(u) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on December 22, 2022.

(i) European Union Aviation Safety Agency (EASA) AD 2021–0250, dated November 17, 2021.

(ii) [Reserved]

(4) The following service information was approved for IBR on June 24, 2016 (81 FR 31844, May 20, 2016).

(i) Airbus Service Bulletin A330–27–3199, dated July 15, 2014.

(ii) [Reserved]

(5) The following service information was approved for IBR on November 26, 2019 (84 FR 56378, October 22, 2019).

(i) Airbus A330 Airworthiness Limitations Section (ALS) Part 4, System Equipment Maintenance Requirements (SEMR), Revision 07, dated October 15, 2018.

(ii) [Reserved]

(6) For EASA AD 2021–0250, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(7) For Airbus SAS service information, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *airbus.com.*

(8) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(9) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on September 2, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

Editorial Note: This document was received for publication by the Office of the Federal Register on November 10, 2022.

[FR Doc. 2022–24991 Filed 11–16–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–371]

Schedules of Controlled Substances: Placement of Amineptine in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places amineptine (chemical name: 7-[(10,11-dihydro-5*H*-dibenzo[*a,d*]cyclohepten-5-yl)amino]heptanoic acid), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle amineptine.

DATES: Effective date: December 19, 2022.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention adding a drug or other substance to a specific schedule, the Secretary of the Department of Health and Human Services (HHS),[1] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[2] In the event that the Secretary of HHS (Secretary) did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling are set forth in 21 U.S.C. 811(a) and (b). Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of the Drug Enforcement Administration (Administrator).[3]

Background

Amineptine (chemical name: 7-[(10,11-dihydro-5*H*-dibenzo[*a,d*]cyclohepten-5-yl)amino]heptanoic acid) is a synthetic tricyclic antidepressant with central nervous system (CNS) stimulating properties.

In April 2003, the United Nations Commission on Narcotic Drugs (CND), on the advice of the Director-General of the World Health Organization (WHO), added amineptine to Schedule II of the 1971 Convention, thus notifying all parties to the 1971 Convention.

DEA and HHS Eight Factor Analyses

On November 8, 2011, in accordance with 21 U.S.C. 811(b), and in response to the Drug Enforcement Administration's (DEA) August 12, 2008 request, HHS provided to DEA a scientific and medical evaluation and a scheduling recommendation for amineptine. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data, and conducted its own analysis under the eight factors stipulated in 21 U.S.C.

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

[2] 21 U.S.C. 811(d)(3).

[3] 28 CFR 0.100.

811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I. Both DEA and HHS analyses are available in their entirety under ''Supporting and Related Material'' of the public docket for this rule at *https://www.regulations.gov* under docket number DEA–371.

Notice of Proposed Rulemaking to Schedule Amineptine

On July 22, 2021, DEA published a notice of proposed rulemaking (NPRM) entitled ''Schedules of Controlled Substances: Placement of amineptine in schedule I.'' [4] The NPRM provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations on or before August 23, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before September 20, 2021.

Comments Received

DEA received three comments on the proposed rule to control amineptine in schedule I of the CSA.

Support for rulemaking: Two commenters recognized the dangers and public health risks, and supported the placement of amineptine in schedule I.

DEA Response: DEA appreciates the comments in support of this rulemaking.

Opposition to rulemaking: One commenter opposed the placement of amineptine in schedule I due to the lack of abuse in the United States, and contended it showed potential as an ''anti-addictive agent and antidepressant'' in clinical settings.

DEA Response: DEA does not agree. As discussed in DEA and HHS eight-factor analyses which accompanied the published NPRM, amineptine is not approved by the Food and Drug Administration for use in the United States. While amineptine has previously been used in Europe and Asia as an antidepressant, its use has been withdrawn from the market in 49 of 66 countries. Strong evidence of abuse, severe adverse effects including hepatotoxicity, pancreatic injury, and severe acne eruption that required hospitalization, and overconsumption, have been documented by the WHO's Expert Committee on Drug Dependence report [5] and HHS in their scientific and medical evaluation where amineptine was recommended for control in schedule I of the CSA.[6]

In addition, DEA conducted an eight-factor analysis pursuant to 21 U.S.C. 811(c), and based its scheduling determination on a comprehensive evaluation of all available data. As stated in the proposed rulemaking, after careful review of all data, DEA concurred with HHS' assessment that amineptine has a high potential for abuse, and it has no currently accepted medical use in treatment in the United States and lacks accepted safety for use under medical supervision. Congress established only one schedule, schedule I, for drugs of abuse with ''no currently accepted medical use in treatment in the United States'' and ''lack of accepted safety for use under medical supervision.'' [7] DEA is therefore promulgating this final rule placing amineptine in schedule I under the CSA.

Scheduling Conclusion

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA finds substantial evidence of potential for abuse of amineptine. As such, DEA is permanently scheduling amineptine as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule.[8] After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) Amineptine has a high potential for abuse. This potential is comparable to certain schedule II substances (*e.g.,* amphetamine or cocaine);

(2) Amineptine has no currently accepted medical use in treatment in the United States; [9] and

(3) There is a lack of accepted safety for use of amineptine under medical supervision.

Based on these findings, the Administrator concludes that amineptine, including its salts, isomers, and salts of isomers, warrants control in schedule I of the CSA.[10]

Requirements for Handling Amineptine

Amineptine is subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) amineptine, or who desires to handle amineptine, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles amineptine and is not registered with DEA must submit an application for registration and may not continue to handle amineptine, unless DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender all quantities of currently held amineptine, or may transfer all quantities of currently held amineptine to a person registered with DEA. Amineptine is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Amineptine is subject to schedule I security requirements and

[4] 86 FR 38619.

[5] World Health Organization (WHO) Critical Review of Psychoactive Substances prepared for evaluation by the 33rd Meeting of the WHO Expert Committee on Drug Dependence. Annex, 2002.1–14.

[6] While HHS's Secretary is the expert on scientific and medical matters in scheduling decisions of this type, DEA is not bound by HHS's recommendation to schedule a substance. DEA's Administrator is obligated to determine ''that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control'' prior to following set rulemaking proceedings for control. 21 U.S.C. 811(b); *see* 76 FR 77330, 77334–77335, Dec. 12, 2011. This is what DEA is doing in this rulemaking.

[7] 21 U.S.C. 812(b).

[8] 21 U.S.C. 812(b).

[9] Although there is no evidence suggesting that amineptine has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. the drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

[10] 21 U.S.C. 812(b)(1).

must be handled and stored pursuant to 21 U.S.C. 821 and 823 and in accordance with 21 CFR parts 1301.71–1301.76. Non-practitioners handling amineptine must also comply with the employee screening requirements of 21 CFR parts 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of amineptine must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture amineptine in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of amineptine must take an inventory of amineptine on hand pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including amineptine) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including amineptine) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to amineptine, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding amineptine to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes amineptine must comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of amineptine must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving amineptine not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing the substance amineptine, including its salts, isomers, and salts of isomers, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle amineptine.

Based on the review of HHS' scientific and medical evaluation and all other relevant data, DEA determined that amineptine has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA's research confirms that there is no legitimate commercial market for amineptine in the United States. DEA is not aware of any availability or source of amineptine in the United States. Therefore, DEA estimates that no United States entity currently handles amineptine and does not expect any United States entity to handle amineptine in the foreseeable future. DEA concludes that no legitimate United States entity would be affected by this rule. As such, this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to the Government Accountability Office, the House, and the Senate under the CRA.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995.[11]

[11] 44 U.S.C. 3501–3521.

This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 1308

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

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.11 by re-designating paragraphs (f)(1) through (f)(9) as paragraphs (f)(2) through (f)(10), and adding a new paragraph (f)(1) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(f) * * *

(1) Amineptine (7-[(10,11-dihydro-5*H*-dibenzo[*a,d*]cyclohepten-5-yl)amino]heptanoic acid) 1219

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on November 9, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–25003 Filed 11–16–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9947]

RIN 1545–BO90

Section 199A Rules for Cooperatives and Their Patrons; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to Treasury Decision 9947, published in the **Federal Register** on Tuesday, January 19, 2021. Treasury Decision 9947 contained final regulations under the qualified business income provisions of the Internal Revenue Code regarding the deduction for income attributable to domestic production activities of specified agricultural or horticultural cooperatives.

DATES: These corrections are effective on *November 17, 2022* and applicable after January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Jason Deirmenjian at (202) 317–4470 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9947) subject to this correction are issued under sections 1381 through 1388 and section 199A(g) of the Internal Revenue Code.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.199A–7 is amended by:

■ a. Revising the first sentence of paragraph (c)(1).

■ b. Revising the second sentence of paragraph (c)(2) introductory text.

■ c. Revising paragraphs (c)(2)(ii) and (iii).

■ d. Revising the first sentence of paragraph (c)(3).

■ e. Revising the first sentence of paragraph (d)(1).

■ f. Revising the first sentence of paragraph (d)(3)(i).

■ g. Redesignating paragraph (d)(3)(ii)(B)(i*2*) as paragraph (d)(3)(ii)(B)(*2*).

The revisions read as follows:

§ 1.199A–7 Section 199A(a) Rules for Cooperatives and their patrons.

* * * * *

(c) * * *

(1) * * * QBI means the net amount of qualified items of income, gain, deduction, and loss with respect to any trade or business as determined under the rules of section 199A(c)(3) and § 1.199A–3(b). * * *

(2) * * * In situations where the patron receives distributions described in paragraph (c)(1) of this section, the Cooperative must determine whether those distributions include qualified items of income, gain, deduction, and loss as determined under rules of section 199A(c)(3) and § 1.199A–3(b). * * *

* * * * *

(ii) The distributions are qualified items of income, gain, deduction, and loss as determined under rules of section 199A(c)(3) and § 1.199A–3(b) at the Cooperative's trade or business level;

(iii) The distributions are not items from an SSTB as defined in section 199A(d)(2) at the Cooperative's trade or business level (except as permitted by the threshold rules in section 199A(d)(3) and § 1.199A–5(a)(2)); and

* * * * *

(3) * * * In the case of a Cooperative that makes distributions described in paragraph (c)(1) of this section to a patron, the Cooperative must determine the amount of qualified items of income, gain, deduction, and loss as determined under the rules of section 199A(c)(3) and § 1.199A–3(b) in those distributions. * * *

(d) * * *

(1) * * * This section provides guidance on the determination of SSTBs as defined in section 199A(d)(2) and § 1.199A–5. * * *

* * * * *

(3) * * *

(i) * * * In the case of a Cooperative that makes distributions described in paragraph (c)(1) of this section to a