Rules and Regulations

Federal Register
Vol. 75, No. 20
Monday, February 1, 2010

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1309

[Docket No. DEA–294F]

RIN 1117–AB09

Registration Requirements for Importers and Manufacturers of Prescription Drug Products Containing Ephedrine, Pseudoephedrine, or Phenylpropanolamine

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is amending its registration regulations to ensure that a registration is obtained for every location where ephedrine, pseudoephedrine, or phenylpropanolamine, or drug products containing one of these chemicals, are imported or manufactured. These amendments will make it possible to establish the system of quotas and assessment of annual needs for the importation and manufacture of these chemicals that Congress mandated in the Combat Methamphetamine Epidemic Act of 2005.

DATES: This rule is effective March 3, 2010.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; telephone: (202) 307–7297.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1316. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, and industrial purposes and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA as amended also requires DEA to regulate the manufacture, distribution, import, and export of chemicals that may be used to manufacture controlled substances illegally. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances (21 U.S.C. 802(34)). Those classified as List II chemicals may be used to manufacture controlled substances (21 U.S.C. 802(35)).

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 (Pub. L. 109–177). Much of CMEA is self-implementing; the provisions related to importation of ephedrine, pseudoephedrine, and phenylpropanolamine, import quotas, manufacturing quotas, and procurement quotas became effective on March 9, 2006.

CMEA Requirements and Impact on Registration

CMEA amended the CSA to include ephedrine, pseudoephedrine, and phenylpropanolamine in 21 U.S.C. 826 (Production quotas for controlled substances) and 21 U.S.C. 952(a) (Importation of controlled substances). Congress essentially imposed the same requirements for importation of ephedrine, pseudoephedrine, and phenylpropanolamine as are imposed on narcotic raw materials—crude opium, poppy straw, concentrate of poppy straw, and coca leaves. That is, imports of ephedrine, pseudoephedrine, and phenylpropanolamine are prohibited except for such amounts as the Attorney General (DEA by delegation) finds to be necessary to provide for medical, scientific, or other legitimate purposes. Congress also imposed the same requirements on the manufacture of ephedrine, pseudoephedrine, and phenylpropanolamine as are established for Schedule I and II controlled substances. That is, Congress mandated the establishment of a total need for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These requirements apply equally to products containing these three List I chemicals as they do to the List I chemicals themselves.

Until the passage of CMEA, chemical importers were required to notify DEA of imports of ephedrine, pseudoephedrine, and phenylpropanolamine before or at the time of importation under 21 U.S.C. 971. DEA had no authority to limit the importation or manufacture of ephedrine, pseudoephedrine, and phenylpropanolamine, except for the ability to suspend a proposed import under 21 U.S.C. 971(c) on the ground that it may be diverted to the clandestine manufacture of a controlled substance. Most of the ephedrine, pseudoephedrine, and phenylpropanolamine used in the United States is imported rather than manufactured domestically.

Ephedrine, pseudoephedrine, and phenylpropanolamine are used to produce drug products lawfully marketed under the Federal Food, Drug and Cosmetic Act (FFD&CA), many of which are prescription drugs. DEA has not subjected these prescription drug products to all List I chemical regulatory requirements because they are available only in response to a prescription and are stored in and dispensed at pharmacies. These chemicals are also used in over-the-counter (OTC) drug products (lawfully marketed and distributed under the FFD&CA as a non-

prescription drug). These products have been widely used in the illegal manufacture of methamphetamine and amphetamine. CMEA defined these OTC drug products as scheduled listed chemical products (21 U.S.C. 802(45)(A)). DEA has regulated the distribution, import, and export of scheduled listed chemical products.

There are firms manufacturing drug products lawfully marketed under the FFD&CA containing ephedrine, pseudoephedrine, or phenylpropanolamine that are not registered with DEA at all because those firms do not handle controlled substances and the only products those firms produce containing the three chemicals are prescription drugs. There are also firms that manufacture scheduled listed chemical products, but only distribute or dispense controlled substances. Because those firms are registered as controlled substance distributors or dispensers, those firms are not currently required to register as chemical manufacturers. Finally, there may be some firms that are not registered that import prescription drug products that contain the three chemicals.

Note: For a more detailed discussion of the history of the regulation of ephedrine, pseudoephedrine, and phenylpropanolamine see the preamble to the Notice of Proposed Rulemaking published on January 18, 2008 (73 FR 3432).

Because of the new CMEA mandates for importation, import quotas, and production quotas for ephedrine, pseudoephedrine, and phenylpropanolamine, DEA is revising its registration provisions. As discussed in the NPRM, the changes made by the CMEA render current DEA regulations inadequate for two reasons. First, although DEA registers bulk manufacturers of the three chemicals in the United States and importers of the bulk chemicals, some of those chemicals are distributed to non-registered companies that process them into prescription drugs. Under 21 U.S.C. 826, production quotas are available only to registered manufacturers. DEA cannot meet the CMEA mandate to establish an annual need and import quotas, and then issue individual quotas for each of the chemicals unless all persons manufacturing or procuring the chemicals and manufacturing drug products that contain the chemicals are registered as manufacturers, even if the distribution of the final drug products is not regulated. DEA also must know the quantity of prescription drug products containing the three chemicals being imported; without this information, DEA would not be able to determine an assessment of annual need for the chemicals. Any person importing prescription drug products containing any of the three chemicals must register although the distribution of these products would not be subject to DEA regulation.

The second inadequacy is that the existing language allows a controlled substance distributor or dispenser to avoid registration as a chemical manufacturer if that person manufactures scheduled listed chemical products or other products containing a List I chemical that is described and included in the definition of "regulated transaction" in 21 CFR 1300.02(b)(28)(i)(D). [DEA notes that there may be a limited number of drug products containing List I chemicals other than ephedrine, pseudoephedrine, and phenylpropanolamine which meet this description.] Therefore, this provision is being changed so that controlled substance registrants will not need to obtain a chemical registration only if they engage in the same activity for both drug products containing List I chemicals and controlled substances as is already the case for bulk manufacture, imports, and exports. In this way, any registrant that must obtain a quota to manufacture or procure one or more of the chemicals will be a registered manufacturer, as required by the CSA.

DEA recognizes that this change requires some manufacturers and locations to register that had not previously been subject to DEA regulations; other registrants are required to obtain separate registrations for chemicals and controlled substances. The new requirements, however, are both consistent with the statutory language on registration and the CMEA amendments and with the intent of the CMEA requirements to establish a system of quotas for the manufacture of these three chemicals and the products that contain them. Without these changes, DEA would not be able to meet the CMEA mandates. In addition, without these changes, companies that manufacture and import prescription drug products containing the three chemicals would not be able to purchase the chemicals legally nor would the assessment of annual needs reflect their requirements.

Explanation of DEA Categories of Registration and Effect of This Rule Regarding DEA Registration

The CSA defines the term "manufacture" to include the physical manufacture of a chemical or product, as well as the packaging, labeling, repackaging, and relabeling of that product (21 U.S.C. 802(15)). Thus, under the CSA, "manufacture" is defined to include all of the following:

- The manufacturing of a substance or chemical in bulk, either by extraction from raw materials, chemical synthesis, or a combination of extraction and chemical synthesis.
- The processing of the substance or chemical into products, such as drugs in dosage form.
- The packaging or repackaging of the processed substances or chemicals or labeling or relabeling of containers holding the chemicals.

After this final rule takes effect, persons who manufacture or import ephedrine, pseudoephedrine, or phenylpropanolamine, or who manufacture or import a product containing ephedrine, pseudoephedrine, or phenylpropanolamine, or who plan to engage in such activities, will be required to register with DEA if they are not already registered for the appropriate business activity. As required by the CSA, registration is location-specific; a person must obtain a registration for each principal place of business at one general physical location where controlled substances or List I chemicals are manufactured, distributed, imported, or exported. If a person manufactures controlled substances at one location and drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine at another location, the person will be required to obtain a separate registration for each location. Under the waiver previously described in this rulemaking (21 CFR 1309.24(b)), persons who are currently registered as controlled substances manufacturers at a location where drug products containing these List I chemicals are also manufactured will not be required to register separately to conduct the same activity, manufacturing, with these List I chemicals. A controlled substances registration for that one physical location will cover both the manufacturing of controlled substances and drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine, at that location. Those controlled substances manufacturers will, however, be required to identify to DEA the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine they handle as part of their next registration renewal. DEA notes that the manufacture of bulk List I chemicals requires a separate chemical registration; this is not a change from existing regulations.

However, if a person manufactures a drug product containing ephedrine,

pseudoephedrine, or phenylpropanolamine at a location, but is registered to conduct other (nonmanufacturing) activities with controlled substances at that location (e.g., distribution), the person will need to obtain a List I chemical manufacturing registration for the location. The following table indicates the changes in registration requirements for various business activities.

Previous	Final rule
Chemical Manufacturers (no Controlled Substances)	
All bulk manufacturers of List I chemicals must register unless all of the chemical produced is consumed internally and is not available for use in products.	No change.
Manufacturers of scheduled listed chemical products must register if they also distribute.	All manufacturers of drug products containing List I chemicals * must register.
Manufacturers of prescription products ** containing List I chemicals do not register	
Chemical Distributors	
Distributors of List I chemicals and scheduled listed chemical products must register.	No change.
Distributors of prescription products ** containing List I chemicals do not register	
Chemical Importers and Exporters	
Importers of List I chemicals and scheduled listed chemical products must register.	Importers of List I chemicals and all drug products containing List I chemicals * must register.
Importers of prescription products ** containing List I chemicals do not register if they import controlled substances	
Exporters of List I chemicals and scheduled listed chemical products must register.	No change.
Exporters of prescription products ** containing List I chemicals do not register	
Manufacturers and Distributors of Controlled Substances and Drug Products Containing List I Chemicals	
Manufacturers of both controlled substances and drug products containing List I chemicals may register as only controlled substance manufacturers.	No change.
Manufacturers of drug products containing any List I chemical * who distribute or dispense controlled substances may register for only their controlled substance activity. A separate registration for the chemical activity is permissible.	Manufacturers of controlled substances and drug products containing any List I chemical * must register as controlled substances manufacturers. If they manufacture drug products containing any List I chemical * and only distribute or dispense controlled substances at the same location, they must register separately for each activity.
Distributors of both controlled substances and drug products containing List I chemicals may register as only controlled substance distributors.	No change.
Importers/Exporters of Controlled Substances and Drug Products Containing List I Chemicals	
Importers of both controlled substances and drug products containing List I chemicals must register as controlled substance importers.	No change.
Exporters of both controlled substances and drug products containing List I chemicals must register as controlled substance exporters.	No change.
Manufacturers, Distributors, Importers, and Exporters of Bulk List I Chemicals	
Manufacturers, distributors, importers, and exporters of bulk List I chemicals must register, regardless of whether they handle controlled substances.	No change.

* "drug products containing List I chemicals" refers to scheduled listed chemical products or other products containing a List I chemical that is described and included in the definition of "regulated transaction" in 21 CFR 1300.02(b)(28)(i)(D). Such drug products must be in packaged/labeled form as required under the FFD&CA for lawful marketing.

** "Prescription products," for purposes of this table, refers to "any transaction in a List I 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 * * *" (21 U.S.C. 802(39)(A)(iv)). To comply with the marketing and distribution requirements of the FFD&CA for prescription drugs, such drugs must be packaged and labeled in accordance with the FFD&CA as prescription drugs.

Notice of Proposed Rulemaking

On January 18, 2008, DEA published a Notice of Proposed Rulemaking (NPRM) (73 FR 3432) proposing that persons who manufacture or import a prescription drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine be required to register with DEA, even if the distribution of the final drug product is not regulated. Further, the rule proposed clarification that controlled substance registrants need not obtain a separate chemical registration only if they engage in the same activity for both

drug products containing List I chemicals and controlled substances.

Discussion of Comments

DEA received three comments on the proposed rule. Commenters included two individuals and one DEA-registered manufacturer.

Support for proposed rule: One commenter strongly supported any amendments to the regulations necessary to help regulate the importation and manufacture of chemicals used in the illicit manufacture of methamphetamine.

DEA Response: DEA appreciates the support for this rulemaking. As noted previously, this regulation is necessary to fully implement the provisions of the CMEA related to quotas for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

Opposition to NPRM: Another commenter stated that the proposed rule was shortsighted and ill-equipped to meet the goal of the CMEA. The commenter believed that market demand, not a governmental agency, should determine how much ephedrine, pseudoephedrine, and phenylpropanolamine should be imported.

DEA Response: This regulation addresses neither the establishment of procedures for the implementation of quotas nor the quotas themselves. Rather, this rule revises DEA regulations to require certain persons to obtain a DEA registration so that they may apply for quota. As discussed previously, the CMEA amended the CSA to require production quotas for manufacturers handling the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. CMEA also authorized the Attorney General (DEA by delegation), to establish import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. The CSA requires that quotas be issued to registrants. Were DEA not to issue this rule, it would have no mechanism to permit the registration of persons handling prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine. If these persons were not permitted to register, there would be no mechanism by which they would be permitted to apply for import or production quotas. Therefore, these persons would have no means by which to acquire the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine necessary for them to conduct business.

Registration of analytical laboratories and researchers: The third commenter requested DEA clarification of the scope of the proposed revision to 21 CFR 1309.24(c). The commenter believed that DEA intended to include controlled substances analytical laboratories in the waiver for controlled substances importer registrants who are permitted to import drug products regulated pursuant to 21 U.S.C. 802(39)(A)(iv). The commenter indicated its support for an allowance to permit controlled substances analytical laboratory registrants to be able to import List I chemical product samples for testing purposes.

DEA Response: DEA believes that the commenter has misunderstood the waiver of the requirement of registration provided in 21 CFR 1309.24(c), as well as the authority granted to controlled substances researchers and persons permitted to conduct chemical analysis to import certain substances.

As proposed to be revised in the NPRM, 21 CFR 1309.24(c) states:

> The requirement of registration is waived for any person who imports or exports a scheduled listed chemical product or other product containing a List I chemical that is described and included in the definition of "regulated transaction" in § 1300.02(b)(28)(i)(D), if that person is registered with the Administration to engage in the same activity with a controlled substance.[1]

The definition of "regulated transaction" describes the following: "Any transaction in a listed chemical that is contained in a drug other than a scheduled listed chemical product that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act, * * *" (21 U.S.C. 802(39)(A)(iv), 21 CFR 1300.02(b)(28)(i)(D)).

A scheduled listed chemical product is defined as a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine that may be marketed or distributed lawfully in the United States under the FFD&CA as a nonprescription drug (21 U.S.C. 802(45)(A), 21 CFR 1300.02(b)(34)(i))).

As discussed previously, for a drug to be "marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act," such drug product must be in packaged/labeled form as required under the FFD&CA. Thus, regardless of whether the product being imported or exported is a scheduled listed chemical product or another drug product containing a List I chemical, for a person to use the waiver granted in 21 CFR 1309.24(c) to import a drug containing a List I chemical, that drug must be in a packaged/labeled form in compliance with the marketing and distribution requirements of the FFD&CA.

Thus, the waiver pertains only to those products which are fully formulated and packaged pursuant to the FFD&CA, not to the importation of bulk chemical, which would include any product not fully formulated, packaged, and labeled as required to meet the terms of the waiver, as well as any chemical in an unfinished form (*e.g.,* bulk powder, bulk liquid). DEA questions whether any person conducting research or chemical analysis involving a List I chemical or a product containing a List I chemical would choose to import a product meeting the marketing/distribution requirements of the FFD&CA. As has been discussed previously, if a person were to import a List I chemical, or a product containing a List I chemical, which did not meet the criteria for lawful distribution or marketing under the FFD&CA, then that person would be required to obtain a separate registration as a chemical importer to conduct the importation.

The commenter appears to believe that controlled substances research and chemical analysis registrants are permitted to import List I chemicals based on their controlled substance research or chemical analysis registration. For Schedule I researchers, the regulations provide the following regarding coincident activities: "A researcher may manufacture or import the basic class of substance or substances for which registration was issued, provided that such manufacture or import is set forth in the protocol required in § 1301.18 * * *" (21 CFR 1301.13(e)(1)(v)). That coincident activity clearly limits the importation authority only to those controlled substances set forth in the researcher protocol, and does not grant any authority related to importation of List I chemicals for any purpose, including research. Thus, a Schedule I researcher would be required to obtain a separate chemical importer registration to import any List I chemical for any purpose, regardless of whether that chemical was lawfully marketed or distributed under the FFD&CA.

For Schedule II–V researchers, the regulations provide the following regarding coincident activities: "May

[1] Prior to the proposed revision, 21 CFR 1309.24(c) stated: "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 § 1300.02(b)(28)(i)(D), if that person is registered with the Administration to engage in the same activity with a controlled substance." The revision DEA proposed sought merely to provide specificity regarding those products regulated pursuant to 21 CFR 1300.02(b)(28)(i)(D) and did not change the requirements regarding to whom the waiver of the requirement of registration applied.

conduct chemical analysis with controlled substances in those schedules for which registration was issued; * * * import such substances for research purposes; * * *" (21 CFR 1301.13(e)(1)(vi)). Again, the importation of the substances is based on the activity of research, not on the importation activity itself.

For persons conducting chemical analysis, the regulations provide the following regarding coincident activities:

> May manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to § 1301.24; may export such substances to persons in other countries performing chemical analysis or enforcing laws related to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances. (21 CFR 1301.13(e)(1)(x))

Again, the importation of the substances is based on the activity of chemical analysis, not on the importation activity itself.

Conversely, the language of 21 CFR 1309.24(c) contemplates that the person importing the product containing the List I chemical is "registered with the Administration to engage in the same activity [importation] with a controlled substance." The activity of a controlled substances researcher is not the same as the activity of a controlled substances importer. Nor is the activity of a controlled substances chemical analyst the same as the activity of a controlled substances importer. As discussed above, researchers have very limited authority to import controlled substances, based specifically on the research being conducted. Those conducting chemical analysis have similarly limited authority related solely to the analysis of controlled substances.

Based on the comment received, and to clarify that the waiver of the requirement of registration in 21 CFR 1309.24(c) is intended for importers and exporters of controlled substances, DEA is revising the language of 21 CFR 1309.24(c) to state that:

> The requirement of registration is waived for any person who imports or exports a scheduled listed chemical product or other product containing a List I chemical that is described and included in the definition of "regulated transaction" in § 1300.02(b)(28)(i)(D), if that person is registered with the Administration to import or export a controlled substance.

DEA notes that if a controlled substances researcher or registrant permitted to conduct chemical analysis receives the List I chemicals from another registrant, *e.g.,* a person registered to import, manufacture, or distribute List I chemicals, and if the researcher or chemical analyst does not further distribute the List I chemicals, that researcher or chemical analyst would be considered to be a List I chemical end-user and would not be required to be registered with DEA to receive the List I chemicals.

Requirements of This Final Rule

DEA is requiring that a person who manufactures or imports a prescription drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine must comply with the following:

Registration. Any person who manufactures or imports a drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine, or who proposes to engage in the manufacture or importation of a drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine, is required to obtain a registration under the CSA (21 U.S.C. 822 and 958). Regulations describing registration for List I chemical handlers are set forth in 21 CFR Part 1309.

A separate registration is required for manufacturing, distributing, importing, and exporting, except that a person registered to manufacture or import a List I chemical or a product containing ephedrine, pseudoephedrine, or phenylpropanolamine may distribute that List I chemical or drug product without obtaining a separate registration to do so. A separate registration is required for each principal place of business at one general physical location where the List I chemicals are manufactured, distributed, imported, or exported by a person (21 CFR 1309.23).

As a result of the change, any person manufacturing or importing a prescription drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine is subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons who are newly subject to the registration requirement to complete and submit an application for registration and for DEA to issue registrations for those activities immediately. Therefore, to allow continued legitimate commerce, DEA is establishing in 21 CFR 1309.25 a temporary exemption from the registration requirement for persons desiring to engage in manufacturing or importing prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine, provided that DEA receives a properly completed application for registration on or before March 3, 2010. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, will remain in effect. Additionally, the temporary exemption does not suspend applicable Federal criminal laws relating to these chemicals, nor does it supersede State or local laws or regulations. All manufacturers and importers of ephedrine, pseudoephedrine, or phenylpropanolamine, or any product containing any of these three List I chemicals, must comply with applicable State and local requirements in addition to the CSA regulatory controls.

DEA notes that warehouses are exempt from the requirement of registration and may lawfully possess List I chemicals, if the possession of those chemicals is in the usual course of business (21 U.S.C. 822(c)(2), 21 U.S.C. 957(b)(1)(B)). For purposes of this exemption, the warehouse must receive the List I chemical from a DEA registrant and shall only distribute the List I chemical back to the DEA registrant and registered location from which it was received. All other activities conducted by a warehouse do not fall under this exemption; a warehouse that distributes List I chemicals to persons other than the registrant and registered location from which they were obtained is conducting distribution activities and is required to register as such (21 CFR 1309.23(b)(1)).

Importation. All persons importing ephedrine, pseudoephedrine, or phenylpropanolamine, or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine are required to comply with all requirements regarding importation.

Records and Reports. The CSA (21 U.S.C. 830) requires certain records to be kept and reports to be made involving listed chemicals. Regulations describing recordkeeping and reporting requirements are set forth in 21 CFR Part 1310. A record must be made and maintained for two years after the date of a regulated transaction involving a List I chemical. Each regulated bulk manufacturer of a regulated mixture must submit manufacturing, inventory, and use data on an annual basis (21 CFR 1310.05(d)). Bulk manufacturers producing the chemicals solely for internal consumption are not required to submit this information; internal consumption does not include using the

chemical to produce drug products. Existing standard industry reports containing the required information are acceptable, provided the information is readily retrievable from the report.

Under 21 CFR 1310.05, regulated persons are required to report to DEA any regulated transaction involving an extraordinary quantity, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the CSA. Regulated persons are also required to report to DEA any proposed regulated transaction with a person whose description or other identifying information has been furnished to the regulated person. Finally, regulated persons are required to report any unusual or excessive loss or disappearance of a listed chemical.

Security. All applicants and registrants must provide effective controls against theft and diversion of chemicals as described in 21 CFR 1309.71.

Administrative Inspection. Places, including factories, warehouses, or other establishments and conveyances, where regulated persons may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of ephedrine, pseudoephedrine, or phenylpropanolamine, or products containing ephedrine, pseudoephedrine, or phenylpropanolamine, or where records relating to those activities are maintained, are controlled premises as defined in 21 CFR 1316.02(c). The CSA (21 U.S.C. 880) allows for administrative inspections of these controlled premises as provided in 21 CFR Part 1316, Subpart A.

Section by Section Description of Final Rule Changes

DEA is revising the authority citation for 21 CFR part 1309 to add 21 U.S.C. 802, definitions, and 21 U.S.C. 952, importation of controlled substances, to the authority for that part.

DEA is amending 21 CFR 1309.11 and 1309.12 to replace "manufacture for distribution" with "manufacture." In addition, in both sections, DEA is removing references to retail distributors. In amendments to 21 U.S.C. 823(h) the CMEA expressly stated that distributors of scheduled listed chemical products at retail are not required to register under the CSA. To avoid confusion, DEA decided to address all registration revisions related to CMEA implementation in this rulemaking.

Section 1309.21 is revised to state that every person who manufactures or proposes to manufacture a List I chemical or a drug product containing a List I chemical must register. The change requires manufacturers of prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine to register even though they are not required to register to distribute or export the products. DEA is also adding a table to the section, similar to the table in 21 CFR 1301.13 on controlled substance registration requirements, to summarize the requirements for each business activity. As discussed above, this revision does not alter the registration requirements for bulk manufacturers of List I chemicals and for manufacturers of scheduled listed chemical products.

Section 1309.22 is revised to remove retail distributing as a registration activity and to add manufacturing. As explained above, CMEA explicitly states that retail distributors of scheduled listed chemical products are not required to register. DEA is also adding a new paragraph to state that a person registered to manufacture a List I chemical is authorized to distribute that chemical under the manufacturing registration. The registrant may not distribute, under a manufacturer's registration, any List I chemical that is not covered in the manufacturing registration. This limitation parallels the existing limitation for importers.

In 21 CFR 1309.24, paragraph (b) is revised to clarify that a person who manufactures or distributes a scheduled listed chemical product or other product containing a List I chemical that is described and included in the definition of "regulated transaction" in 21 CFR 1300.02(b)(28)(i)(D) is exempted from registration only if registered to conduct the same activity with controlled substances. Paragraph (c) is revised to clarify that a person who imports or exports a scheduled listed chemical product or other product containing a List I chemical that is described and included in the definition of "regulated transaction" in 21 CFR 1300.02(b)(28)(i)(D) is exempted from registration only if registered to conduct the same activity with controlled substances. Paragraph (e) waiving registration for retail distributors is removed because CMEA statutorily does not require them to register. The remaining paragraphs (f) through (l) are redesignated as (e) through (k). DEA notes that the waiver of the requirement of registration continues for bulk manufacturers who manufacture and consume all of the List I chemical internally.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the provisions of the Regulatory Flexibility Act (5 U.S.C. 601–612). CMEA amended the CSA to require production quotas for manufacturers handling the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. CMEA also authorized the Attorney General, DEA by delegation, to establish import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. The CSA requires that quotas be issued to registrants. Were DEA not to issue this rule, it would have no mechanism to permit the registration of persons handling prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine. If these persons were not permitted to register, there would be no mechanism by which they would be permitted to apply for production or import quotas. Therefore, these persons would have no means by which to acquire the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine necessary for them to conduct business.

This rule codifies provisions necessary for implementation of the Combat Methamphetamine Epidemic Act. As discussed further below, DEA has examined the potential impacts of this rule. DEA has no basis for estimating the number of firms that may be small, but given the definition of small entities, it is likely that a substantial number of the new registrants will be small. The cost of compliance, however, will not impose a significant economic burden. The only cost is the $2,293 registration fee for manufacturers, and the $1,147 registration fee for importers, respectively. The recordkeeping and reporting requirements can be met using existing business and manufacturing records. The security provisions are general and require the registrant to provide effective controls and procedures to guard against theft and diversion of List I chemicals. Any manufacturer approved by the FDA and complying with good manufacturing practices or currently registered to handle controlled substances will have internal controls that meet this requirement. The smallest pharmaceutical firms (with 1 to 4 employees) had an average value of shipments of $824,000 in 2002 ($886,000 in 2007 dollars, based on GDP). Even for these firms, which are unlikely to be producing the covered drug products, the $2,293 registration

fee will represent less than 0.3 percent of sales and, therefore, is not a significant burden. Therefore, this rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 § 1(b). It has been determined that this is "a significant regulatory action." Therefore, this action has been reviewed by the Office of Management and Budget. As discussed above, this action is necessary to implement statutory provisions. DEA has, nonetheless, reviewed the potential costs.

DEA has a limited basis for determining the number of manufacturers of prescription drug products that will need to obtain a DEA registration for the first time. DEA reviewed a list of pseudoephedrine products and ephedrine prescription drug products and identified 230 firms based on their labeler codes. Of all firms identified, 164 do not appear to be registered with DEA as manufacturers and 95 are not registered as either manufacturers or controlled substance distributors. The firms currently registered to manufacture controlled substances may not manufacture List I chemical drugs at the same locations. Seventy firms are currently registered as controlled substance distributors. There may be some firms that import prescription drug products that are not now registered to import either controlled substances or List I chemicals. DEA estimates that approximately 200 firms may have to obtain a new DEA registration. As noted above, the only cost imposed by the rule is the registration fee of $2,293 for the registration of each manufacturing location, and $1,147 for each importing location. The total cost of these rule changes will be less than $500,000. The cost to individual firms is relatively small, compared with their revenues. The benefit of the rule is that it will make it possible for DEA to meet the statutory mandate to assess the annual need for the chemicals accurately and provide manufacturers with the quotas they need to continue to produce drug products containing the three chemicals. As DEA noted previously, the CSA provides that quotas may only be issued to registrants. Were DEA not to issue this rule, it would have no mechanism to permit the registration of persons handling prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine. If these persons were not permitted to register, there would be no mechanism by which they would be permitted to apply for production or import quotas. Therefore, these persons would have no means by which to acquire the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine necessary for them to conduct business.

Paperwork Reduction Act

This Final Rule requires that certain persons who were not previously registered with DEA obtain a registration to handle the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Specifically, persons manufacturing prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine were not previously required to register, but now are required to obtain a registration so that they may be eligible to apply for individual quotas for these List I chemicals. Additionally, importers of prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine who were not previously registered as List I chemical importers now are required to register so that they may be eligible to apply for import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. DEA estimates that approximately 200 firms will have to obtain a new DEA registration. DEA assumes that these firms will complete the registration application electronically, with each application taking 15 minutes to complete. The receipt of these additional applications increases the hour burden by 50 hours annually. Therefore, DEA is revising an existing approved information collection, "Application for Registration under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration Under Domestic Chemical Diversion Control Act of 1993" (OMB # 1117–0031), to reflect the increase in population associated with this rule.

Further, DEA is amending the forms associated with the existing approved information collection "Application for Registration (DEA Form 225) and Application for Registration Renewal (DEA Form 225a)" (OMB # 1117–0012) to include a listing of all List I chemicals on the application forms. Currently, controlled substances registrant applicants, who use these forms to apply for DEA registration, are not required to identify the List I chemicals they handle. Without this identification, it is not possible for these persons to apply for individual quotas for these chemicals. The addition of the List I chemicals will allow persons to identify which chemicals they handle. New applicants are required to identify the List I chemicals they handle upon their initial application; persons renewing their registration will identify the chemicals at the time of their renewal. This information must merely be verified for each succeeding renewal. Thus, the addition of this list will not have a measurable effect on the time needed to complete the application. Therefore, DEA is not revising the collection itself, but rather is making changes only to the application forms themselves.

The Department of Justice, Drug Enforcement Administration, submitted an information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with review procedures of the Paperwork Reduction Act of 1995. The proposed information collection was published in the NPRM to obtain comments from the public and affected agencies. No comments were received.

Overview of Information Collection 1117–0031

(1) *Type of information collection:* Revision of an existing collection.

(2) *Title of form/collection:* Application for Registration under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration Under Domestic Chemical Diversion Control Act of 1993.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:*

Form Number: DEA Forms 510 and 510a.

Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: business or other for-profit.

Other: Not-for-profit, government agencies.

Abstract: The Domestic Chemical Diversion Control Act requires that manufacturers, distributors, importers, and exporters of List I chemicals which may be diverted in the United States for the production of illicit drugs must register with DEA. Registration provides a system to aid in the tracking of the distribution of List I chemicals.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* DEA estimates that 1,805 persons respond to this collection annually. DEA estimates that it takes 30

minutes for an average respondent to respond when completing the application on paper, and 15 minutes for an average respondent to respond when completing an application electronically. This application is submitted annually.

(6) *An estimate of the total public burden (in hours) associated with the collection:* DEA estimates that this collection has a public burden of 612 hours annually.

	Respondents	Burden (hours)	Total hour burden
DEA–510 (paper)	60	0.5	30
DEA–510 (electronic)	325	0.25	81.25
DEA–510a (paper)	580	0.5	290
DEA–510a (electronic)	840	0.25	210
Total	1,805		611.25

Executive Order 12988

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

Executive Order 13132

This rulemaking does not impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1309

Administrative practice and procedure; Drug traffic control; Exports; Imports; Security measures.

■ For the reasons set out above, 21 CFR part 1309 is amended as follows:

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

■ 1. The authority citation for part 1309 is revised to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 952, 958.

■ 2. Section 1309.11 is revised to read as follows:

§ 1309.11 Fee amounts.

(a) For each application for registration or reregistration to manufacture the applicant shall pay an annual fee of $2,293.

(b) For each application for registration or reregistration to distribute, import, or export a List I chemical, the applicant shall pay an annual fee of $1,147.

■ 3. Section 1309.12 is revised to read as follows:

§ 1309.12 Time and method of payment; refund.

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

(b) Payments should be made in the form of a credit card; a personal, certified, or cashier's check; or a 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.

■ 4. Section 1309.21 is revised to read as follows:

§ 1309.21 Persons required to register.

(a) Unless exempted by law or under §§ 1309.24 through 1309.26 or §§ 1310.12 through 1310.13 of this chapter, the following persons must annually obtain a registration specific to the List I chemicals to be handled:

(1) Every person who manufactures or imports or proposes to manufacture or import a List I chemical or a drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine.

(2) Every person who distributes or exports or proposes to distribute or export any List I chemical, other than those List I chemicals contained in a product exempted under § 1300.02(b)(28)(i)(D) of this chapter.

(b) Only persons actually engaged in the activities are required to obtain a registration; related or affiliated persons who are not engaged in the 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.)

(c) The registration requirements are summarized in the following table:

SUMMARY OF REGISTRATION REQUIREMENTS AND LIMITATIONS

Business activity	Chemicals	DEA forms	Application fee	Registration period (years)	Coincident activities allowed
Manufacturing ...	List I, Drug products containing ephedrine, pseudoephedrine, phenylpropanolamine.	New—510 ..... Renewal—510a	$2,293 2,293	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.

SUMMARY OF REGISTRATION REQUIREMENTS AND LIMITATIONS—Continued

Business activity	Chemicals	DEA forms	Application fee	Registration period (years)	Coincident activities allowed
Distributing	List I, Scheduled listed chemical products.	New—510	1,147	1	
		Renewal—510a	1,147		
Importing	List I, Drug Products containing ephedrine, pseudoephedrine, phenylpropanolamine.	New—510	1,147	1	May distribute that chemical for which registration was issued; may not distribute any chemical for which not registered.
		Renewal—510a	1,147		
Exporting	List I, Scheduled listed chemical products.	New—510	1,147	1	
		Renewal—510a	1,147		

■ 5. Section 1309.22 is revised to read as follows:

§ 1309.22 Separate registration for independent activities.

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

(1) Manufacturing of List I chemicals or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine.

(2) Distributing of List I chemicals and scheduled listed chemical products.

(3) Importing List I chemicals or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine.

(4) Exporting List I chemicals and scheduled listed chemical products.

(b) Except as provided in paragraphs (c) and (d) of this section, every person who engages in more than one group of independent activities must obtain a separate registration for each group of activities, unless otherwise exempted by the Act or §§ 1309.24 through 1309.26.

(c) 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.

(d) A person registered to manufacture any List I chemical shall be authorized to distribute that List I chemical after manufacture, but no other chemical that the person is not registered to manufacture.

■ 6. In § 1309.23, paragraph (a) is revised to read as follows:

§ 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 manufactured, distributed, imported, or exported by a person.

* * * * *

■ 7. Section 1309.24 is revised to read as follows:

§ 1309.24 Waiver of registration requirement for certain activities.

(a) 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 the agent or employee is acting in the usual course of his or her business or employment.

(b) The requirement of registration is waived for any person who manufactures or distributes a scheduled listed chemical product or other product containing a List I chemical that is described and included in the definition of "regulated transaction" in § 1300.02(b)(28)(i)(D) of this chapter, if that person is registered with the Administration to engage in the same activity with a controlled substance.

(c) The requirement of registration is waived for any person who imports or exports a scheduled listed chemical product or other product containing a List I chemical that is described and included in the definition of "regulated transaction" in § 1300.02(b)(28)(i)(D) of this chapter, if that person is registered with the Administration to engage in the same activity with a controlled substance.

(d) The requirement of registration is waived for any person who only distributes a prescription drug product containing a List I chemical that is regulated pursuant to § 1300.02(b)(28)(i)(D) of this chapter.

(e) The requirement of registration is waived for any person whose activities with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or hypophosphorous acid (and its salts) to another location operated by the same firm solely for internal end-use, or an EPA or State licensed waste treatment or disposal firm for the purpose of waste disposal.

(f) The requirement of registration is waived for any person whose distribution of red phosphorus or white phosphorus is limited solely to residual quantities of chemical returned to the producer, in reusable rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2,500 gallons in a single container).

(g) The requirement of registration is waived for any person whose activities with respect to List I chemicals are limited solely to the distribution of Lugol's Solution (consisting of 5 percent iodine and 10 percent potassium iodide in an aqueous solution) in original manufacturer's packaging of one fluid ounce (30 ml) or less.

(h) 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.

(i) If any person exempted under paragraph (b), (c), (d), (e), or (f) of this section also engages in the distribution, importation, or exportation of a List I chemical, other than as described in such paragraph, the person shall obtain a registration for the activities, as required by § 1309.21.

(j) The Administrator may, upon finding that continuation of the waiver would not be in the public interest, suspend or revoke a waiver granted under paragraph (b), (c), (d), (e), or (f) of this section pursuant to the procedures set forth in §§ 1309.43 through 1309.46 and §§ 1309.51 through 1309.55. In considering the revocation or suspension of a person's waiver granted pursuant to paragraph (b) or (c) of this section, the Administrator shall also consider whether action to revoke or suspend the person's controlled substance registration pursuant to section 304 of the Act (21 U.S.C. 824) is warranted.

(k) Any person exempted from the registration requirement under this section must comply with the security requirements set forth in §§ 1309.71 through 1309.73 and the recordkeeping and reporting requirements set forth under Parts 1310, 1313, 1314, and 1315 of this chapter.

■ 8. Section 1309.25 is amended by adding a new paragraph (c) to read as follows:

§ 1309.25 Temporary exemption from registration for chemical registration applicants.

* * * * *

(c) Each person required by sections 302 or 1007 of the Act (21 U.S.C. 822 or 957) to obtain a registration to manufacture or import prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before March 3, 2010. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied the application. This exemption applies only to registration; all other chemical control requirements set forth in this part and parts 1310, 1313, and 1315 of this chapter remain in full force and effect.

Dated: January 22, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 2010–1968 Filed 1–29–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

28 CFR Part 0

[Docket No. DEA–315F]

Redelegation of Functions; Delegation of Authority to Drug Enforcement Administration Official

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: Under delegated authority, the Administrator of the Drug Enforcement Administration (DEA), Department of Justice, is amending the appendix to the Justice Department regulations to redelegate certain functions and authority which were vested in the Attorney General by the Controlled Substances Act and subsequently delegated to the Administrator of DEA.

DATES: *Effective Dates:* This Final Rule is effective February 1, 2010.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1399. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial purposes and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA, as amended, also requires DEA to regulate the manufacture and distribution of chemicals that may be used to manufacture controlled substances illegally. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances.

Retail Sales Provisions of the Combat Methamphetamine Epidemic Act of 2005

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 (Pub. L. 109–177). Among other things, the CMEA amended the CSA to change the regulations for selling nonprescription products that contain ephedrine, pseudoephedrine, and phenylpropanolamine, their salts, optical isomers, and salts of optical isomers. CMEA created a new category of products called scheduled listed chemical products. A scheduled listed chemical product is defined as a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug (21 U.S.C. 802(45)(A), 21 CFR 1300.02(b)(34)(i))).

CMEA established provisions regarding the retail sale of these scheduled listed chemical products by regulated sellers (i.e., retail distributors including mobile retail vendors) and distributors required to submit reports under 21 U.S.C. 830(b)(3) (*i.e.,* mail order distributors). These requirements, which were promulgated in 21 CFR, part 1314, include, but are not limited to:

- Packaging requirements for nonliquid forms of scheduled listed chemical products (*i.e.,* blister packs, with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches) (21 CFR 1314.05).
- Daily sales limits (21 CFR 1314.20).
- Product placement (i.e., placing the product so that customers do not have direct access before the sale is made, referred to as "behind the counter" placement, including circumstances in which the product is stored in a locked cabinet located in an area of the facility where customers do have direct access) (21 CFR 1314.25(b)).
- Recordkeeping (*i.e.,* logbook provisions) (21 CFR 1314.30).
- Employee training (21 CFR 1314.35).
- Self-certification (21 CFR 1314.40).

Redelegation of Authority

The Attorney General has delegated his functions under the CSA to the Administrator of the Drug Enforcement Administration (21 U.S.C. 871(a) and 28 CFR 0.100(b)). The Attorney General has also authorized the Administrator to redelegate any of his functions under the CSA to any subordinates (28 CFR 0.104). To further enhance the administration of the CSA and its regulations, the Administrator is redelegating to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, and the authority to exercise all necessary functions with respect to the promulgation and implementation of regulations in 21 CFR, part 1314. This redelegation will empower the Deputy Assistant Administrator, among other things, to exercise signing authority for any rules, regulations, or procedures which he may deem necessary for the efficient execution of the retail sales provisions contained in part 1314. Final orders in connection with the suspension or revocation of a regulated seller's or mail order distributor's right to sell scheduled listed chemical products shall continue to be made by the Deputy