PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

34. The authority citation for 21 CFR part 524 continues to read as follows:

§ 524.2481 [Redesignated as § 524.2483]
35. Redesignate § 524.2481 as § 524.2483.

§ 524.2483 [Amended]

36. In paragraph (b) of newly redesignated § 524.2483, remove “015914, 053501, and 054925” and in its place add “000010, 015914, and 054925”.

PART 526—INTRAMAMMARY DOSAGE FORMS

37. The authority citation for 21 CFR part 526 continues to read as follows:

§ 526.363 [Amended]
38. In paragraph (b) of § 526.363, remove “000856” and in its place add “000010”.

§ 526.365 [Amended]
39. In paragraph (b) of § 526.365, remove “000856” and in its place add “000010”.
40. In § 526.464a, revise the section heading and paragraph (c) to read as follows:
§ 526.464a Cloxacillin benzathine.

* * * * *
(c) Sponsor. See No. 000010 in § 510.600(c) of this chapter for use in dairy cows.

* * * * *

§ 526.1130 [Amended]
41. In § 526.1130, in paragraph (b), remove “000856” and in its place add “000010”; and in paragraph (c)(3), remove the first sentence.


Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2010–4560 Filed 3–4–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1313
[Docket No. DEA–295F]

RIN 1117–AB07

Information on Foreign Chain of Distribution for Ephedrine, Pseudoephedrine, and Phenylpropanolamine

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is finalizing, without change, the Notice of Proposed Rulemaking published in the Federal Register on March 31, 2008 (73 FR 16793). The Combat Methamphetamine Epidemic Act of 2005 (CMEA) requires DEA to collect from importers of ephedrine, pseudoephedrine, and phenylpropanolamine all information known to the importer on the foreign chain of distribution of the chemical from the manufacturer to the importer. This rule amends DEA regulations to incorporate the requirement for this information.

DATES: Effective Dates: This Final Rule is effective May 4, 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:
Background and 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 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, 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. Those classified as List II chemicals may be used to manufacture controlled substances. 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). The changes made by this rule are needed to implement the statutory provisions. This Final Rule amends the language of the regulations to be consistent with that of the statute.

Import/Export Declaration Requirements

Under existing DEA regulations (21 CFR part 1313), importers of listed chemicals are required to provide DEA with advance notification of imports unless the importer has met the requirements as a regular importer of the listed chemical; for regular importers, the notification must be filed by the date of importation. In the importation declaration (DEA Form 486), the importer must provide information on the chemical (name, size and weight of the container, number of containers, total weight of chemical), importation (date, foreign port of shipment, United States port of entry) and the foreign supplier (name, address, contact information).

CMEA imposes several new requirements on imports of listed chemicals. CMEA amended 21 U.S.C. 971, “Notification, suspension of shipment, and penalties with respect to importation and exportation of listed chemicals,” to require DEA to collect information regarding persons to whom the U.S. importer, exporter, broker, or trader transfers the listed chemical, actual quantities shipped, and the date the shipment occurred. If the person to whom the listed chemical is to be transferred is not a regular customer of the U.S. importer or exporter, then the importer or exporter must notify DEA no later than 15 days before the transaction is to take place. Further, if the person to whom the chemical is to be transferred changes subsequent to initial notification of DEA, or if the amount of the chemical to be transferred increases, the importer or exporter shall
update the notice to DEA to identify the most recent prospective transferees or the most recent quantity or both (as the case may be) and may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the update is submitted to DEA, except that such 15-day restriction does not apply if the prospective transferee identified in the update is a regular customer. These changes apply to all listed chemicals. On April 9, 2007, DEA published an Interim Final Rule with Request for Comment codifying these provisions (72 FR 17401). Subsequently, due to requests from the regulated industry, DEA temporarily stayed certain provisions of that rule (72 FR 28601, May 22, 2007). That Interim Final Rule became effective June 8, 2007.

**Imports of Ephedrine, Pseudoephedrine, and Phenylpropanolamine**

CMEA added a new paragraph (h) to 21 U.S.C. 971 that applies specifically to the importation of ephedrine, pseudoephedrine, and phenylpropanolamine. In paragraph (h)(1), the Act states that the import declaration “shall include all information known to the importer on the chain of distribution of such chemical from the manufacturer to the importer.” Paragraphs 971(h)(2) and (h)(3) state that the Attorney General may ask foreign manufacturers and distributors to provide information known to them on distribution of the chemical, including sales. If the foreign manufacturer or distributor refuses to cooperate, the Attorney General may issue an order prohibiting the importation of the three chemicals if the foreign manufacturer or distributor is part of the chain of distribution. Not later than 60 days prior to issuing the order, the Attorney General must publish in the *Federal Register* a notice of intent to issue the order. Imports handled by the foreign distributor may not be restricted during the 60-day period. In the Conference Report (H.R. 109–333), Congress stated that the “provision will assist U.S. law enforcement agencies to better track where meth precursors come from, and how they get to the U.S. At present, very little information exists about the international ‘chain of distribution’ for these chemicals, hindering effective controls.”

In its Notice of Proposed Rulemaking proposing implementation of the provisions of 21 U.S.C. 971(h) (73 FR 16799, March 28, 2008), DEA proposed to add a new paragraph (d) to 21 CFR 1313.13. Contents of import declaration, to state that importers of ephedrine, pseudoephedrine, and phenylpropanolamine may provide information known to them on the chain of distribution from the manufacturer to the importer. DEA also proposed to add a new 21 CFR 1313.42 to cover the provisions of paragraphs (h)(2) and (h)(3) on orders to prohibit imports from foreign manufacturers and distributors who refuse to cooperate with requests for information.

**Revision of DEA Form 486: Import/Export Declaration for List I and List II Chemicals**

To comply with the changes made to the CSA by CMEA, DEA proposed to establish a new DEA Form 486A to be used by persons importing ephedrine, pseudoephedrine, or phenylpropanolamine, or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine. This new form responds to the requirement regarding the foreign chain of distribution discussed above, as well as to requirements implemented regarding import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. In a separate rulemaking, “Import and Production Quotas for Certain List I Chemicals” (Docket No. DEA–293, RIN 1117–AB08) (72 FR 37439, July 10, 2007; 73 FR 73549, December 3, 2008), DEA implemented the import quota provisions of CMEA. Importers of ephedrine, pseudoephedrine, and phenylpropanolamine will be required to provide information about their individual import quota on the DEA Form 486A so that DEA may determine whether the importer has enough quota remaining to import the quantity requested. Thus, in addition to the fields currently present on the DEA Form 486, the DEA Form 486A was proposed to contain the following fields:

- Name and address of foreign distributor (if applicable).
- Import quota, including: quota for current year; quota used to date for current year; and, amount of quota remaining.

**Comments Received**

DEA received two comments in response to the Notice of Proposed Rulemaking. Commenters included one member of the public who indicated he was a health care provider and one chemical manufacturer. The commenters generally supported the rulemaking, but had a variety of comments regarding certain aspects of the proposed rule. The comments, and DEA’s responses, are discussed below.

**Safety of medication manufactured overseas**

One commenter stated that he supported the rule because he believed that improving drug safety can save lives. The commenter also asserted that “this rule has the potential to improve safety of the industry even further by putting the burden of finding the foreign chain of distribution on the importer.” The commenter emphasized his concern with the safety of medications manufactured in foreign countries and asserted that the Food and Drug Administration (FDA) does not have adequate resources to regulate overseas manufacturing facilities, and believed this rule could be beneficial in that regard. The commenter believed that the reporting of information about where a drug comes from is of interest not only to the importer, but to all parties concerned, including practitioners who prescribe those medications to their patients. The commenter believed that it is useful to know that medications came from “trustworthy” facilities, and that such a requirement would be a “small price to pay” for protecting lives.

**DEA Response:** DEA appreciates the commenter’s support. Regarding the safety of medications manufactured in foreign countries, DEA does not have jurisdiction regarding foreign manufacture of ephedrine, pseudoephedrine, phenylpropanolamine, or drug products containing those three List I chemicals. DEA also emphasizes that information regarding the foreign chain of distribution will be made known by the importer to DEA, but that information will not be made known to the general public.

**Distributions to countries other than the United States:** The second commenter, a chemical manufacturer, asked whether it was DEA’s intent to collect information about the foreign manufacturer’s use of distribution centers for shipments to any destination in the world, or only collect information on the use of distributors for shipment to the United States.

**DEA Response:** DEA is only requiring collection of the information on the use of distributors for shipment to the United States. The CSA and its implementing regulations address importation of listed chemicals only in regard to the United States, not in regard to foreign countries (21 U.S.C. 951a(1)). Thus, any requirements DEA imposes regarding importation of listed chemicals relate to the U.S.

**Source of distribution data:** The second commenter also asked DEA to clarify in the Final Rule the information required to be included on the DEA Form 486, stating: “** * if distribution...”
data is obtained from a central location should the importer include that information in the existing foreign consignor field (field 2b), or does the manufacturing site information from which the direct export occurs suffice if DEA could obtain distribution data from the contact information being provided in a timely manner?

DEA Response: If a foreign exporter exports a listed chemical from a particular location to the U.S., but the information regarding all exports from the foreign country to the U.S. is aggregated at a central location, the U.S. importer should provide information on the DEA Form 486 regarding the actual export location, not the location at which the information is aggregated. DEA emphasizes that this requirement is not a change from existing requirements or policies.

Quota information on Import Declarations: The commenter also requested that DEA delay implementation of the requirements regarding foreign chain of distribution until calendar year 2009. The commenter believed this would be beneficial to the regulated industry as that industry had already made significant changes to its processes to comply with other requirements of CMEA. The commenter believed that delaying the effective date of the rule until calendar year 2009 would ensure that both importers and DEA have established timely quota processes that will not interfere with compliance to the proposed rule.

DEA Response: DEA acknowledges that the regulated industry has worked to adapt its business process to the statutory requirements imposed by CMEA. The information sought by the new DEA Form 486A regarding foreign chain of distribution should not pose a significant additional burden to importer registrants. Further, the information required pertaining to import quotas is necessary to fully implement the quota provisions of CMEA and should already be maintained by importers. However, to ensure that industry has adequate time in which to begin to use the new form, DEA is making this rule effective May 4, 2010. DEA believes industry will have adequate time to begin to submit the DEA Form 486A based on this effective date.

Implementation of This Rule

Thus, to comply with the provisions of CMEA codified at 21 U.S.C. 971(h), this Final Rule adds a new paragraph (d) to 21 CFR 1313.13, Contents of import declaration, and states that importers of ephedrine, pseudoephedrine, and phenylpropanolamine must provide information known to them on the chain of distribution from the manufacturer to the importer. This rule adds a new 21 CFR 1313.42 to cover the provisions of paragraphs (h)(2) and (h)(3) on orders to prohibit imports from foreign manufacturers and distributors who refuse to cooperate with requests for information.

Effective May 4, 2010, all U.S. importers of the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine will be required to use the new DEA Form 486A “Importation of the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine” to notify DEA of their imports of those three List I chemicals.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy 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). This rule is necessary to comply with statutory mandates which require that notices of importation for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine provide to DEA all information known to the importer on the foreign chain of distribution of the chemical. As noted above, changes to the forms also respond to provisions regarding import quotas, requiring that importers note on the form the amount of quota issued and available for each chemical. Without these changes, DEA will be unable to comply with statutory mandates and will not be able to fully administer the system of import and production quotas mandated for ephedrine, pseudoephedrine, and phenylpropanolamine.

DEA notes that the statute requires importers to provide only information that is known to them; the burden associated with providing names on the foreign chain of distribution will be minimal. This rule does not impose any new costs. DEA notes that, prior to this rule, importers of ephedrine, pseudoephedrine, and phenylpropanolamine were required to complete a DEA Form 486 to import these List I chemicals. Only the information on the form has changed. Therefore, this rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12866

The Deputy 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 codifying statutory provisions and involves no agency discretion. This statutory change imposes minimal costs on importers; they simply have to file a form with DEA in advance of transactions that includes information that is known to them. They are not required to conduct research to obtain information. DEA notes that the requirement to complete the form is already present in DEA regulations. This rule merely requires that importers of these three List I chemicals provide information known to them regarding the foreign chain of distribution of the chemicals.

Paperwork Reduction Act

This Final Rule revises an existing information collection by establishing a new form for the reporting of imports of the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Specifically, DEA is establishing a new DEA Form 486A, “Import Declaration for Ephedrine, Pseudoephedrine, and Phenylpropanolamine”. This form permits the reporting of any information known to the U.S. importer regarding the foreign chain of distribution of the List I chemical(s).

Specifically, DEA estimates that 30 respondents will import ephedrine, pseudoephedrine, and phenylpropanolamine annually. These persons will conduct 350 individual importations, necessitating the submission of 350 forms and 385 import return declarations. Because of the additional information required on the DEA Form 486A, DEA estimates that this form will take 24 minutes to complete, as opposed to the DEA Form 486, which DEA estimates takes 20 minutes to complete. DEA notes here that the completion of the DEA Form 486A will be in lieu of the currently-required completion of the DEA Form 486. Therefore, while the number of responses remains constant, the hour burden increases due to the greater time associated with the DEA Form 486A. The net increase for this collection is 24 hours annually.

DEA solicited comments regarding the Paperwork Reduction Act aspects of the Notice of Proposed Rulemaking and received no comments. Therefore, DEA is finalizing the Paperwork Reduction Act aspects of this rule without change.
The Department of Justice, Drug Enforcement Administration, has submitted the following information collection request to the Office of Management and Budget for review and clearance in accordance with review procedures of the Paperwork Reduction Act of 1995.

Overview of information collection 1117–0023:

(1) Type of Information Collection: Revision of an existing collection.
(2) Title of the Form/Collection: Import/Export Declaration for List I and List II Chemicals.
(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:

<table>
<thead>
<tr>
<th>Form Number</th>
<th>Number of respondents</th>
<th>Number of responses</th>
<th>Average time per response</th>
<th>Total (hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form 486 (export)</td>
<td>193</td>
<td>10,327</td>
<td>0.283 hour (17 minutes)</td>
<td>2,926</td>
</tr>
<tr>
<td>Form 486 (Export Return Declaration)</td>
<td>193</td>
<td>10,327</td>
<td>0.166 hour (10 minutes)</td>
<td>1,721.2</td>
</tr>
<tr>
<td>Form 486 (import)</td>
<td>120</td>
<td>1,268</td>
<td>0.333 hour (20 minutes)</td>
<td>422.6</td>
</tr>
<tr>
<td>Form 486 (import return declaration)</td>
<td>120</td>
<td>1,395</td>
<td>0.2 hour (12 minutes)</td>
<td>279</td>
</tr>
<tr>
<td>Form 486A (import)</td>
<td>30</td>
<td>350</td>
<td>0.4 hour (24 minutes)</td>
<td>140</td>
</tr>
<tr>
<td>Form 486A (import return declaration)</td>
<td>30</td>
<td>385</td>
<td>0.2 hour (12 minutes)</td>
<td>77</td>
</tr>
<tr>
<td>Form 486 (international transaction)</td>
<td>14</td>
<td>14</td>
<td>0.2 hour (12 minutes)</td>
<td>2.8</td>
</tr>
<tr>
<td>Form 486 (international transaction return declaration)</td>
<td>14</td>
<td>14</td>
<td>0.08 hour (5 minutes)</td>
<td>1.2</td>
</tr>
<tr>
<td>Quarterly reports for imports of acetone, 2-butanone, and toluene.</td>
<td>110</td>
<td>440</td>
<td>0.5 hour (30 minutes)</td>
<td>220</td>
</tr>
</tbody>
</table>

Total | 193 | 5,789.8 |

*DEA assumes 10% of all imports will not be transferred in the first 30 days and will necessitate submission of a subsequent return declaration.

(6) An estimate of the total public burden (in hours) associated with the collection: DEA estimates that this collection will take 5,790 hours annually.

If additional information is required, contact Lynn Bryant, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street, NW, Washington, DC 20530.

Executive Order 12988

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

Executive Order 13132

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

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $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 1313

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.


Michele M. Leonhart,
Deputy Administrator.

For the reasons set out above, 21 CFR part 1313 is amended as follows:

PART 1313—IMPORTATION AND EXPORTATION OF LIST I AND LIST II CHEMICALS

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

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

2. Section 1313.13 is amended by adding paragraph (d) to read as follows:

§ 1313.13 Contents of import declaration.

(d) Any regulated person importing ephedrine, pseudoephedrine, or phenylpropanolamine must submit, on the import declaration, all information known to the importer on the chain of distribution of the chemical from the manufacturer to the importer.

Ephedrine, pseudoephedrine, or phenylpropanolamine include each of the salts, optical isomers, and salts of optical isomers of the chemical.
DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9424]

RIN 1545–BB61

Unified Rule for Loss on Subsidiary Stock; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to final regulations (TD 9424) that were published in the Federal Register on Wednesday, September 17, 2008. The final regulations (TD 9424) contain an error that may prove to be misleading and is in need of clarification. The final regulations revised § 1.1502–35(a) to provide that, in general, § 1.1502–35 would only apply to transactions completed prior to September 17, 2008. The final regulations also revised the operative rules in § 1.1502–35. However, the effective date prescribed in § 1.1502–35(j) appeared to preclude the application of the revised § 1.1502–35 to transactions completed prior to September 17, 2008. The final regulations are clarified to provide that the revised rules in § 1.1502–35 (including the ten-year termination of application of § 1.1502–35 described in Background section 2.A. of the preamble) apply after September 16, 2008, to all transactions subject to that section.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendment:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.1502–35 is amended by revising the first sentence of paragraph (j) to read as follows:

§ 1.1502–35 Transfers of subsidiary stock and deconsolidations of subsidiaries.

(j) Effective/applicability dates. This section applies after September 16, 2008. * * *

LaNita Van Dyke,
Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedures and Administration).

BIBLIOGRAPHIC CODE 4830–01–P