CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
333(g)(1)	250,000	For the first violation in any 3-year period	2007	250,000 (not adjusted)
333(g)(1)	500,000	For each subsequent violation in any 3-year period	2007	500,000 (not adjusted)
335b(a)	275,000	Per violation for an individual	2008	300,000
335b(a)	1,100,000	Per violation for ''any other person''	2008	1,200,000
360pp(b)(1)	1,100	Per violation per person	2008	1,100 (not adjusted)
360pp(b)(1)	330,000	For any related series of violations	2008	355,000
42 U.S.C.				
263b(h)(3)	11,000	Per violation	2008	11,000 (not adjusted)
300aa–28(b)(1)	110,000	Per occurrence	2008	120,000

Dated: October 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–222P]

RIN 1117–AA64

Exempt Chemical Mixtures Containing Gamma-Butyrolactone

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: DEA is proposing 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. If finalized as proposed, this regulation would result in GBL chemical mixtures, in concentrations greater than 70 percent, becoming 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, 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 criteria.

DATES: Written comments must be postmarked and electronic comments sent on or before January 12, 2009.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–222p'' on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to Drug Enforcement Administration, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your

comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., 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 this statute 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 Public Law 106–172, the ''Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000,'' on February 18, 2000.

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 in order to obtain the same type of intoxication.

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. In sum, the information available from the sources discussed above suggests a similar threat to public safety and abuse liability of GBL to GHB.

Other Regulations 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 (21 U.S.C. 802(32)).[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 pretend 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

[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 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.

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.

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) [as amended by Title VII of Pub. L. 109–172] is necessary to reduce the threat to the public health and safety.

Information Gathered by DEA Concerning GBL Chemical Mixtures

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.

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) as amended by Title VII of Pub. L. 109–172).

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) [as amended by Title VII of Pub. L. 109–172].

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 was not a listed chemical when DEA initiated this regulatory action in 1998, regulation of chemical mixtures containing gamma-butyrolactone was not addressed but is the subject of this separate regulatory action.

DEA has concluded that some mixtures of GBL are especially prone to diversion. Since the conversion of GBL to GHB is a simple chemical process, DEA is proposing to automatically exempt only those GBL chemical mixtures that meet the exemption criteria specified in 21 U.S.C. 802(39)(A)(vi) as amended by Title VII of Pub. L. 109–172, i.e., those chemical mixtures 1) that are formulated in such a way that the chemical mixture cannot be easily used in the illicit production of a controlled substance and 2) in which the List I or List II chemical cannot be readily recovered.

Comments

DEA received nine responses to the ANPRM, six from industrial firms and three from national associations. In general, the comments expressed a willingness to inform DEA of their formulations to provide assistance in drafting regulations. Most respondents claimed that GBL could not be readily extracted from their chemical mixtures. All respondents stated that good business practices, such as knowing their customer, prevent (limit) diversion. Responses also stated that selling to end-users (non-retail), the high cost of their GBL-containing chemical mixtures, and the customer not having knowledge of the composition, were also deterrents to diversion. The respondents use GBL-

containing chemical mixtures for the following applications: herbicides, automotive coatings, varnishes, electronics, polymers, and other specialty products.

Specifically, two comments stated that GBL is used in chemical mixtures having application to automotive coatings. Because of the low concentration of GBL and the complex composition of these chemical mixtures, DEA agrees with the commenters' statements that these mixtures do not pose a significant risk of diversion. In a Final Rule published in the **Federal Register** on December 15, 2004 (69 FR 74957; corrected at 70 FR 294, January 4, 2005), DEA amended 21 CFR 1310.12 by adding subparagraph 1310.12(d)(2) that defines completely formulated paints and coatings as automatically exempt from CSA regulatory control pertaining to chemicals. This exemption also applies to completely formulated paints and coatings that contain GBL.

In addition, three comments informed DEA that GBL is contained in chemical mixtures used in agricultural chemicals. GBL and other solvent chemicals act as a delivery system for the active ingredient and prevent crystallization. Other chemicals used in these chemical mixtures are emulsifying and defoaming agents. The commenters stated that these chemical mixtures contain up to 20 percent GBL, that the GBL is difficult to extract, and that these chemical mixtures are toxic.

Four comments notified DEA that some chemical mixtures have application in the semiconductor industry contain GBL. In general, these chemical mixtures are used to form films and/or for the processing and cleaning of these films and associated equipment. Commenters indicated that the concentration of GBL ranges from a few percent to approximately 90 percent. From a review of the comments, DEA concludes that the majority of these chemical mixtures are film forming. DEA notes that 21 CFR 1310.12(d)(2) automatically exempts from CSA regulatory control completely formulated paints and coatings and includes these types of film-forming chemical mixtures. This exemption is based on the codified definition of completely formulated paints and coatings in 21 CFR 1310.12(d)(2) that includes a ''functional adherent film.'' In an effort to further clarify that these film forming agents are automatically exempt from CSA chemical regulatory controls, DEA is proposing that 21 CFR 1310.12(d)(2) be revised to state that, ''Included in this category are clear coats, top-coats, primers, varnishes, sealers, adhesives, lacquers, stains, shellacs, inks, temporary protective coatings and film-forming agents.''

One of the aforementioned commenters had concerns about small amounts of GBL in discarded waste streams and informed DEA that these waste materials should be exempt. DEA has finalized regulations (69 FR 74957, December 15, 2004; corrected at 70 FR 294, January 4, 2005) that exempt ''chemical mixtures that are distributed directly to an incinerator for destruction or authorized waste recycler or reprocessor where such distributions are documented on United States Environmental Protection Agency Form 8700–22'' (21 CFR 1310.12(d)(1)).

Finally, DEA was informed that some foods and food flavorings contain GBL in minute amounts that are measured in parts per million (ppm). In 1972, an expert panel of the Flavor and Extract Manufacturers Association of the United States concluded that these levels of GBL to be Generally Recognized as Safe (GRAS) as flavoring agents. The commenter informed DEA that typical concentrations are extremely small and less than 22 ppm. DEA recognizes that foods and flavorings that contain GBL levels in the ppm concentration range are GRAS and that such food items have no pharmacological activity.

Food flavorings are chemical mixtures, and if above concentration limits, these mixtures are subject to CSA regulatory controls and provisions. GBL can be treated as a schedule I controlled substance analogue if intended for human consumption. However, currently marketed food flavorings that contain GBL and are GRAS are very unlikely to lead to criminal prosecution as schedule I controlled substance analogues. This is based on (1) Food flavorings being concentrates and consumed only after addition to a food item and not meant to be consumed in the concentrated form, (2) the food flavoring lacks abuse potential because the low concentration of GBL (i.e., ppm concentrations) does not produce pharmacological activity, and (3) treatment of GBL use in food flavorings as GRAS had been in effect prior to placement of GBL in the CSA with no threat to public safety. However, persons who divert food flavorings that contain GBL above the GRAS ppm concentrations for the purposes of manufacturing a controlled substance in violation of the CSA or for human consumption are subject to prosecution. Also, knowing or intentional distribution of GBL or GBL mixtures, regardless of concentration, to persons for the purpose of abuse is subject to prosecution.

Defining Exempt Chemical Mixtures Containing GBL

In defining exempt chemical mixtures containing GBL for purposes of this 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 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.

After examination of the comments on the ANPRM and after weighing the risk of diversion, DEA is proposing a 70 percent concentration limit (by weight or volume) to identify GBL chemical mixtures that do not pose a significant risk of diversion. The comments on the ANPRM suggest that some companies' formulations are no more than 70 percent GBL. DEA anticipates 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). Other chemical mixtures identified in the comments having concentrations of GBL over 70 percent may qualify for exemption via the application process (21 CFR 1310.13). DEA is proposing 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). DEA has concluded that these products could be useful to traffickers.

Thresholds and Excluded Transactions for Regulated GBL Chemical Mixtures

GBL, a List I chemical 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 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 958). 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. In order to allow continued legitimate commerce in GBL-containing regulated chemical mixtures, DEA is proposing to establish in 21 CFR 1310.09(i) 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 60 days after publication of the Final Rule implementing this Notice of Proposed Rulemaking. 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 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 proposed rule will have a significant economic impact upon a substantial number of small entities. The proposed 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 proposed rule would 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.

In accordance with the Regulatory Flexibility Act, the Acting 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 recognizes that there may be products of which it is not aware that could be subject to the rule and seeks comments on that subject. 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 proposes that chemical mixtures regulated due to the presence of GBL are automatically exempt if the concentration of GBL is 70 percent or less by weight or volume. Under this proposed 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. For persons handling chemical mixtures containing GBL in concentration levels of greater than 70 percent, 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 proposed to be 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) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export regulated GBL-containing chemical mixtures, pursuant to §§ 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption on or before [60 days from date of publication of the Final Rule implementing this Notice of Proposed Rulemaking]. 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.

3. Section 1310.12 is amended in the Table of Concentration Limits in paragraph (c) by adding an entry for 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 the component 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: October 31, 2008.

Michele M. Leonhart,

Acting Administrator.

[FR Doc. E8–26606 Filed 11–10–08; 8:45 am]

BILLING CODE 4410–09–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 51, 54, 61, and 69

[WC Docket Nos. 06–122, 05–337, 04–36, 03–109; CC Docket Nos. 01–92, 99–200, 99–68, 96–98, 96–45; FCC 08–262]

Universal Service Contribution Methodology; High-Cost Universal Service Support; IP-Enabled Services; Lifeline and Link Up; Developing a Unified Intercarrier Compensation Regime; Numbering Resource Optimization; Intercarrier Compensation for ISP-Bound Traffic; Implementation of the Local Competition Provisions in the Telecommunications Act of 1996; Federal-State Joint Board on Universal Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission seeks comment on three specific proposals that are available in the appendices of the document. We note that members of industry, Congress, and the general public have urged the Commission to seek comment on these proposals. We also seek particular comment on two questions. First, should the additional cost standard utilized under section 252(d)(2) of the Act be either the existing TELRIC standard or the incremental cost standard described in the draft order? Second, should the terminating rate for all section 251(b)(5) traffic be set as either a single, statewide rate or a single rate per operating company?

DATES: Comments are due on or before November 26, 2008 and reply comments are due on or before December 3, 2008.

ADDRESSES: You may submit comments, identified by WC Docket Nos. 06–122, 05–337, 04–36, 03–109; CC Docket Nos. 01–92, 99–200, 99–68, 96–98, 96–45 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web Site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- *E-mail: ecfs@fcc.gov,* and include the following words in the body of the message, ''get form.'' A sample form and directions will be sent in response. Include the docket number in the subject line of the message.
- *Mail:* Secretary, Federal Communications Commission, 445 12th Street, SW., Washington, DC 205544.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jennifer McKee, Telecommunications Access Policy Division, Wireline Competition Bureau, 202–418–7400 or TTY: 202–418–0484 (universal service), or Victoria Goldberg, Pricing Policy Division, Wireline Competition Bureau, 202–418–1520 or TTY 202–418–0484 (intercarrier compensation).

SUPPLEMENTARY INFORMATION: In this Further Notice of Proposed Rulemaking (FNPRM), the Commission seeks comment on three specific proposals. *See Universal Service Contribution Methodology; High-Cost Universal Service Support; IP-Enabled Services; Lifeline and Link Up; Developing a Unified Intercarrier Compensation Regime; Numbering Resource Optimization; Intercarrier Compensation for ISP-Bound Traffic; Implementation of the Local Competition Provisions in the Telecommunications Act of 1996; of Federal-State Joint Board on Universal Service,* WC Docket Nos. 06–122, 05–337, 04–36, 03–109; CC Docket Nos. 01–92, 99–200, 99–68, 96–98, 96–45, Order on Remand and Report and Order and Further Notice of Proposed Rulemaking, FCC 08–262 (rel. Nov. 5, 2008) (*Order on Remand and Report and Order and Further Notice of Proposed Rulemaking*). Copies of the *Order on Remand and Report and Order and Further Notice of Proposed Rulemaking* and any subsequently filed documents in this matter are or will be available on the Commission's Internet site at *http://www.fcc.gov* and for public inspection Monday through Thursday from 8 a.m. to 4:30 p.m. and Friday from 8 a.m. to 11:30 a.m. at the FCC Reference Information Center, Portals II, 445 12th St., SW., Room CY–A257, Washington, DC 20554. Copies of any such documents may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI), Portals II, 445 12th St., SW., Room CY–B402, Washington, DC 20554, telephone (202) 488–5300, facsimile (202) 488–5563, TTY (202) 488–55672, e-mail