NGA to provide non-discriminatory service and the non-discriminatory provisions of the Standards of Conduct regarding the implementation of tariffs should serve as a guideline for Texas Gas's behavior in complying with sections 4 and 5 of the NGA.

G. Miscellaneous Corrections

50. The Commission is also making some miscellaneous corrections to typographical errors in the regulatory text. Specifically, Entergy has pointed out that § 358.4(b)(3)(vi) contains a reference to § 37.3 which Entergy believes should be § 37.6. The Commission agrees, and § 358.4(b)(3)(vi) is being corrected to reference § 37.6. Also, § 358.3(d)(6)(vi) is revised to remove ''producer'' and replace it with ''processor'' to reflect the Commission's intent of this provision as described in paragraph 30 of Order No. 2004–B.

By the Commission.

Linda Mitry,

Deputy Secretary.

■ In consideration of the foregoing, the Commission amends part 358, Chapter I, Title 18 of the Code of Federal Regulations, as follows:

PART 358—STANDARDS OF CONDUCT

■ 1. The authority citation for part 358 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 791–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

§ 358.3 [Amended]

■ 2. In § 358.3(d)(6)(vi) the word ''producer'' is removed and the word ''processor'' is inserted in its place.

§ 358.4 [Amended]

■ 3. In § 358.4(b)(3)(vi) the word ''§ 37.3'' is removed and the word ''§ 37.6'' is inserted in its place.

§ 358.5 [Amended]

■ 4. In § 358.5(d), the words ''the quantity of power or gas scheduled to be moved'' are removed and the words ''the quantity of power or gas upon which the discount is based,'' are inserted in their place.

Note: This Appendix A will not be published in the Code of Federal Regulations.

Appendix A

List of Petitioners Requesting Rehearing or Clarification or submitting Comments
American Gas Association (AGA)
AES Ocean Express LLC (AES)
Algonquin Gas Transmission, LLC; jointly with East Tennessee Natural Gas, LLC; Egan Hub Storage, LLC; Gulfstream Natural Gas System, L.L.C.; Maritimes & Northeast Pipeline, L.L.C.; and Texas Eastern Transmission, LP (collectively, Duke Pipelines)
Calpine Corporation (Calpine)
Cinergy Services, Inc. (Cinergy)
Edison Electric Institute (EEI)
Entergy Services, Inc. (Entergy)
Interstate Natural Gas Association of America (INGAA)
National Fuel Gas Supply Corporation jointly with National Fuel Gas Distribution Corporation (collectively, National Fuel)
National Grid USA (National Grid)
Natural Gas Supply Association (NGSA)
OkTex Pipeline Company (OkTex)
Public Service Commission of the State of New York (PSC New York)
Southwest Gas Corporation (Southwest Gas)
Tractebel Calypso Pipeline, LLC (Tractebel)
Utah Public Service Commission (Utah PSC)
Wyoming Public Service Commission (Wyoming PSC)

[FR Doc. 05–16 Filed 1–3–05; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1304, 1306, and 1310

[Docket No. DEA–234F]

RIN 1117–AA71

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

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA is amending 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 makes these changes under 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.

EFFECTIVE DATE: February 3, 2005.

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:

Controlled Substances and Listed Chemicals

Controlled substances are drugs that have a potential for abuse and addiction; these include opiates, stimulants, depressants, hallucinogens, anabolic steroids, and substances that are immediate precursors to these controlled substances. Controlled substances are listed in 21 CFR part 1308. The substances are divided into five schedules. Schedule I substances are drugs for which there is a high potential for abuse, no currently accepted medical treatment in use in the United States, and lack accepted safety for use under medical supervision. Schedule II–V substances have accepted medical uses, but have a potential for abuse and may lead to physical and psychological dependence. Such drugs are subject to varying levels of control. Chemicals that can be used to manufacture controlled substances are regulated as either List I chemicals (important to the manufacture) or List II chemicals (used in the manufacture) of controlled substances.

Background

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

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 chemical that is used in the illicit manufacture of GHB. GBL and 1,4-butanediol, another industrial chemical, are also abused for their GHB-like effects. Due to their structural and pharmacological similarities to GHB, GBL and 1,4-butanediol are considered controlled substance analogues as defined by 21 U.S.C. 802(32). Manufactured GHB usually results in a clear solution that can be disguised by adding food coloring, flavorings, or storing it in different kinds of bottles and containers.

The listed chemical GBL has many industrial applications, and has not been scheduled at this time to prevent an undue regulatory burden to legitimate commerce in this substance. Because GBL is a controlled substance analogue, individuals who manufacture or distribute or possess with intent to manufacture or distribute this chemical intending it for human consumption may be prosecuted under provisions of the Controlled Substances Act. This is

because a controlled substance analogue which is intended for human consumption is treated as a Schedule I controlled substance. When handled for industrial purposes, with no intent for human consumption, it is not treated as a Schedule I controlled substance and those handling it are not subject to any Schedule I controlled substances penalties under the Controlled Substances Act.

Regulatory History

On February 18, 2000, the ''Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000'' was enacted (Pub. L. 106–172, 114 Stat. 7). Public Law 106–172 declared GHB an imminent hazard to public safety that required immediate regulatory action under the Controlled Substances Act. Public Law 106–172 required the Attorney General to list GHB as a Schedule I controlled substance and designated GBL as a List I chemical. As a result of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act, 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 the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act, 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 (FDCA) (21 U.S.C. 355). The exception placed any such drug products—there were none approved at the time the legislation was passed—in Schedule III. Therefore, registered manufacturers and distributors of FDA-approved drug products containing GHB are subject to Schedule III regulatory requirements. However, criminal penalties for unlawful distributions of these drug products are those for Schedule I controlled substances.

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

Notice of Proposed Rulemaking

The March 13, 2000 final rule did not address the recordkeeping and reporting requirements recommended by the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act for drug products containing GHB for which an application is approved under section 505 of the FDCA. On November 25, 2003 DEA issued a notice of proposed rulemaking (68 FR 66048) to establish requirements to prevent the diversion of Schedule III GHB drug products for illicit purposes as was intended by Congress as part of the regulatory scheme for these products. DEA received no comments in response to the November 25, 2003 notice of proposed rulemaking and is adopting the rule language as proposed.

In response to section 4 of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act, this rule establishes recordkeeping requirements for practitioners dispensing Schedule III GHB drug products and reporting requirements for manufacturers and distributors of Schedule III GHB drug products. Under existing 21 CFR 1304.22(c), dispensers of any controlled substance, including GHB, are required to maintain the name and address of the person to whom the controlled substance 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. This final rule adds 21 CFR 1304.26, which requires 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. Section 4 of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act 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 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 statutory requirement, DEA has amended 21 CFR 1306.05 to require that the medical need be written on the prescription.

This final rule also amends 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 that 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 final rule adds Schedule III GHB drug products to this list for both manufacturers and distributors.

In addition, section 4 of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act 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 (B)(i) of such section.'' DEA has complied with these recommendations in this final rule by amending 21 CFR 1310.03(c), which makes GHB subject to mail order requirements established under the Methamphetamine Anti-Proliferation Act of 2000 (MAPA) (Title XXXVI of the ''Children's Health Act of 2000'' (Pub. L. 106–310, 114 Stat. 1101)). The Methamphetamine Anti-Proliferation Act of 2000 imposed mail order reporting requirements for export transactions involving ephedrine, pseudoephedrine, or phenylpropanolamine. These reporting requirements do not apply to distributions of drug products, including GHB, under a valid prescription, which were excluded under MAPA (21 U.S.C. 830(b)(3)(D)). Regulations implementing MAPA were published October 7, 2003 (68 FR 57799). The net effect is that all export transactions involving GHB must 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 certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)). The Deputy Assistant Administrator 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 substance 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 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 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 $114.5 million or more 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.

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 dispensing practitioners under 21 CFR 1304.26, including the prescribing 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 dispensing practitioner. The reporting requirements in 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 drug 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 amended as follows:

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

■ 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 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 under a prescription must also comply with § 1304.26.

* * * * *

■ 3. Section 1304.26 is 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 information 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 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

■ 5. The authority citation for part 1306 continues to read as follows:

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

■ 6. Section 1306.05 is 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

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

Authority: 21 U.S.C. 802, 827(h), 830, 871(b) 890.

■ 8. Section 1310.03 is 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, 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: December 22, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 05–56 Filed 1–3–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–137f2]

RIN 1117–AA31

Exemption of Chemical Mixtures; Correction

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule with request for comment; correction.

SUMMARY: This document corrects the Final Rule with request for comment ''Exemption of Chemical Mixtures'' [Docket No. DEA–137f2, RIN 1117–AA31] which DEA published in the **Federal Register** on Wednesday, December 15, 2004 (69 FR 74957). The Final Rule concerned the exemption of certain chemical mixtures containing listed chemicals from the provisions of the Controlled Substances Act.

DATES: This correction is effective January 14, 2005.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7183

SUPPLEMENTARY INFORMATION: