Dated: March 14, 1996.
Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[DEA–135F]

RIN 1117–AA30

Manufacturer Reporting

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final Rule.

SUMMARY: This rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to implement provisions of the Domestic Chemical Diversion Control Act of 1993 (Pub. 103–200) (DCDCA) to specify certain reporting requirements for manufacturers of listed chemicals. This rule requires bulk manufacturers of listed chemicals to provide annual reports containing certain production data to the DEA.

EFFECTIVE DATE: April 29, 1996. The first annual reports which detail data for calendar year 1995, shall be submitted on or before June 27, 1996.

FOR FURTHER INFORMATION CONTACT: Howard McClain Jr., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537 Telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION: The Domestic Chemical Diversion Control Act 1993 (Pub. 103–200) (DCDCA) amended 21 U.S.C. 830(b) to require that regulated persons who manufacture listed chemicals (other than a drug product that is exempted under 21 U.S.C. 802(39)(A)(iv)) report annually to DEA information detailing the specific quantities manufactured. This rule specifies certain reporting requirements for manufacturers of listed chemicals and finalizes a proposed rule published in the Federal Register on September 26, 1995 (60 FR 49529). Interested parties were given 60 days to submit written comments regarding the proposed rule.

Comments

Five organizations submitted comments in response to the proposed regulations. One comment suggested that Section 1310.03(b) be modified in order to clarify that the reporting requirements pertain to both List I and List II chemicals. Therefore Section 1310.01(b) has been amended to clarify that ''Each regulated person who manufactures a List I or List II chemical shall file reports regarding such manufacture as specified in Section 1310.05.''

Another comment stated that DEA had not clearly established its basis for needing information requested under the reporting requirement. This requirement, which was established by the Domestic Chemical Diversion Control Act of 1993, will provide the DEA with information on the amounts of listed chemicals available in the U.S. and provide specific strategic information and parameters on the size and direction of the legitimate listed chemical market and the availability of such chemicals for diversion. It will also enable the DEA to provide the International Narcotics Control Board (INCB) with aggregate data regarding the production and availability of chemicals controlled under provisions of the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

Two comments requested that hydrochloric acid be exempted and one comment suggested that sulfuric acid be exempted since only exports of these chemicals to certain countries are currently regulated. However, both these chemicals are controlled in Table II of the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. This reporting provision will enable the DEA to provide the INCB with aggregate manufacturing data on hydrochloric and sulfuric acid.

The DEA recognizes that bulk manufacturers must file other similar reports to other government agencies. For example, one of the comments stated that the requested information is provided to the U.S. Environmental Protection Agency (EPA) four times per year. Therefore, as stated in the Notice of Proposed Rulemaking, if an existing standard industry report contains the information required in Section 1310.06(h) and such information is separate or readily retrievable from the report, that report may be submitted in satisfaction of this requirement. Each report shall be submitted to the DEA under company letterhead and signed by an appropriate, responsible official.

One comment stated that even though the DEA has specified that an existing standard industry report may satisfy the reporting requirements, the reporting obligation would end up as a special report for each listed material at each location and therefore would be extremely burdensome. In addition, two comments dealt with the issue of whether data must be reported by individual facility, as opposed to submitting one corporate report which includes data for all facilities.

In response to these concerns, the DEA has determined that either reporting method is acceptable. Therefore, each business entity which manufactures a listed chemical may elect to (1) report separately by individual location or (2) report as an aggregate amount for the entire business entity. These manufacturers, however, must inform the DEA of which method they will use.

One commentor asked whether inventories should be reported for listed chemicals stored in foreign locations. The DEA has determined that such foreign inventories are not subject to the inventory reporting requirements since such material would have already been reported to the DEA under existing export notification requirements if it were manufactured in the U.S. and shipped to a foreign location.

One commentor requested clarification of the term year-end inventory as used in Section 1310.06(h)(3). For purposes of this annual reporting requirement, inventory shall reflect the quantity of listed chemicals, whether in bulk or non-exempt product form, held in storage for later distribution. Inventory does not include waste material for destruction, material stored as an in-process intermediate or other in-process material. The DEA recognizes that bulk manufacturers may have specific situations which will affect the complexity of inventory reporting. Therefore, the Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration is available to provide guidance in response to questions bulk manufacturers may have regarding what material should be included as inventory.

One commentor requested clarification of the terms ''product'' and ''converted'' as used in Section 1310.06(h)(5). The term product refers to all pharmaceutical preparations and chemical mixtures exempted under Sections 1310.01(f)(1)(iv) or 1310.01(f)(1)(v) intended for later distribution. In order to provide clarification of Section 1310.06(h)(5), the term ''converted'' is being removed. This section will now specify that each annual report required by Section 1310.05(d) shall provide ''[t]he aggregate quantity of each listed chemical manufactured which becomes a component of a product exempted

under Section 1310.01(f)(1)(iv) or 1310.01(f)(1)(v) during the preceding calendar year.''

One commentor requested clarification that the reporting requirements do not apply to formulators of chemical mixtures. In response to this comment, a bulk manufacturer is defined under the proposed rule, as a person who produces a listed chemical by means of chemical synthesis or by extraction from other substances. Unless a formulator of chemical mixtures produces a listed chemical by means of chemical synthesis or by extraction from other substances, that formulator is not considered a bulk manufacturer and therefore is not subject to these reporting requirements.

One firm noted that the proposed rule stated that quantities be reported to the nearest kilogram. The comment further stated that this was not feasible due to the large volumes of some of the listed chemicals. In response to this inquiry, be advised that the reference to reporting ''to the nearest kilogram'' was intended to mean that quantities should be reported in kilogram units of measure and was not intended to specify the precision with which data should be supplied. The DEA is therefore modifying the regulatory language to read that information should be reported ''in kilogram units of measure''.

One firm commented that an exemption should be provided for bulk manufacturers that produce listed chemicals solely for internal consumption. The DEA has determined that bulk manufacturers that produce a listed chemical solely for internal consumption shall not be required to report for that listed chemical. For purposes of these reporting requirements, internal consumption shall consist of any quantity of a listed chemical otherwise not available for further resale or distribution. Internal consumption shall include (but not be limited to) quantities used for quality control testing, quantities consumed in-house or production losses. Internal consumption does not include the quantities of a listed chemical consumed in the production of exempted products. (These quantities used in the production of exempted products shall be reported separately.) Section 1310.05 has been modified to reflect this reporting exemption.

One firm commented that the proposed rule establishes a DEA code number for each listed chemical and made a suggestion regarding the use of an alternate numbering system. However, the proposed rule only clarifies and implements manufacturer reporting requirements and does not deal with the issue of DEA code numbers. This issue was previously addressed under the regulations which implemented the Chemical Diversion and Trafficking Act (60 FR 32447). In that notice, DEA responded that it had considered the use of other numbering systems such as the Chemical Abstract Services (CAS) and Harmonized Tariff System (HTS). However, in reviewing these systems DEA determined that they were designed for other purposes and that their use could lead to confusion and jeopardize the accuracy of 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 there are chemicals that are assigned multiple codes. The DEA has produced and made available a chemical reference guide that provides a cross reference to the CAS and HTS numbers.

Conclusion

These reporting requirements will apply only to bulk manufacturers of listed chemicals. The term bulk manufacturer as used in this regulation means a person who manufactures a listed chemical by means of chemical synthesis or by extraction from other substances. It does not include persons whose sole activity consists of repackaging or relabeling listed chemical products or the manufacture of drug dosage form products which contain a listed chemical. For each listed chemical, each manufacturer is required to report annually to DEA (1) the year-end inventory, (2) the aggregate quantity manufactured, (3) the aggregate quantity used for internal consumption and (4) the aggregate quantity of each listed chemical manufactured which becomes a component of a product exempted under Section 1310.01(f)(1)(iv) or 1310.01(f)(1)(v) during the preceding calendar year. While manufacturers are required to report the quantities of listed chemicals used in the production of exempted products (e.g. exempted drug products and chemical mixtures), the manufacturer is not required to report data regarding the aggregate quantity of the exempted products produced.

Data provided under these reporting requirements shall be submitted annually to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington D.C. 20537, on or before the 15th day of March of the year immediately following the calendar year for which submitted. However, in order to provide sufficient time for preparation of the initial annual reports which detail manufacturing data for calendar year 1995, these initial reports shall not be due until June 27, 1996.

The Attorney General has delegated authority under the CSA and all subsequent amendments to the CSA to the Administrator of the DEA (28 CFR 0.100). The Administrator, in turn, has redelegated this authority to the Deputy Administrator pursuant to 28 CFR 0.104. The Deputy Administrator hereby certifies that this rulemaking will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The DEA estimates that only approximately 210 manufacturers of listed chemicals will be impacted by these reporting requirements. The impact is minimal since the requested information is frequently maintained in the normal course of business operation. In an effort to further minimize the impact of these reporting requirements and avoid duplicate reporting, the DEA will accept existing reports which contain the required data, provided the data is separate or readily retrievable from other data in the report.

This final rule is not a significant regulatory action and therefore has not been reviewed by the Office of Management and Budget pursuant to Executive Order 12866.

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

List of Subjects in 21 CFR Part 1310

Drug traffic control, Reporting and recordkeeping requirements, List I and List II Chemicals.

For reasons as set out above, 21 CFR Part 1310 is amended as follows:

PART 1310—[AMENDED]

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

Authority: 21 U.S.C. 801, 830, 871(b).

2. Section 1310.03 is amended by redesignating the existing text as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 1310.03 Persons required to keep records and file reports.

(a) * * *

(b) Each regulated person who manufactures a List I or List II chemical shall file reports regarding such

manufacture as specified in Section 1310.05.

3. Section 1310.05 is amended by adding a new paragraph (d) to read as follows:

§ 1310.05 Reports.

* * * * *

(d) Each regulated bulk manufacturer of a listed chemical shall submit manufacturing, inventory and use data on an annual basis as set forth in § 1310.06(h). This data shall be submitted annually to the Drug and Chemical Evaluation Section, Drug Enforcement Administration (DEA), Washington, D.C. 20537, on or before the 15th day of March of the year immediately following the calendar year for which submitted. A business entity which manufactures a listed chemical may elect to report separately by individual location or report as an aggregate amount for the entire business entity provided that they inform the DEA of which method they will use. This reporting requirement does not apply to drug or other products which are exempted under §§ 1310.01(f)(1)(iv) or 1310.01(f)(1)(v) except as set forth in § 1310.06(h)(5). Bulk manufacturers that produce a listed chemical solely for internal consumption shall not be required to report for that listed chemical. For purposes of these reporting requirements, internal consumption shall consist of any quantity of a listed chemical otherwise not available for further resale or distribution. Internal consumption shall include (but not be limited to) quantities used for quality control testing, quantities consumed in-house or production losses. Internal consumption does not include the quantities of a listed chemical consumed in the production of exempted products. If an existing standard industry report contains the information required in § 1310.06(h) and such information is separate or readily retrievable from the report, that report may be submitted in satisfaction of this requirement. Each report shall be submitted to the DEA under company letterhead and signed by an appropriate, responsible official. For purposes of this paragraph only, the term regulated bulk manufacturer of a listed chemical means a person who manufactures a listed chemical by means of chemical synthesis or by extraction from other substances. The term bulk manufacturer does not include persons whose sole activity consists of the repackaging or relabeling of listed chemical products or the manufacture of drug dosage from products which contain a listed chemical.

4. Section 1310.06 is amended by adding a new paragraph (h) to read as follows:

§ 1310.06 Content of records and reports.

* * * * *

(h) Each annual report required by Section 1310.05(d) shall provide the following information for each listed chemical manufactured:

(1) The name, address and chemical registration number (if any) of the manufacturer and person to contact for information.

(2) The aggregate quantity of each listed chemical that the company manufactured during the preceding calendar year.

(3) The year-end inventory of each listed chemical as of the close of business on the 31st day of December of each year. (For each listed chemical, if the prior period's ending inventory has not previously been reported to DEA, this report should also detail the beginning inventory for the period.) For purposes of this requirement, inventory shall reflect the quantity of listed chemicals, whether in bulk or non-exempt product form, held in storage for later distribution. Inventory does not include waste material for destruction, material stored as an in-process intermediate or other in-process material.

(4) The aggregate quantity of each listed chemical used for internal consumption during the preceding calendar year, unless the chemical is produced solely for internal consumption.

(5) The aggregate quantity of each listed chemical manufactured which becomes a component of a product exempted from Section 1310.01(f)(1)(iv) or 1310.01(f)(1)(v) during the preceding calendar year.

(6) Data shall identify the specific isomer, salt or ester when applicable but quantitative data shall be reported as anhydrous base or acid in kilogram units of measure.

Dated: March 19, 1996.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

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DEPARTMENT OF LABOR

Occupational Safety and Health Review Commission

29 CFR Part 2201

Revisions to Rules Implementing the Freedom of Information Act

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Final rule.

SUMMARY: This document makes certain technical and nomenclature changes. In addition, the Commission is revising its fee structure for documents sought under the Freedom of Information Act to compensate for rising costs.

EFFECTIVE DATE: These amendments are effective March 29, 1996.

FOR FURTHER INFORMATION CONTACT: Linda A. Whitsett, Freedom of Information Act Officer, Occupational Safety and Health Review Commission, Room 903, 1120 20th St. N.W., Washington, DC 20036. Phone (202) 606–5398.

SUPPLEMENTARY INFORMATION: Part 1921 is being amended to reflect certain technical changes in the Commission's implementation of the Freedom of Information Act. Primarily, the Commission has changed the title of the ''Public Information Specialist'' to the ''Freedom of Information Act Officer.'' Part 1921 is revised to reflect that change. In addition, decisions will no longer be available at the Commission's regional offices. Accordingly, references to the field offices are eliminated. Finally, the Commission is increasing several fees associated with Freedom of Information Act requests to compensate for rising costs incurred since the fees were set in 1988.

List of Subjects in 29 CFR Part 2201

Freedom of information, Records.

For the reasons set forth in the preamble, title 29, chapter XX, part 2201 is amended as set forth below:

PART 2201—REGULATIONS IMPLEMENTING THE FREEDOM OF INFORMATION ACT

1. The authority for part 2201 continues to read as follows:

Authority: 29 U.S.C. 661(g); 5 U.S.C. 552.

2. In part 2201 all references to ''Public Information Specialist'' are removed and ''Freedom of Information Act Officer'' added in their places.

3. Section 2201.3 is revised to read as follows: