This action therefore corrects part 1308 to remove any reference to control of benzylfentanyl and thenylfentanyl in schedule I.

Regulatory Certifications

Administrative Procedure Act (5 U.S.C. 553)

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (5 U.S.C. 553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. The temporary placement of benzylfentanyl and thenylfentanyl in Schedule I expired on November 29, 1986. The substances were never scheduled and should have been removed from Title 21 of the Code of Federal Regulations, part 1308. This Final Rule corrects this by removing benzylfentanyl and thenylfentanyl from the listing of controlled substances in schedule I. As this Final Rule makes a technical correction by removing benzylfentanyl and thenylfentanyl from the Code of Federal Regulations, DEA finds it unnecessary and impracticable to permit public notice and comment. Therefore, DEA is publishing this document as a final rule. Further, as the removal of these substances prevents confusion about the scheduling of these substances, DEA finds there is good cause to make this final rule effective immediately upon publication.

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities. This action removes the substances benzylfentanyl and thenylfentanyl from the schedules of controlled substances. These substances were temporarily scheduled in 1985 under the emergency scheduling provisions (21 U.S.C. 811, 21 CFR 1308.11(g)) and that temporary scheduling expired on November 29, 1986; however, the substances were never removed from the listing.

Executive Order 12866

The Deputy Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 § 1(b). It has been determined that this is not "a significant regulatory action." Therefore, this action 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 $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). 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 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

■ For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

■ 2. Section 1308.11 is amended by revising paragraph (g) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(g) *Temporary listing of substances subject to emergency scheduling.* Any material, compound, mixture or preparation which contains any quantity of the following substances:

(1) [Reserved.]

(2) [Reserved.]

Dated: June 19, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–15529 Filed 6–28–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–222F]

RIN 1117–AA64

Exempt Chemical Mixtures Containing Gamma-Butyrolactone

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This rulemaking finalizes a November 12, 2008, Notice of Proposed Rulemaking in which DEA proposed that chemical mixtures that are 70 percent or less gamma-butyrolactone (GBL), by weight or volume, be automatically exempt from regulatory controls under the Controlled Substances Act (CSA). DEA is seeking through this rulemaking to exempt only those chemical mixtures that do not represent a significant risk of diversion. This regulation makes GBL chemical mixtures, in concentrations greater than 70 percent, subject to List I chemical regulatory requirements of the CSA, except if exempted through an existing categorical exemption. DEA is taking this action because there is a serious threat to the public safety associated with the ease by which GBL is chemically converted to the schedule I controlled substance gamma-hydroxybutyric acid (GHB).

DEA recognizes that concentration criteria alone cannot identify all mixtures that warrant exemption. As a result, DEA regulations provide for an application process by which manufacturers may obtain exemptions from CSA regulatory controls for those GBL chemical mixtures that are not automatically exempt under the concentration criteria.

DATES: This rulemaking becomes effective July 29, 2010. Persons seeking registration must apply on or before July 29, 2010 to continue their business pending final action by DEA on their application.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and Controlled Substances Import and Export Act (21 U.S.C. 801 *et seq.*), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), parts 1300 to end. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical purposes and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA as amended also requires DEA to regulate the manufacture and distribution of chemicals that may be used to manufacture controlled substances. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances.

Illicit Uses of Gamma-Butyrolactone

Gamma-Butyrolactone, or GBL, is a chemical that is used as a precursor in the illicit manufacture of the schedule I controlled substance gamma-hydroxybutyric acid, or GHB. GBL is a necessary and important chemical precursor in the clandestine synthesis of GHB because, to date, no other chemical has been identified as a substitute for GBL in the clandestine process. Congress recognized this and regulated GBL as a List I chemical upon enactment of Pub. L. 106–172, the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000, on February 18, 2000.

GBL and GHB induce a sense of euphoria and intoxication and are abused for their central nervous system (CNS) depressant effect. An overdose from GBL or GHB may result in respiratory depression, coma, and even death. Both substances have been associated with drug-facilitated sexual assaults. The Drug Abuse Warning Network (DAWN) is a national surveillance system operated by the Substance Abuse and Mental Health Services Administration (SAMHSA) to monitor trends in drug emergency department visits. SAMHSA collects information on GHB and GBL separately but reports GHB and GBL together in its publications. This reflects the similar threat to public safety and abuse liability of GBL to GHB.

The conversion of GBL to GHB in a clandestine laboratory is a simple one-step process. Availability of GBL is the determining factor in producing GHB, not the execution of complicated chemical procedures or having sophisticated scientific equipment. GBL is a unique chemical precursor. It can be either converted into GHB by a simple chemical reaction or efficiently converted into GHB by the body upon ingestion, thus producing the same pharmacological effects as ingesting GHB. For this reason, abusers or predators seeking to use GBL on their victims routinely substitute GBL for GHB to obtain the same type of intoxication.

Other Laws That Apply to GBL: Controlled Substance Analogue Provisions

Section 802(32)(B) of Title 21 provides 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 under subparagraph (A) of the definition 21 U.S.C. 802(32)(A).[1] A controlled substance analogue is treated, for purposes of Federal law, as a schedule I controlled substance to the extent intended for human consumption (21 U.S.C. 813). The analogue provision of the CSA has been applied to prosecute individuals who have diverted GBL for human consumption. Although a chemical commodity when used by legitimate industry, diversion of GBL is tantamount to diversion of a schedule I controlled substance if intended for human consumption.

Concern Over GBL-Containing Chemical Mixtures

Prior to control as a List I chemical, GBL had been sold under false pretenses to disguise its intended use. Suppliers pretended that GBL was being sold for use as ink jet printer cleaners, room deodorizers, and as educational kits (which purport to demonstrate the scientific principle of an exothermic chemical reaction).

Since the designation of GBL as a List I chemical in 2000, persons who manufacture, distribute, import, or export GBL must be registered with DEA and maintain records of transactions in GBL. These regulatory requirements prevent unscrupulous persons from freely distributing GBL. Persons without a legitimate business need to manufacture or distribute GBL do not receive the required registration from DEA. DEA believes that those wishing to traffic GBL are less willing to purchase GBL from DEA-approved registrants who are required to maintain records that are accessible to DEA.

DEA has observed the retail marketing and promotion of chemical mixtures containing GBL. Exempt chemical mixtures containing GBL were sold as cosmetic products and contained greater than 99 percent GBL (along with dye(s), fragrance(s), skin conditioners, and other ingredients). DEA became aware that persons were purchasing such products for conversion to GHB or directly ingesting these products for their GBL content. Retailers reported that they quickly sold out of these products. DEA notified retailers of the potential for abuse, which resulted in the voluntary withdrawal of these products from store shelves. Manufacturers of said products stated their intent to reformulate these products.

DEA is concerned that legitimate businesses may be unintentionally contributing to the diversion of GBL. Without regulatory controls, DEA is unable to monitor distributions of such chemical mixtures containing GBL, since registration and recordkeeping requirements do not apply. Regulation of GBL chemical mixtures pursuant to 21 U.S.C. 802(39)(A)(vi) is necessary to

[1] 21 U.S.C. 802(32)(A) Except as provided in subparagraph (C), the term "controlled substance analogue" means a substance— (i) The chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(ii) Which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) With respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

(B) The designation of gamma butyrolactone or any other chemical as a Listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to paragraph (A) of this paragraph that the chemical is a controlled substance analogue.

reduce the threat to the public health and safety.

Defining a Chemical Mixture

Title 21 U.S.C. 802(40) defines the term "chemical mixture" as "a combination of two or more chemical substances, at least one of which is not a List I chemical or a List II chemical, except that such term does not include any combination of a List I chemical or a List II chemical with another chemical that is present solely as an impurity." Therefore, a chemical mixture contains any number of listed chemicals in combination with any number of non-listed chemicals.

DEA does not consider a chemical mixture to mean the combination of a listed chemical and an inert carrier. An inert carrier is any chemical that does not modify the function of the listed chemical but is present to aid in the delivery of the listed chemical. Examples include, but are not limited to, dilutions in water and the presence of a carrier gas. For purposes of control under the CSA, these examples would be controlled as List I or List II chemicals, not as a chemical mixture containing a List I or List II chemical.

Past Regulations Regarding Chemical Mixtures

The Chemical Diversion and Trafficking Act of 1988 (Pub. L. 100–690) (CDTA) created the legal definition of a "chemical mixture" (21 U.S.C. 802(40)), and exempted chemical mixtures from regulatory coverage. The CDTA established 21 U.S.C. 802(39)(A)(v) to exclude "any transaction in a chemical mixture" from the definition of a "regulated transaction." The result of such exemption was that it provided traffickers with an unregulated source for obtaining listed chemicals for use in the illicit manufacture of controlled substances.

The Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103–200) (DCDCA), enacted in April 1994, subjected all chemical mixtures containing List I and List II chemicals to CSA regulatory requirements, unless such chemical mixtures were specifically exempted by regulation. The regulatory requirements include recordkeeping, reporting, and security for all regulated chemical mixtures with the additional requirement of registration for handlers of List I chemical mixtures. The DCDCA also provided the Attorney General with the authority to establish regulations exempting chemical mixtures from the definition of a "regulated transaction," "based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered" (21 U.S.C. 802(39)(A)(vi)).

DEA treats all chemical mixtures containing List I and List II chemicals as non-regulated (upon the withdrawal of its proposed rule "Implementation of the Domestic Chemical Diversion Control Act of 1993 (DCDCA)" (59 FR 51887, October 13, 1994; withdrawn at 59 FR 63738, December 9, 1994)) until it promulgates a final rule that identifies chemical mixtures that are exempt for each List I and List II chemical. The withdrawal sought to prevent the immediate regulation of qualified chemical mixtures, which was not necessary and would impose an undue burden on industry. It also provided DEA the opportunity to gather information to implement regulations pursuant to 21 U.S.C. 802(39)(A)(vi).

In 2003, DEA published a Final Rule (68 FR 23195, May 1, 2003) that identified exempt mixtures containing the chemicals ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and pseudoephedrine, with an effective date of June 2, 2003. In a second Final Rule (69 FR 74957, December 15, 2004; corrected at 70 FR 294, January 4, 2005,) DEA promulgated regulations that defined exempt chemical mixtures for 27 of the remaining 38 listed chemicals. The effective date was January 14, 2005. As gamma-butyrolactone (GBL) was not a listed chemical when DEA initiated this regulatory action in 1998, regulation of chemical mixtures containing gamma-butyrolactone was not addressed but was the subject of a separate regulatory action.

Regulations Regarding Chemical Mixtures Containing GBL

On July 19, 2002, DEA published in the **Federal Register** an Advance Notice of Proposed Rulemaking (ANPRM) (67 FR 47403; corrected at 67 FR 53842, August 19, 2002; corrected at 67 FR 56776, September 5, 2002) in anticipation of identifying GBL-containing chemical mixtures to exempt by regulation. The ANPRM invited interested persons to submit information related to legitimate formulations containing GBL, including the concentration of GBL in their mixtures. Comments received to that ANPRM provided information DEA used in its Notice of Proposed Rulemaking.

On November 12, 2008, DEA published a Notice of Proposed Rulemaking (73 FR 66815) which proposed the control of certain GBL chemical mixtures.

Defining Exempt Chemical Mixtures Containing GBL

In defining exempt chemical mixtures containing GBL for purposes of the proposed rule, the clandestine use of GBL and the requirements of 21 U.S.C. 802(39)(A)(vi) were heavily considered. The requirements described by statute do not allow for exemptions based on such factors as: (1) Manufacturers selling only to known customers, (2) the cost of the mixture, (3) the customer's knowledge of the product's chemical content, packaging, and/or such related topics. 21 U.S.C. 802(39)(A)(vi) requires DEA to establish an exemption based on the finding (1)that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and (2) that the listed chemical or chemicals contained in the mixture cannot be readily recovered.

After examination of the comments on the ANPRM and after weighing the risk of diversion, on November 12, 2008 (73 FR 66815), DEA proposed a 70 percent concentration limit (by weight or volume) to identify GBL chemical mixtures that do not pose a significant risk of diversion. In that NPRM, DEA stated that it anticipated that chemical mixtures over 70 percent, as identified for use as protective coatings and films, will be automatically exempt pursuant to 21 CFR 1310.12(d)(2) ("Completely formulated paints and coatings"), which is being revised to clarify that film-forming agents are exempted. Additionally, the NPRM clarified that other chemical mixtures having concentrations of GBL over 70 percent may qualify for exemption via the application process (21 CFR 1310.13). DEA proposed a 70 percent concentration limit in an effort to prevent the automatic exemption of chemical mixtures with higher concentration limits such as solvent-based mixtures (*e.g.,* cleaners or thinners) which DEA had concluded could be useful to traffickers.

Comments

In response to the November 12, 2008, Notice of Proposed Rulemaking (73 FR 66815), DEA received three comments. One comment was from the American Chemistry Council's GBL/1,4-Butanediol (BDO) Panel comprised of companies that domestically produce and/or distribute GBL. The Panel member companies manufacture a large

percentage of the total GBL produced in the United States. The Panel stated that DEA's GBL proposal offers a reasonable approach to help protect the public from risks of potential diversion "without unnecessary administrative and financial burden" and further stated that the Panel "believes that exempting chemical mixtures containing 70 percent or less of GBL from List I requirements of the CSA "provides a balanced criteria for regulatory exemption."

A second comment was received directly from one of the Panel's member companies, which is a major manufacturer and supplier of GBL. The comment stated that this firm is in agreement with the Panel's comments in support of DEA's proposed regulation. The commenter further stated that it believed DEA "thoroughly evaluated the information gathered in response to the Advanced Notice of Proposed Rulemaking for the exemption of GBL chemical mixtures published July 19, 2002 [67 FR 47403] and that DEA has "proposed a reasonable approach for exempting such mixtures."

A third comment was received from the Healthcare Distribution Management Association (HDMA) which represents the nation's primary, full service healthcare product distributors. The comment stated that HDMA reached out to groups in the chemical industry, and to its own members, in an attempt to identify specific products containing GBL (in concentrations greater than 70 percent) which would be subject to the proposed regulatory controls. To date, HDMA stated that it has not identified any such products which are distributed by healthcare product distributors. This conclusion is consistent with information developed by DEA. DEA does not believe that any products distributed by healthcare distributors will fall under the proposed regulatory controls. Therefore, DEA does not believe that this final rule will have any impact upon HDMA members.

After careful consideration of the comments received, DEA is hereby finalizing these regulatory controls exactly as proposed in the November 12, 2008, Notice of Proposed Rulemaking (73 FR 66815). Therefore, chemical mixtures that are 70 percent or less gamma-butyrolactone (GBL), by weight or volume, are automatically exempt from regulatory controls under the CSA. This regulation makes GBL chemical mixtures, in concentrations greater than 70 percent, subject to List I chemical regulatory requirements of the CSA, except if exempted through an existing categorical exemption as provided in 21 CFR 1310.12(d). Most notably, 21 CFR 1310.12(d)(2) provides a category exemption for completely formulated paints and coatings. As such, completely formulated paints and coatings consisting of greater that 70 percent GBL shall not become regulated as a result of this final rule and remain exempt from CSA chemical regulatory controls such as recordkeeping, reporting, registration, and import/export requirements.

DEA recognizes that concentration and category criteria alone cannot identify all mixtures that warrant exemption. As a result, 21 CFR 1310.13 provides for an application process by which manufacturers may obtain exemptions from CSA regulatory controls for those GBL chemical mixtures that are not automatically exempt under the concentration or categorical criteria.

Thresholds and Excluded Transactions for Regulated GBL Chemical Mixtures

The List I chemical GBL, as described in 21 CFR 1310.04(g)(1), does not have a threshold. Therefore, all transactions in regulated GBL chemical mixtures are regulated transactions. Certain transactions described in 21 CFR 1310.08 are excluded from the definition of a regulated transaction. These excluded transactions, as specified in 21 CFR 1310.08(d), are domestic, import, and export distributions of GBL weighing 4,000 kilograms (net weight) or more in a single container. This exclusion also applies to chemical mixtures.

Requirements That Apply to Regulated List I Chemical Mixtures

Persons interested in handling chemical mixtures containing List I chemicals (here referred to as regulated chemical mixtures) must comply with the following:

Registration. Any person who manufactures, distributes, imports or exports a regulated chemical mixture, or proposes to engage in the manufacture, distribution, importation or exportation of a regulated chemical mixture, shall obtain a registration pursuant to the CSA (21 U.S.C. 822 and 957). Regulations describing registration for List I chemical handlers are set forth in 21 CFR part 1309.

A separate registration is required for manufacturing, distribution, importing, and exporting. Different locations operated by a single entity require separate registration if any location is involved with the manufacture, distribution, import, or export of regulated chemical mixtures. DEA recognizes, however, that it is not possible for persons who manufacture, distribute, import, or export GBL-containing regulated chemical mixtures to immediately complete and submit an application for registration and for DEA to issue registrations immediately for those activities. To allow continued legitimate commerce in GBL-containing regulated chemical mixtures, DEA is establishing in 21 CFR 1310.09(k) a temporary exemption from the registration requirement for persons desiring to manufacture, distribute, import, or export GBL-containing regulated chemical mixtures, provided that DEA receives a properly completed application for registration on or before July 29, 2010. 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-containing regulated chemical mixtures, nor does it supersede state or local laws or regulations. All handlers of regulated chemical mixtures must comply with their state and local requirements in addition to the CSA and other federal regulatory controls.

DEA notes that warehouses are exempt from the requirement of registration and may lawfully possess List I chemicals, if the possession of those chemicals is in the usual course of business (21 U.S.C. 822(c)(2), 21 U.S.C. 957(b)(1)(B)). For purposes of this exemption, the warehouse must receive the List I chemical from a DEA registrant and shall only distribute the List I chemical back to the DEA registrant and registered location from which it was received. All other activities conducted by a warehouse do not fall under this exemption; a warehouse that distributes List I chemicals to persons other than the registrant and registered location from which they were obtained is conducting distribution activities and is required to register accordingly (21 U.S.C. 802(39)(A)(ii)).

Records and Reports. The CSA (21 U.S.C. 830) requires that certain records be kept and reports be 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 GBL is a listed chemical for which no minimum threshold has been established (21 CFR

1310.04(g)(1)(v)), a distribution, receipt, sale, importation, or exportation of a GBL-containing regulated chemical mixture in any amount, except those very large distributions described in 21 CFR 1310.08(k), is a regulated transaction (21 CFR 1300.02(b)(28)). Title 21 CFR 1310.08(k) exempts domestic, import, and export distributions of GBL weighing 4,000 kilograms (net weight) or more in a single container from the definition of regulated transaction. This exemption also applies to its chemical mixtures. The net weight of the mixture is determined by measuring the mass of the mixture, not the mass of the GBL contained in the mixture.

Further, 21 U.S.C. 830(b) and 21 CFR 1310.05(a) requires that each regulated person shall report to DEA: (1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the CSA; (2) any proposed regulated transaction with a person whose description or other identifying characteristics the Administration has previously furnished to the regulated person; (3) any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person, and any in-transit loss in which the regulated person is the supplier; and (4) any domestic regulated transaction in a tableting or encapsulating machine.

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

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 regulated chemical mixtures 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 Certifications

Regulatory Flexibility and Small Business Concerns

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to determine whether a rule will have a significant economic impact upon a substantial number of small entities. The final rule would impose no new requirements on manufacturers, distributors, importers, and exporters that are already registered to handle GBL. DEA has not been able to identify any United States firm that handles high purity GBL mixtures that would be subject to the rule. Therefore, the rule will not affect a substantial number of small entities.

In addition, the requirements of the rule other than the registration fee can be met with standard business records, that is, with orders, invoices, shipping papers, etc. that the business creates and maintains in the normal course of business. The registration fee is $2,293 for manufacturers, and $1,147 for distributors, importers, and exporters. DEA registration and reregistration application fees are established by rulemaking in accordance with DEA statutory mandates (21 U.S.C. 886a). The sectors that could be affected by this rule are organic chemical manufacturers (NAICS 325199) and chemical wholesalers (NAICS 42469); importers and exporters could be either manufacturers or wholesalers. The smallest firms (those with fewer than five employees) in the organic chemical manufacturing and chemical wholesale sector have annual shipments and sales of about $1.27 million and $1.05 million, respectively, based on the 2002 Economic Census, updated to 2007 dollars. The registration fee would represent 0.2 percent of a small chemical manufacturer's shipments and 0.1 percent of a wholesaler's sales. Consequently, even if a United States-based small entity exists that markets high purity GBL mixtures, the rule would not impose a significant economic burden.

Further, as discussed above, commenters supported this regulatory action and were, themselves, unable to identify any entities that would be directly impacted by this rule.

In accordance with the Regulatory Flexibility Act, the Deputy 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. It has been determined that this rule is a "significant regulatory action" under Executive Order 12866, Section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget.

As noted in the previous section, DEA is unaware of any United States firm that will have to register as a manufacturer, distributor, importer, or exporter of a GBL mixture. Most commercial mixtures that may exceed the 70 percent concentration are coatings and films, which are already exempt. The only mixtures that DEA has been able to identify that will be covered are essentially pure GBL (99.6–99.9 percent) being sold as paint strippers and cleaners in Europe. Anyone wanting to import these products would be required to register, but DEA considers it unlikely that anyone with a legitimate need for a paint stripper or cleaner would pay the high prices ($120 to $160 per liter) when substitute products are readily available in the U.S. for a fraction of the cost. DEA also notes that any mixture that is more than 70 percent GBL by weight or volume may qualify for an exemption if GBL cannot be readily recovered from the mixture and the mixture cannot be easily used to produce controlled substances.

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 $120,000,000 or more (adjusted for inflation) 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.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). 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.

Paperwork Reduction Act

Persons manufacturing, distributing, importing and exporting chemical mixtures containing a List I chemical are required to register with DEA. This rule regulates chemical mixtures due to the presence of GBL; however, such mixtures are automatically exempt if the concentration of GBL is 70 percent or less by weight or volume. Under this method of automatic exemption, persons who handle chemical mixtures with concentration levels of GBL of 70 percent or less will not be subject to CSA regulatory controls, including the requirement to register with DEA. Further, many GBL chemical mixtures are already categorically exempt from regulatory control as fully formulated paints and coatings (21 CFR 1310.12(d)(2)). As discussed previously, commenters supported this regulatory action and were, themselves, unable to identify handlers of GBL that would be subject to this rule. For persons handling chemical mixtures containing GBL in concentration levels of greater than 70 percent who are not otherwise exempt from regulatory controls, DEA anticipates granting some of these mixtures exempt status by the application process (21 CFR 1310.13). Therefore, although DEA believes the impact of this rulemaking under the Paperwork Reduction Act will be minimal, at this time it is not feasible for DEA to determine the extent of the impact of this rulemaking on the regulated industry. Once DEA has determined the impact, it will make the necessary filing with the Office of Management and Budget to adjust the burden for its information collection "application for Registration under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993" [OMB control number 1117–0031] for the affected industry.

List of Subjects in 21 CFR Part 1310

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

■ For the reasons set out above, 21 CFR part 1310 is amended 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, 827(h), 830, 871(b), 890.

■ 2. Section 1310.09 is amended by adding new paragraph (k) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(k)(1) Each person required by sections 302 or 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated GBL-containing chemical mixtures, pursuant to sections 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption on or before July 29, 2010. 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.

(2) Any person who manufactures, distributes, imports or exports a GBL-containing chemical mixture whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

■ 3. Section 1310.12 is amended in the Table of Concentration Limits in paragraph (c) by adding gamma-butyrolactone in alphabetical order between "Ethylamine and its salts" and "Hydriodic acid" under List I chemicals and by revising paragraph (d)(2) to read as follows:

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

	DEA chemical code No.	Concentration (percent)	Special conditions
List I Chemicals			
* * * * * * *			
Gamma-Butyrolactone	2011	70% by weight or volume.	
* * * * * * *			

* * * * *

(d) * * *

(2) Completely formulated paints and coatings: Completely formulated paints and coatings are only those formulations that contain all of the components of the paint or coating for use in the final application without the need to add any additional substances except a thinner if needed in certain cases. A completely formulated paint or coating is defined as any clear or pigmented liquid, liquefiable or mastic composition designed for application to a substrate in a thin layer that is converted to a clear or opaque solid protective, decorative, or functional adherent film after application. Included in this category are clear coats, top-coats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks,

temporary protective coatings and film-forming agents.

* * * * *

Dated: June 18, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–15518 Filed 6–28–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2010–0430]

Drawbridge Operation Regulation; Black River, Port Huron, MI

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: Commander, Ninth Coast Guard District, issued a temporary deviation from the regulation governing the operation of the Military Street Bridge at Mile 0.33, 7th Street Bridge at Mile 0.50, and the 10th Street Bridge at Mile 0.94 over the Black River, at Port Huron, MI. This deviation temporarily changes the bridge operating schedules to accommodate the City's special events for 2010. This temporary deviation allows the bridges to remain secured to masted navigation on the dates and times listed.

DATES: This deviation is effective on June 26, 2010 from 10:45 p.m. to 11:30 p.m., on July 9, 2010 from 6 p.m. to 8 p.m., and on July 14, 2010 from 6:15 p.m. to 9 p.m.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2010–0430 and are available online by going to *http://www.regulations.gov,* inserting USCG–2010–0430 in the "Keyword" box and then clicking "Search". They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216–902–6085, e-mail; *lee.d.soule@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The City of Port Huron, Michigan, who owns and operates these drawbridges, requested a temporary deviation from the current operating regulations set forth in 33 CFR 117.625. The purpose of this request is to facilitate efficient management of all transportation needs and provide timely public safety services during these special events. The most updated and detailed current marine information for this event, and all bridge operations, is found in the Local Notice to Mariners and Broadcast Notice to Mariners issued by the Ninth District Commander. In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time periods. These deviations from the operating regulations are authorized under 33 CFR 117.35.

Dated: June 11, 2010.

M. N. Parks,

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 2010–15703 Filed 6–28–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2010–0522]

Drawbridge Operation Regulations; Milwaukee, Menomonee, and Kinnickinnic Rivers and South Menomonee and Burnham Canals, Milwaukee, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: Commander, Ninth Coast Guard District, issued a temporary deviation from the regulation governing the operation of the Broadway Street Bridge at Mile 0.79, Water Street Bridge at Mile 0.94, Saint Paul Avenue Bridge at Mile 1.21, the Clybourn Street Bridge at Mile 1.28, Michigan Street Bridge at Mile 1.37, and the Wisconsin Avenue Bridge at Mile 1.46 over the Milwaukee River at Milwaukee, WI, during the scheduled Festa Italiana, and the Summerfest public events for the 2010 season.

DATES: This deviation is effective from 9:30 p.m. to 1 a.m. on June 24, 2010 and July 3, 2010. A rain date of June 25 and July 4, 2010 are authorized. June 25, 2010 through July 2, 2010 from 11 p.m. to 1 a.m. daily, and July 15, 2010 to July 18 from 10 p.m. to midnight daily.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2010–0522 and are available online by going to *http://www.regulations.gov*, inserting USCG–2010–0522 in the "Keyword" box and then clicking "Search". They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. Lee D. Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone 216–902–6085, e-mail *lee.d.soule@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The City of Milwaukee, WI, which owns and operates these drawbridges, has requested a temporary deviation from the current operating regulations set forth in 33 CFR 117.1093. The purpose of this request is to facilitate efficient management of all transportation needs and provide timely public safety services during these special events. The most updated and detailed current marine information for this event, and all bridge operations, is found in the Local Notice to Mariners and Broadcast Notice to Mariners issued by the Ninth District Commander. On June 24, 2010 and including the rain date of June 25, 2010 the bridges need not open for any vessel from 9:30 p.m. to 1 a.m. except at the discretion of the Milwaukee Police Department. From June 25 through July 2, 2010 the bridges need not open for recreational vessels from 11 p.m. to 1 a.m. except at the discretion of the Milwaukee Police Department. From July 15, 2010 through July 18, 2010 the bridges need not open for recreational vessels between the hours of 10 p.m. and midnight for recreational vessels. In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time periods. These deviations from the operating regulations are authorized under 33 CFR 117.35.