§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''Sanofi Animal Health, Inc.'' and by alphabetically adding a new entry for ''Rhone Merieux, Inc., 7101 College Blvd., Overland Park, KS 66210.....050604'' and in the table in paragraph (c)(2) in the entry for ''050604'' by removing the sponsor name ''Sanofi Animal Health, Inc.'' and adding in its place ''Rhone Merieux, Inc., 7101 College Blvd., Overland Park, KS 66210''.

Dated: June 12, 1995.

George A. Mitchell,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1307, 1309, 1310, 1313 and 1316

[DEA No. 112F]

RIN 1117–AA23

Implementation of the Domestic Chemical Diversion Control Act of 1993 (PL 103–200)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This final rule establishes regulations to implement the Domestic Chemical Diversion Control Act of 1993 (DCDCA or Act). These regulations provide additional safeguards to prevent and detect the diversion of listed chemicals by illicit drug manufacturers.

EFFECTIVE DATE: August 21, 1995. Persons seeking registration must apply on or before October 5, 1995 in order to continue their business pending final action by DEA on their application.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: On October 13, 1994, DEA published a notice of proposed rulemaking (NPRM) entitled Implementation of the Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103–200) in the **Federal Register** (59 FR 51887). The NPRM proposed to amend Title 21, Code of Federal Regulations (21 CFR) by adding a new Part 1309, relating to the registration of List I chemical manufacturers, distributors, retail distributors, importers and exporters; revising Parts 1310 and 1313 to amend the recordkeeping and reporting requirements for domestic as well as import/export activities; adding new procedures with respect to the exemption of regulated chemicals, including chemical mixtures and certain drug products that are marketed under the Food, Drug and Cosmetic Act; adding new procedures regarding ''brokers'', ''traders'' and ''international transactions''; and revising Part 1316 with respect of DEA's administrative inspection authority.

There are two additional notices that DEA has published in the **Federal Register** that relate to these regulations. On March 24, 1994 an Interim Rule notice entitled Provisional Exemption From Registration for Certain List I Chemical Handlers was published in the **Federal Register** (59 FR 13881). This rule grants a temporary exemption from the registration requirements of the DCDCA. The exemption will remain in effect for any person who files with DEA a properly completed application for registration on or before October 5, 1995, until such a time as DEA takes final action on their application.

DEA published the second notice in the **Federal Register** on December 9, 1994, (59 FR 63738) withdrawing, for further study, Sections 1310.05(d) and 1310.06(h), which relate to manufacturer reports, and Sections 1310.12 and 1310.13, which relate to the exemption of chemical mixtures. The regulations regarding manufacturer reports and the exemption of chemical mixtures will be re-proposed at a later date following additional consultations with the affected chemical industry. Formal comments that were received in response to the NPRM regarding the withdrawn sections will be given consideration in the redrafting of a new proposal for these sections.

Regulatory Flexibility and Small Business Impact

As required under the Regulatory Flexibility Act (5 U.S.C. 601, et seq.), DEA addressed in detail regulatory flexibility and small business impact as part of the NPRM. The NPRM discussed the difficulty in determining with certainty how many persons would continue to handle regulated ephedrine drug products, and thus be subject to the regulations. This is due to the rapidly changing market affected by state laws restricting the availability of ephedrine, the availability of alternative products that are not regulated, and the intent of the DCDCA to eliminate sales to clandestine laboratories.

No comments were received on this topic or on DEA's estimate of the number of persons that will seek registration to handle regulated ephedrine drug products. Since publication of the NPRM, the number of states taking restrictive actions has increased. DEA is now aware of twelve states that have enacted laws controlling regulated ephedrine drug products, eleven by making them either prescription only or a controlled substance, and one by setting state licensure and reporting requirements. An additional four states have recently introduced legislation to control the products, three by making them a controlled substance and one by setting age restrictions and requiring reports of all transactions. In addition, DEA has documented that several wholesalers of regulated ephedrine drug products, the primary source of supply for retail distributors, have changed their product line to combination products that are not subject to regulation. Finally, recent reports that the Food and Drug Administration (FDA) is considering moving ephedrine into the prescription drug category may further influence persons handling ephedrine drug products. Under the circumstances, the number of retail distributor applicants under the DCDCA remains uncertain.

In the NPRM, DEA was able to provide relief from the chemical registration requirement for persons handling regulated ephedrine drug products who are already registered with DEA to engage in similar activities with controlled substances. In addition, manufacturers of List I chemicals for internal use, with no subsequent distribution or exportation of the chemical, were also exempted from the registration requirement. Both of these proposals have been retained in the final rule. Consideration was also given to exempting retail distributors from the registration, recordkeeping and reporting requirements. However, such an action would negate the purpose of the DCDCA by leaving a significant portion of the sales of regulated ephedrine drug products unregulated.

Following submission and review of the comments concerning the proposed regulations, two requirements were identified which DEA determined could be removed from the final regulations to reduce the impact of compliance without compromising the control goals of the DCDCA. The proposals were the reporting requirement for sales of 375 dosage units or more of regulated ephedrine drug products (proposed

Section 1310.05(a)(2)) and the restrictions regarding employment of certain persons (proposed Section 1309.72). These proposals have been removed from this final rule.

Further, DEA also determined that the proposed regulations regarding manufacturer reporting (proposed Sections 1310.05(d) and 1310.06(h)) and the exemption of chemical mixtures (proposed Sections 1310.12 and 1310.13) could result in a greater than anticipated burden and, possibly, a duplicative reporting requirement, for the industry. The requirements were withdrawn by notice published in the **Federal Register** on December 9, 1994, (59 FR 63738) for reassessment and redrafting following consultation with the affected industry.

DEA has endeavored, within the requirements and goals of the DCDCA, to limit the impact of these regulations on the affected industry. In some instances, as discussed below in the responses to specific comments (e.g., separate registration for separate locations) the specific language of the DCDCA established the parameters of control. However, in other areas, DEA has been able to take additional steps in these final regulations to lessen the impact of the DCDCA's requirements on the affected industry, while simultaneously carrying out the chemical control mandate of the DCDCA.

Public Comments

A total of 22 comments were submitted regarding the proposed rulemaking. While the general tone of the comments was supportive of efforts to prevent the flow of listed chemicals to clandestine laboratories, the commentors raised a number of concerns regarding certain provisions of the proposed regulation, as follows:

Registration

1. Six comments objected to the requirement in Section 1309.23 that a separate registration be obtained for each location at which List I chemical activities are carried out. The comments suggested that DEA allow companies to obtain a single registration, with attendant fee, for multiple locations or activities.

The law is specific on this point. The DCDCA requires that a separate registration be obtained at each location at which List I chemicals are distributed, imported or exported (21 U.S.C. 822(e) and 958(h)). In accordance with the requirements of the Office of Management and Budget (OMB) Circular A–25, the costs associated with each preregistration investigation must be recovered through the fees.

2. Four comments noted the chemical industry's practice of storing and distributing chemicals from independently operated warehouses. These commentors questioned how the requirement for separate registrations for separate locations would apply to these warehouses.

In reviewing these comments, there appeared to be some confusion regarding whether the commentors were addressing warehouse activities that involved List I chemicals or List II chemicals. In subsequent contacts with commentors for clarification, DEA was able to specifically identify only two comments involving warehouses that handle List I chemicals. DEA wishes to clarify that the registration requirement applies only to the distribution, importation or exportation of List I chemicals. Activities involving List II chemicals are not subject to the registration requirement.

With respect to the use of independently owned warehouses, the Controlled Substances Act (CSA), as amended, exempts warehousemen from the registration requirement (21 U.S.C. 802(39), 822(c)(2), and 957(b)(1)(B)) for activities carried out in the normal course of their business. Instead, the person who distributes List I chemicals from independently owned warehouses must register at each location and ensure that the other chemical control requirements, including security, record keeping, reporting, etc., for their products are met while under the supervision of the non-registered warehouseman.

3. One comment questioned what procedures would apply if more than one chemical company stored and distributed chemicals from a single warehouse, and whether separate registrations, if required, would result in duplicative fees.

Each person who distributes, imports or exports a List I chemical must register with DEA for each separate location at which such activities are carried out. If more than one person independently carries out such activities at the same location, then each person must obtain a registration for their activities at that location. Each application would be subject to a separate pre-registration investigation that would require, among other things, a visit to the applicant's business offices (which in this circumstance would be separate from the warehouse). Therefore, the fees would not be duplicative. The fees for registration are based on the costs associated with the registration, as set forth in the NPRM. DEA's experience in working with the chemical industry indicates this is a rare business practice with respect to List I chemicals.

4. Two comments questioned the impact that registration would have on research and development (R&D) activities that were described by the commentors as involving ''very small quantities'' of chemicals in mixtures that may be sent to laboratories for physical property or performance testing.

The DCDCA does not require registration for research or development activities, only distributing, importing or exporting. Thus laboratories performing such testing would not be subject to the registration requirement for research and development activities. Further, the products referenced by the commentors are chemical mixtures, therefore, they will be subject to the chemical mixture exemption regulations that are being developed. It is DEA's intent, to the extent possible, that the distribution of such mixtures to laboratories for testing be exempted from the registration requirement.

5. Two comments expressed concern that manufacturers would be forced to suspend their activities due to delays in the approval of their registrations.

Early in the regulatory development process, DEA recognized that the demands of establishing a new registration program would require a transitional procedure that did not disrupt ongoing legitimate business activities. As a consequence, DEA published a notice in the **Federal Register** on March 24, 1994 (59 FR 13881), that provides a temporary exemption from the registration requirement. Any person who submits a proper application for registration on or before October 5, 1995 will remain exempt from the registration requirement until DEA takes final action regarding their application. There is no cause for current legitimate manufacturers to be concerned that they will have to suspend their activities pending issuance of their registrations.

6. Two comments questioned how the registration requirement would apply to manufacturers of non-regulated chemicals that contain List I chemicals as either unintentional by-products or impurities.

This concern has been raised with respect to the application of chemical diversion control requirements on a number of occasions in the past. The manufacture of a List I chemical as an unintentional by-product during the manufacture of another chemical does not require registration, so long as the List I chemical is not distributed or exported. As to the presence of List I

chemicals as impurities in non-regulated products, it is DEA's understanding that the impurities are present only in trace amounts. It is not DEA's intent that the distribution of non-regulated chemicals that contain trace amounts of List I chemicals as unintentional by-products of the manufacturing process be subject to the registration requirement.

7. One comment suggested that if the Food and Drug Administration (FDA) removes ephedrine from over-the-counter status, the primary reason for, and economic foundation of, the registration program would be removed through the elimination of the need to register and collect fees from the estimated 10,000 retail distributors that handle ephedrine drug products that are regulated as List I chemicals. The comment urged that if such a circumstance occurs, DEA should withdraw the registration requirement.

The DCDCA requires registration of any person who distributes, imports or exports any List I chemical and was not intended solely to control the distribution of regulated ephedrine drug products. DEA's chemical control program, including registration, applies to all List I chemicals. The potential elimination of the need to register retail distributors of ephedrine drug products would not change the purpose of the program. Secondly, the FDA action is only speculative at this time, and its subsequent impact, if passed, is even more uncertain. However, OMB Circular A–25 requires the review of all fees every two years. Under this review, any major change in the registration population would require reassessment of the fees for other registrants. Any change to the fees would be subject to notice and comment.

8. One comment characterized the registration of sites that manufacture List I chemicals as unnecessary, since it duplicates existing site reporting requirements under other Federal laws. A second comment questioned the need for a pre-registrant investigation and fee for high volume manufacturers.

The DCDCA requires persons who distribute, import or export a List I chemical to obtain a registration and requires that DEA determine if such registration would be in the public interest pursuant to the criteria set forth in Section 823(h) of the Act. The pre-registrant investigation must be conducted to determine whether the criteria regarding the public interest are met. The required fee is assessed to cover the costs of that investigation.

9. One comment requested clarification of the exemption from chemical registration found in Section 1309.25, for companies that are registered with DEA to handle controlled substances.

A controlled substance registrant that distributes, imports or exports a List I chemical, other than a regulated drug product that may be marketed or distributed under the Food, Drug, and Cosmetic Act (FDCA), must obtain a chemical registration for such activities. The exemption in Section 1309.25 applies only to controlled substance registrants who engage in similar activities with a regulated drug product that may be marketed or distributed under the FDCA. The exemption is directed at the approximately 65,000 pharmacies and others who are already registered with DEA under the CSA, so as to avoid a duplicative registration requirement on these registrants. In response to this comment and to help clarify the provisions of the exemption, Section 1309.25 has been amended to specify that the exemption applies only to activities involving drug products that may be marketed or distributed under the Food, Drug and Cosmetic Act, that are regulated as List I chemicals pursuant to Section 1310.01(f)(1)(iv).

10. One comment expressed concerns that the regulations will require persons who handle exempt chemical mixtures containing List I chemicals to register.

The proposed Section 1310.13, which was withdrawn for re-publication at a later date, established that the chemical mixtures exempted by the Administrator would not be subject to the registration, recordkeeping, reporting, and import/export provisions of the Act. It is DEA's intention that the same provision will be included in the new chemical mixture exemption regulations. In the interim, chemical mixtures will be exempt until the exemption regulations are promulgated. However, creation of a chemical mixture for the purpose of evading the requirements of the CSA is a violation of CSA (21 U.S.C. 843(a)(8), subject to a penalty of imprisonment for not more than four years, a fine of $30,000, or both.

Brokers and Traders

11. Three comments found the definition of ''broker'' and ''trader'' in Sections 1310.01(k) and 1313.02(m) to be overly broad. Specifically, subparagraph (3) of each section may be read as covering any action, whether deliberate or inadvertent, that results in an international transaction taking place, i.e., a chemical distributor provides a foreign customer with a list of possible sources for a chemical that the distributor does not carry, thus ''bringing together a buyer and a seller.''

DEA agrees that the definition is not intended to cover such circumstances. DEA has amended the wording of subparagraph (3) of the definition to read ''Fulfilling a formal obligation to effect the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter; or by receiving any form of compensation for so doing.''

12. One comment requested clarification of whether import brokers and freight forwarders would be considered brokers or traders.

Brokers and traders are defined as U.S. based persons who assist in arranging international transactions in listed chemicals; the definition does not apply to domestic transactions, including imports into or exports from the United States. Further, brokers and traders, as defined, do not take possession of listed chemicals. Under the circumstances, U.S. based import brokers and freight forwarders would not be considered brokers or traders, as defined, while acting in the normal course of their business. However, it must be understood that imports, exports and distributions of listed chemicals are subject to other provisions of the CDTA and DCDCA and a regulated person is responsible for those transactions.

Security Provisions

13. Two comments questioned the appropriateness of the proposed Section 1309.72, which concerns employment of persons who have been convicted of a felony relating to controlled substances or listed chemicals or have been subject to a denial, suspension or revocation of a DEA registration. One comment raised the issue of whether the requirements violate occupational safety and health, privacy, and non-discrimination laws. The other pointed out that in the absence of the stringent security and storage requirements applied to controlled substances, a far greater number of personnel would have access to List I chemicals, such as ephedrine, thus increasing the burden required to satisfy the requirements of this section.

DEA agrees that the lack of restrictions regarding possession of List I chemicals makes it difficult to employ comprehensive screen practices for all potential employees as proposed in Section 1309.72. However, registrants must employ safeguards to prevent List I chemicals from being diverted from their businesses into the illicit traffic. DEA is, therefore, withdrawing the proposal prohibiting such employment, and in its place establishing that registrants must exercise caution in their employment practices regarding

persons who have been convicted of a felony relating to controlled substances or listed chemicals, or have been subject to denial, suspension or revocation of a DEA registration. The registrant must understand that if an employee diverts a listed chemical, the registrant may be subject to a revocation action. The registrant must assess the risks involved in employing such a person and, in the event of employment, institute procedures to limit the potential for diversion of List I chemicals by such an employee.

14. One comment requested that DEA provide comprehensive guidance regarding assessment of security measures as outlined in Section 1309.71(b).

List I chemical handlers vary greatly in size, type of business and volume handled. Under such circumstances, it would not be desirable to establish specific, inflexible security controls and procedures. The factors outlined in Section 1309.71(b) provide a general framework of elements that allow potential registrants flexibility in assessing the potential threat of diversion and to determine measures necessary to prevent diversion. DEA has made and will continue to make available additional suggestions regarding security in separate publications for the chemical industry. In addition, as set forth in Section 1309.71(c), an applicant or registrant may, following development of a proposed system of controls and procedures, submit materials and plans regarding the system to DEA for assessment.

15. One comment opposed the proposal that retailers stock ephedrine drug products that are regulated as List I chemicals behind a counter on the basis that this requirement creates a third class of drugs (Section 1309.71(a)(2)).

DEA is regulating a List I chemical, not a drug. Section 1309.71(a)(2) provides a basic security measure for a List I chemical that is known to have been diverted from both the retail and wholesale levels for the purposes of manufacturing illicit controlled substances. The section does not prohibit any person from purchasing the product or establish any restrictive requirements, such as sale by prescription only, that must be met by the purchaser. The requirement simply provides an additional means of controlling diversion without restricting public access to the product.

Section 1313.12 Requirement of 486 for Imports

16. One comment questioned the need for advance notice of importation in cases of a return of a previously exported listed chemical and suggested that manufacturers be exempted from this requirement for the return of chemicals which they exported.

DEA previously recognized, under the 1988 Chemical Diversion and Trafficking Act, that exports of listed chemicals might be rejected or otherwise undeliverable, requiring that they be returned to the U.S. exporter. Existing Section 1313.22(e) provides that exports of listed chemicals that are refused, rejected, or otherwise deemed undeliverable may be returned to the U.S. exporter of record without advance notice or a 486 form. That section requires that a written notification be submitted to DEA within a reasonable time following the return.

However, an export that has cleared foreign customs and been accepted by the foreign consignee is not subject to this exception. Any such shipments subsequently returned to the U.S. are imports, subject to all applicable requirements.

17. Two comments questioned the provisions of Section 1313.12(e). One objected that the summary reports of imports required by Section 1313.12(e) are duplicative, since DEA would already have the information available from previously filed 486 forms. The second questioned whether waiver of the advance notice requirement in Section 1313.21(f) would also mean waiver of the quarterly report in Section 1313.21(e), and suggested that DEA publish in Section 1313.21(f) a list of countries with waivers when the final rule is published.

DEA agrees that the wording of this section needed clarification. Section 1313.12(e) proposed minimized reporting procedures for export transactions in circumstances where the Administrator has waived the advance notice requirements as unnecessary for effective chemical diversion control. The comments point out that the proposed section did not specify that a 486 form need not be filed for such transactions. The section has been amended to clarify that a 486 form does not have to be submitted for exports under this section; the regulated person need only file a quarterly summary of such exports. There are presently no waivers established under Section 1313.21(f). This is a new authority granted to the Administrator by the DCDCA. Countries to which this new provision will apply will be determined after implementation of these regulations.

18. One comment raised concerns regarding the need to file an Import 486 form when foreign customers return containers that have not been completely emptied.

DEA has long recognized the standard industry practice to allow a certain level of 'overage' in the amount of chemicals actually shipped in very large tank car/cargo ship type exports due to the difficulty to full recovery and, therefore, that containers that still contain some of the chemicals may be returned. DEA has not required that a 486 form be filed for the return of containers with such ''leavings'', when the amount of chemical is within normal or standard residue levels.

Exports

19. One comment noted the provisions of the DCDCA allowing the Administrator to withdraw the waiver of the advance notice requirement for all exports of listed chemical to a specified country. The commentor asked if, in the future, existing waivers might be withdrawn. The comment also questioned whether other countries have agreed to comply with the same rules.

The DCDCA allows DEA to require, by regulation, that all exports of a listed chemical to a specified country be subject to the advance notice requirement, regardless of regular customer status, if it is determined that advance notification of export is necessary for compliance with international agreements regarding chemical controls or is necessary to support chemical control programs in other countries. It is possible that the waiver of the advance notice requirement for exports of a listed chemical to a specified country may be withdrawn. However, DEA would be required to publish a notice in the **Federal Register** regarding the withdrawal of the waiver and provide an opportunity for public comment. With respect to the question of compliance with these rules by other countries, all parties to the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotrophic Substances of 1988 are required to be able to provide advance notice of exports of List I chemicals, if requested by the importing country.

20. One comment requested clarification of the term ''reasonable cause'' as used in Section 1313.21(g) and of the responsibilities of exporters to know the laws of the countries to which chemicals are exported.

The term ''reasonable cause'' applies to transactions that, due to circumstances such as an unusual method of payment or shipping or quantities inconsistent with stated uses, raise concerns that a customer or a transaction is not what it is represented to be. Exporters should understand the nature of their legitimate transactions and should make informed decisions as to whether the circumstances surrounding a specific transaction give rise to questions regarding the legitimacy of the transaction. As to the laws of other countries, the exporter is expected to make a reasonable effort to determine the validity of a transaction prior to exporting a listed chemical to a country. DEA has published information regarding foreign import restrictions in the **Federal Register.** If further restrictions become known to DEA, they also will be published in the **Federal Register.**

21. One comment objected to the general export reporting requirements as burdensome and unnecessary.

The general export reporting requirements were established by the CDTA in 1988, and have been in continuous use for over five years without presenting any significant obstacles to legitimate chemical exports. As noted in the preamble to the NPRM, the export controls have been successful in significantly reducing the availability of U.S. chemicals to clandestine laboratories in foreign countries.

Definition of Therapeutically Insignificant

22. Two comments argued that the U.S. Food and Drug Administration (FDA) is the appropriate authority for determining whether a product contains therapeutically significant quantities of a medicinal ingredient and that FDA's tentative final monograph for ephedrine combination products should be used as the standard for making such determinations.

At this time, the monograph is a proposed rule. FDA acknowledges that it must publish a final rule in order to actually establish a monograph. When FDA publishes the final monograph, DEA will consider use of the monograph as the determinative standard for therapeutically significant quantities of a medicinal ingredient under the DCDCA. Until such a time, the compendiums set forth in Section 1310.01(f)(1)(iv)(A) provide additional flexibility and will be the primary standard for determining if therapeutically significant quantities of a medicinal ingredient are present in a product.

23. Two comments objected to the provision that a person applying for exemption of a product, the formulation of which is not listed in the compendiums, must submit verification from FDA that the product may be lawfully marketed under the Food, Drug and Cosmetic Act. The commentor noted that FDA does not provide such verifications.

DEA agrees and has removed that language. In its place, the person applying for the exemption must certify to DEA that the product may be lawfully marketed under the Food, Drug and Cosmetic Act.

24. One comment questioned the lack of justification for the choices of compendiums and suggested that the regulation be expanded to include any recognized authority, such as textbooks, treatises, compendia, statements of qualified experts, medical/scientific journals or clinical studies conducted by outside researchers or by a drug company.

The listed compendiums were chosen because they are readily available and are widely recognized as reliable, scientifically accurate and comprehensive listings of products that are commercially available. With respect to the additional sources of information suggested, if a product does not appear in the named compendiums, DEA has provided manufacturers an additional avenue for product exemption. A person requesting a determination from the Administrator that a product does contain therapeutically significant amounts of a certain medicinal ingredient may submit any such information that the person believes supports their request.

25. One comment suggested that wholesalers do not have the expertise to determine whether a drug meets the therapeutically significant standard. Manufacturers should be responsible for making the determination and providing notification to wholesalers that the product meets the requirements.

DEA agrees that manufacturers are responsible for determining whether a product meets the therapeutically significant standard and for notifying their customers of whether the product is, therefore, exempt from List I chemical controls. However, if a distributor has any reason to question a product, then the distributor has an obligation to attempt to determine whether the product meets the standard. If any person, wholesaler or otherwise, is unable to determine from the listed compendiums that a product meets the therapeutically significant criteria, then that person may contact the DEA for assistance in making such a determination.

Contents of Records and Reports

26. One comment acknowledged that most of the information required by the regulations is already maintained in general business records for all transactions. The exception is the registration number of the purchaser. The comment objected that manufacturers should not be required to inquire about the registration number of the customer so long as the legitimacy of the customer is known.

DEA attempted to design the DCDCA recordkeeping requirements to be consistent with existing business records to the extent possible, as recognized by this commentor. One step in establishing the legitimacy of a customer is determining the customer's activity with the regulated chemical and, if that activity requires registration, that the customer is registered to engage in the activity. A record of the customer's registration number confirms that the supplier has taken one of the appropriate steps to determine the legitimacy of the customer and the transaction.

27. One comment noted that the disparity between the requirements for maintenance of records for controlled substances (2 years) and List I chemicals (4 years) would compel the maintenance of separate recordkeeping systems for chemical and pharmaceutical records.

Although both laws are enforced by DEA, the chemical control requirements of the CDTA and DCDCA are entirely separate from the pharmaceutical requirements under the CSA. Each law establishes different recordkeeping standards (21 U.S.C. 827 for controlled substances and 21 U.S.C. 830 for listed chemicals), and with the exception of one List I chemical (regulated ephedrine products) there is little overlap between firms required to keep records under the two laws.

28. One comment objected to the reporting requirement in Section 1310.05(a)(2) as inappropriate. The commentor suggested that establishing a specific level for what constitutes an extraordinary quantity and subjecting a registrant to civil and criminal penalties for failing to file such reports should not be a role for DEA. DEA has not set specific levels for what constitutes extraordinary quantities for controlled substances, and should not do so for OTC drug products. Further, the pharmacist counseling provision would create a third class of drugs and would limit availability of the drugs to the public, since there are many more retailers that sell the regulated

ephedrine products than there are pharmacies.

This reporting requirement was proposed with the intent of providing a clear standard with respect to reportable transactions involving regulated ephedrine drug products. However, the comments demonstrate that industry would prefer flexibility and discretion based on the circumstances of the transaction rather than a specific standard. Therefore, the proposed section 1310.05(a)(2) and related language in Section 1310.05(b) have been removed.

However, removal of the specific standard for reporting does not relieve regulated persons and registrants of the responsibility to report transactions involving an extraordinary quantity of a listed chemical. Registrants must review transactions involving the sale of regulated ephedrine drug products to individuals for personal use within the context of the established FDA guideline regarding the manner in which the products should be used and the appropriate dosing levels. In this regard, 375 dosage units of regulated ephedrine drug products within a calendar month for individual use provides a valid reference for registrants in determining whether additional efforts should be made to confirm the validity of a transaction.

Miscellaneous

29. Two comments were received questioning the use of the DEA Chemical Code Numbers set forth in Section 1310.02, rather than the familiar Chemical Abstract Services (CAS) or Harmonized Tariff System, (HTS) Numbers.

DEA has reviewed these numbering systems and determined that they were designed for other purposes and that their use could lead to confusion and jeopardize the accuracy of the information reported to DEA. In the HTS numbering system there are multiple chemicals that are assigned the same number and in the CAS numbering system that are chemicals that are assigned multiple codes. DEA has produced and made available a chemical reference guide that provides a cross reference to the CAS and HTS numbers, which will be updated to include the new Chemical Code Numbers.

With respect to the chemical codes, DEA discovered, following publication of the NPRM, that the Chemical Code Numbers assigned to Benzyl Chloride (8568) and Benzyl Cyanide (8570) were incorrect. The correct Chemical Code Number for Benzyl Chloride is 8570 and for Benzly Cyanide is 8735. These corrections have been made in this final order.

30. Three comments were submitted regarding the addition of new chemicals to List I or List II. The first comment questioned the addition of hydrochloric and sulfuric acid to List II without any justification. The second questioned the addition of benzaldehyde and nitroethane without specific justification of the addition or the thresholds. The third recommended that DEA continue to publish the proposed addition of any new chemicals for notice and comment and suggested that DEA hold public hearings on the proposed addition of new chemicals.

With respect to the hydrochloric and sulfuric acid, these chemicals were added to List II by final order published in the **Federal Register** on September 22, 1992 (57 FR 43615). The justification for the action was provided in the **Federal Register** notice regarding the addition of the two chemicals. With respect to nitroethane and benzaldehyde, Section 8 of the DCDCA amended Section 802(34) of the CSA to add the chemicals to List I; there addition to Section 1310.02 is simply a conforming amendment. Regarding the thresholds, benzaldehyde and nitroethane are diverted and used in clandestine laboratories for the illicit manufacture of controlled stimulants in a manner similar to other List I chemicals. These other chemicals, with the exception of ephedrine, have established threshold levels that were based on a review of data regarding the quantities distributed and used licitly, the quantities diverted and used illicitly, and the amount of each chemical necessary to synthesize a certain amount of controlled substance. DEA has reviewed the same type of data for benzaldehyde and nitroethane and found that the data supported the establishment of similar thresholds for the two chemicals. The specific thresholds of 4 kilograms for benzaldehyde and 2.5 kilograms for nitroethane were based on the licit and illicit uses of the two chemicals, and are consistent with the thresholds set for other List I chemicals used in the illicit production of controlled stimulants. Regarding the third comment, Section 1310.02 already clearly establishes that any proposed addition or deletion of chemicals from List I or List II must be published in the **Federal Register** with opportunity for public comment. It has been DEA's experience that the notice and comment procedure provides a satisfactory opportunity for affected persons to provide important information and advice regarding the proposed action. The comment period also satisfies the compelling need for quick response while providing DEA the option to extend the comment period, should the need for additional comment arise.

31. Two comments argued that DEA cannot regulate ''herb-containing dietary supplements and herbs containing Ephedra and its alkaloids'' on the grounds that the products are dietary or nutritional supplements and not drugs.

The CDTA and DCDCA define and establish controls over List I and List II chemicals. Under these acts, the only exceptions to the application of regulatory controls over products containing listed chemicals are for certain drug products that are lawfully marketed under the Food, Drug and Cosmetic Act (21 U.S.C. 802(39)(A)(iv)) and for chemical mixtures. Within this context, DEA has reviewed the issue of ephedra, e.g., the entire plant or the overground portion the ephedra plant and determined that the unprocessed plant material ephedra and products containing the unprocessed plant material ephedra are not subject to the regulatory provisions of the CDTA and DCDCA. However, preparations of the ephedra plant, such as extracts and concentrates, that contain ephedrine, do fall within the definition of *chemical mixture* (21 C.F.R. 1310.01(g)), thus, they are subject to the regulations as they apply to chemical mixtures. Chemical mixtures are currently exempt from the regulatory provisions of the CDTA and DCDCA, pending promulgation of regulations concerning the exemption of chemical mixtures.

32. One comment requested clarification of what constitutes ''unusual or excessive loss or disappearance of a listed chemical.''

This term applies to circumstances that appear to be outside the framework of normal business occurrences. Regulated persons and registrants understand the nature of their chemical activities and should be able to make informed decisions as to whether the above term applies to conditions they may encounter and to be able to explain their decision sufficiently to convince a ''reasonable person.''

33. One comment requested clarification of the term transshipments.

For purposes of DEA's regulations, a transshipment is an exportation of a listed chemical from one foreign country to another foreign country, which exportation transits the jurisdiction of the United States.

34. Two comments questioned the format of paragraphs (f)(1)(iv)(B) and (f)(1)(iv)(C) of Section 1310.01. The first noted that while the present format suggests independent subjects, the use

of ''and'' at the end of (B) implies that (C) is a subpart of (B). A second comment suggested that paragraph (f)(1)(iv)(B) should contain a reference to Section 1310.10, which sets the criteria for removal of the exemption.

DEA agrees. The two paragraphs have been redesignated as paragraphs (f)(1)(iv)(B)(*1*) and (f)(1)(iv)(B)(*2*) of Section 1310.01, and the appropriate citation to Section 1310.10 will be included. Further, in order to keep the language of the section consistent with the language of the DCDCA, the period at the end of Section 1310.01(f)(1)(iv)(A)(*4*) will be deleted and ''; or '' will be inserted in its place.

35. One comment requested clarification of the term ''imminent danger'' as used in the revocation provisions as uses in Section 1309.44.

The term ''imminent danger'', as used in Section 1309.44, refers to actions by a registrant that demonstrate a flagrant indifference to and disregard for the law and the health and safety of the public. There are no specific criteria for determining what constitutes ''imminent danger''. However, interested persons may wish to review the **Federal Register** for past notices of suspension of controlled substance registrations. In any action under this section related to the activities of a specific registrant, DEA will list the facts that are considered to present an imminent danger.

36. One comment requested clarification of Section 1310.01(f)(1)(ii), with specific emphasis on whether a common or contract carrier would be required to register with DEA for activities involving the delivery of a listed chemical either to or by the carrier.

Section 1310.01(f)(1)(ii) specifically excludes the delivery of a listed chemical by a common or contract carrier for carriage in the lawful and usual course of business from the definition of a regulated transaction. The common or contract carrier is not subject to the registration requirement when transporting chemicals on a registrant's behalf. The registrant remains responsible for the listed chemicals until they are delivered to and accepted by the consignee. In this regard, it is important that a registrant take reasonable measures to insure that any common or contract carrier used to ship listed chemicals to customers will provide adequate security against in-transit losses or thefts.

37. Two comments questioned the provisions in Sections 1310.11(b) and 1310.15(b), which establish recordkeeping and reporting requirements for regulated persons who manufacture exempted drug products, on the grounds that a person who manufactures an exempted drug product is not a regulated person.

The referenced sections as well as Section 1310.13(b), were written with respect to a regulated person who also manufactures an exempted drug product. Upon further consideration, DEA has determined that regulated persons should not be required, solely because of their status as a regulated person, to keep records and make reports of transactions that would otherwise be exempted from those requirements. Sections 1310.11(b), 1310.13(b) and 1310.15(b) have been removed.

38. One comment requested clarification of Section 1309.45 and raised questions regarding procedures to be followed if an application for registration renewal form (DEA Form 510a) is not received in a timely manner.

Section 1309.45 applies only to a registrant who is subject to action by the Administrator to revoke or suspend his or her registration. If the registrant submits a renewal application within the prescribed time period and the Administrator has not issued a final order suspending or revoking the registration, then the registration is deemed to continue in effect until the Administrator issues his final order. As to renewal in circumstances other than those set out in Section 1309.45, Section 1309.32(c) establishes the procedures. DEA will mail out renewal notices to registrants approximately 60 days prior to the date of expiration. If a registrant has not received their renewal notice within 45 days of their expiration date, then a written request for a replacement form must be provided to DEA. A properly completed renewal application and fee must be received by DEA prior to the registrant's expiration date if registration is to be continued without interruption. If a registration is allowed to expire, the registrant is no longer authorized to distribute, import or export a List I chemical. DEA will mail delinquency notices to expired registrants approximately 90 days after the expiration date.

39. One comment questioned the DEA's placing priority on the completion of pre-registration investigations of non-retail firms while DEA's **Federal Register** notice of March 17, 1994 (59 FR 12562, Elimination of Threshold for Ephedrine) focused on the diversion of ephedrine tablets at the retail level. The comment also questioned why DEA has proposed steps to lessen the impact on retail distributors and yet has not specifically proposed steps to lessen the impact on non-retail distributors.

By directing its focus at the non-retail level during the initial registration phase, DEA will identify those firms that have failed to adequately identify their customers or have been shipping to questionable retail firms. With this information, DEA can focus its initial retail investigations on the most likely sources of diversion. With respect to the second question, DEA has taken steps to limit the impact of the chemical controls on all persons. The exemption from the registration requirement in Section 1309.25 applies to any person, either retail or non-retail, registered with DEA to handle controlled substances, who also engages in activities with regulated ephedrine drug products. Further, DEA has attempted to design the chemical control requirements to be consistent with existing business practices, as noted in comment number 26 with respect to the recordkeeping requirements.

40. One comment objected to the exclusion of mail order activities from the definition of retail distribution.

As noted in the supplemental information to the NPRM, retail distributors engage in a limited activity as regulated by the DCDCA. The amounts of product distributed per transaction are generally small and sales are to individuals only. By contrast, it has been DEA's experience that mail order distributors of ephedrine drug products that are regulated deal with both individuals and businesses and the volume of sales and product can be quite large. Additionally, such firms are often less readily able to positively identify their customers. Investigations will be significantly more complex and time consuming for a mail order distributor than for a retail distributor. It is appropriate that mail order activities remain classified as distributors rather than retail distributors.

Protection of Confidential Business Information

41. Four comments expressed concern regarding the safeguarding of confidential business information (CBI) that will be collected by DEA in connection with chemical control activities. Two of the comments suggested that DEA establish specific and strong provisions regarding protection of CBI.

DEA operates national diversion control programs related to controlled substances and listed chemicals. The controlled substance program has been in effect since the early 1970's and the chemical program since the late 1980's.

In each program, DEA collects CBI in the course of investigations and required reporting. With respect to the chemical program, the release of CBI that is protected from disclosure under Exemption 4 of the Freedom of Information Act, 5 U.S.C. 552(b)(4) (FOIA), is governed by Section 830(c) of the CSA (21 U.S.C. 830(c)) and the Department of Justice procedures set forth in 28 CFR 16.7.

Section 830(c) provides that information collected under Section 830 that is protected from disclosure under Exemption 4 may only be released in circumstances related to the enforcement of controlled substance or chemical laws, customs laws, or for compliance with U.S. obligations under treaty or international agreements. The Department of Justice procedures establish that if a FOIA request is received for release of information that is protected under Exemption 4, the submitter of the protected information must be notified of such a request, given an opportunity to object to the disclosure and allowed to provide justification as to why the information should not be disclosed.

In addition to the statutory and regulatory requirements, DEA has established internal guidelines governing the handling of CBI, including provisions that the material be maintained in locked containers, that access to the information be on a need-to-know basis, and that any disclosure under Section 830 be made only pursuant to a non-disclosure agreement by the receiving party.

This regulation has been drafted and reviewed in accordance with Executive Order 12866, Section 1(b), Principals of Regulation. The DEA has determined that this rule is a significant regulatory action under Executive Order 12866, Section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1307

Drug traffic control.

21 CFR Part 1309

Administrative practice and procedure, Drug Traffic Control, Security measures, List I and List II chemicals.

21 CFR Part 1310

Drug Traffic Control, Reporting Requirements, List I and List II chemicals.

21 CFR Part 1313

Drug Traffic Control, Imports, Exports, Transshipment and in-transit shipments, List I and List II Chemicals.

21 CFR Part 1316

Administrative practice and procedure, Drug Traffic Control, Research, Seizures and forfeitures.

For the reasons set out above, 21 CFR Parts 1307, 1309, 1310, 1313 and 1316 are amended as follows:

PART 1307—[AMENDED]

1. The authority citation for part 1307 continues to read as follows:

Authority: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

2. Section 1307.03 is revised to read as follows:

§ 1307.03 Exceptions to regulations.

Any person may apply for an exception to the application of any provision of parts 1301–1313, or 1316 of this chapter by filing a written request stating the reasons for such exception. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, D.C. 20537. The Administrator may grant an exception in his discretion, but in no case shall he be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

1. 21 CFR Part 1309 is added to read as follows:

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

General Information

Sec.

Fees for Registration and Reregistration

Requirements for Registration

Application for Registration

Action on Applications for Registration: Revocation or Suspension of Registration

Hearings

Modification, Transfer and Termination of Registration

Security Requirements

Authority: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 958.

General Information

§ 1309.01 Scope of Part 1309.

Procedures governing the registration of manufacturers, distributors, importers and exporters of List I chemicals pursuant to Sections 102, 302, 303, 1007 and 1008 of the Act (21 U.S.C. 802, 822, 823, 957 and 958) are set forth generally by those sections and specifically by the sections of this part.

§ 1309.02 Definitions.

(a) The term *Act* means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term *hearing* means any hearing held pursuant to the part for the

granting, denial, revocation, or suspension of a registration pursuant to sections 303 and 304 of the Act (21 U.S.C. 823–824).

(c) The term *person* includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(d) The term *register* and *registration* refer only to registration required and permitted by sections 302 and 1007 of the Act (21 U.S.C. 822 and 957).

(f) The term *registrant* means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 and 958).

(g) The term *retail distributor* means a distributor whose List I chemical activities are restricted to the sale of drug products that are regulated as List I chemicals pursuant to Section 1310.01(f)(1)(iv), directly to walk-in customers for personal use.

(h) Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or in Sections 1310.01 and 1313.02 of this chapter.

§ 1309.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Drug Enforcement Administration, Chemical Operations Section, Office of Diversion Control, Washington, D.C. 20537.

Fees for Registration and Reregistration

§ 1309.11 Fee amounts.

(a) For each initial registration to manufacture for distribution, distribute, import, or export, the applicant shall pay a fee of $595 for a annual registration.

(b) For each reregistration to manufacture for distribution, distribute, import, or export, the registrant shall pay a fee of $477 for an annual registration.

(c) For each initial registration to conduct business as a retail distributor the applicant shall pay an application processing fee of $7 and an investigation fee of $248, for an annual registration.

(d) For each reregistration to conduct business as a retail distributor the registrant shall pay a fee of $116.

§ 1309.12 Time and method of payment; refund.

(a) For each application for registration or reregistration to manufacture for distribution, distribute, import, or export, the applicant shall pay the fee when the application for registration or reregistration is submitted for filing.

(b) For retail the distributor initial applications, the applicant shall pay the application processing fee when the application for registration is submitted for filing. The investigation fee shall be paid within 30 days DEA notifies the applicant that the preregistration investigation has been scheduled.

(c) For retail distributor reregistration applications, the registrant shall pay the fee when the application for reregistration is submitted for filing.

(d) Payments should be made in the form of a personal, certified, or cashier's check or money order made payable to ''Drug Enforcement Administration.'' Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. These application fees are not refundable.

Requirements for Registration

§ 1309.21 Persons required to register.

(a) Every person who distributes, imports, or exports any List I chemical, other than those List I chemicals contained in a product exempted under § 1310.01(f)(1)(iv), or who proposes to engage in the distribution, importation, or exportation of any List I chemical, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§ 1309.24 through 1309.27. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation distributing List I chemicals is not required to obtain a registration.)

(b) Every person who distributes or exports a List I chemical they have manufactured, other than a List I chemical contained in a product exempted under § 1310.01(f)(1)(iv), or proposes to distribute or export a List I chemical they have manufactured, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§ 1309.24 through 1309.27.

§ 1309.22 Separate registration for independent activities.

(a) The following groups of activities are deemed to be independent of each other:

(1) Retail distributing of List I chemicals;

(2) Non-Retail distributing of List I chemicals;

(3) Importing List I chemicals; and

(4) Exporting List I chemicals.

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, unless otherwise exempted by the Act or §§ 1309.24 through 1309.26, except that a person registered to import any List I chemical shall be authorized to distribute that List I chemical after importation, but no other chemical that the person is not registered to import.

§ 1309.23 Separate registration for separate locations.

(a) A separate registration is required for each principal place of business at one general physical location where List I chemicals are distributed, imported, or exported by a person.

(b) The following locations shall be deemed to be places not subject to the registration requirement:

(1) A warehouse where List I chemicals are stored by or on behalf of a registered person, unless such chemicals are distributed directly from such warehouse to locations other than the registered location from which the chemicals were originally delivered; and

(2) An office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals (other than chemicals for display purposes) nor serves as a distribution point for filling sales orders.

§ 1309.24 Exemption of agents and employees.

The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his or her business or employment.

§ 1309.25 Exemption of certain controlled substance registrants.

(a) The requirement of registration is waived for any person who distributes a product containing a List I chemical that is regulated pursuant to § 1310.01(f)(1)(iv), if that person is registered with the Administration to manufacture, distribute or dispense a controlled substance.

(b) The requirement of registration is waived for any person who imports or exports a product containing a List I chemical that is regulated pursuant to § 1310.01(f)(1)(iv), if that person is registered with the Administration to engage in the same activity with a controlled substance.

(c) The Administrator may, upon finding that continuation of the waiver would not be in the public interest, suspend or revoke a person's waiver

pursuant to the procedures set forth in §§ 1309.43 through 1309.46 and 1309.51 through 1309.57. In considering the revocation or suspension of a person's waiver, the Administrator shall also consider whether action to revoke or suspend the person's controlled substance registration pursuant to 21 U.S.C. 824 is warranted.

(d) Any person exempted from the registration requirement under this section shall comply with the security requirements set forth in Sections 1309.71–1309.73 and the recordkeeping and reporting requirements set forth under Parts 1310 and 1313 of this chapter.

§ 1309.26 Exemption of law enforcement officials.

(a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(1) Any officer or employee of the Administration, any officer of the U.S. Customs Service, any officer or employee of the United States Food and Drug Administration, any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to listed chemicals, controlled substances, drugs or customs, and is duly authorized to possess and distribute List I chemicals in the course of official duties; and

(2) Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to listed chemicals and controlled substances and is duly authorized to possess and distribute List I chemicals in the course of his official duties.

(b) Any official exempted by this section may, when acting in the course of official duties, possess any List I chemical and distribute any such chemical to any other official who is also exempted by this section and acting in the course of official duties.

§ 1309.27 Exemption of certain manufacturers.

The requirement of registration is waived for any manufacturer of a List I chemical, if that chemical is produced solely for internal consumption by the manufacturer and there is no subsequent distribution or exportation of the List I chemical.

Application for Registration

§ 1309.31 Time for application for registration; expiration date.

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is approved and a Certificate of Registration is issued by the Administrator to such person.

(b) Any person who is registered may apply to be reregistered not more than 60 days before the expiration date of his registration.

(c) At the time a person is first registered, that person shall be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last day of the month designated for that group. In assigning any of the above persons to a group, the Administration may select a group the expiration date of which is less than one year from the date such business activity was registered. If the person is assigned to a group which has an expiration date less than eleven months from the date of which the person is registered, the registration shall not expire until one year from that expiration date; in all other cases, the registration shall expire on the expiration date following the date on which the person is registered.

§ 1309.32 Application forms; contents; signature.

(a) Any person who is required to be registered pursuant to Section 1309.21 and is not so registered, shall apply on DEA Form 510.

(b) Any person who is registered pursuant to Section 1309.21, shall apply for reregistration on DEA Form 510a.

(c) DEA Form 510 may be obtained at any divisional office of the Administration or by writing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. DEA Form 510a will be mailed to each List I chemical registrant approximately 60 days before the expiration date of his or her registration; if any registered person does not receive such forms within 45 days before the expiration date of the registration, notice must be promptly given of such fact and DEA Form 510a must be requested by writing to the Registration Unit of the Administration at the foregoing address.

(d) Each application for registration shall include the Administration Chemical Code Number, as set forth in Section 1310.02 of this chapter, for each List I chemical to be distributed, imported, or exported.

(e) Registration shall not entitle a person to engage in any activity with any List I chemical not specified in his or her application.

(f) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(g) Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. An applicant may authorize one or more individuals, who would not otherwise be authorized to do so, to sign applications for the applicant by filing with the application or other document a power of attorney for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this paragraph and shall contain the signature of the individual being authorized to sign the application or other document. The power of attorney shall be valid until revoked by the applicant.

§ 1309.33 Filing of application; joint filings.

(a) All applications for registration shall be submitted for filing to the Registration Unit, Drug Enforcement Administration, Chemical Registration/ODC, Post Office Box 2427, Arlington, Virginia 22202–2427. The appropriate registration fee and any required attachments must accompany the application.

(b) Any person required to obtain more than one registration may submit all applications in one package. Each application must be complete and must not refer to any accompanying application for required information.

§ 1309.34 Acceptance for filing; defective applications.

(a) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Administrator may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within 10 days of receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time.

(b) Accepting an application for filing does not preclude any subsequent request for additional information

pursuant to Section 1309.35 and has no bearing on whether the application will be granted.

§ 1309.35 Additional information.

The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

§ 1309.36 Amendments to and withdrawals of applications.

(a) An application may be amended or withdrawn without permission of the Administration at any time before the date on which the applicant receives an order to show cause pursuant to § 1309.46. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, including a request that the applicant submit the required fee, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

Action on Applications for Registration: Revocation or Suspension of Registration

§ 1309.41 Administrative review generally.

The Administrator may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to subpart A of Part 1316 of this chapter. The Administrator shall review the application for registration and other information gathered by the Administrator regarding an applicant in order to determine whether the applicable standards of Section 303 of the Act (21 U.S.C. 823) have been met by the applicant.

§ 1309.42 Certificate of registration; denial of registration.

(a) The Administrator shall issue a Certificate of Registration (DEA Form 511) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of section 303 of the Act (21 U.S.C. 823). In the event that the issuance of registration or reregistration is not required, the Administrator shall deny the application. Before denying any application, the Administrator shall issue an order to show cause pursuant to Section 1309.46 and, if requested by the applicant, shall hold a hearing on the application pursuant to § 1309.51.

(b) The Certificate of Registration (DEA Form 511) shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the amount of fee paid, and the expiration date of the registration. The registrant shall maintain the certificate of registration at the registered location in a readily retrievable manner and shall permit inspection of the certificate by any official, agent or employee of the Administration or of any Federal, State, or local agency engaged in enforcement of laws relating to List I chemicals or controlled substances.

§ 1309.43 Suspension or revocation of registration.

(a) The Administrator may suspend any registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) for any period of time he determines.

(b) The Administrator may revoke any registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)).

(c) Before revoking or suspending any registration, the Administrator shall issue an order to show cause pursuant to Section 1309.46 and, if requested by the registrant, shall hold a hearing pursuant to Section 1309.51. Notwithstanding the requirements of this Section, however, the Administrator may suspend any registration pending a final order pursuant to § 1309.44.

(d) Upon service of the order of the Administrator suspending or revoking registration, the registrant shall immediately deliver his or her Certificate of Registration to the nearest office of the Administration.

§ 1309.44 Suspension of registration pending final order.

(a) The Administrator may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he finds that there is an imminent danger to the public health or safety. If the Administrator so suspends, he shall serve with the order to show cause pursuant to § 1309.46 an order of immediate suspension that shall contain a statement of his findings regarding the danger to public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly return his Certificate of Registration to the nearest office of the Administration.

(c) Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause pursuant to Section 1309.46, which request shall be granted by the Administrator, who shall fix a date for such hearing as early as reasonably possible.

§ 1309.45 Extension of registration pending final order.

In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

§ 1309.46 Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Administration regarding the applicant, the Administrator is unable to make the determinations required by the applicable provisions of section 303 of the Act (21 U.S.C. 823) to register the applicant, the Administrator shall serve upon the applicant an order to show cause why the application for registration should not be denied.

(b) If, upon information gathered by the Administration regarding any registrant, the Administrator determines that the registration of such registrant is subject to suspension or revocation pursuant to section 304 of the Act (21 U.S.C. 824), the Administrator shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon Receipt of an order to show cause, the applicant or registrant must, if he desires a hearing, file a request for a hearing pursuant to § 1309.54. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, pursuant to § 1309.51.

(e) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.

Hearings

§ 1309.51 Hearings generally.

(a) In any case where the Administrator shall hold a hearing on any registration or application therefore, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by sections 303 and 304 of the Act (21 U.S.C. 823–824), by §§ 1309.52 through 1309.57, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41 through 1316.67 of this chapter.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the United States.

§ 1309.52 Purpose of hearing.

If requested by a person entitled to a hearing, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

§ 1309.53 Waiver or modification of rules.

The Administrator or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

§ 1309.54 Request for hearing or appearance; waiver.

(a) Any person entitled to a hearing pursuant to §§ 1309.42 and 1309.43 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) Any person entitled to a hearing pursuant to §§ 1309.42 and 1309.43 may, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(c) If any person entitled to a hearing pursuant to §§ 1309.42 and 1309.43 fails to file a request for a hearing, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing, unless he shows good cause for such failure.

(d) If any person entitled to a hearing waives or is deemed to waive his or her opportunity for the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1309.57 without a hearing.

§ 1309.55 Burden of proof.

(a) At any hearing for the denial of a registration, the Administration shall have the burden of proving that the requirements for such registration pursuant to section 303 of the Act (21 U.S.C. 823) are not satisfied.

(b) At any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) are satisfied.

§ 1309.56 Time and place of hearing.

The hearing will commence at the place and time designated in the order to show cause or notice of hearing published in the **Federal Register** (unless expedited pursuant to Section 1309.44(c)) but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 1309.57 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall cause to be published in the **Federal Register** his final order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. This order shall specify the date on which it shall take effect, which date shall not be less than 30 days from the date of publication in the **Federal Register** unless the Administrator finds that the public interest in the matter necessitates an earlier effective date, in which case the Administrator shall specify in the order his findings as to the conditions which led him to conclude that an earlier effective date was required.

Modification, Transfer and Termination of Registration

§ 1309.61 Modification in registration.

Any registrant may apply to modify his or her registration to authorize the handling of additional List I chemicals or to change his or her name or address, by submitting a letter of request to the Drug Enforcement Administration, Chemical Registration/ODC, Post Office Box 2427, Arlington, Virginia 22202–2427. The letter shall contain the registrant's name, address, and registration number as printed on the certificate of registration, and the List I chemicals to be added to his registration or the new name or address and shall be signed in accordance with § 1309.32(g). No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration. If the modification in registration is approved, the Administrator shall issue a new certificate of registration (DEA Form 511) to the registrant, who shall maintain it with the old certificate of registration until expiration.

§ 1309.62 Termination of registration.

The registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues

business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Administrator promptly of such fact.

§ 1309.63 Transfer of registration.

No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administrator may specifically designate and then only pursuant to his written consent.

Security Requirements

§ 1309.71 General security requirements.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of List I chemicals. Specific attention shall be paid to storage of and controlling access to List I chemicals as follows:

(1) Chemicals shall be stored in containers sealed in such a manner as to indicate any attempts at tampering with the container. Where chemicals cannot be stored in sealed containers, access to the chemicals should be controlled through physical means or through human or electronic monitoring.

(2) In retail settings open to the public where drugs containing List I chemicals that are regulated pursuant to § 1310.01(f)(1)(iv) are distributed, such drugs will be stocked behind a counter where only employees have access.

(b) In evaluating the effectiveness of security controls and procedures, the Administrator shall consider the following factors:

(1) The type, form, and quantity of List I chemicals handled;

(2) The location of the premises and the relationship such location bears on the security needs;

(3) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(4) The availability of electronic detection and alarm systems;

(5) the extent of unsupervised public access to the facility;

(6) The adequacy of supervision over employees having access to List I chemicals;

(7) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel in areas where List I chemicals are processed or stored;

(8) The adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List I chemicals in its operations.

(c) Any registrant or applicant desiring to determine whether a proposed system of security controls and procedures is adequate may submit materials and plans regarding the proposed security controls and procedures either to the Special Agent in Charge in the region in which the security controls and procedures will be used, or to the Chemical Operations Section Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537.

§ 1309.72 Felony conviction; employer responsibilities.

(a) The registrant shall exercise caution in the consideration of employment of persons who will have access to listed chemicals, who have been convicted of a felony offense relating to controlled substances or listed chemicals, or who have, at any time, had an application for registration with the DEA denied, had a DEA registration revoked, or surrendered a DEA registration for cause. (For purposes of this subsection, the term ''for cause'' means a surrender in lieu of, or as a consequence of, any Federal or State administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances or listed chemicals.) The registrant should be aware of the circumstances regarding the action against the potential employee and the rehabilitative efforts following the action. The registrant shall assess the risks involved in employing such persons, including the potential for action against the registrant pursuant to § 1309.43, If such person is found to have diverted listed chemicals, and, in the event of employment, shall institute procedures to limit the potential for diversion of List I chemicals.

(b) It is the position of DEA that employees who possess, sell, use or divert listed chemicals or controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

§ 1309.73 Employee responsibility to report diversion.

Reports of listed chemical diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of chemical diversion will be considered in determining the feasibility of continuing to allow an employee to work in an area with access to chemicals. The employer shall inform all employees concerning this policy.

PART 1310—[AMENDED]

1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b).

2. Section 1310.01 is amended by revising paragraphs (b), (c), (d), (e), (f)(1) and (g), redesignating paragraph (k) as paragraph (m) and inserting new paragraphs (k) and (l) as follows:

§ 1310.01 Definitions.

* * * * *

(b) The term *listed chemical* means any List I chemical or List II chemical.

(c) The term *List I chemical* means a chemical specifically designated by the Administrator in § 1310.02(a) that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act and is important to the manufacture of a controlled substance.

(d) The term *List II chemical* means a chemical, other than a List I chemical, specifically designated by the Administrator in Section 1310.02(b) that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act.

(e) The term *regulated person* means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, tableting machine, or encapsulating machine.

(f) The term *regulated transaction* means:

(1) A distribution, receipt, sale, importation, or exportation of a listed chemical, or an international transaction involving shipment of a listed chemical, or if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount

for multiple transactions, of a listed chemical, except that such terms does not include:

(i) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with this part or parts 1309 and 1313 of this chapter;

(iii) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act;

(iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act unless—

(A) The drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient. For purposes of this paragraph, the term ''therapeutically insignificant quantities'' shall apply if the product formulation (i.e., the qualitative and quantitative composition of active ingredients within the product) is not listed in *American Pharmaceutical Association (Apha) Handbook of Nonprescription Drugs; Drug Facts and Comparisons* (published by Wolters Kluwer Company); or *USP DI* (published by authority of the United States Pharmacopeial Convention, Inc.); or the product is not listed in § 1310.15 as an exempt drug product. For drug products having formulations not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in § 1310.14, whether the active medicinal ingredients are present in quantities considered therapeutically significant for purposes of this paragraph; or

(B) The Administrator has determined pursuant to the criteria in § 1310.10 that:

(*1*) The drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(*2*) The quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Administrator;

(v) Any transaction in a chemical mixture listed in § 1310.13.

* * * * *

(g) The term *chemical mixture* means a combination of two or more chemical substances, at least one of which is not a listed chemical, except that such term does not include any combination of a listed chemical with another chemical that is present solely as an impurity or which has been created to evade the requirements of the act.

* * * * *

(k) The terms *broker* and *trader* mean any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by—

(1) negotiating contracts;

(2) serving as an agent or intermediary; or

(3) fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter, or by receiving any form of compensation for so doing.

(l) The term *international transaction* means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

* * * * *

3. Section 1310.02 is amended by revising the introductory text and paragraphs (a) and (b) to read as follows:

§ 1310.02 Substances Covered.

The following chemicals have been specifically designated by the Administrator of the Drug Enforcement Administration as the listed chemicals subject to the provisions of this part and parts 1309 and 1313 of this chapter. Each chemical has been assigned the DEA Chemical Code Number set forth opposite it.

(a) List I chemicals

(1) Anthranilic acid, its esters, and its salts 8530
(2) Benzyl cyanide 8735
(3) Ephedrine, its salts, optical isomers, and salts of optical isomers 8113
(4) Ergonovine and its salts 8675
(5) Ergotamine and its salts 8676
(6) N-Acetylanthranilic acid, its esters, and its salts 8522
(7) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers 8317
(8) Phenylacetic acid, its esters, and its salts 8791
(9) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers 1225
(10) Piperidine and its salts 2704
(11) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers 8112
(12) 3,4-Methylenedioxyphenyl-2-propanone 8502
(13) Methylamine and its salts 8520
(14) Ethylamine and its salts 8678
(15) Propionic anhydride 8328
(16) Insosafrole (Isosafrole) 8704
(17) Safrole 8323
(18) Piperonal 8750
(19) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine) 8115
(20) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers 8119
(21) Hydriotic acid (Hydriodic Acid) 6695
(22) Benzaldehyde 8256
(23) Nitroethane 6724

(b) List II Chemicals:

(1) Acetic anhydride 8519
(2) Acetone 6532
(3) Benzyl chloride 8570
(4) Ethyl ether 6584
(5) Potassium permanganate 6579
(6) 2-Butanone (or Methyl Ethyl Ketone or MEK) 6714
(7) Toluene 6594
(8) Hydrochloric acid 6545
(9) Sulfuric acid 6552
(10) Methyl Isobutyl Ketone (MIBK) 6715

* * * * *

4. Section 1310.04 is amended by revising paragraphs (a), (b), (f)(1) introductory, and (f)(2) introductory text and (iv), by removing paragraphs (f)(1)(xiv), (f)(1)(xx), and (f)(1)(xxii); redesignating paragraphs (f)(1)(xv) through (xix) as (f)(1)(xiv) through (xviii), paragraph (f)(1)(xxi) as (f)(1)(xix) and paragraph (f)(1)(xxiii) as (f)(1)(xx); and adding new paragraphs (f)(1)(xxi) and (xxii) to read as follows:

§ 1310.04 Maintenance of records.

(a) Every record required to be kept subject to Section 1310.03 for a List I chemical, a tableting machine, or an encapsulating machine shall be kept by the regulated person for four years after the date of the transaction.

(b) Every record required to be kept subject to Section 1310.03 for List II chemical shall be kept by the regulated

person for two years after the date of the transaction.

* * * * *

(f) * * *

(1) List I Chemicals:

Chemical	Threshold by base weight
(i) * * *.	
(xxii) Benzaldehyde	4 Kilograms.
(xxiii) Nitroethane	2.5 Kilograms.

(2) List II chemicals:

(i) * * *

(iv) Exports, transshipments and international transactions to Designated Countries set forth in § 1310.08(b)

* * * * *

5. Section 1310.06 is amended by revising paragraphs (a) introductory text, (a)(1), (c), and (d) to read as follows:

§ 1310.06 Content of records and reports.

(a) Each record required by § 1310.03 shall include the following:

(1) The name, address, and, if required, DEA registration number of each party to the regulated transaction.

* * * * *

(c) Each report required by Section 1310.05(a) shall include the information as specified by Section 1310.06(a) and, where obtainable, the registration number of the other party, if such party is registered. A report submitted pursuant to § 1310.05(a)(1) or (a)(4) must also include a description of the circumstances leading the regulated person to make the report, such as the reason that the method of payment was uncommon or the loss unusual. If the report is for a loss or disappearance under § 1310.05(a)(4), the circumstances of such loss must be provided (in-transit, theft from premises, etc.)

(d) A suggested format for the reports is provided below:

Supplier:

Registration Number _____
Name _____
Business Address _____
City _____
State _____
Zip _____
Business Phone _____

Purchaser:

Registration Number _____
Name _____
Business Address _____
City _____
State _____
Zip _____
Business Phone _____
Identification _____

Shipping Address (if different than purchaser Address):

Street _____
City _____
State _____
Zip _____
Date of Shipment _____
Name of Listed Chemical(s) _____
Quantity and Form of Packaging _____

Description of Machine:

Make _____
Model _____
Serial # _____
Method of Transfer _____

If Loss or Disappearance:

Date of Loss _____
Type of Loss _____
Description of Circumstances _____

Public reporting burden for this collection of information is estimated to average ten minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Drug Enforcement Administration, Records Management Section, Washington, D.C. 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117–0024, Washington, D.C. 20503.

* * * * *

6. Section 1310.07 is amended by revising paragraphs (a) and (b) to read as follows:

§ 1310.07 Proof of identity.

(a) Each regulated person who engages in a regulated transaction must identify the other party to the transaction. For domestic transaction, this shall be accomplished by having the other party present documents which would verify the identity, or registration status if a registrant, of the other party to the regulated person at the time the order is placed. For export transactions, this shall be accomplished by good faith inquiry through reasonably available research documents or publicly available information which would indicate the existence of the foreign customer. No proof of identity is required for foreign suppliers.

(b) The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, tableting machine or encapsulating machine. For domestic transactions, this may be accomplished by such methods as checking the telephone directory, the local credit bureau, the local Chamber of Commerce or the local Better Business Bureau, or, if the business entity is a registrant, by verification of the registration. For export transactions, a good faith inquiry to verify the existence and apparent validity of a foreign business entity may be accomplished by such methods as verifying the business telephone listing through international telephone information, the firm's listing in international or foreign national chemical directories or other commerce directories or trade publications, confirmation through foreign subsidiaries of the U.S. regulated person, verification through the country of destination's embassy Commercial Attache, or official documents provided by the purchaser which confirm the existence and apparent validity of the business entity.

* * * * *

7. Section 1310.08 is amended by revising paragraph (b) introductory text to read as follows:

§ 1310.08 Excluded transactions.

* * * * *

(b) Exports, transshipments, and international transactions of hydrochloric and sulfuric acids, except for exports, transshipments and international transactions to the following countries:

* * * * *

8. Sections 1310.10 and 1310.11 are added to read as follows:

§ 1310.10 Removal of the exemption of drugs distributed under the Food, Drug and Cosmetic Act.

(a) The Administrator may remove from exemption under 1310.01(f)(1)(iv) any drug or group of drugs that the Administrator finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance. In removing a drug or group of drugs from the exemption the Administrator shall consider:

(1) the scope, duration, and significance of the diversion;

(2) whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(3) whether the listed chemical can be readily recovered from the drug or group of drugs.

(b) Upon determining that a drug or group of drugs should be removed from the exemption under paragraph (a) of this section, the Administrator shall issue and publish in the **Federal Register** his proposal to remove the drug or group of drugs from the exemption, which shall include a reference to the legal authority under which the proposal is based. The Administrator shall permit any interested person to file written comments on or objections to

the proposal. After considering any comments or objections filed, the Administrator shall publish in the **Federal Register** his final order.

(c) The Administrator shall limit the removal of a drug or group of drugs from exemption under paragraph (a) of this section to the most identifiable type of the drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

(d) Any manufacturer seeking reinstatement of a particular drug product that has been removed from an exemption under paragraph (a) of this section, may apply to the Administrator for reinstatement of the exemption for that particular drug product on the grounds that the particular drug product is manufactured and distributed in a manner that prevents diversion. In determining whether the exemption should be reinstated the Administrator shall consider:

(1) the package sizes and manner of packaging of the drug product;

(2) the manner of distribution and advertising of the drug product;

(3) evidence of diversion of the drug product;

(4) any actions taken by the manufacturer to prevent diversion of the drug product; and

(5) such other factors as are relevant to and consistent with the public health and safety, including the factors described in paragraph (a) of this section as applied to the drug product.

(e) Within a reasonable period of time after receipt of the application for reinstatement of the exemption, the Administrator shall notify the applicant of his acceptance or non-acceptance of his application, and if not accepted, the reason therefor. If the application is accepted for filing, the Administrator shall issue and publish in the **Federal Register** his order on the reinstatement of the exemption for the particular drug product, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any such comments raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(f) Unless the Administrator has evidence that the drug product is being diverted, as determined by applying the factors set forth in paragraph (a) of this section, and the Administrator so notifies the applicant, transactions involving a specific drug product will not be considered regulated transactions during the following periods:

(1) while a bonafide application for reinstatement of exemption under paragraph (d) of this section for the specific drug product is pending resolution, provided that the application for reinstatement is filed not later than 60 days after the publication of the final order removing the exemption; and

(2) for a period of 60 days following the Administrator's denial of an application for reinstatement.

(g) An order published by the Administrator in the **Federal Register**, pursuant to paragraph (e) of this section, to reinstate an exemption may be modified or revoked with respect to a particular drug product upon a finding that:

(1) applying the factors set forth in paragraph (a) of this section to the particular drug product, the drug product is being diverted; or

(2) there is a significant change in the data that led to the issuance of the final rule.

§ 1310.11 Reinstatement of exemption for drug products distributed under the Food, Drug and Cosmetic Act.

(a) The Administrator has reinstated the exemption for the drug products listed in paragraph (e) of this section from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–823, 830, and 957–958), to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No reinstated exemption granted pursuant to 1310.10 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in exempt drug product compositions: Any change in the quantitative or qualitative composition, trade name or other designation of an exempt drug product listed in paragraph (d) requires a new application for reinstatement of the exemption.

(d) The following drug products, in the form and quantity listed in the application submitted (indicated as the ''date'') are designated as reinstated exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS

Supplier	Product name	Form	Date
[Reserved]	.....	.....	

9. Section 1310.14 and 1310.15. are added to read as follows:

§ 1310.14 Exemption of drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) Any manufacturer of a drug product containing ephedrine in combination with another active medicinal ingredient, the product formulation of which is not listed in the compendiums set forth in section 1310.01(f)(1)(iv)(A), may request that the Administrator exempt the product as one which contains ephedrine together with a therapeutically significant quantity of another active medicinal ingredient.

(b) An application for an exemption under this section shall contain the following information:

(1) The name and address of the applicant;

(2) The exact trade name of the drug product for which exemption is sought;

(3) The complete quantitative and qualitative composition of the drug product;

(4) A brief statement of the facts which the applicant believes justify the granting of an exemption under this section; and

(5) Certification by the applicant that the product may be lawfully marketed or distributed under the Food, Drug, and Cosmetic Act.

(6) The identification of any information on the application which is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information by government employees.

(c) The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application which he deems necessary for determining if the application should be granted.

(d) Within a reasonable period of time after the receipt of a completed application for an exemption under this section, the Administrator shall notify the applicant of acceptance or non-acceptance of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any of the information required in paragraph (b) of this section or requested pursuant to paragraph (c) of this section is lacking or not readily

understood. The applicant may, however, amend the application to meet the requirements of paragraphs (b) and (c) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the **Federal Register** an order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend the original order as deemed appropriate.

§ 1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) The drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient listed in paragraph (e) of this section have been exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–3, 830, and 957–8) to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No exemption granted pursuant to 1310.14 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in drug product compositions: Any change in the quantitative or qualitative composition of an exempt drug product listed in paragraph (d) requires a new application for exemption.

(d) In addition to the drug products listed in the compendium set forth in § 1310.01(f)(1)(iv)(A), the following drug products, in the form and quantity listed in the application submitted (indicated as the ''date'') are designated as exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS CONTAINING EPHEDRINE AND THERAPEUTICALLY SIGNIFICANT QUANTITIES OF ANOTHER ACTIVE MEDICINAL INGREDIENT

Supplier	Product name	Form	Date
[Reserved]	.....	.....	

PART 1313—[AMENDED]

1. The authority citation for part 1313 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b), 971.

2. Section 1313.02 is amended by revising paragraphs (c), (d) introductory text, (d)(1), (h) and (i); redesignating paragraph (m) as paragraph (o) and adding new paragraphs (m) and (n) to read as follows:

§ 1313.02 Definitions.

* * * * *

(c) The term *regulated person* means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(d) The term *regulated transaction* means:

(1) A distribution, receipt, sale, importation, exportation, or international transaction of a listed chemical, or if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple transactions, of a listed chemical, except that such term does not include:

(i) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with this part or parts 1309 and 1310 of this chapter;

(iii) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act;

(iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act unless)—

(A) The drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient (for purposes of this paragraph, the term ''therapeutically insignificant quantities'' shall apply if the product formulation (i.e., the qualitative and quantitative composition of active ingredients within the product) is not listed in *American Pharmaceutical Association (Apha) Handbook of Nonprescription Drugs*; *Drug Facts and Comparisons* (published by Wolters Kluwer Company); or *USP DI* (published by authority of the United States Pharmacopeial Convention, Inc.); or the product is not listed in Section 1310.15 as an exempt drug product. For drug products having formulations not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in Section 1310.14, whether the active medicinal ingredients are present in quantities considered therapeutically significant for purposes of this paragraph; or

(B) The Administrator has determined pursuant to the criteria in Section 1310.10 that:

(*1*) The drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(*2*) The quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Administrator;

(v) Any transaction in a chemical mixture listed in Section 1310.13.

* * * * *

(h) The term *regular importer* means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Administrator.

(i) The term *established record as an importer* means that the regulated

person has imported a listed chemical at least once within the past six months, or twice within the past twelve months from a foreign supplier. The term also means that the regulated person has provided the Administration with the following information in accordance with the waiver of the 15-day advance notice requirements of Section 1313.15:

(1) the name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and

(2) the frequency and number of transactions occurring during the preceding 12-month period.

* * * * *

(m) The terms *broker* and *trader* mean any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by—

(1) negotiating contracts;

(2) serving as an agent or intermediary; or

(3) fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter, or by receiving any form of compensation for so doing.

(n) The term *international transaction* means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

* * * * *

3. Section 1313.12 is amended by revising paragraph (c) and adding new paragraphs (d), (e) and (f) to read as follows:

§ 1313.12 Requirement of authorization to import.

* * * * *

(c) The 15-day advance notification requirement for listed chemical imports may be waived for:

(1) Any regulated person who has satisfied the requirements for reporting to the Administration as a regular importer of such listed chemicals; or

(2) A specific listed chemical, as set forth in paragraph (f) of this section, for which the Administrator determines that advance notification is not necessary for effective chemical diversion control.

(d) For imports where advance notification is waived pursuant to paragraph (c)(1) of this section, the DEA Form 486 must be received by the Drug Enforcement Administration, Chemical Operations Section, on or before the date of importation through use of the mailing address listed in § 1313.12(b) or through use of electronic facsimile media.

(e) For importations where advance notification is waived pursuant to paragraph (c)(2) of this section no DEA Form 486 is required, however, the regulated person shall submit quarterly reports to the Drug Enforcement Administration, Chemical Operations Section, P.O. Box 28346, Washington, DC 20038, by no later than the 15th day of the month following the end of each quarter. The report shall contain the following information regarding each individual importation:

(1) The name of the listed chemical;

(2) The quantity and date imported;

(3) The name and full business address of the supplier;

(4) The foreign port of embarkation; and

(5) The port of entry.

(f) The 15 day advance notification requirement set forth in paragraph (a) has been waived for imports of the following listed chemicals:

(1) [Reserved]

4. Section 1313.15 is revised to read as follows:

§ 1313.15 Waiver of 15-day advance notice for regular importers.

(a) Each regulated person seeking designation as a ''regular importer'' shall provide, by certified mail return receipt requested, to the Administration such information as is required under § 1313.02(i), documenting their status as a regular importer.

(b) Each regulated person making application under paragraph (a) of this section shall be considered a ''regular importer'' for purposes of waiving the 15-day advance notice, 30 days after receipt of the application by the Administration, as indicated on the return receipt, unless the regulated person is otherwise notified in writing by the Administration.

(c) The Administrator, may, at any time, disqualify a regulated person's status as a regular importer on the grounds that the chemical being imported may be diverted to the clandestine manufacture of a controlled substance.

(d) Unless the Administration notifies the chemical importer to the contrary, the qualification of a regular importer of any one of these three chemicals, acetone, 2-Butanone (MEK), or toluene, qualifies that importer as a regular importer of all three of these chemicals.

(e) All chemical importers shall be required to file a DEA Form 486 as required by Section 1313.12.

5. Section 1313.21 is amended by redesignating paragraph (d) as paragraph (g) by revising paragraph (c) and newly designated paragraph (g) and by adding new paragraphs (d), (e), and (f) to read as follows:

§ 1313.21 Requirement of authorization to export.

* * * * *

(c) The 15-day advance notification requirement for listed chemical exports may be waived for:

(1) any regulated person who has satisfied the requirements of Section 1313.24 for reporting to the Administration an established business relationship with a foreign customer as defined in § 1313.02(j).

(2) A specific listed chemical to a specified country, as set forth in paragraph (f) of this section, for which the Administrator determines that advance notification is not necessary for effective chemical diversion control.

(d) For exports where advance notification is waived pursuant to paragraph (c)(1) of this section, the DEA Form 486 must be received by the Drug Enforcement Administration, Chemical Operations Section, on or before the date of exportation through use of the mailing address listed in Section 1313.12(b) or through use of electronic facsimile media.

(e) For exportations where advance notification is waived pursuant to paragraph (c)(2) of this section, the regulated person shall file quarterly reports to the Drug Enforcement Administration, Chemical Operations Section, P.O. Box 28346, Washington, DC 20038, by no later than the 15th day of the month following the end of each quarter. The report shall contain the following information regarding each individual importation:

(1) The name of the listed chemical;

(2) The quantity and date exported;

(3) The name and full business address of the foreign customer;

(4) The port of embarkation; and

(5) The foreign port of entry.

(f) The 15 day advance notification requirement set forth in paragraph (a) of this section has been waived for exports of the following listed chemicals to the following countries:

Name of Chemical	Country
[Reserved]	

(g) No person shall export or cause to be exported any listed chemical, knowing or having reasonable cause to believe the export is in violation of the laws of the country to which the chemical is exported or the chemical will be used to manufacture a controlled substance in violation of the Act or the

laws of the country to which the chemical is exported. The Administration will publish a notice of foreign import restrictions for listed chemicals of which DEA has knowledge as provided in § 1313.25.

6. A new undesignated center heading is added preceding § 1313.31 to read as follows:

Transshipments, In-Transit Shipments and International Transactions Involving Listed Chemicals

7. Sections 1313.32, 1313.33, and 1313,34 are added to read as follows:

1313.32 Requirement of authorization for international transactions.
1313.33 Contents of an international transaction declaration.
1313.34 Distribution of the international transaction declaration.

§ 1312.32 Requirement of authorization for international transactions.

(a) A broker or trader shall notify the Administrator prior to an international transaction involving a listed chemical which meets or exceeds the threshold amount identified in Section 1310.04 of this chapter, in which the broker or trader participates. Notification must be made no later than 15 days before the transaction is to take place. In order to facilitate an international transaction involving listed chemicals and implement the purpose of the Act, regulated persons may wish to provide advance notification to the Administration as far in advance of the 15 days as possible.

(b) (1) A completed DEA Form 486 must be received at the following address not later than 15 days prior to the international transaction:

Drug Enforcement Administration, P.O. Box 28346, Washington, D.C. 20038

(2) A copy of the DEA Form 486 may be transmitted directly to the Drug Enforcement Administration, Chemical Operations Section, through electronic facsimile media not later than 15 days prior to the exportation.

(c) No person shall serve as a broker or trader for an international transaction involving a listed chemical knowing or having reasonable cause to believe that the transaction is in violation of the laws of the country to which the chemical is exported or the chemical will be used to manufacture a controlled substance in violation of the laws of the country to which the chemical is exported. The Administration will publish a notice of foreign import restrictions for listed chemicals of which DEA has knowledge as provided in Section 1313.25.

§ 1313.33 Contents of an international transaction declaration.

(a) An international transaction involving a chemical listed in § 1310.02 of this chapter which meets the threshold criteria established in § 1310.04 of this chapter may be arranged by a broker or trader if the chemical is needed for medical, commercial, scientific, or other legitimate uses.

(b) Any broker or trader who desires to arrange an international transaction involving a listed chemical which meets the criteria set forth in Section 1310.04 shall notify the Administration through the procedures outlined in Section 1313.32(b).

(c) The DEA Form 486 must be executed in triplicate and must include all the following information:

(1) The name, address, telephone number, telex number, and, where available, the facsimile number of the chemical exporter; the name, address, telephone number, telex number, and, where available, the facsimile number of the chemical importer;

(2) The name and description of each listed chemical as it appears on the label or container, the name of each listed chemical as it is designated in Section 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;

(3) The proposed export date, the port of exportation, and the port of importation; and

(4) The name, address, telephone, telex, and where available, the facsimile number, of the consignee in the country where the chemical shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

§ 1313.34 Distribution of the international transaction declaration.

The required three copies of the DEA Form 486 will be distributed as follows:

(a) Copies 1 and 3 shall be retained on file by the broker or trader as the official record of the international transaction. Declaration forms involving List I chemicals shall be retained for List II chemicals shall be retained for two years.

(b) Copy 2 is the Drug Enforcement Administration copy used to fulfill the notification requirements of Section 1313.32.

* * * * *

7. In the heading of part 1313, the undesignated center heading preceding section 1313.12, and the undesignated center heading preceding section 1313.21 remove the words ''Precursors and Essential Chemicals'' and add, in their place, the words ''Listed Chemicals'';

§ 1313.01 [Amended]

8. In Section 1313.01 remove the words ''precursors and essential chemicals'' and add, in their place, the words ''listed chemicals'';

§ 1313.14 [Amended]

9. In Section 1313.14 introductory text, and in Section 1313.23 introductory text, remove the words ''precursor and essential chemical'' and add, in their place, ''listed chemical''.

§ 1313.13 [Amended]

10. In Sections 1313.13(a) and 1313.22(a) DEA is removing the words ''precursor or essential chemical'' and adding, in their place, the words ''List I or List II chemical''.

§ 1313.14 [Amended]

11. In Sections 1313.14(a) and 1313.23(a) DEA is removing the words ''listed precursor chemical'' and ''listed essential chemical'' and adding, in their place, the words ''List I chemical'' and ''List II chemical'' respectively.

PART 1316—[AMENDED]

1. The authority citation for part 1316 is amended to read as follows:

Authority: 21 U.S.C. 822(f), 830(a), 871(b), 880, 958(f), 965.

2. Section 1316.02 is amended by revising paragraph (c)(2) to read as follows:

§ 1316.02 Definitions.

* * * * *

(c) * * *

(2) Places, including factors, warehouses, or other establishments and conveyances, where persons registered under the Act or exempted from registration under the Act, or regulated persons may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or where records relating to those activities are maintained.

* * * * *

3. Section 1316.03 is amended by revising paragraphs (b), (c), (d) and (e) to read as follows:

§ 1316.03 Authority to make inspections.

* * * * *

(b) Inspecting within reasonable limits and to a reasonable manner all pertinent equipment, finished and unfinished controlled substances, listed chemicals, and other substances or materials, containers, and labeling

found at the controlled premises relating to this Act;

(c) Making a physical inventory of all controlled substances and listed chemicals on-hand at the premises;

(d) Collecting samples of controlled substances or listed chemicals (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on DEA Form 84 to the owner, operator, or agent in charge of the premises);

(e) Checking of records and information on distribution of controlled substances or listed chemicals by the registrant or regulated person (i.e., has the distribution of controlled substances or listed chemicals increased markedly within the past year, and if so why);

* * * * *

4. Section 1316.09 is amended by revising paragraph (a)(3) to read as follows:

§ 1316.09 Application for administrative inspection warrant.

(a) * * *

(3) A statement relating to the nature and extent of the administrative inspection, including, where necessary, a request to seize specified items and/or to collect samples of finished or unfinished controlled substances or listed chemicals;

* * * * *

Dated: May 1, 1995.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 95–14978 Filed 6–21–95; 8:45 am]

BILLING CODE 4410–09–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–5225–1]

Determination of Attainment of Ozone Standard by Ashland, Kentucky, Northern Kentucky (Cincinnati Area), Charlotte, North Carolina, and Nashville, Tennessee, and Determination Regarding Applicability of Certain Reasonable Further Progress and Attainment Demonstration Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is determining, through direct final procedure, that the Ashland, Kentucky, Northern Kentucky, Charlotte-Gastonia, North Carolina, and Nashville, Tennessee ozone nonattainment areas have attained the National Ambient Air Quality Standard (NAAQS) for ozone. This determination is based upon three years of complete, quality assured ambient air monitoring data for the years 1992–94 that demonstrate that the ozone NAAQS has been attained in these areas. On the basis of this determination, EPA is also determining that certain reasonable further progress and attainment demonstration requirements, along with certain other related requirements, of Part D of Title 1 of the Clean Air Act are not applicable to the areas for so long as the areas continue to attain the ozone NAAQS. In the proposed rules section of this **Federal Register**, EPA is proposing these determinations and soliciting public comment on them. If adverse comments are received on this direct final rule, EPA will withdraw this final rule and address these comments in a final rule on the related proposed rule which is being published in the proposed rules section of this **Federal Register**.

DATES: This action will be effective August 7, 1995 unless notice is received by July 24, 1995 that any person wishes to submit adverse or critical comments. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: A copy of the air quality data and EPA's analysis are available for inspection at the following address:

Environmental Protection Agency, Region 4 Air Programs Branch, 345 Courtland Street, NE, Atlanta, Georgia 30365

Commonwealth of Kentucky, Division of Air Quality, Department for Environmental Protection, Natural Resources and Environmental Protection Cabinet, 803 Schenkel Lane, Frankfort, Kentucky 40601

State of North Carolina, Air Quality Section, Division of Environmental Management, North Carolina Department of Environment, Health, and Natural Resources, Raleigh, North Carolina 27626

Environmental Management Division, Mecklenburg County Department of Environmental Protection, 700 N. Tryon Street, Charlotte, North Carolina 28202–2236

State of Tennessee, Division of Air Pollution Control, Tennessee Department of Environment and Conservation, L & C Annex, 9th Floor, 401 Church Street, Nashville, Tennessee 37243–1531

Bureau of Environmental Health Services, Metropolitan Health Department, Nashville-Davidson County, 311–23rd Avenue, North, Nashville, Tennessee 37203

Written comments can be mailed to: Kay Prince, Regulatory Planning and Development Section, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4, Environmental Protection Agency, 345 Courtland Street, NE, Atlanta, Georgia 30365. The telephone number is 404/347–3555 extension 4221.

FOR FURTHER INFORMATION CONTACT: Kay Prince, Regulatory Planning and Development Section, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4, Environmental Protection Agency, 345 Courtland Street, NE, Atlanta, Georgia 30365. The telephone number is 404/347–3555 extension 4221.

SUPPLEMENTARY INFORMATION:

I. Background

Subpart 2 of Part D of Title I of the Clean Air Act (CAA) contains various air quality planning and state implementation plan (SIP) submission requirements for ozone nonattainment areas. EPA believes it is reasonable to interpret provisions regarding reasonable further progress (RFP) and attainment demonstrations, along with certain other related provisions, so as not to require SIP submissions if an ozone nonattainment area subject to those requirements is monitoring attainment of the ozone standard (i.e., attainment of the NAAQS demonstrated with three consecutive years of complete, quality assured air quality monitoring data). As described below, EPA has previously interpreted the general provisions of subpart 1 of part D of Title I (sections 171 and 172) so as not to require the submission of SIP revisions concerning RFP, attainment demonstrations, or contingency measures. As explained in a memorandum dated May 10, 1995, from John S. Seitz, Director, Office of Air Quality Planning and Standards to the Regional Air Division Directors, entitled Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard, EPA believes it is appropriate to interpret the more specific RFP, attainment demonstration and related provisions of subpart 2 in the same manner.

First, with respect to RFP, section 171(1) states that, for purposes of part D of Title I, RFP ''means such annual incremental reductions in emissions of the relevant air pollutant as are required by this part or may reasonably be required by the Administrator for the