs are sold annually.

With this regulation, patients who would have used generic albuterol CFC MDIs are expected generally to switch to albuterol HFA MDIs. We estimated in section V.C.6 of this document a weighted average price difference at retail pharmacies (across all payer types) of about $26 between these products. If this difference can be applied to future transactions involving 48 million generic albuterol MDIs annually (less the 2 million free samples promised by GSK and decreased demand of 300,000 to 900,000 MDIs resulting from price increases—as calculated later in this analysis), then increased expenditures from consumers and private or public third-party payers would reach about $1.2 billion per year. This estimate is based, in part, on estimated increases in Medicaid prices that do not take into account rebates given directly to States by drug companies. To the extent that such rebates are larger for branded albuterol MDIs, which are more expensive, the increased expenditures are overestimated.

The present value of these increased expenditures in 2005 is about $6.2 billion using a 7 percent annual discount rate and $8.3 billion using a 3 percent annual discount rate. In estimating this increased spending, we focus on the period between December 31, 2008, and December 2017, when the last patent listed in the Orange Book will expire. We also ignore the fact that after a VENTOLIN HFA MDI is first used, it expires much more quickly than a PROVENTIL HFA MDI or albuterol CFC MDIs. Although this change in the usable life of some MDIs may affect the quantity consumed, we are unable to quantify the magnitude of such an effect.

These increased expenditures represent primarily transfers from consumers and third-party payers, including State and Federal Governments, to branded pharmaceutical manufacturers; they are, therefore, not net costs to society. Because these estimates are based on average retail prices, they include additional spending that will go to parties other than innovative manufacturers, such as distributors and retail pharmacies. We estimate that about 11 percent of this increase—about $130 million annually—may be paid by uninsured customers ($130 million) (Ref. 10). We derive these estimates assuming increased spending is the product of the number of albuterol MDIs sold for cash and the difference between the average price for generic albuterol MDIs and the simple mean of the prices for albuterol HFA MDIs. We estimate that 5 million generic albuterol MDIs are sold to uninsured patients annually and that retail cash prices for albuterol MDIs will rise by about $27 per MDI (details of these estimates follow later in this section of the document.) Taking in to account savings from coupons and free samples, uninsured albuterol users would therefore spend about $120 million more each year.[16]

According to MEPS, private nongroup and uninsured individuals used, on average, 3.3 albuterol prescriptions per year (Ref. 12). Based on IMS data, we estimate the average albuterol prescription is for 1.2 MDIs (Ref. 10). The average uninsured, or underinsured, albuterol user would therefore use about 4 MDIs/year. Based on these figures, we estimate that a population of uninsured albuterol users of about 1.25 million[17] would pay, on average, $95 more per year for albuterol.[18] This estimate does not take in to account the reduced use of albuterol MDIs among the uninsured that may result from higher prices or the extent to which quicker expiration of some HFA albuterol MDIs, relative to CFC MDIs, will increase albuterol MDI demand and expenditures. In the future, some fraction of these cash payers will likely be covered by Medicare (Ref. 10).

We expect price increases resulting from market withdrawal of less expensive generic albuterol MDIs will reduce albuterol use by several hundred thousand MDIs annually (as explained below), although there is substantial uncertainty about these estimates. The impact of this reduction on health outcomes is too uncertain to quantify given available data. Some patients, however, respond to price increases for medications for chronic conditions in ways that may adversely affect their health. A recent article found that:

> ***copayment increases led to increased use of emergency department visits and hospital days for the sentinel conditions of diabetes, asthma, and gastric acid disorder: predicted annual emergency department visits increased by 17 percent and hospital days by 10 percent when copayments doubled * * *.

However, the article proceeds to characterize these results as ''not definitive.'' (Ref. 4) This finding

[15] Analysis completed by FDA based on information provided by IMS Health, IMS MIDAS™, United States, Germany, France and the United Kingdom, 2003.

[16] (5 million MDIs - 300,000 free sample MDIs) x ($25/MDI) - (450,000 coupons) x ($10) = $117,500,000. Here, we assume coupons and free samples reach uninsured albuterol users in proportion to estimates of the uninsured fraction of the overall population (15 percent).

[17] (5 million MDIs) / 4 MDIs per uninsured user = 1.25 million uninsured users.

[18] ($117,500,000) / (1.25 million uninsured users) = $94.00 per uninsured user.

suggests that increased prices for albuterol may lead to some adverse public health effects among the populations that would face increased prices. This evidence is insufficient to permit us to quantify any adverse public health effects. We use expected reductions in albuterol MDI purchases as a surrogate measure of the impact.

Our approach to estimating the effects of the rule assumes that the primary effect of an elimination of albuterol CFC MDIs from the market would be an increase in the average price of albuterol MDIs. Given the price increase expected from the elimination of generics and existing estimates of market responses to price increases, we have projected how the quantity of albuterol MDIs consumed may decline as a result of this rule. As in the 2004 proposed rule, we assume that the reduction in the use of albuterol MDIs attributable to this rule can be calculated as the product of the sensitivity of use with respect to the price increase, the baseline use of albuterol MDIs among price—sensitive patients, and the price increase in percentage terms. We discuss these in turn.

We have no information about how consumers react to increases in the price of MDIs per se or to increases in the price of ''rescue'' types of MDIs, such as albuterol, in particular. Economists have researched the response of consumers to higher insurance copayments for drugs in general. The results appear to indicate price elasticities in the range of -.1 to -.2, meaning that a 10 percent increase in insurance copayments appears to lead to a reduction in the number of prescriptions of between 1 and 2 percent (Ref. 13). Some researchers have reported estimates of price elasticities as great as -.3 for asthma drugs (Ref. 4), but the authors report that there is wide variance based on the availability of over-the-counter substitutes. For example, for drugs with no over-the-counter substitute—a set that presumably includes albuterol—the reported price elasticity was -.15.[19] We have used price elasticities of between -.05 and -.15 to estimate the potential effect of price increases on demand. We recognize that elasticity estimates derived from insurance copayment studies may not be specifically applicable to the effects of average retail price increases on uninsured patients' demand for albuterol.

To derive an estimate of the number of albuterol MDIs not sold as a result of this rule, we need an estimate of the baseline use of albuterol MDI sales by price-sensitive consumers. From data on retail sales by payer type from the first half of 2004, we find about 5 million generic albuterol MDIs are sold to uninsured patients annually. This estimate includes sales to people over age 65 not covered by Medicaid who we expect will be covered by Medicare in the future, but it excludes mail order and Internet sales and sales through hospitals and nursing homes. Alternatively, if uninsured individuals under age 65 use albuterol MDIs in proportion to their share of the population (roughly 15 percent) (Ref. 14), then roughly 7 million of 46 million generic albuterol MDIs would be sold to the uninsured (46 million = 48 million generic albuterol MDIs - 2 million free samples).

Finally, to estimate the price increase from this rule, we first assess IMS data, which indicate that cash payers paid, on average, $19.10 for generic albuterol MDIs and $46.30 for albuterol HFA MDIs, a difference that would suggest a price increase of $27.20 per MDI, or 142 percent. However, alternative assumptions about the future market share of different albuterol HFA MDI manufacturers would result in a smaller price increase—130 percent. These estimated price differences faced by cash payers are only a proxy for price differences faced by uninsured patients, because some people with insurance may pay cash, and some uninsured patients may buy drugs from mail-order and Internet pharmacies.

We believe that estimates of the recent price premium for albuterol HFA MDIs may be a reasonable approximation of the price increase anticipated from this rule, at least to the extent that patent protection and the more costly criteria for FDA approval of albuterol HFA MDIs substantially curb competition. At least one listed patent is expected to expire in December 2017. While increased competition from new patented albuterol HFA MDIs may reduce future albuterol HFA MDI prices, such reduction may be small until generic albuterol MDIs are reintroduced into the market. Apart from any patents, marketing of new albuterol HFA MDIs before the patents expire requires FDA approval of a completed NDA. After the patents expire, FDA can approve generic albuterol HFA MDIs by the abbreviated new drug application (ANDA) process. The NDA process is more complicated, expensive, and time consuming than the ANDA process by which new generic drugs are brought to market. This NDA requirement constitutes a barrier to entry in the market that will tend to further limit competition until the patents expire as compared to markets where generic drugs can be marketed. Finally, as noted previously in this document, one manufacturer has also announced a voluntary price freeze on its albuterol HFA MDI until 2008.

We combine different measures of price elasticities (-.05 to -.15), the size of the uninsured generic albuterol MDI market (5 to 7 million MDIs), and estimated price increases (130 percent to 140 percent) to estimate the impact of price increases on use. For example, assuming a price elasticity of .15 and 6 million generic albuterol MDIs sold to the uninsured annually, a 130 percent price increase would reduce demand for albuterol MDIs from the uninsured by about 1.2 million MDIs annually (6 million x -.15 elasticity x 130 percent price increase = 1,200,000 MDIs). These preliminary estimates do not take into account offsetting increases in consumption from changes in promotional efforts already announced by GSK. We also note that the elasticity estimates are based on relatively small price changes and may not be applicable to large price changes such as these.

Manufacturers have announced programs to distribute free samples and coupons to mitigate any adverse effect of higher prices on utilization. For example, GSK has committed to provide 2 million albuterol HFA MDIs each year to physician offices in expectation that they would be distributed to patients in need (2003P–0029/CR1, p. 7). In addition, GSK has committed to annually providing 3 million coupons worth $10 each in rebates for VENTOLIN HFA to any patient. Both GSK and Schering currently operate outreach programs that assist patients to obtain needed medications, but we are unable to assess how many albuterol MDI users are currently helped by these programs or how many more would be helped in the future.

Free samples and coupons help mitigate adverse impacts on uninsured patients only to the extent that they are distributed to physicians and other health care professionals who then give them to uninsured individuals.[20] To assess how free samples and coupons might affect albuterol MDI use, we conducted a thorough review of the relevant peer-reviewed literature and

[19] Some patients may view PRIMATENE, an epinephrine MDI available over the counter, as a substitute for prescription albuterol MDIs. If this view is widespread, the decline in albuterol MDI use may be greater than that estimated here. However, insofar as PRIMATENE is effective in treating asthma, the adverse health effects would not be greater. We lack data to evaluate patients' willingness to substitute PRIMATENE for albuterol MDIs.

[20] We found no information addressing how pharmaceutical companies distribute free samples among physicians and clinics, but assume that GSK will not systematically channel free samples away from low-income areas.

found two pertinent articles. One found that, while 54 percent of the free samples were actually distributed to patients, only 9 percent of the patients who received free samples were uninsured (Ref. 15). These data suggest that 4.8 percent of the free samples were actually distributed to uninsured patients. Assuming this estimate is applicable to the albuterol HFA MDIs distributed by the GSK program, then about 96,000 albuterol HFA MDIs per year would reach the uninsured. The second article estimated that 71 percent of free samples were given to patients (Ref. 16). As an upper bound, assuming all samples are distributed to patients and that the uninsured receive them in proportion to their share of the population, approximately 300,000 MDIs (15 percent of 2 million) would reach the uninsured each year.

We expect coupons will do relatively little to improve access to albuterol among the uninsured. If 150,000 (5 percent (Ref. 15)) to 450,000 (15 percent) of the 3 million coupons reach uninsured patients each year and 100 percent of them are redeemed, this would increase albuterol MDI consumption by roughly 2,000 to 15,000 MDIs per year, based on the range of price elasticities considered.

Taking into account the offsetting effect of free samples and coupons, we focus on a range of 300,000 to 900,000 fewer albuterol MDIs sold each year as a result of increased prices stemming from removal of generic albuterol MDIs from the market. This assessment does not take into account Schering's and GSK's patient assistance programs designed to provide free or low cost drugs to low-income patients as we are unable to assess how many albuterol MDI users are currently helped by these programs or how many more would be helped in the future. Over the course of the evaluation period, this would equal between 2.7 million and 8.1 million fewer albuterol MDIs sold. We recognize that due to varying measures of the size of the generic albuterol MDI market for the uninsured, uncertainty about the magnitude of price increases, consumers' response, and the impact of free samples and coupons, and other factors, the true impact of the rule could fall outside this range.

4. Effects on Medicare and Medicaid

In order to apportion the possible spending increases described previously in this document to the Medicaid and Medicare programs, FDA and the Centers for Medicare & Medicaid Services (CMS) have analyzed utilization data related to Medicaid and Medicare, as well as Medicaid program spending data. As explained in this section of the document, these data suggest that, were this rule in effect in 2003, Medicaid spending (including spending by States) would have increased by approximately $100 million for that year. In addition (based on 2001 utilization and 2004 prices), it would have increased drug spending on Medicare beneficiaries by roughly $240 million, although this estimate includes copayments and coinsurance paid by individuals and may be too low because the estimate does not take into account increases in utilization associated with the increase in insurance coverage. These data yield the very rough estimate that the rule would increase Medicare and Medicaid spending by $340 million annually relative to a situation where access to generic albuterol CFC MDIs continued.

a. *Medicaid*. Medicaid spending on albuterol MDIs would have been higher by roughly $100 million in 2003—after taking into account rebates from drug companies—if albuterol CFC MDIs were not available. CMS estimates that 58 percent of this amount would be paid by the Federal Government and 42 percent by States.

Deriving this cost estimate required making some adjustments to available data. Our point of departure is the State Drug Utilization Data, available at *http://www.cms.hhs.gov/medicaid/drugs/drug5.asp* for 2003. These data on utilization and spending on drugs paid for by the Medicaid program suggest that State reimbursements under Medicaid would have been approximately $127 million higher in 2003 if no albuterol CFC MDIs were available (that is, if only albuterol HFA MDIs were available). This estimate assumes substitutes for all albuterol CFC MDIs were purchased at the weighted average price of albuterol HFA MDIs. However, it does not take into account the effect of the rebates from drug companies to States and the Federal Government. CMS estimates that Medicaid program rebates constitute roughly 20 percent of gross spending on prescription drugs under the Medicaid program, suggesting that Medicaid spending on albuterol MDIs after rebates would have been roughly $100 million higher in 2003 if albuterol CFC MDIs were not available. It is important to note that this is a rough estimate, as rebates for a specific drug may differ from the 20 percent estimate. Incomplete data for 2004 suggest that comparable estimates for 2004 are higher but we believe that these are not reliable because of the incompleteness of the data.

b. *Medicare*. Our analysis of the impacts of this rule on Medicare addresses: (1) The total utilization of albuterol MDIs, (2) the likely price increase, and (3) the aggregate spending increase.

CMS estimates that noninstitutionalized Medicare beneficiaries not eligible for Medicaid drug coverage filled about 8 million prescriptions for albuterol MDIs (including VENTOLIN and PROVENTIL) in 2001, based on the Medicare Current Beneficiary Survey (MCBS) and with an adjustment for under-reporting for aggregate analysis purposes. As noted in this section of the document, this estimate is based on Medicare beneficiaries' self-reported outpatient prescription drug utilization, including prescriptions filled at both retail and mail order pharmacies. In addition, the adjustment for underreporting is normally used for aggregate use or spending data in MCBS and may not necessarily reflect actual underreporting for albuterol.

This analysis used data from the 2001 MCBS, a continuous, multipurpose survey of a nationally representative sample of Medicare beneficiaries. The survey is focused on health care use, cost, and sources of payment. No ''paid claims'' data on use of albuterol MDIs exist because Medicare will pay for albuterol MDIs only after the implementation of the new Medicare outpatient prescription drug benefit in January 2006. MCBS is the largest nationally representative set of data available on prescription drug utilization and spending by Medicare beneficiaries. The MCBS data have been used by both CMS's Office of the Actuary and the Congressional Budget Office to prepare estimates related to the new Medicare prescription drug benefit. However, because the data are self-reported, there are considerable limitations, most notably underreporting. CMS has studied the underreporting in the survey and has developed methods to adjust the data. For purposes of the estimates done for the Medicare drug benefit, the data on drug spending are analyzed in the aggregate (that is, for large collections of drugs). Estimates of individual drug product utilization and spending, however, may be even more vulnerable to the limitations inherent in self-reported utilization data.

A reliable assessment of impacts must avoid double counting of people who are eligible for both Medicaid and Medicare. With the implementation of the new Medicare prescription drug benefit, payment for outpatient prescription drugs on behalf of

Medicare beneficiaries who are also eligible for prescription drug benefits under Medicaid will be moved from the Medicaid program to the Medicare program. For purposes of this analysis, this population of dually eligible beneficiaries (that is, Medicare beneficiaries also eligible for full-benefits under Medicaid) is excluded from the analysis of the MCBS data, since their albuterol MDI utilization is captured within the Medicaid data. Approximately half of total Medicaid prescription drug spending is for this dually eligible population. However, the proportion will vary based on the type of drug involved. It is worth noting that albuterol MDIs are used to treat asthma in both the aged and disabled in the Medicare/Medicaid dually eligible population, as well as to treat asthma in children, who make up a large share of Medicaid beneficiaries.

For purposes of this analysis, we assess only data for the time periods for which data are available and we do not make projections for future years. As was noted in the impact analysis for the proposed rule on the Medicare prescription drug benefit (69 FR 46632, August 3, 2004), there is considerable uncertainty in making estimates when there is no program experience from prior years. This uncertainty is exacerbated in the context of making estimates related to a particular drug. For example, in the context of preparing aggregate estimates for the Medicare drug benefit, CMS makes assumptions about how increased coverage induces greater utilization and, based on the National Health Expenditures, projects growth in per capita drug spending. But making such calculations for a specific individual drug would be difficult and not likely reliable. Furthermore, in the case of albuterol MDIs, the drug is subject to large annual fluctuations in demand per user and size of population using the drug due to the nature of the conditions being treated, such as asthma where acute episodes may vary by environmental factors (for example, allergies), prevalence of infectious diseases (for example, colds), and seasonal weather conditions (for example, temperature-related bronchial conditions). In addition, analyzing the effect on Medicare of a change related to one drug is further complicated, for example, by the need to consider the interactions with beneficiary cost-sharing in the context of the Medicare drug benefit design and the availability of additional low-income subsidies for certain populations. Also, the introduction of an albuterol HFA MDI from IVAX is expected to increase competition in the market to some extent, potentially dampening anticipated price increases in part. Our estimates, therefore, apply only to past years.

We believe that prices paid by private insurers offer a potentially reasonable approximation of prices negotiated in the context of a privately administered risk-based insurance program such as the new Medicare Part D drug plans. Using proprietary data from IMS Health, we determined that prices for patients with third-party insurance were on average about $30 more per prescription for albuterol HFA MDIs than for albuterol CFC MDIs, according to IMS's National Prescription Audit for the first half of 2004 (Ref. 10). This price estimate reflects transactions in U.S. retail pharmacies, excluding Internet and mail-order sales. It also reflects both payments by insurers and copayments or coinsurance payments by patients. We calculate the average price per prescription for the albuterol HFA MDIs and the albuterol CFC MDIs, respectively, as the weighted average of the price per prescription of different firms' products, where the weights are the firms' shares of the total albuterol MDIs sold. Price differences per prescription are larger than price differences per MDI, because some prescriptions are for more than one MDI.

Given this estimate of the price difference that would have existed without CFC albuterol MDIs, spending by, and on behalf of, Medicare beneficiaries without Medicaid drug coverage could have been roughly $240 million more in order to fill the 8 million prescriptions estimated to have been filled in 2001 (based on the MCBS data). This estimate is quite approximate because it relies on an estimate of albuterol MDI prescriptions from 2001 and estimates of prescription price differences from the first half of 2004. In addition, albuterol MDI use may grow as the Medicare drug benefit reduces the cost to individuals of using albuterol MDIs.

E. Alternative Phaseout Dates

In developing this rule, we considered removing the essential-use designation for ODSs in albuterol MDIs for different dates between 12 months after issuance of a final rule and December 31, 2009. As shown previously in this document, earlier removal would increase consumer expenditures while increasing environmental benefits. A later date would reduce the potential health effect from reduced access, but also reduce the environmental benefit and potentially put at risk international cooperation. We also considered and rejected small business exemptions as inconsistent with international commitments.

Table 4 of this document shows the effects of selecting December 31, 2005, as the effective date, and Table 5 of this document shows the effects if we had selected December 31, 2009 (assuming continued availability of CFCs).

TABLE 4.—EFFECTS OF PHASEOUT AS OF DECEMBER 31, 2005

Number of Affected of Albuterol MDIs (millions)	Increased Expenditures for Albuterol MDIs Present Value in 2005 (billions)		Possible Reduction in MDI Use (millions)	Reduced Aggregate CFC Emissions Related to Phaseout (metric tons)	Relative Return on Investment to New Technology (return for 12/31/08 phaseout = 1)	
	3-percent discount rate	7-percent discount rate			3-percent discount rate	7-percent discount rate
576	$11.6	$9.3	3.6 to 9.8	14,400	1.4	1.5

TABLE 5.—EFFECTS OF PHASEOUT AS OF DECEMBER 31, 2009

Number of Affected Albuterol MDIs (millions)	Increased Expenditures for Albuterol MDIs Present Value in 2005 (billions)		Possible Reduction in Albuterol MDI Use (millions)	Reduced Aggregate CFC Emissions Related to Phaseout (metric tons)	Relative Return on Investment to New Technology (return for 12/31/08 phaseout = 1)	
	3-percent discount rate	7-percent discount rate			3-percent discount rate	7-percent discount rate
384	$7.3	$5.3	2.4 to 7.2	8,400	.88	.85

F. Sensitivity Analyses

We have conducted a sensitivity analysis to address how key sources of uncertainty may affect our estimates. Our key focus is the effect of alternative dates when generic competition for albuterol HFA MDIs may begin.

In Table 6 of this document, we present estimates assuming that generic competition arrives in 2015.

TABLE 6.—EFFECTS OF PHASEOUT ON DECEMBER 31, 2008—ASSUMING GENERIC ENTRY IN 2015

Number of Affected Albuterol MDIs (millions)	Increased Expenditures for Albuterol Present Value in 2005 (billions)		Possible Reduction in MDI Use (millions)	Reduced Aggregate Emissions Related to Phaseout (metric tons)	Relative Return on Investment to New Technology (return for 12/31/08 phaseout with genetic entry in 017 = 1)	
	3-percent discount rate	7-percent discount rate			3-percent discount rate	7-percent discount rate
336	$6.7	$5.2	2.1 to 5.6	8,400	.81	.84

This analysis suggests that the eventual date that generic competition arrives will have a substantial effect on the total reduction in albuterol MDI use and the aggregate reductions in CFC emissions. Further analysis of the arrival of generic competition would require an evaluation of the legal merits of the different patents, but such an evaluation is beyond the expertise of FDA.

G. Small Business Impact

Current HHS guidance (Ref. 17) suggests that a 3 to 5 percent impact on total costs or revenues of small entities could constitute a significant regulatory impact. We lack the data to certify that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, this analysis, together with other relevant sections of this document, serves as FDA's Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

1. Affected Sector and Nature of Impacts

The affected industry sector includes manufacturers of pharmaceutical products (NAICS 32514). We obtained data on this industry from the 1997 Economic Census and estimated revenues per establishment. Although other economic measures, such as profitability, may provide preferable alternatives to revenues as a basis for estimating the significance of regulatory impacts, we do not believe it would change the results of this analysis.

The impact of this rule on generic manufacturers is the lost revenues currently generated by sales of generic albuterol CFC MDIs. While ''lost revenues'' are an imperfect measure, because production resources could be shifted to alternative markets, they provide a measure that suggests the magnitude of the impact.

The Small Business Administration (SBA) has defined as small any entity in this industry with fewer than 750 employees. According to Census data, 84 percent of the industry is considered small. The average annual revenue for a small entity is $26.6 million per entity. However, the agency does not have revenue information specific to the affected entities. According to retail sales in the first half of 2004, of the 22.7 million generic or relabeled annual prescriptions for albuterol, approximately 63 percent (14.3 million MDIs) were distributed by Schering, a large firm, under the Warrick label. Six different companies marketed the other 8.4 million albuterol MDIs, with three companies accounting for over 99 percent of these 8.4 million (Ref. 10). According to data collected by the Congressional Budget Office (Ref. 18), the value of shipments from manufacturers of generic drug products accounts for approximately 35 percent of the retail price of the product. If so, revenue from 1.7 million albuterol MDIs would approximate $8.0 million per year (1.7 million prescriptions X $13.50 per generic prescription X 35 percent). Because we lack company-specific revenue data, we are unable to estimate the impact of this rule on these small entities. To the extent that generic albuterol HFA MDIs might become available prior to the removal of the essential-use designation, any impact on small entities would be mitigated.

2. Outreach

The Montreal Protocol and Clean Air Act have been in place for more than a decade. Manufacturers of albuterol CFC MDIs have long known that CFCs would eventually lose their essential-use designations for this purpose. During the proposal stage of this rulemaking, we specifically solicited comments on the impact on small entities. No comments were received that explicitly addressed this issue.

H. Conclusion

This final rule could result in increased health care expenditures of about $1.2 billion for each year between the removal of the essential-use designation and reintroduction of generic competition at patent expiration. Taking into account GSK's commitment to provide free samples and coupons, we estimate that higher prices due to the elimination of generic competition will reduce the number of MDIs sold by between 300,000 and

900,000 per year. This estimate does not take into account Schering's and GSK's patient assistance programs designed to provide free or low cost drugs to low-income patients as we are unable to assess how many albuterol MDI users are currently helped by these programs or how many more would be helped in the future. In addition, each year without using CFCs in albuterol MDIs will reduce atmospheric emissions of ODSs by 1,200 metric tons and provide increased investment returns for environmentally friendly technology that may induce further gains. Removal of the essential-use designation is consistent with FDA's role in determining the essentiality of MDIs under section 601 of the Clean Air Act, and also meets U.S. obligations under international agreements. Finally, we lack the data to certify that this final rule will not have a significant economic impact on a substantial number of small entities.

VI. The Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have 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. While this rule may result in States increasing spending for albuterol MDIs in programs such as Medicaid, the increased spending is not a substantial direct compliance cost, as the term is used in Executive Order 13132. Accordingly, we have 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 (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Food and Drug Administration, ''Guidance for Industry: Integration of Dose-Counting Mechanisms into MDI Drug Products,'' March 2003.

2. Penick, T. B. et al., ''Accuracy of Float Testing for Metered-Dose Inhaler Canisters,'' *Journal of the American Pharmaceutical Association*, 42:582, July/August 2002.

3. Craig-McFeely, P. M. et al., ''Prospective Observational Cohort Safety Study to Monitor the Introduction of a Non-CFC Formulation of Salbutamol with HFA 134a in England,'' *International Journal of Clinical Pharmacology and Therapeutics*, 41:67–76, 2003.

4. Goldman, D. P. et al., ''Pharmacy Benefits and the Use of Drugs by the Chronically Ill,'' *The Journal of the American Medical Association*, 291:2344–2350, 2349, May 19, 2004.

5. United Nations Environmental Programme, ''Production and Consumption of Ozone-Depleting Substances 1986–2000,'' 2002.

6. U.S. Environmental Protection Agency, ''The Benefits and Costs of the Clean Air Act: 1990–2010'' (*http://www.epa.gov/air/sect812/copy99.html*).

7. Mannino, D. M. et al., ''Chronic Obstructive Pulmonary Disease Surveillance—United States, 1971–2000,'' *Morbidity and Mortality Weekly Report*, 51(SS06):1–16, August 2, 2002.

8. American Lung Association, ''Trends in Asthma Morbidity and Mortality,'' Epidemiology & Statistics Unit, Research and Scientific Affairs, April 2004.

9. Mannino, D. M. et al., ''Surveillance for Asthma—United States, 1980–1999,'' *Morbidity and Mortality Weekly Report*, 51(SS01):1–13, March 29, 2002.

10. Analysis completed by FDA based on information provided by IMS Health, IMS National Prescription Audit™, 2004; IMS Health, IMS MIDAS™, Q1/2004—Q2/2004. These data can be purchased from IMS Health. Please send all inquiries to: IMS Health, Attn: Brian Palumbo, Account Manager, 660 West Germantown Pike, Plymouth Meeting, PA 19462.

11. Rozek, R. P., and E. R. Bishko, ''Economics Issues Raised in the FDA's Proposed Rule on Removing the Essential-Use Designation for Albuterol MDIs,'' National Economic Research Associates, August 13, 2004 (FDA Docket No. 2003P–0029/C25).

12. Agency for Healthcare Research and Quality, ''Albuterol Inhalers: Prescriptions per User, Price per Prescription and Expenditure Given Use,'' spreadsheet prepared at FDA's request for this rulemaking, 2004.

13. Ringel, J. S. et al., ''The Elasticity of Demand for Health Care,'' National Defense Research Institute, Rand Health, 2002.

14. U.S. Census Bureau, ''Income, Poverty, and Health Insurance Coverage in the United States: 2003,'' Current Population Reports, U.S. Department of Commerce, pp. 14–15, August 2004.

15. Morelli, D., and M. R. Koenigsberg, ''Sample Medication Dispensing in a Residency Practice,'' *Journal of Family Practice*, 34(1):42–48, 1992.

16. Peterson, M. C. et al., ''Disposition of Pharmaceutical Samples from a Private Medical Clinic,'' *Journal of the American Pharmacists Association*, 44(3):397–398, 2004.

17. U.S. Department of Health & Human Services, ''Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services,'' May 2003.

18. Congressional Budget Office, ''How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry,'' July 1998.

List of Subjects in 21 CFR Part 2

Administrative practice and procedure, Cosmetics, Devices, Drugs, Foods.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and the Clean Air Act and under authority delegated to the Commissioner of Food and Drugs, after consultation with the Administrator of the Environmental Protection Agency, 21 CFR part 2 is amended as follows:

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

■ 1. The authority citation for 21 CFR part 2 continues to read as follows:

Authority: 15 U.S.C. 402, 409; 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374; 42 U.S.C. 7671 *et seq.*

§ 2.125 [Amended]

■ 2. Section 2.125 is amended by removing and reserving paragraph (e)(2)(i).

Dated: March 29, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6599 Filed 3–31–05; 8:45 am]

BILLING CODE 4160–01–S

Federal Register

Monday,
April 4, 2005

Part IV

The President

Memorandum of March 31, 2005—Assignment of Function To Submit a Report Relating to Millennium Challenge Corporation Activities

Federal Register
Vol. 70, No. 63
Monday, April 4, 2005

Presidential Documents

Title 3—

The President

Memorandum of March 31, 2005

Assignment of Function to Submit a Report Relating to Millennium Challenge Corporation Activities

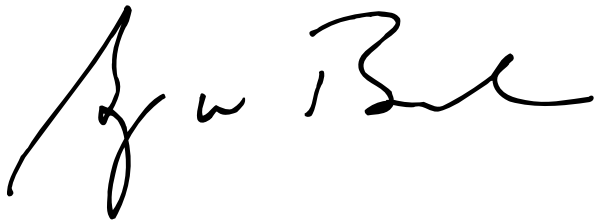
Memorandum for the Secretary of State

Consistent with section 301 of title 3, United States Code, the function of the President under section 613 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 2004 (Division D of Public Law 108–199) is assigned to the Secretary of State.

The Secretary of State shall perform such function in a manner consistent with the President's constitutional authority to withhold information the disclosure of which could impair foreign relations, national security, the deliberative processes of the Executive, or the performance of the Executive's constitutional duties. Heads of departments and agencies shall, to the extent permitted by law, furnish to the Secretary information the Secretary requests to perform such function, in the format and on the schedule specified by the Secretary.

Any reference in this memorandum to the provision of any Act shall be deemed to include references to any hereafter-enacted provision of law that is the same or substantially the same as such provision.

You are authorized and directed to publish this memorandum in the **Federal Register**.



THE WHITE HOUSE,
Washington, March 31, 2005.

[FR Doc. 05–6735
Filed 4–1–05; 10:07 am]
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[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period January 1, 2004, through January 1, 2005. The CFR volume issued as of January 1, 2004 should be retained.

[5] No amendments to this volume were promulgated during the period April 1, 2000, through April 1, 2004. The CFR volume issued as of April 1, 2000 should be retained.

[6] No amendments to this volume were promulgated during the period July 1, 2000, through July 1, 2004. The CFR volume issued as of July 1, 2000 should be retained.

[7] No amendments to this volume were promulgated during the period July 1, 2002, through July 1, 2004. The CFR volume issued as of July 1, 2002 should be retained.

[8] No amendments to this volume were promulgated during the period July 1, 2003, through July 1, 2004. The CFR volume issued as of July 1, 2003 should be retained.