FDA notes that the agency has used certain criteria such as disqualifying or disclosure levels and minimum ''qualifying'' criteria to ensure that foods that bear a health claim fit within the context of a healthy diet and contain adequate amounts of the substance of interest. Given the absence of these types of criteria for dietary guidance statements, how can FDA ensure that recommendations for making food or substance ''substitutions'' or ''replacements'' are not misleading? FDA requests comments on how such statements can be provided for in a way that is based on sound science and is helpful and nonmisleading to consumers. Moreover, FDA requests comments on whether and how recommendations to make dietary substitutions or replacements can, or should, be differentiated from claims about the effects of biologically active substances for the purposes of food labeling and appropriate consumer communication.

4. Dietary Guidance on Food Labels

FDA is seeking comment on dietary guidance statements on food labels generally and on approaches appropriate for FDA to consider under its statutory authorities. As part of this consideration, FDA is requesting comments on whether providing a list of dietary guidance statements that FDA recommends for inclusion on food labels would be desirable or useful to manufacturers. In addition, FDA is requesting comments on these topics: (1) Whether and how the agency should partner with other Federal agencies to identify and agree upon recommended dietary guidance statements for food labeling, (2) the appropriate criteria for evaluating the scientific validity of dietary guidance statements that appear on products in the marketplace, and (3) whether and how the agency should address dietary guidance statements from non-federal sources (e.g., States, trade associations, professional associations, etc.).

IV. Future Analysis of Benefits and Costs

For the agency's future analysis of benefits and costs of the regulatory options for qualified health claims, FDA requests comments, including available data, on the following questions:

- What effects do health claims have on consumer purchases of foods and dietary supplements? What effects do health claims have on the total diet?
- Is there a difference between consumers' willingness to buy products with qualified health claims and consumers' willingness to buy products with health claims based on SSA?
- What effects would the different qualifying phrases described in the interim procedures for qualified health claims guidance[16] (Ref. 3) and the Task Force report (Ref. 4) have on the willingness of consumers to buy the products containing the claims? Is there evidence that consumers would find the differences among qualifying phrases to be substantial?
- What types of foods and dietary supplements are most likely to use qualified health claims in their labeling? What types of claims are most likely to be used by those products?
- What types of existing products will manufacturers re-formulate in order to be able to make qualified health claims? What types of claims are most likely to lead to re-formulation?
- What new products might be developed in response to qualified health claims?
- Would any of the regulatory options discussed in this ANPRM have a significant effect on small businesses or other small entities?
- What additional research should FDA, other government agencies, or other organizations sponsor to answer these questions?

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday, except on Federal Government holidays. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

1. Task Force Final Report, ''Consumer Health Information for Better Nutrition Initiative'' (July 10, 2003) (Internet addresses: *http://www.fda.gov/oc/mcclellan/chbn.html* or *http://www.fda.gov/ohrms/dockets/default.htm*).

2. ''Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data'' (Internet addresses: *http://www.cfsan.fda.gov/guidance.html* or *http://www.fda.gov/ohrms/dockets/default.htm*).

3. ''Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements'' (Internet addresses: *http://www.cfsan.fda.gov/guidance.html* or *http://www.fda.gov/ohrms/dockets/default.htm*).

4. Task Force Final Report, Attachment A: ''Possible Regulatory Frameworks for Qualified Health Claims'' (Internet addresses: *http://www.fda.gov/oc/mcclellan/chbn.html* or *http://www.fda.gov/ohrms/dockets/default.htm*).

5. CFSAN, Office of Nutritional Products, Labeling and Dietary Supplements, ''Dietary Guidance Message About Fruits and Vegetables'' (July 29, 2003; revised August 28, 2003) (Internet address: *http://www.cfsan.fda.gov/~dms/lab-dg.html*).

[16] The guidance identifies three different qualifying phrases (or standardized qualifying language) for qualified health claims. These phrases are used according to a scientific ranking assigned to the claim (which is discussed in the interim evidence-based ranking system guidance (Ref. 2)). FDA has categorized these phrases as B, C, and D, as follows: *Category B*: ''Although there is scientific evidence supporting the claim, the evidence is not conclusive.''; *Category C*: ''Some scientific evidence suggests * * * however, FDA has determined that this evidence is limited and not conclusive.''; *Category D*: ''Very limited and preliminary scientific research suggests * * * FDA concludes that there is little scientific evidence supporting this claim.'' The Task Force report lists the same three qualifying phrases in its overview of the interim procedures for qualified health claims guidance.

VI. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29448 Filed 11–21–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1304, 1306, and 1310

[Docket No. DEA–234P]

RIN 1117–AA71

Recordkeeping and Reporting Requirements for Drug Products Containing Gamma-Hydroxybutyric Acid (GHB)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: DEA proposes to amend its regulations to require additional recordkeeping and reporting requirements for drug products containing gamma-hydroxybutyric acid (GHB) for which an application has been approved under the Federal Food, Drug, and Cosmetic Act. DEA proposes

these changes pursuant to section 4 of the ''Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000.'' These additional requirements are necessary to protect against the diversion of GHB for illicit purposes.

DATES: Comments must be postmarked by January 26, 2004.

ADDRESSES: Comments should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

What Is Gamma-Hydroxybutyric Acid?

Gamma-hydroxybutyric acid (GHB) is a central nervous system depressant drug. In recent years, the abuse of GHB has increased substantially. GHB is abused to produce euphoric and hallucinogenic states, and for its alleged role as an agent to stimulate muscle growth. GHB can produce drowsiness, dizziness, nausea, visual disturbances, unconsciousness, seizures, severe respiratory depression, and coma.

GHB can be produced in clandestine laboratories using a relatively simple synthesis with readily available and inexpensive source materials. Gamma-butyrolactone (GBL), a List I chemical, is an industrial solvent that is used in the illicit manufacture of GHB. GBL and 1,4-butanediol are also abused for their GHB-like effects. Due to their structural and pharmacological similarities to GHB, GBL and 1,4-butanediol may be considered controlled substance analogs and treated as Schedule I substances if they are intended for human consumption. GHB is usually manufactured in a clear solution that can be disguised by adding food coloring, flavorings, and/or storing it in different kinds of bottles and containers.

Regulatory History

On February 18, 2000, Public Law 106–172 (114 Stat. 7) the ''Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000'' was enacted. Pub. L. 106–172 declared GHB an imminent hazard to public safety that requires immediate regulatory action under the Controlled Substances Act. Pub. L. 106–172 requires the Attorney General to list GHB as a Schedule I controlled substance and designates GBL as a List I chemical. As a result of Pub. L. 106–172, DEA issued two final rules: Schedules of Controlled Substances: Addition of Gamma-Hydroxybutyric Acid to Schedule I (65 FR 13235, March 13, 2000) (corrected at 65 FR 17440, April 3, 2000) and Placement of Gamma-Butyrolactone in List I of the Controlled Substances Act (21 U.S.C. 802(34)) (65 FR 21645, April 24, 2000).

Under the March 13, 2000 final rule, GHB and its salts, isomers, and salts of isomers were placed in Schedule I and GHB became subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a Schedule I controlled substance. As required by Pub. L. 106–172, the March 13, 2000 final rule created an exception for drug products containing GHB, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The exception placed these substances in Schedule III. Therefore, registered manufacturers and distributors of FDA-approved Drugs containing GHB are subject to Schedule III requirements.

On July 17, 2002, the Food and Drug Administration (FDA) approved Xyrem'', a drug containing gamma-hydroxybutyric acid, as a Schedule III controlled substance for the treatment of cataplexy associated with narcolepsy.

Additional Recordkeeping and Reporting Requirements Proposed for Schedule III GHB Drug Products

The March 13, 2000 final rule did not address the recordkeeping and reporting requirements recommended by Public Law 106–172 for drug products containing GHB, for which an application is approved under section 505 of the FFDCA. The additional requirements are necessary to prevent the diversion of Schedule III GHB drug products for illicit purposes and were intended by Congress to be part of the regulatory scheme for these products. Representative Thomas Bliley explained Congress' intent in legislating these requirements as follows:

> Also, under H.R. 2130, as amended, if a drug product that contains GHB receives FDA approval, the approved GHB drug product will be placed in Schedule III of the CSA. However, given the dangers involving this drug, H.R. 2130 adds additional reporting and accountability requirements to conform with the requirements for schedule I substances, schedule II drugs, and schedule III narcotics, and, significantly would maintain the strict schedule I criminal penalties for the unlawful abuse of the approved drug product. Simply put, these additional requirements and penalties in my opinion are needed to provide greater protection to our nation's youth, and to give our law enforcement agencies the ability to penalize those who abuse this product to the fullest extent under the law. (Mr. Bliley, Cong. Record Jan. 31, 2000, H61)

In response to Public Law 106–172, Section 4, this rule proposes recordkeeping requirements for practitioners dispensing Schedule III GHB drug products and reporting requirements for manufacturers and distributors of Schedule III GHB drug products. Under current 21 CFR 1304.22(c) dispensers of GHB, including pharmacies, are required to maintain the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to these requirements, proposed 21 CFR 1304.26 would require pharmacies and practitioners dispensing GHB to maintain and make available for inspection the name of the prescribing practitioner, the prescribing practitioner's Federal and State registration numbers with expiration dates, verification that the prescribing practitioner possesses appropriate registration, and the patient's insurance provider, if available. Pub. L. 106–172, Section 4 also recommended that DEA establish a recordkeeping requirement for ''documentation by a medical practitioner licensed and registered to prescribe the drug of the patient's medical need for the drug.'' Part of this recommendation is currently satisfied by existing DEA requirements in 21 CFR 1306.04 which state that prescriptions ''must be issued for a legitimate medical purpose.'' To further satisfy this requirement, DEA is proposing the amendment of 21 CFR 1306.05 to require that the medical need be written on the prescription.

This rule also proposes to amend 21 CFR 1304.33 to include Schedule III GHB drug products as controlled substances that must be reported under the Automation of Reports and Consolidated Orders System (ARCOS). ARCOS is an automated, comprehensive drug reporting system, which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level, *e.g.*, hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials

(manufacturers and distributors); Schedule III narcotic materials (manufacturers and distributors); and selected Schedules III and IV psychotropic controlled substances (manufacturers only). This proposal would add Schedule III GHB drug products to this list.

In addition, Public Law 106–172, Section 4 (amending 21 U.S.C. 827(h)(6)) recommended that DEA apply the mail order reporting requirements of 21 U.S.C. 830(b)(3) to ''gamma hydroxybutyric acid to the same extent and in the same manner as such section applies with respect to the chemicals and drug products specified in subparagraph (A)(i) of such section.'' While DEA is proposing the amendment of its regulations to include these provisions, Congress also passed Pub. L. 106–310, the ''Children's Health Act of 2000'', Title XXXVI of which is the Methamphetamine Anti-Proliferation Act of 2000 (MAPA). One of the consequences of MAPA was to redesignate 21 U.S.C. 830(b)(3)(A)(i) as 21 U.S.C. 830(b)(3)(B)(i). Further, MAPA required mail order reporting requirements for export transactions involving ephedrine, pseudoephedrine, or phenylpropanolamine. These reporting requirements would not apply to distributions of drug products, including GHB, pursuant to a valid prescription, which were excluded under MAPA (21 U.S.C. 830(b)(3)(D)). Regulations implementing the Methamphetamine Anti-Proliferation Act of 2000 were published October 7, 2003 (68 FR 57799). Thus, the net effect is that all export transactions involving GHB be reported to DEA. Transactions involving prescriptions of GHB are not required to be reported to DEA.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that it will not have a significant economic impact upon a substantial number of small entities. This rulemaking creates new recordkeeping and reporting requirements which will have an extremely limited impact on a small number of registrants due to the restricted use of GHB for legitimate medical purposes. As a condition of Xyrem's® (the FDA-approved product containing GHB) approval, a risk management program was designed to limit its distribution. Under this program, Xyrem® will only be available to physicians and patients through a single centralized pharmacy. As a result of this program, at this time, controlled substances distributors and retail pharmacies will not be handling Xyrem® and, thus, will not be affected by these requirements. For those few persons affected by these proposed regulations, the information requested by these added records is readily and commonly available, and due to the limited distribution of GHB the impact on reporting requirements should be minimal.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this regulation has been drafted in accordance with the principles of Executive Order 12866, Section 1(b). This action has been determined to be a ''significant regulatory action'' under Executive Order 12866, and accordingly this proposed rule has been reviewed by the Office of Management and Budget.

Executive Order 12988

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

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 rulemaking will not result in the expenditure by state, local, and tribal governments in the aggregate, or by the private sector, of $100 million or more in any one year, and would not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Paperwork Reduction Act

While, technically, this rule requires new, minimal recordkeeping and reporting requirements for drug products containing GHB, DEA does not believe that these recordkeeping and reporting requirements create any greater hour or cost burden for respondents than what already exists. Records required to be maintained by practitioners under proposed 21 CFR 1304.26, including the practitioner's name, address, state license and federal registration numbers, and the patient's insurance provider (if available) are all records which are maintained as a usual course of professional practice by a practitioner. The reporting requirements proposed under 21 CFR 1304.33 are part of an already-approved collection of information (OMB 1117–0003: ARCOS Transaction Reporting—DEA Form 333). DEA believes that the additional reporting requirements will have no impact on the hour or cost burden for respondents as reports are generated and submitted electronically. As has been stated previously, due to the risk management plan established for Xyrem'' (the FDA-approved product containing GHB) this product has an extremely limited distribution potential. Because of the nature of this product's distribution, DEA anticipates that fewer than five persons will be impacted by the requirement to report handling Schedule III GHB products to ARCOS, and those persons are already filing reports with DEA for other controlled substances handled. The system modifications necessary to generate this report will occur as a normal part of a registrant's handling of this product. Therefore, DEA is not submitting any changes or amendments to its active information collections under the Paperwork reduction Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

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

List of Subjects

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1306

Drug traffic control, Prescription drugs.

21 CFR Part 1310

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

For the reasons set out above, 21 CFR Parts 1304, 1306 and 1310 are proposed to be amended as follows:

PART 1304—RECORDS AND REPORTS OF REGISTRANTS [AMENDED]

1. The authority citation for 21 CFR Part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 871(b), 958, 965, unless otherwise noted.

2. Section 1304.22 is proposed to be amended by revising paragraph (c) to read as follows:

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.

* * * * *

(c) *Records for dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2) (i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this paragraph practitioners dispensing gamma-hydroxybutyric acid pursuant to a prescription must also comply with § 1304.26.

* * * * *

3. Section 1304.26 is proposed to be added to read as follows:

§ 1304.26 Additional recordkeeping requirements applicable to drug products containing gamma-hydroxybutyric acid.

In addition to the recordkeeping requirements for dispensers and researchers provided in § 1304.22, practitioners dispensing gamma-hydroxybutyric acid that is manufactured or distributed in accordance with an application under section 505 of the Federal Food, Drug, and Cosmetic Act must maintain, and make available for inspection and copying by the Attorney General, all of the following records for each prescription:

(a) Name of the prescribing practitioner.

(b) Prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations.

(c) Verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance.

(d) Patient's name and address.

(e) Patient's insurance provider, if available.

4. Section 1304.33 is proposed to be amended by revising paragraph (c) and the introductory text of paragraph (d)(1) to read as follows:

§ 1304.33 Reports to ARCOS.

* * * * *

(c) *Persons reporting.* For controlled substances in Schedules I, II, narcotic controlled substances in Schedule III, and gamma-hydroxybutyric acid drug product controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repackage, label or relabel, and each person who is registered to distribute, including each person who is registered to reverse distribute, shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, gamma-hydroxybutyric acid drug product controlled substances in Schedule III, and on each psychotropic controlled substance listed in Schedules III and IV as identified in paragraph (d) of this section.

(d) *Substances covered.* (1) Manufacturing and acquisition/distribution transaction reports shall include data on each controlled substance listed in Schedules I and II, on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V), and on gamma-hydroxybutyric acid drug products listed in Schedule III. Additionally, reports on manufacturing transactions shall include the following psychotropic controlled substances listed in Schedules III and IV:

* * * * *

PART 1306—PRESCRIPTIONS [AMENDED]

1. The authority citation for Part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b).

2. Section 1306.05 is proposed to be amended by revising paragraph (a) to read as follows:

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (*e.g.*, J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

* * * * *

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES [AMENDED]

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

Authority: 21 U.S.C. 802, 827(h), 830, 871(b).

2. Section 1310.03 is proposed to be amended by revising paragraph (c) to read as follows:

§ 1310.03 Persons required to keep records and file reports.

* * * * *

(c) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction that involves ephedrine, pseudoephedrine, or phenylpropanolamine, or gamma-hydroxybutyric acid, including drug products containing these chemicals, and uses or attempts to use the Postal Service or any private or commercial carrier must file monthly reports of each such transaction as specified in § 1310.05 of this part.

Dated: November 14, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 03–29336 Filed 11–24–03; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309, 1310

[Docket No. DEA–189P]

RIN 1117–AA67

Chemical Registration Waivers; Exemption From Chemical Registration Fees for Certain Persons

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: DEA is proposing amending its regulations to waive the requirement of registration for contract processors, medical/first aid kit providers, distributors of sample packages of drug products, and distributors of research/reference standards pursuant to 21 U.S.C. 822(d). These actions are being taken in response to industry comments and suggestions. DEA has determined that requiring registration for these activities is not necessary for effective enforcement under the Controlled Substances Act (CSA), and waiving the requirement of registration will ease regulatory burdens for the affected industries. DEA is also proposing exempting charitable organizations and governmental entities from initial and renewal registration fees. These fee exemptions will bring the chemical regulations into conformance with the controlled substances regulations (21 CFR 1301.21).

DATES: Written comments must be postmarked on or before January 26, 2004.

ADDRESSES: Comments should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Special Notice

Due to concerns regarding possible harmful side effects, the Food and Drug Administration (FDA) initiated action in November, 2000, to remove phenylpropanolamine from the market. As a result, many firms voluntarily discontinued marketing products containing phenylpropanolamine and removed them from the shelves for disposal. However, since some products containing phenylpropanolamine are still available, DEA has written these proposed regulations to include drug products containing phenylpropanolamine, where appropriate, as well as drug products containing pseudoephedrine.

I. Background

What Legislation Permits DEA to Regulate the Chemicals Industry, and What Laws Allow DEA To Waive Registration Requirements?

The Domestic Chemical Diversion Control Act of 1993 (DCDCA) established that persons distributing, importing, or exporting List I chemicals must register with DEA. In addition, it removed the exemption of single-entity ephedrine drug products from the chemical regulations. The Comprehensive Methamphetamine Control Act of 1996 (MCA) expanded on the registration requirement of the DCDCA by removing the exemption for pseudoephedrine, phenylpropanolamine and combination ephedrine drug products. Persons distributing, importing or exporting these drug products must register with DEA (21 U.S.C. 822, 957).

The registration requirement is not absolute. Section 302(c) of the CSA (21 U.S.C. 822(c)) provides that certain persons, including common or contract carriers and warehousemen, are not subject to the registration requirement. Further, section 302(d) of the CSA (21 U.S.C. 822(d)) provides that the Attorney General may waive the registration requirement for certain persons if it is consistent with the public health and safety.

As DEA has worked to implement the DCDCA and MCA, a number of issues have been raised regarding waiving the requirement of registration for persons engaged in certain activities under the regulations. In some cases there are parallels between identified activities and activities previously exempted from the registration requirement. DEA has reviewed the requests received from industry and has determined that the requirement of registration is not necessary for contract processors, medical/first aid kit providers, distributors of sample packages, and distributors of research/reference standards as discussed below. Further, DEA has determined that charitable organizations and governmental entities should be exempted from payment of the application fee for registration and reregistration, but that the requirement of registration itself must remain in effect for effective diversion control. These proposed fee exemptions are also discussed below.

How Will These Proposed Waivers and Exemptions Benefit the Regulated Industry?

Current DEA regulations require that any person who manufactures, distributes, imports, or exports a List I chemical must first register with DEA annually as a List I chemicals handler and pay a registration fee. DEA has recognized that, for certain industries, registration is unnecessary for effective enforcement of the law, and has accommodated the waiver of registration through Memoranda of Understanding (MOUs) between DEA and affected persons. In this rulemaking, DEA is proposing to waive the requirement of registration for contract processors, medical/first aid kit providers, distributors of sample packages, and distributors of research/reference standards. Were DEA not to propose these regulations, thereby codifying present Administration policy, each affected person would be required to register with DEA annually and pay an initial registration fee of $595 and annual reregistration fees of $477. If finalized, these proposed regulations will require exempt persons to notify DEA only once of their activities, at a cost of mailing one letter, as opposed to an annual registration fee. Industry would benefit from a significant cost savings as no fee would be charged for the one-time notification. Further, in this rulemaking DEA is proposing to exempt charitable organizations and governmental entities from payment of the application fee for registration and reregistration as List I chemical handlers. These exemptions will reduce regulatory requirements for the applicable industry, creating a cost savings for affected persons.

What Chemicals Would Be Affected by These Proposed Regulations?

The proposed waiver of the requirement of registration or reregistration for contract processors will affect all List I chemicals. List I chemicals have legitimate uses within commercial industry, being used for research and manufacturing purposes. List I chemicals include, but are not