§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9G, *Airspace Designations and Reporting Points,* dated September 1, 1999, and effective September 16, 1999, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Unalaska, AK [Revised]

Unalaska Airport
(Lat. 53°53′57″ N., long. 166°32′ 42″ W.)
Dutch Harbor NDB
(Lat. 53°54′19″ N., long. 166°32′57″ W.)

That airspace extending upward from 700 feet above the surface within 6.4-mile radius of the Unalaska Airport and within 2.9 miles each side of the Dutch Harbor NDB 360° bearing extending from the 6.4-mile radius to 9.5 miles north of the airport; and that airspace extending upward from 1,200 feet above the surface within 20-mile radius north of the airport between the Dutch Harbor NDB 305° bearing extending clockwise to the 075° bearing.

* * * * *

Issued in Anchorage, AK, on April 14, 2000.

Anthony M. Wylie,

Acting Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 00–10015 Filed 4–21–00; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[DEA Number 199F]

RIN 1117–AA52

Placement of Gamma-Butyrolactone in List I of the Controlled Substances Act (21 U.S.C. 802(34))

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: Public Law 106–172, signed into law on February 18, 2000, and known as the ''Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 1999,'' amends section 102(34) of the Controlled Substances Act as amended (CSA) by designating gamma-butyrolactone (GBL), the precursor to gamma-hydroxybutyric acid (GHB), as a List I chemical. Reflecting this change in stature, the Drug Enforcement Administration (DEA) is amending its regulation to reflect the status of GBL as a List I chemical subject to the requirements of the CSA and its regulations. Establishment of a threshold for GBL will be the subject of a separate rulemaking. Therefore, unless and until a threshold is established, any distribution of GBL is a regulated transaction as described by 21 CFR 1300.02(b)(28). All handlers of GBL must comply with the CSA regulatory requirements pertaining to List I chemicals as described in the body of this document.

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

DATES: *Effective:* April 24, 2000.

Registration application deadline: DEA must receive a properly completed DEA–510 registration application with fee from handlers of GBL on or before July 24, 2000.

SUPPLEMENTARY INFORMATION:

What Is DEA Doing and Whom Does It Effect?

GBL is gamma-butyrolactone, the precursor used in the clandestine production of gamma-hydroxybutyric acid (GHB). This Final Rule deals solely with amending 21 CFR 1310.02(a) to reflect that GBL is a List I chemical as established by Public Law 106–172. Consequently any person who imports, exports, or distributes GBL must register with DEA and make required records and reports.

What Authority Does DEA Have To Do This?

On February 18, 2000, Public Law 106–172 was enacted. This law requires the Attorney General (AG) to add gamma-hydroxybutyric acid (GHB) to Schedule I no later than April 18, 2000. Effective on February 18, 2000, Congress also specifically designated the GHB precursor, gamma-butyrolactone (GBL) as a List I chemical.

Why Is This Being Published as a Final Rule?

This publication amends 21 CFR 1310.02(a) to reflect the fact that Congress made GBL a List I chemical. For regulatory purposes, this action leaves DEA no discretion. Therefore, DEA is publishing this action as a Final Rule.

Why Was Control of GBL Necessary?

Law enforcement authorities have identified GBL in many GHB clandestine laboratories and documented its use as a precursor in the clandestine synthesis of GHB. There are no chemical substitutes for GBL as a precursor in the clandestine synthesis of GHB. Congress recognized that control of GBL as a List I chemical is necessary to prevent diversion for use in the illicit production of GHB and made it a List I chemical. This Final Rule amends 21 CFR 1310.02(a) to reflect the fact that GBL is a List I chemical subject to the requirements of the CSA and its regulations.

Is GBL Subject to Any Other Controls Under the CSA?

In addition to GBL functioning as a chemical precursor for the manufacture of GHB, it also produces psychoactive effects. If taken for human consumption, GBL and other chemicals, including 1,4-butanediol, are swiftly converted into GHB by the body. Abuse of these and other GHB-like substances is a significant law enforcement and public health problem. GBL and 1,4-butanediol are structurally and pharmacologically similar to GHB and are often substituted for GHB. Under certain circumstances they may satisfy the definition of a controlled substance analogue (21 U.S.C. 802(32)). Congress expressly contemplated this possibility by amending 21 U.S.C. 802(32) to state that the designation of GBL or any other chemical as a Listed chemical does not preclude a finding that the chemical is a controlled substance analogue and subject to the provisions of 21 U.S.C. 813.

Is There a Threshold for Transactions in GBL?

Public Law 106–172 did not establish a threshold for regulated transactions involving GBL. Therefore, the DEA is reviewing available data, including that provided by commenters in response to the **Federal Register** publication ''Industrial Uses and Handling of Gamma-butyrolactone; Solicitation of Information'' (63 FR 56941), regarding an appropriate threshold. This will be the subject of a separate rulemaking and will provide an opportunity for public comment. Until and unless a threshold is established, all covered transactions involving any amount of GBL are subject to the CSA regulatory requirements.

Each regulated person who engages in a regulated transaction involving GBL must keep a record of the transaction and file reports under certain circumstances (21 CFR 1300.02(b)(28)). If a threshold is established for GBL, the recordkeeping and reporting requirements will only apply to transactions, including cumulative

transactions, which meet or exceed the threshold (21 CFR part 1310). These transactions also include the importation and exportation of GBL.

Are Chemical Mixtures Containing GBL Subject to Control?

Chemical mixtures containing GBL will be treated the same as chemical mixtures containing any listed chemical. Currently, chemical mixtures containing listed chemicals are not subject to regulation. However, DEA is conducting a separate rulemaking to develop regulations governing the distribution of chemical mixtures that contain listed chemicals. A Notice of Proposed Rulemaking that addresses regulation of chemical mixtures containing listed chemicals was published in the **Federal Register** on September 16, 1998, (63 FR 49506). Because GBL was not a listed chemical at that time, the issue of GBL was not addressed. Therefore, DEA will publish a Notice of Proposed Rulemaking followed by a comment period to address the regulation of chemical mixtures containing GBL.

As a List I Chemical, What Specific Requirements Apply to GBL?

Persons interested in handling GBL must comply with the following:

1. *Registration.* Any person who manufactures or distributes GBL, or proposes to engage in the manufacture or distribution of GBL, shall obtain a registration pursuant to the CSA (21 U.S.C. 822). Regulations describing registration for List I handlers are set forth in 21 CFR part 1309.

Separate registration is required for retail distribution, non-retail distribution, importing, and exporting. Different locations operated by a single entity require separate registration if any location is involved with the distribution, import, or export of GBL. Effective Friday, February 18, 2000, any person distributing, importing, or exporting GBL became subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons who distribute, import, or export GBL to immediately complete and submit an application for registration and for DEA to immediately issue registrations for those activities. Therefore, in order to allow continued legitimate commerce in GBL, DEA is establishing in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to distribute, import, or export GBL, provided that DEA receives a properly completed application for registration to DEA on or before July 24, 2000. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration. The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, remain in effect. Additionally, the temporary exemption does not suspend applicable federal criminal laws relating to GBL, nor does it supersede state or local laws or regulations. All handlers of GBL must comply with their state and local requirements in addition to the CSA regulatory controls.

2. *Records and Reports.* The CSA (21 U.S.C. 830) requires that records are kept and reports are made that involve listed chemicals. Regulations describing recordkeeping and reporting requirements are set forth in 21 CFR part 1310. A record must be made and maintained for two years after the date of a transaction involving a List I chemical, provided the transaction is a regulated transaction. Because a threshold has not yet been established, a distribution, receipt, sale, importation, or exportation of GBL in any amount is a regulated transaction (21 CFR 1300.02(b)(28)).

Each regulated bulk manufacturer of GBL shall submit manufacturing, inventory and use data on an annual basis (21 CFR 1310.05(d)). Bulk manufacturers that produce GBL solely for internal consumption are not required to submit this information. Existing standard industry reports containing the required information are acceptable, provided the information is readily retrievable from the report.

21 CFR 1310.05 requires that each regulated person shall report to DEA any regulated transaction involving an extraordinary quantity, an uncommon method of payment or delivery, or any other circumstance that causes the regulated person to believe that the listed chemical will be used in violation of the CSA.

3. *Import/Export.* All imports/exports of GBL shall comply with the CSA (21 U.S.C. 957 and 971). Regulations for importation and exportation of List I chemicals are described in 21 CFR part 1313. Separate registration is necessary for each activity (21 CFR 1309.22).

4. *Administrative Inspection.* Places, including factories, warehouses, or other establishments and conveyances, where regulated persons may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of GBL or where records relating to those activities are maintained, are controlled premises as defined in 21 CFR 1316.02(c). The CSA (21 U.S.C. 880) allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316 subpart A.

Regulatory Flexibility and Small Business Concerns

Public Law 106–172 amended the CSA to make GBL a List I chemical effective February 18, 2000. DEA has no discretion in this matter. This Final Rule simply makes the necessary amendment to the regulations to bring them into conformance with the new requirement of the law. However, to insure the orderly continuation of legitimate commerce DEA is providing in the Final Rule temporary exemption from the registration requirement for persons handling GBL provided that DEA receives a properly completed application for registration on or before July 24, 2000.

This Final Rule deals solely with amending 21 CFR 1310.02(a) to reflect the placement of GBL in List I by Public Law 106–172. It does not address a threshold; therefore, economic impact is based on registration. DEA will address the issue of a threshold and its impact in a separate Notice of Proposed Rulemaking followed by a comment period.

Prior to enactment of Public Law 106–172, DEA had been aware of the possibility that GBL could become regulated under the CSA pending the scheduling of GHB in the CSA. Anticipating this, DEA sought information on the manufacturing, distribution, consumption, storage, disposal, and uses of GBL from legitimate handlers of GBL. DEA published a notice in the **Federal Register** on October 23, 1998, titled, ''Industrial Uses and Handling of Gamma-butyrolactone; Solicitation of Information'' (63 FR 56941). The DEA received eight responses, one each from the three GBL manufacturers, one from a European association, and four from end-users. Information on the extent of distributors and wholesalers of GBL was not provided.

In the absence of specific information from the industry, DEA must estimate the number of companies distributing GBL. GBL is a common and widely used industrial solvent, therefore DEA is assuming that whoever distributes the common solvents acetone, toluene, or methyl ethyl ketone is likely to distribute GBL. DEA has identified approximately 1,400 firms that distribute one or more of these chemicals.

Provided the number of GBL handlers is 1,400, the initial total registration cost would be $833,000, based on the current new application fee of $595.00 for each

individual company. The total annual re-registration cost, based on the present renewal fee of $477.00 for each individual company, would be $667,800. It should be noted that DEA published a proposed rule in the **Federal Register** on December 1, 1999 (64 FR 67216) that proposed to reduce the new application fee to $326.00 and the renewal fee to $171.00 for each individual company, respectively. If finalized, these revised fees would reduce the total burden for initial registration and for annual re-registration to $456,400 and $239,400, respectively. In addition to the specific dollar cost, the registration requirement would require an annual reporting burden of 700 hours. This is based on the estimated one-half hour required to complete and submit an application for registration or re-registration. Therefore, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Deputy administrator has reviewed this application 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. The 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.

Administrative Procedure Act—Good Cause Exemption

DEA finds that there is good cause to exempt this action from the notice and comment requirements of Section 553 of the Administrative Procedures Act on the grounds that notice and comment are unnecessary. Public Law 106–172 amended the CSA to make GBL a List I Chemical effective February 18, 2000. This action is a conforming amendment to 21 CFR 1310.02(a) to make the regulations consistent with the requirements of the law. DEA has no discretion in this action and can not deviate from what Congress has enacted. Therefore, DEA is publishing this action as a Final Rule. To ameliorate this final action, DEA has included a temporary exemption from the registration requirement for persons handling GBL provided that DEA receives a properly completed application for registration on or before July 24, 2000.

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.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Plain Language Instructions

The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of this regulation, call or write Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Washington, DC 20537, Telephone (202) 307–7297.

List of Subjects in 21 CFR Part 1310

Drug traffic control, Reporting and recordkeeping requirements.

For reasons set out above, 21 CFR part 1310 is amended as follows:

PART 1310—[AMENDED]

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

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

2. Section 1310.02 is amended by adding a new paragraph (a)(24) to read as follows:

§ 1310.02 Substances covered

* * * * *

(a) List I chemicals:

* * * * *

(24) gamma-Butyrolactone (Other names include: GBL; Dihydro-2 (3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxy-butyric acid lactone) 2011

3. Section 1310.09 is amended by adding a new paragraph (c) to read as follows:

§ 1310.09 Temporary exemption from registration

* * * * *

(c) Each person required by section 302 of the act (21 U.S.C. 822) to obtain a registration to distribute, import, or export GBL is temporarily exempted from the registration requirement, provided that the DEA receives a proper application for registration on or before July 24, 2000. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

Dated: April 14, 2000.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 00–9988 Filed 4–21–00; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–00–029]

RIN 2115–AE46

Special Local Regulations: Annual Suncoast Kilo Run, Sarasota Bay, Sarasota, FL

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is amending the final rule for the Annual Suncoast Kilo Run to change the date from the first Friday in July to the last Friday in June for 2000 only. The high-speed boat race event will be held from 8 a.m. to 1 p.m. Eastern Daylight Time (EDT) on June 30, 2000, in Sarasota Bay, Sarasota, Florida. These regulations are needed to provide for the safety of life on navigable waters during the event.