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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rules and rule amendments regarding the regulation of exchanges and alternative trading systems.[1] The Commission also repealed Exchange Act Rule 17a–23 and amended the books and records rules by transferring the recordkeeping requirements from Rule 17a–23 to Rules 17a–3 and 17a–4, as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

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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