

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<sup>®</sup>, 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