

**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