(b) Every person who distributes or exports a List I chemical they have manufactured, other than a List I chemical contained in a product exempted under § 1310.01(f)(1)(iv), or proposes to distribute or export a List I chemical they have manufactured, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§ 1309.24 through 1309.28.

3. Section 1309.22 is proposed to be amended by revising paragraph (b) to read as follows:

§ 1309.22 Separate registration for independent activities.

(a) * * *

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, unless otherwise exempted by the Act or §§ 1309.24 through 1309.28, except that a person registered to import any List I chemical shall be authorized to distribute that List I chemical after importation, but no other chemical that the person is not registered to import.

4. Section 1309.28 is proposed to be added to read as follows:

§ 1309.28 Exemption of distributors of regulated prescription drug products.

(a) The requirement of registration is waived for any person who distributes a prescription drug product containing a List I chemical that is regulated pursuant to § 1310.01(f)(1)(iv).

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

(c) The Administrator may, upon finding that continuation of the waiver granted in paragraph (a) of this section would not be in the public interest, suspend or revoke a person's waiver pursuant to the procedures set forth in §§ 1309.43 through 1309.46 and 1309.51 through 1309.57 of this part.

PART 1310—[AMENDED]

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

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

6. Section 1310.06 is proposed to be amended by revising paragraph (b) to read as follows:

§ 1310.06 Content of records and reports.

* * * * *

(b) For purposes of this section, normal business records shall be considered adequate if they contain the information listed in paragraph (a) of this section and are readily retrievable from other business records of the regulated person. For prescription drug products, prescription and hospital records kept in the normal course of medical treatment shall be considered adequate for satisfying the requirements of paragraph (a) with respect to dispensing to patients, and records required to be maintained pursuant to the Federal Food and Drug Administration guidelines relating to the distribution of prescription drugs, as set forth in 21 CFR part 205, shall be considered adequate for satisfying the requirements of paragraph (a) with respect to distributions.

* * * * *

Dated: September 11, 1995.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

FR Doc. 95–23774 Filed 9–25–95; 8:45 am]

BILLING CODE 4410–09–M

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21 CFR Part 1310

[DEA–135P/RIN 1117–AA30]

Manufacturer Reporting

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule.

SUMMARY: This proposed 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 (Public Law 103–200) (DCDCA) to specify certain reporting requirements for manufacturers of listed chemicals. In a proposed rule published in the Federal Register on October 13, 1994 (59 FR 51887), the DEA previously proposed regulations to implement the requirement that bulk manufacturers of listed chemicals report certain data to the DEA. After receiving comments from the affected chemical industry, on December 9, 1994 (59 FR 63738) the DEA withdrew the portions of the proposed rule pertaining to manufacturer reporting requirements, for further study and consultation with industry. The proposed manufacturer reporting requirements as specified in this Notice of Proposed Rulemaking have been prepared with additional input from the affected chemical industry.

DATES: Written comments and objections must be received by November 27, 1995.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, Washington DC 20537, Attention: DEA Federal Register Representative/CCR.

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 of 1993 (Pub. L. 103–200) (DCDCA) was signed into law on December 17, 1993 and became effective on April 16, 1994. A final rule implementing most of the provisions of the DCDCA (60 FR 32447) was published on June 22, 1995.

The DCDCA amended 21 U.S.C. 830(b) to require that regulated persons who manufacture a listed chemical (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. The purpose of this provision is to provide DEA with information on the amounts of listed chemicals available in the U.S. and to 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.

In a proposed rule published in the Federal Register on October 13, 1994 (59 FR 51887), the DEA proposed regulations to implement the provisions of the DCDCA. That notice proposed to amend Section 1310.03 to require that bulk manufacturers of listed chemicals report certain data to the DEA. In addition, Sections 1310.05 and 1310.06 were proposed to be amended to set forth the specific requirements for the chemical manufacturer reports. Comments received from the affected industry expressed concerns that the proposed manufacturer reports as set forth in Sections 1310.05 and 1310.06 may duplicate existing reports made by chemical manufacturers, did not take into consideration the treatment of confidential business information and were unduly burdensome. Therefore, on December 9, 1994, the DEA published a notice in the Federal Register (59 FR 63738) to withdraw the proposed provisions for manufacturer reporting (as set forth in 1310.05 and 1310.06) for reassessment and consultation with industry. Subsequent to the withdrawal, the DEA has solicited further input and advice from representatives of the affected chemical industry. Following

further discussions and consultation with the Chemical Manufacturers Association (CMA) and other relevant industry groups, the DEA has prepared the proposed regulations for manufacturer reporting.

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.

Industry groups expressed concerns regarding the burden of generating special reports to satisfy this new reporting requirement. In order to minimize such a burden 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. Thus, if an existing standard industry report contains the information required in Section 1310.06(h), the preparation of a separate report will not be necessary.

Industry groups also expressed concerns that the DEA would require each manufacturer to perform ''mass balance'' accountabilities for each listed chemical. In addition, industry representatives also raised concerns regarding such accountabilities as they pertain to the production of chemical mixtures. However, the DEA wishes to emphasize that the purpose of this reporting requirement is to allow the DEA to monitor the overall availability of each listed chemical in the U.S. and report aggregate information to the INCB, when requested. 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 converted to 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.

For purposes of these reporting requirements, internal consumption shall be defined as any quantity of a listed chemical otherwise not available for further resale or distribution to any outside party. 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.)

Industry groups also expressed concern regarding the protection of data provided to the DEA if it is designated as confidential business information. The DEA has considerable experience in safeguarding similar confidential business information. The issue of protection of confidential business information has been addressed by the DEA in the Federal Register Notice published on June 22, 1995 which finalizes specific provisions of the DCDCA (60 FR 32453).

The release of confidential business information that is protected from disclosure under Exemption 4 of the Freedom of Information Act, 5 U.S.C. 552(b)(4) (FOIA), is governed by section 830(c) of the CSA (21 U.S.C. 830(c)) and the Department of Justice procedures set forth in 28 CFR 16.7.

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

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

As proposed, data provided under these reporting requirements shall be submitted annually to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington DC 20537, on or before the 15th day of March of the year immediately following the calendar year for which submitted.Therefore, the first annual reports which detail manufacturing data for calendar year 1995, shall be submitted on or before March 15, 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 proposed 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 the required data, 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.

The proposed 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 proposed 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 proposed to be amended as follows:

PART 1310—[AMENDED]

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

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

2. Section 1310.03 is proposed to be amended by redesignating the introductory 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 manufacturers a listed chemical shall file reports regarding such manufactures as specified in § 1310.05.

3. Section 1310.05 is proposed to be 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, DC 20537, on or before the 15th day of March of the year immediately following the calendar year for which submitted. 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). 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 form products which contain a listed chemical.

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

§ 1310.06 Content of records and reports.

* * * * *

(h) Each annual report required by § 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.)

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

(5) The aggregate quantity of each listed chemical manufactured and converted to a product exempted under § 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 to the nearest kilogram.

Dated: September 11, 1995.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 95–23775 Filed 9–25–95; 8:45 am]

BILLING CODE 4410–09–M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2615

RIN 1212–AA77

Reportable Events

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of meeting.

SUMMARY: This notice announces the first meeting of the Reportable Events Negotiated Rulemaking Advisory Committee.

DATES: The first meeting of the committee will be held at 10 a.m. on Wednesday, October 11, 1995.

ADDRESSES: The first meeting will be held at PBGC's offices at 1200 K Street, N.W., Washington, D.C. 20005–4026.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, or James L. Beller, Attorney, Office of the General Counsel, PBGC, 1200 K Street, N.W., Washington, DC 20005–4026, 202–326–4024 (202–326–4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION:

Background

On August 11, 1995, the PBGC published a notice of intent to establish a negotiated rulemaking advisory committee to develop proposed amendments to the PBGC's regulations governing reportable events (60 FR 41033).

The PBGC expects to receive approval of the committee's establishment from the Office of Management and Budget shortly. Upon receipt of approval, the PBGC will publish a notice of the establishment of the committee. The PBGC is publishing this notice before the official establishment of the committee to give 15 days' notice of the meeting.

First Committee Meeting

The first meeting of the committee will be held at 10:00 a.m. on Wednesday, October 11, 1995, at the PBGC's offices and will be open to the public. The purpose of the first meeting will be to establish procedures for the conduct of committee activity. The procedures will be consistent with the requirements of the Federal Advisory Committee Act and the Negotiated Rulemaking Act.

Issued in Washington, D.C., this 21st day of September, 1995.

Martin Slate,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 95–23912 Filed 9–25–95; 8:45 am]

BILLING CODE 7708–01–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR 183

[CGD 95–041]

Propeller Accidents Involving Houseboats and Other Displacement Type Recreational Vessels

AGENCY: Coast Guard, DOT.

ACTION: Notice of availability of report.

SUMMARY: In a notice published in the Federal Register on May 11, 1995 (60 FR 25191), the Coast Guard solicited comments from all segments of the marine community and other interested persons on various aspects of propeller accident avoidance. In a second notice published August 9, 1995 (60 FR 40545), the Coast Guard reopened and extended the comment period until November 7, 1995. This notice announces the availability of a report published by the Propeller Guard Subcommittee of the National Boating Safety Advisory Council (NBSAC) dated November 7, 1989.

Background Information

By law the Coast Guard is required to consult with NBSAC regarding regulations or other major recreational