MARINETTE COUNTY
WATERFALLS CAPITAL OF WISCONSIN

OFFICE OF THE
DISTRICT ATTORNEY

Joseph J. Klumb
District Attorney

Allen R. Brey
Assistant District Attorney

Brian S. Asmus
Assistant District Attorney

February 21, 2002

Senator Gary George
Chair of the Judiciary, Consumer Affairs
and Campaign Finance Reform Committee
State Senate
State of Wisconsin
P.O. Box 7882
Madison, WI 53707-7882

RE: AB 464

Dear Senator George:

I am writing to urge that you support AB 464 and its amendments, and that you place them before the Judiciary, Consumer Affairs and Campaign Finance Reform Committee for a hearing.

Last spring a young lady in our jurisdiction died after consuming 1,4-Butanediol (commonly known as 1,4-BD). The consumption occurred in a recreational setting and the substance was provided to her by another individual. I believe that if 1,4-BD were a prohibited substance under Chapter 961, I would be able to prosecute that case under our version of the Len Bias statute. Unfortunately, that substance is not currently a prohibited substance. AB 464 and the proffered amendments would close this loophole in the law.

Our statutes prohibit the possession and/or consumption of analogs of certain substances. Among them are Gamma-hydroxybutyric acid (commonly known as GHB) a date rape drug. In attempting to learn what 1,4-BD is, I spoke extensively with members of our State Crime Laboratories. They were unable to state an opinion whether or not 1,4-BD is an analog of GHB. I did learn that if a person consumes 1,4-BD, the human body processes it and GHB is a by-product. I also learned that the affects of the GHB in 1,4-BD are the same as if GHB had originally been consumed.

1926 Hall Avenue • Marinette, WI 54143-1717 • Phone 715-732-7490 • FAX 715-732-7496

I believe that the proffered Bill and amendments will close an important loophole in the current statutory scheme. I have located an expert in the metropolitan St. Louis, Missouri area who advises me that there have been several deaths in that region due to the consumption of 1,4-BD. I am in the process of engaging him as an expert so that I may attempt a prosecution concerning the death of the young lady in our jurisdiction. If AB 464 and the proffered amendments had been law at the time of the young lady's death, I would already be prosecuting her case.

I am willing to speak with you, your staff members, or other interested legislators concerning the need to prohibit the possession and distribution of 1,4-BD when intended for human consumption. Please feel free to contact me concerning this matter.

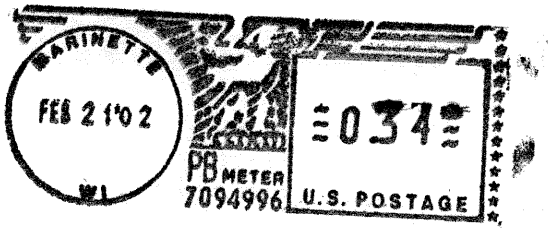
Sincerely yours,

Allen R. Brey
Assistant District Attorney

ARB/mp
cc: Senator Scott Fitzgerald
Senator Joanne Huelsman
Senator Fred Risser
Senator Robert Wirch

MARINETTE COUNTY
DISTRICT ATTORNEY

JOSEPH J. KLUMB
1926 Hall Avenue
Marinette, WI 54143-1717



Senator Gary George
Chair of the Judiciary, Consumer Affairs
and Campaign Finance Reform Committee
State Senate
State of Wisconsin
P.O. Box 7882
Madison, WI 53707-7882

53707+7882 31

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRBa1323/1dn
RLR:jld:rs

February 28, 2002

AB 464

Dan Rossmiller:

The treatment of GBL and 1,4–BD in this amendment is different from the treatment of these substances under federal law. Under federal law, a drug may be designated as a "controlled substance" or as a "listed chemical." Federal law prohibits the manufacture, distribution, or possession of controlled substances, except by certain persons. However, under federal law, activities related to listed chemicals are regulated rather than prohibited. In 2000, the federal government designated GHB as a controlled substance and designated GBL as a listed chemical. (See 65 FR 13235–13238 and 65 FR 21645–21647.) Federal law does not designate 1,4–BD as either a controlled substance or a listed chemical. In addition, the federal government suggested in supplementary material to the April 24, 2000, federal rule concerning GBL that GBL and 1,4–BD could possibly be treated as analogs of GHB for purposes of prosecution. (See 65 FR 21645–21467.) Under Wisconsin law, the manufacture, distribution, and possession of an analog of a controlled substance is prohibited.

In order to be consistent with federal law, you may wish to remove GBL from the controlled substances schedule and leave 1,4–BD off the controlled substances schedule. Please note that, as treated in the amendment, GBL and 1,4–BD are the only substances for which there is a qualifier stating that the substances are only controlled if intended for human ingestion.

Robin Ryan
Legislative Attorney
Phone: (608) 261–6927
E–mail: robin.ryan@legis.state.wi.us

State of Wisconsin
2001 – 2002 LEGISLATURE

LRBa1323/1
RLR:jld:rs

SENATE AMENDMENT ,

TO 2001 ASSEMBLY BILL 464

At the locations indicated, amend the bill as follows:

1. Page 1, line 5: delete the material inserted by assembly amendment 1 and substitute "prohibitions related to certain controlled substances".

2. Page 2, line 1: before that line insert:

"**SECTION 1g.** 961.14 (5) (ac) of the statutes is created to read:

961.14 **(5)** (ac) 1,4–Butanediol, commonly known as "1,4–BD," if it is intended for ingestion by humans.

SECTION 1m. 961.14 (5) (ag) of the statutes is amended to read:

961.14 **(5)** (ag) Gamma–hydroxybutyric acid (commonly known as gamma hydroxybutyrate or "GHB") ~~and gamma–butyrolactone~~ except any drug product containing gamma–hydroxybutyric acid that is approved by the U.S. department of health and human services under 21 USC 355 or 356.

SECTION 1r. 961.14 (5) (aj) of the statutes is created to read:

961.14 **(5)** (aj) Gamma–butyrolactone if it is intended for ingestion by humans.

SECTION 1v. 961.18 (3) (bm) of the statutes is created to read:

961.18 **(3)** (bm) Any drug product containing gamma–hydroxybutyric acid that is approved by the U.S. department of health and human services under 21 USC 355 or 356.

SECTION 1x. 961.41 (1) (hm) (intro.) of the statutes, as created by 2001 Wisconsin Act 16, is amended to read:

961.41 **(1)** (hm) (intro.) Gamma–hydroxybutyric acid, gamma–butyrolactone, 1,4–Butanediol, 3,4–methylenedioxymethamphetamine, 4–bromo–2,5–dimethoxy–beta–phenylethylamine, 4–methylthioamphetamine, ketamine, or a controlled substance analog of gamma–hydroxybutyric acid, gamma–butyrolactone, 3,4–methylenedioxymethamphetamine, 4–bromo–2,5–dimethoxy–beta–phenylethylamine, or 4–methylthioamphetamine is subject to the following penalties if the amount manufactured, distributed, or delivered is:

SECTION 1y. 961.41 (1m) (hm) (intro.) of the statutes, as created by 2001 Wisconsin Act 16, is amended to read:

961.41 **(1m)** (hm) (intro.) Gamma–hydroxybutyric acid, gamma–butyrolactone, 1,4–Butanediol, 3,4–methylenedioxymethamphetamine 4–bromo–2,5–dimethoxy–beta–phenylethylamine, 4–methylthioamphetamine, ketamine, or a controlled substance analog of gamma–hydroxybutyric acid, gamma–butyrolactone, 3,4–methylenedioxymethamphetamine 4–bromo–2,5–dimethoxy–beta–phenylethylamine, or 4–methylthioamphetamine is subject to the following penalties if the amount possessed, with intent to manufacture, distribute, or deliver is:".

3. Page 7, line 25: after page 1, line 10, of the material inserted by assembly amendment 2, insert:

"**SECTION 12m.** 961.41 (3g) (f) of the statutes is amended to read:

961.41 **(3g)** (f) If a person possesses or attempts to possess gamma–hydroxybutyric acid, gamma–butyrolactone, 1,4–Butanediol, ketamine or flunitrazepam, the person may be fined not more than $5,000 or imprisoned for not more than 2 years or both.".

(END)

Senator Gary R. George
State of Wisconsin
Sixth Senate District

118 South, State Capitol Building
P. O. Box 7882
Madison, WI 53707-7882
(608) 266-2500

4011 W. Capitol Drive
Milwaukee, WI 53216
(414) 445-9436
(877) 474-2000

Facsimile Cover Sheet

To: Mr. William Black, Esq.

From: Office of State Senator Gary R. George

Recipient's Fax Number: 1-7083

Number of pages: 5, including cover sheet.

Please review and call me
Dan Rossmiller, Chief of Staff.

If you have difficulty receiving this fax transmission please call (608) 266-2500.

* Amdt. to AB 464.

Senator Gary R. George
State of Wisconsin
Sixth Senate District

118 South, State Capitol Building
P. O. Box 7882
Madison, WI 53707-7882
(608) 266-2500

4011 W. Capitol Drive
Milwaukee, WI 53216
(414) 445-9436
(877) 474-2000

Facsimile Cover Sheet

To: Ron Sklansky

From: Office of State Senator Gary R. George

Recipient's Fax Number: 6-3830

Number of pages: 5, including cover sheet.

Amdt. to AB 464

If you have difficulty receiving this fax transmission please call (608) 266-2500.

Testimony of
R. Martin Smith, Ph.D.
Wisconsin Department of Justice
Crime Laboratories

Providing information on A.B. 464
5 March, 2002

The language in Chapter 961.14 that currently controls the use and distribution of gamma-hydroxybutyric acid ("GHB") and gamma-butyrolactone ("GBL") does not address several issues. These issues are addressed in the changes to s. 961.14(5) that are proposed in A.B. 464.

- First, "GBL" is a widely used industrial solvent. It is not a federal controlled substance, but is instead a "List I chemical." This means that industrial producers and distributors of this substance need only register the production and distribution of "GBL" with the federal Drug Enforcement Administration (DEA) in order to meet federal requirements. Under the current language, industrial producers and distributors in Wisconsin must apply for a separate license in order to produce and distribute "GBL" for legitimate purposes. The new language would limit illicit possession and distribution to situations in which the "GBL" is "intended for human consumption."
- "GBL" is converted to "GHB" in the body, and thereby acts as a biochemical "precursor" to "GHB." Another substance that is similarly converted to "GHB" in the body is 1,4-butanediol ("1,4-BD"). The Wisconsin Crime Laboratories, as well as other forensic laboratories around the country, have seen an increase in cases in which "1,4-BD" was administered in order to produce the same effect as "GHB." "1,4-BD" therefore appears to pose the same dangers for abuse and human consumption as "GHB."
- Like "GBL," "1,4-BD" is also an industrial solvent that is produced and distributed in large quantities. Therefore language that limits illicit possession and distribution to situations in which it is "intended for human consumption" seems desirable.
- At this time there are no other known chemicals that can be ingested and converted by the body into "GHB." However, a number of substances can be envisioned that might fall into this category. Since these chemicals may or may not fall under the "analog" portion of Chapter 961 (which allows prosecution of a chemical analog of a Schedule I or II substance to begin as if it were a Schedule I controlled substance), language has been added to the entry for "GHB" to include unspecified substances that could be "metabolically converted to GHB."

ORPHAN MEDICAL

Testimony for the Judiciary, Consumer Affairs and Campaign Finance Reform Committee
Tuesday, March 5, 2002
11:00 am • Room 411 South

Good Morning Chairperson George and Members of the Committee:
My name is Sara Wolff and I am a Policy Analyst to Orphan Medical, a small pharmaceutical company in Minneapolis dedicated to developing medicines for people who suffer from rare diseases. I submit this testimony in support of AB464 and the amendment offered by the Controlled Substances Board.

We have been working with the federal government and states around the country to appropriately control the various forms of gamma hydroxybutyrate, or GHB. Unlike other legal or illegal drugs, GHB comes in several forms:

- **An easily-made, homebrewed concoction** used by body builders as a muscle enhancer, rave party-goers as a euphoric when mixed with alcohol, and by sexual predators to facilitate sexual assault. Wisconsin appropriately lists this form of GHB in Schedule I.

- **Commonly used industrial chemicals** that when consumed naturally turn into GHB in the body. The most common examples are gamma butyrolactone (GBL — a substance currently controlled by Wisconsin law) and 1,4 butanediol (1,4 BD — a substance *not* currently controlled by Wisconsin law), which are produced in millions of pounds each year for legitimate industrial use. Law enforcement officials in Florida, Texas, California, Arkansas and other states report that these GHB substitutes have largely replaced the use of homemade GHB.

- **A promising, FDA-sanctioned investigational new drug** for the treatment of cataplexy, a disabling symptom of the rare disease, narcolepsy. This medical form of GHB is being developed by Orphan Medical. FDA action is anticipated next month.

In 1998, Wisconsin was ahead of most of the country when it recognized the danger to public health posed by the recreational use of GHB and GBL by listing the substances in Schedule I.

However, the legislature did not realize at the time that placing GBL in schedule I would create problems for Wisconsin industries that commonly use GBL as a degreaser and solvent in the processing of plastics, cosmetics, and computer equipment.

Meanwhile, law enforcement and crime labs in Wisconsin report increases in the abuse of 1,4 BD, another GHB substitute that, like GBL, is a chemical legitimately used by industry, but unlike GBL, goes uncontrolled in Wisconsin. Prosecutors do not have the necessary tools to deal with those who abuse 1,4 BD for its GHB effects.

The amendment offered by the Controlled Substances Board places both GBL and 1,4 BD in Schedule I, "when intended for human consumption," thereby protecting legitimate industrial use while giving law enforcement tools to appropriately combat illicit use of these substances. This approach has been adopted by states including Maine, New Mexico and Oklahoma.

In addition, the amendment places an FDA approved medical formulation of GHB in Schedule III, allowing an estimated 1,700 Wisconsin residents with narcolepsy access to life-changing medication. All other forms of GHB including the homebrewed and the industrial chemicals remain in Schedule I. This split-schedule model was adopted by the federal government in 2000 with the enactment of the Hillory Farias and Samantha Reid Date Rape Prohibition Act. Wisconsin law ensures that illicit use of Schedule I or Schedule III GHB receives the same penalties.

We believe this bill and amendment is a win-win solution: for rape-crisis advocates, industry, law enforcement, prosecutors and narcolepsy patients — everyone except drug dealers.

We urge you to support passage of AB464 and the amendment. Thank you for your time.

Sara E. Wolff

Sara E. Wolff
Policy Analyst
to Orphan Medical
888-738-2332, ext. 1801
wolff@collemcvoy.com

Senator Gary R. George
State of Wisconsin
Sixth Senate District

118 South, State Capitol Building
P. O. Box 7882
Madison, WI 53707-7882
(608) 266-2500

4011 W. Capitol Drive
Milwaukee, WI 53216
(414) 445-9436
(877) 474-2000

Facsimile Cover Sheet

To: Cindy Benning

From: Office of State Senator Gary R. George

Recipient's Fax Number: (414) 961-5521

Number of pages: 5, including cover sheet.

amdt. to AB 464. Please review and call me.

If you have difficulty receiving this fax transmission please call (608) 266-2500.

FAX COVER SHEET

Columbia Hospital Pharmacy
2025 East Newport Avenue
Milwaukee, WI 53211
Telephone: (414) 961-3070
Fax: (414) 961-5521

Date: 2/13/02

To: Dan Rosmiller

Fax: 608-266-7381

From: Cindy Benning

Comments: Hope this is clear. Any questions, please call. Thank you for your interest.
414-961-3873

This Fax contains 2 pages, including this cover sheet.

Suggested amendment to SS 961 to encompass illicit use of GHB, GBL and 1-4BD

Bolded are additions, strick-out, deletions

961.14 (5) Depressants. Any material, compound, mixture or preparation which contains any quantity of any of the following substances having a depressant effect on the central nervous system, including any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation:

(ad) 1,4-Butanediol (commonly known as "1,4-BD), when intended for human consumption

(ag) Gamma-hydroxybutyric acid (commonly known as gamma hydroxybutyrate or "GHB") ~~and gamma butyrolactone~~ **or, except those substances specifically listed in subparagraphs (ad) and (aj) of this paragraph, any substance that is metabolically converted to gamma-hydroxybutyric acid.**

(aj) Gamma-butyrolactone (commonly known as "GBL"), when intended for human consumption.

This section is copied from 21CFR 1308.13(c)(5)

961.18(3) (?)
Any drug product containing gamma hydroxybutyric acid including salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug and Cosmetic Act

8500 Normandale Lake Blvd Suite 2400
Minneapolis MN 55437-3809
T 952 852 7500 F 952 852 8100

COLLE + McVOY

February 15, 2002

The Honorable Gary George
Chair of the Judiciary,
Consumer Affairs and Campaign Finance Reform Committee
State Senate
State of Wisconsin
State Capitol, Room 118 South
Madison, WI 53707

Dear Senator George:

On behalf of the law enforcement community, rape crisis advocates and the estimated 2,600 Wisconsin residents who suffer from the rare disease called narcolepsy, I am seeking your committee's consideration of AB 464 and an accompanying amendment proposed by the Controlled Substances Board. The proposal would help solve several significant problems caused by the current statutes regarding the control of various forms of gamma hydroxybutrate, or GHB.

The federal government and many state authorities now recognize that unlike most available legal or illegal drugs, GHB comes in several forms:

- **An easily made, home-brewed concoction** used by body-builders as a muscle enhancer, rave party-goers as a euphoric when mixed with alcohol and by sexual predators to facilitate sexual assault. Recipes and supply kits are available on the Internet, but use of homemade GHB has been decreasing. This substance is currently listed in Schedule I in Wisconsin.

- **Commonly used industrial chemicals** that when consumed are naturally converted into GHB in the body. The use of these GHB substitutes by body builders, partygoers and sexual predators is rising. The most common examples are gamma butyrolactone (GBL — a substance currently controlled by Wisconsin law) and 1,4 butanediol (1,4 BD — a substance *not* currently controlled by Wisconsin law), which are produced in millions of pounds each year for legitimate industrial use.

- **A promising, FDA-sanctioned investigative new drug for the treatment of cataplexy**, a disabling symptom of narcolepsy. Cataplexy is the complete loss of muscle control. It affects about 65 percent of the estimated 2,600 Wisconsin residents with narcolepsy. The pharmaceutical formulation is being developed by Orphan Medical, a Minnesota-based developer of therapies to treat rare diseases. FDA action is anticipated this April.

Wisconsin's current statutes pose three problems for industry, law enforcement and patient groups.

Issue #1: Industrial Use of GBL

In 1998, Wisconsin was ahead of most of the country when it recognized the danger to public health posed by the recreational use of GHB and GBL by listing the substances in Schedule I.

However, the legislature did not realize at the time that placing GBL in Schedule I would create regulatory problems for Wisconsin industries that commonly use GBL in the processing of plastics, cosmetics, and computer equipment.

Issue #2: 1,4 BD Loophole

Meanwhile, law enforcement and crime labs in Wisconsin report increases in the abuse of 1,4 BD, another GHB substitute. Like GBL, 1,4 BD is a chemical legitimately used by industry, but unlike GBL, 1,4 BD is uncontrolled in Wisconsin. Prosecutors do not have the necessary tools to deal with those who abuse 1,4 BD for its GHB effects.

Solution

Both of the above problems can be addressed by listing GBL and 1,4 BD in Schedule I "when intended for human ingestion." This language protects legitimate use by industry while providing law enforcement with laws to combat illicit consumption of these chemicals for their GHB effects.

Issue #3: Allowing Narcolepsy Patients Access to Life-Changing Medication

In 2000, Congress distinguished illicit GHB from a doctor prescribed formula of GHB in the federal Controlled Substances Act. FDA-approved medical GHB was listed in Schedule III, thus allowing narcolepsy patients suffering from cataplexy access to this life-changing medication. Homemade GHB and industrial chemicals abused for their GHB effects were placed in Schedule I.

Solution

Wisconsin may wish to adopt a similar schedule by placing FDA-approved medical GHB in Schedule III. Under Wisconsin law, illicit use of the medical product would still be punishable with Schedule I penalties.

The amendment drafted by the Controlled Substance Board to AB 464 offers a simple solution to address the problems currently facing industry, law enforcement and narcolepsy patients in Wisconsin.

As most of the provisions in AB 464 concerning enhanced penalties were adopted last session, the thrust of AB 464 lies in the fact that it brings penalties for abuse of MDMA (or Ecstasy — one of the fastest growing drugs of abuse among young people) in line with that of GHB, Flunitrazepam and Ketamine.

Please consider using AB 464 as an opportunity for the Senate Judiciary Committee to also provide law enforcement with the tools to combat the newest form of illicit GHB abuse. Without some action, use of 1,4 BD for its GHB effects will continue to be legal in Wisconsin.

Sincerely,

Sara Wolff
for Orphan Medical

State Legislatures

Title: Legal Chemicals Being Used for Date Rape.

Summary: Twenty states have passed laws to protect women from the effects of the date rape drug, GHB, but almost as soon as the statutes were signed, criminals found ways to use perfectly legal substitutes. These odorless, tasteless chemicals mix easily in drinks and render the victim unconscious. GHB also has cropped up on college campuses and at rave (all-night dance) parties.

Source: State Legislatures
Date: 02/01/2001
Price: $2.95
Document Size: Very Short (337 words)
Document ID: UU20010305150003820
Subject(s): Acquaintance rape--Laws, regulations, etc.; Women--Crimes against; Drugs--Laws, regulations, etc.; Gamma-hydroxybutyrate--Usage
Citation Information: (ISSN: 0147-6041), Vol. 27 No. 2 Pg. 9
Document Type: Article

State Legislatures

Legal Chemicals Being Used for Date Rape.

Twenty states have passed laws to protect women from the effects of the date rape drug, GHB, but almost as soon as the statutes were signed, criminals found ways to use perfectly legal substitutes. These odorless, tasteless chemicals mix easily in drinks and render the victim unconscious. GHB also has cropped up on college campuses and at rave (all-night dance) parties.

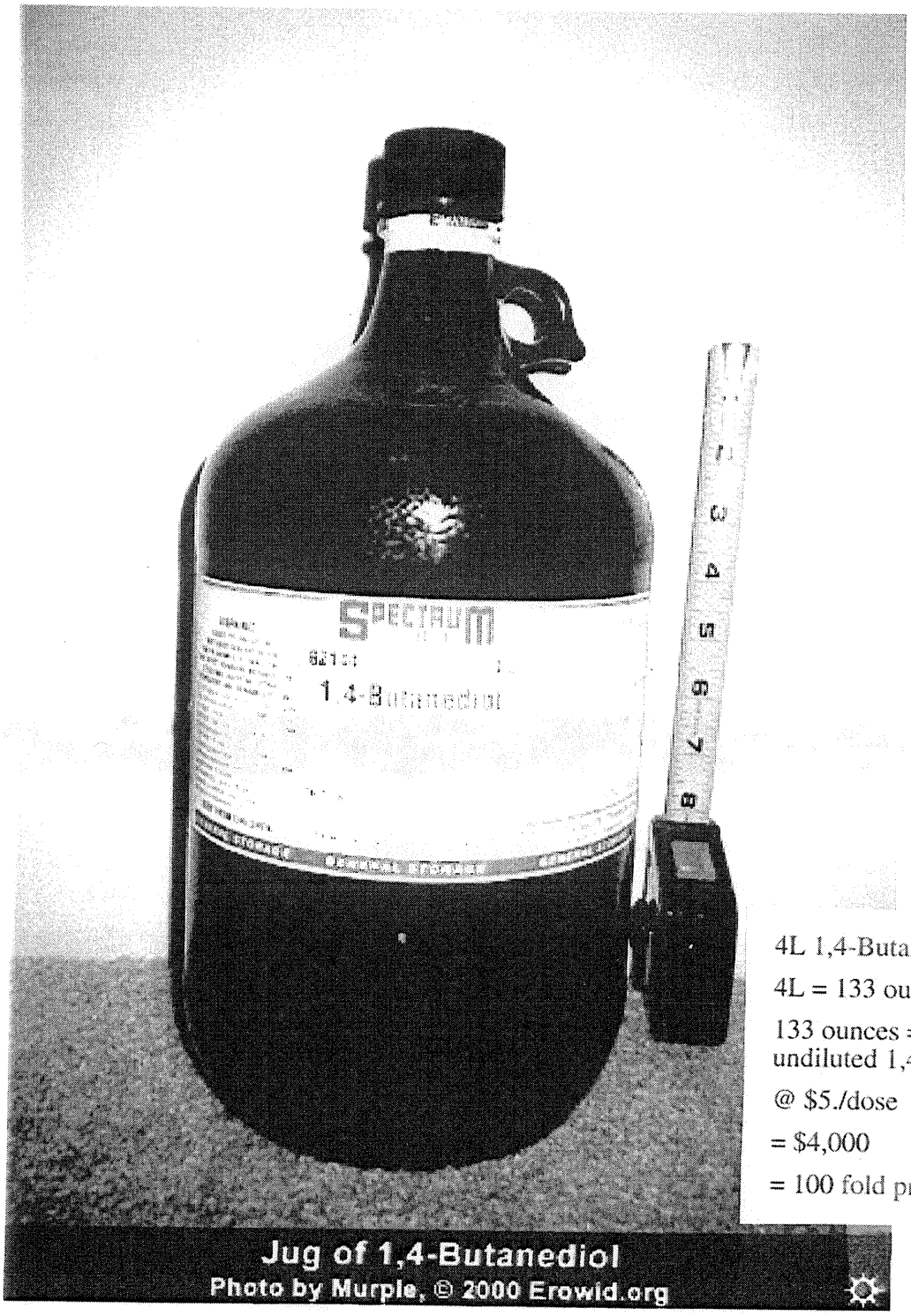
To combat these GHB substitutes, legislators in Pennsylvania strengthened their "analogue" statutes by enlarging them to include chemicals that have "substantially similar structures or substantially similar effects."

A prior state law, one of the strongest date rape statutes in the nation, makes use of any substance to facilitate sexual assault a first-degree felony. Senator Jane Earll and Representative Thomas Gannon used that law as a springboard to successfully draft the new law that bans analogue drugs such as the GHB substitutes. The lawmakers also said that legislators should turn to an overlooked part of the federal Controlled Substances Act, which allows enactment of a "controlled substance analogue statute."

One of the more worrisome analogues of GHB is a widely used chemical solvent, gamma butyrolactone (GBL). Last year, more than 140 million pounds of GBL was produced for industrial uses. It's not supposed to be used as a drug. But drink GBL and it turns into GHB inside the body. It can be sold as GHB for three times its price by dealers.

Another chemical, 1,4 BD (1,4 butanediol) has also appeared on the illicit drug scene. It too turns to GHB when ingested. Last year, more than 800 million pounds of 1,4 BD were made for use as an industrial degreaser and in making plastics.

Scientific papers easily available on the Internet have identified other legal chemicals that turn to GHB after ingestion. And it's only a matter of time before drug dealers switch to using them. Earll and Gannon say that an analogue statute modeled after the federal language is the best way states can get out in front of this issue.



Jug of 1,4-Butanediol
Photo by Murple, © 2000 Erowid.org

4L 1,4-Butanediol costs $40.

4L = 133 ounces

133 ounces = 798 teaspoons of undiluted 1,4 BD

@ $5./dose

= $4,000

= 100 fold profit

Deterring Illicit GHB and GHB Analog Use Without Hurting the Treatment of People with Narcolepsy

Various Forms of GHB

- Gamma hydroxybutyrate (GHB) is unlike other legal or illegal drugs because it comes in several forms:

1) An easily-made, homebrew used by body builders as a muscle enhancer, rave party-goers as a euphoric when mixed with alcohol, and by sexual predators to facilitate sexual assault. Wisconsin appropriately lists this form of GHB in Schedule I.

2) Commonly used industrial chemicals that when consumed naturally turn into GHB in the body. The most common examples are gamma butyrolactone (GBL) and 1,4 butanediol (1,4 BD), which are produced in the millions of pounds each year for legitimate industrial use. Law enforcement officials in Florida, Texas, California, Arkansas and other states report that these drug substitutes, or analogs, have largely replaced the use of homemade GHB.

3) A promising, FDA-sanctioned investigational new drug for the treatment of cataplexy, a disabling symptom of the rare disease, narcolepsy. This medical form of GHB is being developed by Orphan Medical of Minneapolis. FDA action is anticipated this April 2002.

GHB Analogs: GBL and 1,4 BD

- GBL is known by several chemical names. It is used as a solvent in the manufacture of beer, paint, and electronic components. It is also the key ingredient in some floor stripper products. In January 1999, FDA issued a nationwide recall of all dietary supplements containing GBL.

- When taken orally, GBL is converted in the body to GHB. According to FDA, GBL-related products have been associated with reports of at least 55 adverse health effects, including one death. There are reports of at least five children under 18 years of age who have been injured or who have suffered these kinds of effects from GBL.

- As federal and state authorities began to crack down on GBL, abuse shifted to another industrial chemical, 1,4 BD.

- When taken orally, 1,4 BD is converted in the body to GHB. According to FDA, 1,4 BD products have been associated with reports of at least 100 adverse health effects, including at least three deaths. In May 1999, FDA issued a nationwide recall of all dietary supplements containing 1,4 BD.

- Wisconsin currently controls GBL as a Schedule I chemical, though this may have created problems for its legitimate industrial use. Illicit use of GBL is also controlled by Wisconsin's current Controlled Substance Analog definition. However, Wisconsin's definition is not as broad as federal law and does not cover 1,4 BD. 1,4 BD does produce a similar effect in the body as GHB, but it does not have a substantially similar structure. Licit or illicit use of 1,4 BD is not controlled in Wisconsin.

- Authorities across the United States report a decrease in homemade GHB use and an increase in the use of GBL and 1,4 BD. Additionally, they note that the primary age of abusers has dropped to include young people in their teens and early 20s.

Allowing Narcolepsy Patients Access to Life-Changing Medication

- Cataplexy is the sudden loss of muscle control triggered by emotional highs and lows — stress, laughter, surprise, sadness. A total cataplectic attack results in a total body collapse.

- Because of the unpredictability and frequency of attacks, people with cataplexy are unable to live a normal life. They often can't work outside the home. They can't drive a car. Moms can't even hold their babies for fear of dropping them.

- Cataplexy affects about 65 percent of the estimated 135,000 Americans with narcolepsy. In Wisconsin, about 2,600 residents have narcolepsy – about the population of the city of Adams – of which an estimated 1,700 suffer from cataplexy.

- According to clinical studies being reviewed by FDA, doctor-prescribed GHB restores natural sleep, allowing patients to live a normal life. Absent GHB therapy, they suffer daily attacks of cataplexy.

- In 2000, the U.S. Congress approved a law that listed illicit GHB in Schedule I of the federal Controlled Substances Act and medical GHB, approved for use by FDA, in Schedule III. Illict use of any form of GHB is treated with the penalties of Schedule I drugs.

- Over 30 states have adopted the split schedule for GHB either by rule or legislation.

- Since the medical formulation of GHB will treat such a small patient population, it will not occupy the shelves of pharmacies across Wisconsin. Instead, Wisconsin patients will obtain medical GHB from one source, a centralized nationwide pharmacy based in another state. This restricted distribution system was created by Orphan Medical after consultation with regulators and law enforcement officials throughout the United States. We believe it will minimize potential diversion of medical GHB and provide timely data for law enforcement authorities.

Rules and Regulations

Federal Register
Vol. 65, No. 49
Monday, March 13, 2000

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 240 and 242

[Release No. 34–40760B; File No. S7–12–98]

RIN 3235–AH41

Regulation of Exchanges and Alternative Trading Systems; Technical Amendments

AGENCY: Securities and Exchange Commission.

ACTION: Technical amendments.

SUMMARY: The Securities and Exchange Commission ("Commission") today is making a technical change to Exchange Act Rules 17a–4(b)(1) and 301(b)(4). These and other rules and rule amendments that relate to the regulation of exchanges and alternative trading systems were published on December 22, 1998 (63 FR 70844).

EFFECTIVE DATE: March 7, 2000.

FOR FURTHER INFORMATION CONTACT: Elizabeth King, Associate Director, at (202) 942–0140, Constance Kiggins, Special Counsel, at (202) 942–0059, and John Roeser, Attorney, at (202) 942–0762, Division of Market Regulation.

SUPPLEMENTARY INFORMATION:

Background

On December 8, 1998, the Commission adopted new rules and rule amendments regarding the regulation of exchanges and alternative trading systems.[1] The Commission also repealed Exchange Act Rule 17a–23 and amended the books and records rules by transferring the recordkeeping requirements from Rule 17a–23 to Rules 17a–3 and 17a–4, as those rules apply to broker-dealer internal trading systems. The Commission amended Exchange Act Rule 17a–3 by adding paragraph (a)(16), which requires broker-dealers to make records regarding the activities of internal broker-dealer systems.[2] The Commission stated in the adopting release that the amendments to Exchange Act Rule 17a–4 would require that the records required under Rule 17a–3(a)(16) be preserved for three years, the first two years in an accessible place. This requirement, however, was not included in the amended rule language of Rule 17a–4. Consequently, the Commission is making a technical amendment to Rule 17a–4(b)(1) to include the records required under Rule 17a–3(a)(16).

In addition, Exchange Act Rule 301(b)(4) contains a typographical error that may prove misleading and requires clarification. Specifically, the first sentence of Rule 301(b)(4), prohibits an alternative trading system from charging fees to broker-dealers, that access the alternative trading system through a national securities exchange or national securities association, that are inconsistent with equivalent access, as "required by paragraph (b)(3)(iv)." The equivalent access requirement, however, is a paragraph (b)(3)(iii). The Commission is making a technical amendment to correctly refer to the equivalent access requirement in paragraph (b)(3)(iii).

List of Subjects

17 CFR Part 240

Brokers-dealers, Fraud, Issuers, Reporting and recordkeeping requirements, Securities.

17 CFR Part 242

Securities.

Accordingly, Title 17 CFR Part II is amended by making the following technical amendments:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for Part 240 continues to read in part as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78f, 78i, 78j, 78j–1, 78k, 78k–1, 78*l*, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll*(d), 78mm, 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

2. § 240.17a–4 is amended by revising paragraph (b)(1) to read as follows:

§ 240.17a–4 Records to be preserved by certain members, brokers and dealers.

* * * * *

(b) * * *

(1) All records required to be made pursuant to paragraphs (a)(4), (a)(6), (a)(7), (a)(8), (a)(9), (a)(10), and (a)(16) of § 240.17a–3.

* * * * *

PART 242—REGULATIONS M AND ATS

3. The authority citation for part 242 continues to read as follows:

Authority: 15 U.S.C. 77g, 77q(a), 77s(a), 78b, 78c, 78i(a), 78j, 78k–1(c), 78*l*, 78m, 78mm, 78n, 78o(b), 78o(c), 78o(g), 78q(a), 78q(b), 78q(h), 78w(a), 78dd–1, 80a–23, 80a–29, and 80a–37.

§ 242.301 [Amended]

4. In § 242.301, the first sentence of paragraph (b)(4), the reference "(b)(3)(iv)" is revised to read "(b)(3)(iii)".

Dated: March 7, 2000.

Jonathan G. Katz,

Secretary.

[FR Doc. 00–5993 Filed 3–10–00; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1308

[DEA–200F]

Schedules of Controlled Substances: Addition of Gamma-Hydroxybutyric Acid to Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This is a final rule issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) placing gamma-hydroxybutyric acid (GHB) and its salts, isomers, and salts of isomers into Schedule I of the Controlled Substances Act (CSA) pursuant to Public Law 106–172. Public

[1] Securities Exchange Act Release No. 40760 (December 8, 1998), 63 FR 70844 (December 22, 1998).

[2] 17 CFR 240.17a–3(a)(16).

Law 106–172 also imposes Schedule III physical security requirements for storage on registered manufacturers and distributors of GHB when it is manufactured, distributed or possessed in accordance with Food and Drug Administration (FDA)-authorized Investigational New Drug (IND) exemptions under the Federal Food, Drug and Cosmetic Act (FFDCA). In addition, this final rule places FDA-approved products containing GHB into Schedule III, if or when they are approved.

EFFECTIVE DATE: March 13, 2000.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, (202) 307–7183.

SUPPLEMENTARY INFORMATION:

What Is GHB and Why Is It Being Controlled?

GHB is gamma-hydroxybutyric acid, including its salts, isomers and salts of isomers. In recent years, the abuse of GHB has increased substantially. GHB is a drug classified as a central nervous system depressant. It is not approved for marketing as a medicine in the United States, although FDA-authorized studies are in progress to examine its potential use in the treatment of cataplexy associated with narcolepsy. GHB is abused to produce euphoric and hallucinogenic states, and for its alleged role as growth hormone releasing agent to stimulate muscle growth. GHB can produce drowsiness, dizziness, nausea, visual disturbances, unconsciousness, seizures, severe respiratory depression and coma. Overdose usually requires emergency medical treatment, including intensive care for respiratory depression and coma. Several Poison Control Centers have characterized and reported cases of GHB-dependence and withdrawal to the DEA. To date, DEA has documented over 5,700 overdoses and law enforcement encounters with GHB in 45 states. DEA has also documented 65 GHB-related deaths.

On November 8, 1990, the FDA issued an advisory declaring GHB unsafe and illicit, except under FDA-approved physician-supervised protocols. On February 18, 1997, FDA reissued its warning on GHB as an unapproved and potentially dangerous, illegal drug in the United States.

GHB is produced in clandestine laboratories using a relatively simple synthesis with readily available and inexpensive starting materials. Gamma-butyrolactone (GBL) is an industrial solvent which is used in the clandestine manufacture of GHB. Once manufactured, GHB is a clear liquid and has been disguised by adding food coloring, flavorings, and/or storing it in different kinds of bottles and containers.

The DEA has received reports that GBL, the solvent precursor for GHB, is being abused due to its rapid conversion to GHB soon after ingestion. On January 21, 1999, the FDA issued a request for a voluntary recall of all GBL-containing products sold in health food stores and warned the public of its danger to the public health. FDA has also declared 1,4-butanediol, a chemical related to both GHB and GBL, a Class I Health Hazard. On May 11, 1999, the FDA issued another warning on 1,4 butanediol, GHB, and GBL stating that these substances pose a significant health hazard. Public Law 106–172 also placed certain controls on GBL. These will be the subject of a separate **Federal Register** Notice.

Under What Authority Is GHB Being Controlled?

"The Samantha Reid and Hillory J. Farias Date-Rape Prevention Act of 1999" (Pub. L. 106–172) declared that the abuse of GHB is an imminent hazard to the public safety. Section (3)(a)(1) of Public Law 106–172 directs the Attorney General, notwithstanding sections 201(a), 201(b), 201(c), and 202 of the CSA (21 U.S.C. 811(a), 811(b), 811(c) and 812), to issue a final order placing GHB in the same schedule as would apply to a scheduling of a substance under section 201(h)(1) of the CSA (21 U.S.C 811(h)(1)). All substances controlled under 201(h)(1) are placed in Schedule I. Therefore, this final rule will place GHB in Schedule I.

With the issuance of this final order, GHB becomes subject to the regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, dispensing, importing and exporting of a Schedule I controlled substance with one exception. Section 3(a)(1)(A) of Public Law 106–172 provides that registered manufacturers and distributors of GHB that is subject to an investigational new drug (IND) application exemption under the FFDCA subject to Schedule III physical security requirements rather than the otherwise applicable Schedule I physical security requirements for storage.

In Sections (3)(a)(1)(A) and (B) of Public Law 106–172, reference is made to certain scheduling recommendations contained in the May 19, 1999, letter from the Department of Health and Human Services (DHHS) to the DEA. Pursuant to Public Law 106–172, the DEA is publishing a copy of the May 19, 1999 letter from David Satcher, M.D., Ph.D., Assistant Secretary for Health and Surgeon General. The letter follows:

Assistant Secretary for Health, Office of Public Health and Science, Washington, D.C. 20201

Mr. Donnie R. Marshall, Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537

Dear Mr. Marshall:

In response to your request dated September 16, 1997, and pursuant to the Controlled Substances Act (CSA), 21 U.S.C. § 811(b), (c), and (f), the Department of Health and Human Services (HHS) recommends that gamma-hydroxybutyric acid (GHB) should be subject to control under Schedule I of the CSA, except that GHB substances and products that are the subject of investigational new drug (IND) applications authorized by the Food and Drug Administration (FDA) should be subject to control under Schedule III.

GHB is a central nervous system depressant. As discussed in the attached analysis, GHB has a high potential for abuse relative to substances controlled in Schedules III, IV, and V. GHB has no accepted medical use, and when manufactured clandestinely, it is unsafe for use under medical supervision. Accordingly, and except as provided below, HHS recommends that GHB be controlled in Schedule I of the CSA.

Formulations of GHB currently are being studied under FDA-authorized INDs. At least one sponsor's formulation has been granted orphan drug status under Section 526 of the Food, Drug and Cosmetic Act, and is available under a treatment use protocol under 21 CFR § 312.34. None of the reports of actual abuse of GHB that support the Schedule I recommendation have involved GHB that was diverted from an authorized study. Moreover, given the ease with which GHB can be synthesized from readily available materials, it is unlikely that authorized studies will become a source for abuse. Rather, the abuse potential of GHB, when used under an authorized research protocol, is consistent with substances typically controlled under Schedule IV. Information on the dependence-producing effects of GHB is limited, but available data suggest that its potential for physical and psychological dependence is also consistent with control under Schedule IV.

Authorized formulations of GHB, however, do not meet the "accepted medical use" criteria set forth in Schedule IV. An authorized formulation of GHB is far enough along in the development process to meet the standard under Schedule II of a drug or substance having a "currently accepted medical use with severe restrictions." Under these circumstances, HHS recommends placing authorized formulations of GHB in Schedule III.

You will find enclosed a document prepared by FDA's Drug Abuse Evaluation Staff that is the basis for the combined Schedule I/Schedule III recommendation.

Should you have any questions regarding this recommendation, please contact Stuart L. Nightingale, M.D., FDA's Associate

Commissioner for Health Affairs, at (301) 443–6143.

Sincerely yours,

David Satcher, M.D., Ph.D., Assistant Secretary for Health and Surgeon General

Enclosure

Specifically, as noted above, Section (3)(a)(1)(A) of Public Law 106–172 directs that the physical security requirements for registered manufacturers and distributors of GHB that is subject to an IND application exemption under the FFDCA shall be those which apply to the schedule recommended in the first paragraph of the DHHS letter. The schedule referred to in this paragraph is Schedule III. This paragraph applies only to GHB which is the subject of an FDA-authorized exemption and does not affect the physical security requirements for GHB manufactured, distributed or possessed for any other purpose or for any other controlled substance handled by the registrant.

Section (3)(a)(1)(B) of Public Law 106–172 directs that a drug product containing GHB for which an application is approved under section 505 of the FFDCA, shall be placed in the schedule recommended in the last sentence of the fourth paragraph of the DHHS May 19, 1999, letter. This sentence recommends Schedule III. Currently, there are no GHB drug products approved under section 505 of the FFDCA. However, if or when a drug product containing GHB is approved by the FDA under this section, it shall be a Schedule III controlled substance except that it will be subject to the criminal sanctions applicable to a Schedule I controlled substance, pursuant to Public Law 106–172. This paragraph applies only to drug products containing GHB which are approved under section 505 of the FFDCA and does not affect the schedule of any other form of GHB handled by the registrant.

Therefore, pursuant to Public Law 106–172 and notwithstanding sections 201(a), 201(b), 201(c), and 202 of the CSA, the Deputy Administrator of the DEA orders that GHB and its salts, isomers, and salts of isomers be placed in Schedule I. With the issuance of this final order, GHB will be subject to the regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, dispensing, importing and exporting of a Schedule I controlled substance with the following one exception. Registered manufacturers and distributors of FDA-authorized IND exempted GHB shall be subject to Schedule III physical security requirements for storage purposes. In addition, an FDA-approved drug product containing GHB for which an application is approved under section 505 of the FFDCA shall be placed in Schedule III.

What Requirements Will GHB Be Subject To?

Except as noted below, the Schedule I controls on GHB and, where applicable, the Schedule III physical security requirements on GHB will be effective on March 13, 2000. In the event that any of these requirements impose special hardships on the registrants, the DEA will entertain any justified request for an extension of time to comply with the Schedule I regulations regarding GHB. The applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports GHB or who engages in research or conducts instructional activities with GHB, or who proposes to engage in such activities, must submit an application for Schedule I registration in accordance with part 1301 of Title 21 of the Code of Federal Regulations (CFR) by May 12, 2000.

However, if and when there is an FDA-approved GHB-containing product for which an application is approved under section 505 of the FFDCA, any person who manufactures, distributes, dispenses, imports or exports that product or who engages in research or conducts instructional activities with such an FDA-approved GHB-containing product, or who proposes to engage in such activities, must submit an application for Schedule III registration in accordance with part 1301 of Title 21 of the Code of Federal Regulations.

2. *Security.* GHB is subject to Schedule I security requirements and must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(a), (c), and (d), 1301.73, 1301.74, 1301.75(a) and (c) and 1301.76 of Title 21 of the Code of Federal Regulations.

There is, however, an exception for registered manufacturers and distributors of GHB when manufactured, distributed or possessed in accordance with FDA-authorized IND exemptions under the FFDCA for storage. GHB used in FDA-authorized IND studies and FDA-approved GHB containing products are subject to Schedule III security requirements and must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c) and 1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and packaging.* All labels on commercial containers of, and all labeling of GHB, including FDA-authorized IND exempted formulations, which are distributed on or after May 12, 2000 shall comply with the requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations. Any commercial containers of GHB packaged on or before May 12, 2000 and not meeting the requirements specified in §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations shall not be distributed on or after June 12, 2000.

Any labels on commercial containers of, and all labeling of, an FDA-approved GHB-containing drug product shall comply with the requirements of §§ 1302.03–1302.7 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* Quotas for GHB are established pursuant to part 1303 of Title 21 of the Code of Federal Regulations. Any manufacturer who desires either a manufacturing or procurement quota for GHB shall apply for such quota to DEA on or before May 12, 2000.

5. *Inventory.* Registrants possessing GHB are required to take inventories pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations. Every registrant who desires registration in Schedule I for GHB shall conduct an inventory of all stocks of GHB on or before May 12, 2000.

6. *Records.* All registrants must keep records on GHB pursuant to §§ 1304.03, 1304.04 and §§ 1394,21–1394,23 if Title 21 of the Code of Federal Regulations.

7. *Reports.* All registrants are required to submit reports on GHB to the DEA pursuant to §§ 1304.33 of Title 21 of the Code of Federal Regulations.

8. *Order Forms.* Each distribution of GHB, with the exception of an FDA-approved GHB-containing product for which an application is approved under section 505 of the FFDCA, shall utilize an order form pursuant to part 1305 of Title 21 of the Code of Federal Regulations.

9. *Prescriptions.* If a drug product containing GHB is approved under section 505 of the FFDCA, all prescriptions for that product are to be issued pursuant to §§ 1306.03–1306.06 and 1306.21–1306.26 of Title 21 of the Code of Federal Regulations.

10. *Important and Exportation.* All importation and exportation of GHB shall be in compliance with part 1312 of Title 21 of the Code of Federal Regulations.

11. *Criminal Liability.* Any activity with GHB not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful on or after March 13, 2000.

Public Law 106–172 directs DEA to publish this final rule and DEA has no discretion in this matter. However, this action is structured in such a manner that limits its financial impact by reducing the physical security requirements for GHB under certain circumstances. Specifically, Congress directed DEA to apply Schedule III physical security requirements to registered manufacturers and registered distributors for the storage of GHB and GHB-containing formulations that are the subject of IND exemptions authorized by FDA.

This regulation has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulation. DEA has determined that this rule is not a significant regulatory action under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget. Further, this action will not have a significant economic impact on a substantial number of entities whose interests must be considered under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*). This action places GHB in Schedule I of the GSA, but provides a reduction of the physical security requirements for GHB under certain circumstances. Specifically, Schedule III physical security requirements will apply to registered manufacturers and registered distributors for the storage of GHB and GHB-containing formulations that are the subject of IND exemptions authorized by FDA.

Unfunded Mandate Reform Act

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 13132 Federalism

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

Plain English

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

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR parts 1301 and 1308 as follows:

PART 1301—[AMENDED]

1. The authority citation for Part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

2. Section 1301.72 is amended by revising the introductory text of paragraphs (a) and (b) to read as follows:

1301.72 Physical Security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

(a) *Schedules I and II.* Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA which shall be subject to the requirements of paragraph (b) of this section) shall be stored in one of the following secured areas:

* * * * *

(b) *Schedules III, IV and V.* Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V, and GHB when it is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA, shall be stored in the following secure storage areas:

* * * * *

PART 1308—[AMENDED]

1. The authority citation for 21 CFR 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 redesignating the existing paragraphs (e)(1) through (e)(2) as (e)(2) through (e)(3) and by adding a new paragraph (e)(1) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(e) * * *

(1) gamma-hydroxybutyric acid (some other names include GHB; gamma-hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate)	2010

* * * * *

3. Section 1308.13 is amended by redesignating the existing paragraphs (c)(5) through (c)(11) as (c)(6) through (c)(12) and by adding a new paragraph (c)(5) to read as follows:

§ 1308.13 Scheduling III.

* * * * *

(c) * * *

(5) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act	2012

* * * * *

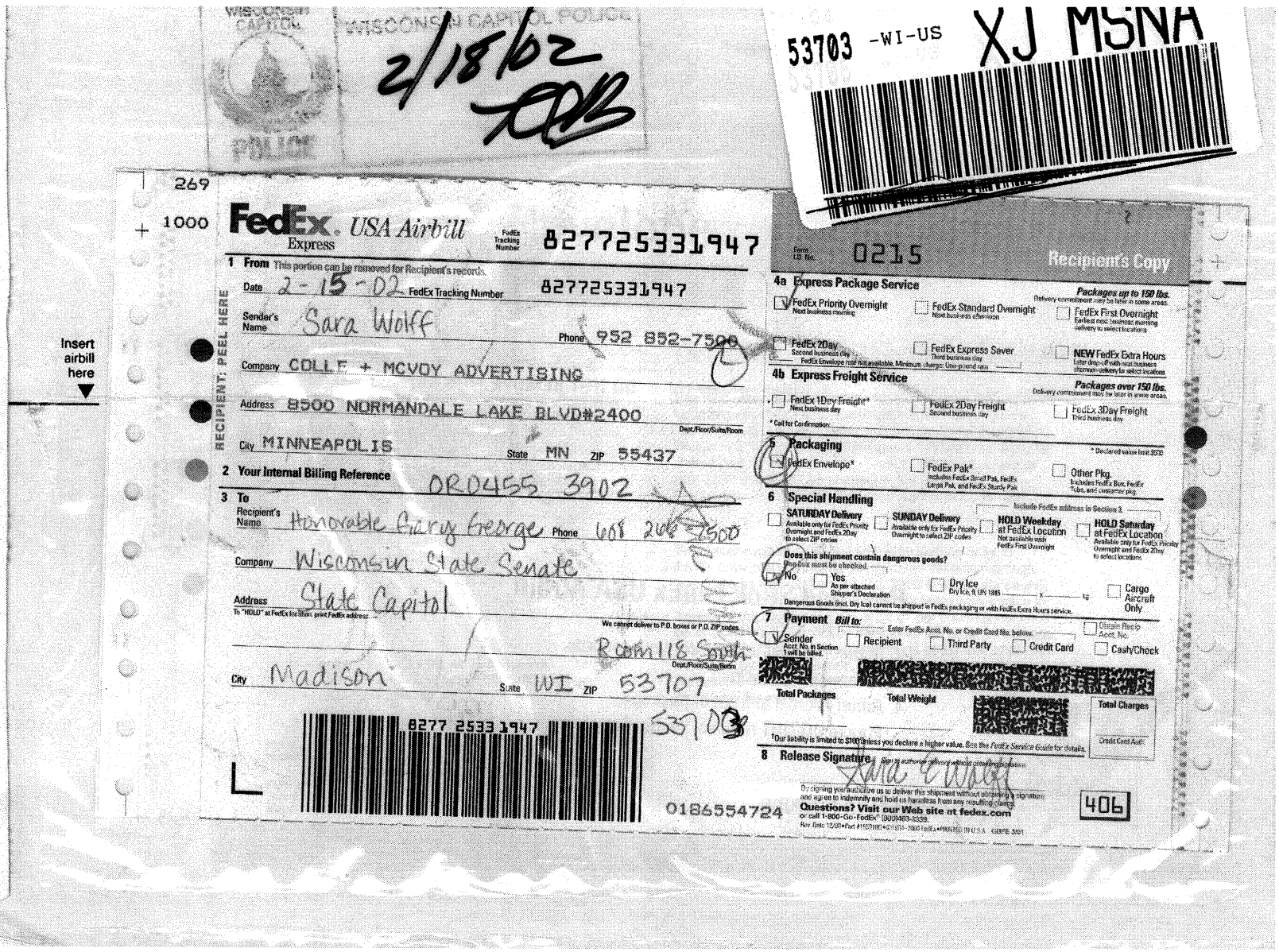
Dated: March 3, 2000.

Donnie R. Marshall,

Deputy Administrator.

[FR Doc. 00–5925 Filed 3–10–00; 8:45 am]

BILLING CODE 4410–09–M



WISCONSIN CAPITOL POLICE

2/18/02 JDB

53703 -WI-US XJ MSNA

269
1000

FedEx. USA Airbill Express

FedEx Tracking Number 827725331947

1 From This portion can be removed for Recipient's records.

Date 2-15-02 FedEx Tracking Number 827725331947

Sender's Name Sara Wolff Phone 952 852-7500

Company COLLE + MCVOY ADVERTISING

Address 8500 NORMANDALE LAKE BLVD#2400 Dept./Floor/Suite/Room

City MINNEAPOLIS State MN ZIP 55437

2 Your Internal Billing Reference OR0455 3902

3 To

Recipient's Name Honorable Gary George Phone 608 266 7500

Company Wisconsin State Senate

Address State Capitol

To "HOLD" at FedEx location, print FedEx address here. We cannot deliver to P.O. boxes or P.O. ZIP codes.

Room 118 South Dept./Floor/Suite/Room

City Madison State WI ZIP 53707

53703

8277 2533 1947

0186554724

Insert airbill here

RECIPIENT: PEEL HERE

Form 0215 Recipient's Copy

4a Express Package Service — Packages up to 150 lbs. Delivery commitment may be later in some areas.

- [x] FedEx Priority Overnight — Next business morning
- [ ] FedEx Standard Overnight — Next business afternoon
- [ ] FedEx First Overnight — Earliest next business morning delivery to select locations
- [ ] FedEx 2Day — Second business day. FedEx Envelope rate not available. Minimum charges: One-pound rate
- [ ] FedEx Express Saver — Third business day
- [ ] NEW FedEx Extra Hours — Later drop-off with next business afternoon delivery for select locations

4b Express Freight Service — Packages over 150 lbs. Delivery commitment may be later in some areas.

- [ ] FedEx 1Day Freight* — Next business day
- [ ] FedEx 2Day Freight — Second business day
- [ ] FedEx 3Day Freight — Third business day

* Call for Confirmation:

5 Packaging — * Declared value limit $500

- [x] FedEx Envelope*
- [ ] FedEx Pak* — Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak
- [ ] Other Pkg. — Includes FedEx Box, FedEx Tube, and customer pkg.

6 Special Handling — Include FedEx address in Section 3.

- [ ] SATURDAY Delivery — Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
- [ ] SUNDAY Delivery — Available only for FedEx Priority Overnight to select ZIP codes
- [ ] HOLD Weekday at FedEx Location — Not available with FedEx First Overnight
- [ ] HOLD Saturday at FedEx Location — Available only for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods? One box must be checked.

- [x] No
- [ ] Yes — As per attached Shipper's Declaration
- [ ] Dry Ice — Dry Ice, 9, UN 1845 ..... x ..... kg
- [ ] Cargo Aircraft Only

Dangerous Goods (incl. Dry Ice) cannot be shipped in FedEx packaging or with FedEx Extra Hours service.

7 Payment Bill to: — Enter FedEx Acct. No. or Credit Card No. below.

- [x] Sender — Acct. No. in Section 1 will be billed.
- [ ] Recipient
- [ ] Third Party
- [ ] Credit Card
- [ ] Cash/Check
- [ ] Obtain Recip Acct. No.

Total Packages | Total Weight | Total Charges | Credit Card Auth.

*Our liability is limited to $100 unless you declare a higher value. See the FedEx Service Guide for details.

8 Release Signature — Sign to authorize delivery without obtaining signature.

Sara E Wolff

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

Questions? Visit our Web site at fedex.com or call 1-800-Go-FedEx® (800)463-3339.

Rev. Date 12/01 • Part #150718 • ©1994-2000 FedEx • PRINTED IN U.S.A. GEPE 3301

406