**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR PART 1310**

**[Docket No. DEA–203F]**

**RIN 1117–AA52**

## Establishment of a Threshold for Gamma-Butyrolactone

**AGENCY:** Drug Enforcement Administration (DEA), Justice.

**ACTION:** Final rule.

**SUMMARY:** On October 24, 2001, DEA published a Notice of Proposed Rulemaking titled ''Establishment of a Threshold for Gamma-Butyrolactone'' (66 FR 53746) that proposed a zero kilogram threshold and the exemption of transactions of 16,000 kilograms (net weight) or more in a single container. This final rule establishes a zero kilogram threshold for domestic, export, and import transactions of gamma-butyrolactone (GBL) and excludes from the definition of a ''regulated transaction'' all transactions of 4,000 kilograms (net weight) or more in a single container. The DEA is reducing the weight required for exclusion from what was proposed in response to a comment that showed that transactions of 4,000 kilograms or more in a single container are not likely to be diverted.

**EFFECTIVE DATE:** This final rule is effective October 10, 2003.

**FOR FURTHER INFORMATION CONTACT:** Frank L. Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537.

**SUPPLEMENTARY INFORMATION:**

### I. Background

*Action Being Taken in This Rulemaking*

This rulemaking amends Title 21 of the Code of Federal Regulations (CFR) 1310.04(g)(1) by adding a new paragraph to establish that GBL is not assigned a threshold. In addition, 21 CFR 1310.08 is being amended by adding a new paragraph to identify as an ''excluded transaction,'' transactions in GBL of 4,000 kilograms (net weight) or more in a single container. This rulemaking applies to import, export, and domestic (including retail) transactions. All transactions in GBL, unless defined in 21 CFR 1310.08, are regulated transactions. Persons who handle GBL must be registered with DEA, even if their distributions are excluded from the definition of a ''regulated transaction.'' Regulated persons include manufacturers who distribute, distributors, importers, and exporters of GBL.

*Illicit Use of GBL*

Law enforcement authorities have identified GBL in gamma-hydroxybutyric acid (GHB) clandestine laboratories and documented its use as a GHB precursor. GBL is a necessary chemical precursor in the clandestine synthesis of GHB because, to date, no other chemical has been substituted for GBL in this process. Congress recognized this and controlled GBL as a List I chemical upon enactment of Pub. L. 106–172 on February 18, 2000.

GBL is a unique chemical precursor. It can be converted to GHB by a simple chemical reaction or it can be ingested directly, without running a chemical reaction. That is, the body efficiently converts GBL to GHB when ingested. Because GBL is converted to GHB by the body's own action, GBL is routinely substituted for GHB to obtain the same type of intoxication. Congress recognized this and adopted in Pub. L. 106–172 a new subparagraph to 21 U.S.C. 802(32), the section of the Controlled Substances Act (CSA) that defines a ''controlled substance analogue.'' The subparagraph maintains that the placement of GBL, or any other chemical, as a listed chemical does not preclude a finding that the chemical is a controlled substance analogue. DEA recognizes this concern of Congress that GBL is being used as a direct substitute for a Schedule I controlled substance. Although GBL is a chemical commodity when used by legitimate industry, diversion of GBL can be tantamount to diversion of a Schedule I controlled substance when it is intended for human consumption.

*Steps Leading to This Rulemaking*

GBL was placed in the CSA as a List I chemical effective February 18, 2000, by enactment of Pub. L. 106–172, the ''Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 1999'' (65 FR 21645, April 24, 2000). That law, however, did not establish a threshold. Consequently, all transactions in GBL are regulated transactions as described in 21 CFR 1300.02(b)(28) until publication of this final rule.

The final rule titled, ''Placement of Gamma-Butyrolactone in List I of the Controlled Substances Act (21 U.S.C. 802(34))'' was published in the **Federal Register** on April 24, 2000 (65 FR 21645). It amended 21 CFR 1310.02(a) (List I chemicals) to reflect the status of GBL as a List I chemical. For regulatory purposes, DEA had no discretion in taking this action. Therefore, 21 CFR 1310.02(a) was amended as a final rule. Since it was published as a final rule, a threshold was not established because the process of notice and comment would have been circumvented.

A Notice of Request for Information was published in the **Federal Register** on October 23, 1998, at 63 FR 56941. The Notice was published in anticipation of GBL becoming a listed chemical. In response to that Notice, DEA received information on how GBL is distributed. In a Notice of Proposed Rulemaking, published in the **Federal Register** on October 24, 2001 (66 FR 53746), a zero threshold was proposed along with a means to exclude large scale industrial-type transactions from the definition of a ''regulated transaction.'' DEA learned of these large-scale transactions by comment in response to the Notice of Request for Information.

*Thresholds and How They Are Used*

Transactions involving listed chemicals that are not exempt by statute may be removed from the definition of ''regulated transaction'' (21 U.S.C. 802(39)) if regulation of such transactions is determined to be unnecessary for purposes of law enforcement. One option for doing so includes the establishment of a quantity threshold under 21 U.S.C. 802(39)(A).

DEA determined that it is necessary for purposes of law enforcement that no threshold be established for GBL. In the Notice of Proposed Rulemaking (NPRM) published at 66 FR 53746, DEA gave reasons why no threshold should be established. These included the small weights of GBL diverted for production of GHB and the fact that GBL is substituted directly, without chemical conversion, for GHB. No comments were received objecting to a zero threshold. Therefore, 21 CFR 1310.04(g)(1) is being modified to add a new paragraph to include GBL, thus finalizing that no threshold is established. This means that all transactions in GBL, except those defined at 21 CFR 1310.08(k), are regulated transactions. If the transaction is considered a regulated transaction, recordkeeping and reporting requirements as specified in 21 CFR Part 1310 apply.

*Exclusions and How They Are Used*

DEA is authorized to remove certain categories of transactions from the definition of a ''regulated transaction.'' Under 21 U.S.C. 802(39)(A)(iii) the agency may, by regulation, exempt ''any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by

regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this subchapter or subchapter II of this chapter.'' DEA is amending 21 CFR 1310.08 to exclude from the definition of a ''regulated transaction,'' transactions involving 4,000 kilograms (net weight) or more in a single container. This amendment is in response to a comment to the NPRM and is different than what the DEA originally proposed. Adopting the suggestion in the comment is expected to give more comprehensive regulatory relief to industry without significantly increasing the risk of diversion.

DEA would like to emphasize that the exclusion applies only to transactions of one or more single containers holding 4,000 kilograms (net weight) or more of GBL. That is, in multi-container shipments, it is a regulated transaction if any container has less than 4,000 kilograms or if the 4,000 kilograms is reached only by combining the weight of GBL in each container.

**II. Comments**

DEA received one comment in response to the Notice of Proposed Rulemaking ''Establishment of a Threshold for Gamma-Butyrolactone'' published at 66 FR 53746. The comment generally supported the proposal and offered comments on specific issues.

The comment informed DEA that some tank truck shipments of bulk chemicals are made by single segmented compartments. The minimum weight of GBL distributed by these bulk shipments is 9,000 pounds or 4,086 kilograms. Therefore, under the proposed exclusion of bulk distributions of 16,000 kilograms (net weight), these 4,086 kilogram shipments would be regulated. DEA was not aware of the lower minimum bulk shipment at the time the exclusion was proposed. DEA determined that this lower net weight for bulk shipments would not pose a greater risk of diversion and, therefore, based on the comment received, is providing an exclusion for domestic, import, and export distributions of gamma-butyrolactone weighing 4,000 kilograms (net weight) or more in a single container. This action will eliminate all industrial distributions identified by DEA that are not at significant risk of diversion.

The commenter requested clarification as to whether a DEA Form 486 will continue to be required for bulk export shipments. A DEA Form 486 is necessary only for exports involving regulated transactions. If the transaction is excluded from the definition of a ''regulated transaction'' pursuant to 21 CFR 1310.08, a DEA Form 486 is not necessary. If the export does not meet the conditions in 21 CFR 1310.08, a DEA Form 486 is necessary.

The commenter requested clarification of the definition of ''non-regulated transaction.'' A non-regulated transaction is specified in 21 CFR 1310.08 as an ''excluded transaction'' pursuant to 21 U.S.C. 802(39)(A)(iii). An excluded transaction is not subject to the recordkeeping or reporting requirements of 21 U.S.C. 830(a) and (b) except that 21 U.S.C. 830(b)(1)(C) applies to all regulated persons. That is, all regulated persons are required to report any unusual or excessive loss or disappearance of a listed chemical.

The definition of a ''regulated person'' is given at 21 U.S.C. 802(38) to include anyone who manufactures, distributes, imports, or exports a listed chemical, or acts as a broker or trader for an international transaction involving a listed chemical. Except for persons acting as brokers or traders for an international transaction, regulated persons handling any List I chemical are required to register pursuant to 21 U.S.C. 822. This registration requirement also applies to those regulated persons who are involved in only ''excluded transactions.'' In the case of this final rule, persons who only distribute 4,000 kilograms (net weight) or more of GBL in a single container are not subject to recordkeeping and reporting requirements but are required to register. A regulated person does not include someone who receives a listed chemical and consumes it by making a chemical mixture, as defined at 21 U.S.C. 802(40), or changes the listed chemical into a non-listed chemical by means of a chemical reaction.

*Regulatory Flexibility and Small Business Concerns*

This final rule will not have a significant economic impact on small business. Pub. L. 106–172 amended the CSA to make GBL a List I chemical effective February 18, 2000. Regulatory impact due to registration requirements was addressed in the final rule ''Placement of gamma-butyrolactone in List I of the Controlled Substances Act (21 U.S.C. 802(34))'' (65 FR 21645). In that final rule, DEA concluded that making GBL a List I chemical would not have a significant economic impact. That conclusion was based on an estimated number of new registrants and that all distributions in GBL are regulated. This final rule does not add new regulatory controls. In fact, it eliminates some large-scale industrial transactions from the definition of ''regulated transaction,'' thus, granting additional relief to industry. DEA identified 4,000 kilograms as the minimum amount available by tank-truck. DEA determined that clandestine operations will have difficulty handling tank-truck shipments but will be able to divert self-contained shipments of GBL, *i.e.,* containers of 55-gallons or less. Therefore, DEA is exempting tank-truck sized shipments (4,000 kilograms or more, net weight) from the requirements of this regulation.

New 21 CFR 1310.04(g)(1)(v) and 1310.08(k) are being added in this final rule. The designations of these new paragraphs are different than what was originally proposed because the CFR has been modified since the proposal was published.

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Administrator has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities.

*Executive Order 12866*

This regulation has been drafted and reviewed in accordance with Executive Order 12866, Section 1(b), Principles of Regulation. DEA has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, Section 3(f), Regulatory Planning and Review, and accordingly this rule has not 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 Civil Justice Reform.

*Executive Order 13132*

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

*Unfunded Mandates Reform Act of 1995*

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 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.

*Small Business Regulatory Enforcement Fairness Act of 1996*

This rule 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 $100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

**List of Subjects in 21 CFR Part 1310**

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

■ For the reasons set out above, 21 CFR part 1310 is amended to read as follows:

## PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

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

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

■ 2. Section 1310.04 is amended by adding a new paragraph (g)(1)(v), to read as follows:

**§ 1310.04 Maintenance of records.**

* * * * *

(g) * * *

(1) * * *

(v) gamma-Butyrolactone (Other names include: GBL; Dihydro-2(3H)-furanone; 1,2–Butanolide; 1,4–Butanolide; 4–Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone)

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■ 3. Section 1310.08 is amended by adding a new paragraph (k) to read as follows:

**§ 1310.08 Excluded transactions.**

* * * * *

(k) Domestic, import, and export distributions of gamma-butyrolactone weighing 4,000 kilograms (net weight) or more in a single container.

Dated: September 2, 2003.

**Karen P. Tandy,**

*Administrator.*

[FR Doc. 03–22963 Filed 9–9–03; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

## Office of Surface Mining Reclamation and Enforcement

## 30 CFR Part 946

**[VA–120–FOR]**

## Virginia Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

**ACTION:** Final rule; approval of amendment.

**SUMMARY:** We are approving a proposed amendment to the Virginia regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The program amendment increases the permit and anniversary fees for Coal Surface Mining and Reclamation permits issued by the Virginia Department of Mines, Minerals and Energy (DMME).

**EFFECTIVE DATE:** September 10, 2003.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert A. Penn, Director, Big Stone Gap Field Office; Telephone: (540) 523–4303. Internet: *rpenn@osmre.gov.*

**SUPPLEMENTARY INFORMATION:**



### I. Background on the Virginia Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, ''* * * a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.'' *See* 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Virginia program on December 15, 1981. You can find background information on the Virginia program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Virginia program in the December 15, 1981, **Federal Register** (46 FR 61088). You can also find later actions concerning Virginia's program and program amendments at 30 CFR 946.12, 946.13, and 946.15.

### II. Submission of the Amendment

By letter dated May 16, 2003 (Administrative Record Number VA–1029), the DMME submitted an amendment to the Virginia program. In its letter, the DMME stated that the 2003 Virginia General Assembly enacted legislation (House Bill 2465/ Senate Bill 1173 approved March 18, 2003) to increase the permit and anniversary fees for Coal Surface Mining and Reclamation permits issued by DMME.

The proposed amendment revises the Code of Virginia at section 45.1–235.E and the Virginia Coal Surface Mining and Reclamation Regulations at 4VAC25–130–777.17 concerning permit fees. Specifically, Virginia is increasing the permit application fee for a surface coal mining and reclamation permit from $12.00 to $26.00 per acre or any fraction thereof for the total acreage permitted. In addition, the anniversary fee is being increased from $6.00 to $13.00 per acre or any fraction thereof for areas disturbed under the permit. This fee is paid each year on the anniversary of the permit's issuance, and represents an ongoing permitting cost.

We announced receipt of the proposed amendment in the July 7, 2003, **Federal Register** (68 FR 40227). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment (Administrative Record Number VA–1031). We did not hold a public hearing or meeting because no one requested one. The public comment period ended on August 6, 2003. We received comments from four Federal agencies.

### III. OSM's Findings

We are approving the amendment. Our findings concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17 are presented below.

The Federal regulations at 30 CFR 777.17, concerning permit fees, provide that an application for a surface coal mining and reclamation permit shall be accompanied by a fee determined by the regulatory authority. The Federal regulations also provide that the fee may be less than, but shall not exceed, the actual or anticipated cost of reviewing, administering, and enforcing the permit. The fee increases proposed by Virginia are the first such increases since the State received permanent program approval in 1981. We find that the permit fees proposed by Virginia are reasonable and consistent with the