Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 19, 2022, 87 FR 57569 (September 21, 2022); Notice of November 8, 2022, 87 FR 68015 (November 10, 2022).

■ 2. Supplement No. 4 to part 744 is amended under RUSSIA by revising the entry for ''Private Military Company 'Wagner' '' to read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	**Federal Register** citation
*	*	*	*	*
RUSSIA	*	*	*	*
	Private Military Company 'Wagner', a.k.a., the following five aliases: —Chastnaya Voennaya Kompaniya 'Vagner'; —Chvk Vagner; —PMC Wagner; —Wagner Group; *and* —Vagner Group. 15 Zolnaya Street, Saint Petersburg, 195213, Russia	For all items subject to the EAR. (See §§ 734.9(g),[3] 746.8(a)(3), and 744.21(b) of the EAR). The license requirements under this entry also extend to any export, reexport and transfer (in-country) to the entity wherever located worldwide	Policy of denial for all items subject to the EAR apart from food and medicine designated as EAR99, which will be reviewed on a case-by-case basis. See §§ 746.8(b) and 744.21(e).	82 FR 28408, 6/22/17. 87 FR [INSERT FR PAGE NUMBER] 12/23/22.
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*	*	*	*	*

* * * * *

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2022–28033 Filed 12–21–22; 4:15 pm]

BILLING CODE 3510–JT–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 130 and 131

[Docket No. FDA–2000–P–0126 (formerly Docket No. 2000P–0658)]

RIN 0910–AI40

International Dairy Foods Association and Chobani, Inc.: Response to the Objections and Requests for a Public Hearing on the Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objections and denial of public hearing requests; removal of administrative stay; correction.

SUMMARY: The Food and Drug Administration is correcting a final rule entitled ''International Dairy Foods Association and Chobani, Inc.: Response to the Objections and Requests for a Public Hearing on the Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt'' that appeared in the **Federal Register** of December 15, 2022. The final rule revoked the standards of identity for lowfat yogurt and nonfat yogurt and amended the standard of identity for yogurt in numerous respects. The document was published with an errant reference to its effective date in the preamble discussion. This document corrects that error.

DATES: This correction is effective January 17, 2023, and applicable December 15, 2022.

FOR FURTHER INFORMATION CONTACT: Andrea Krause, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371, or Joan Rothenberg, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, December 15, 2022 (87 FR 765590), appearing on page 76567, in FR Doc. 2022–27040, the following correction is made:

1. On page 76567, in the third column, in the fifth sentence of the third paragraph under IV. Summary and Conclusions, ''[DATE OF PUBLICATION IN THE **FEDERAL REGISTER**]'' is corrected to read ''January 17, 2023''.

Dated: December 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27816 Filed 12–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–945]

Schedules of Controlled Substances: Removal of Fenfluramine From Control

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration removes fenfluramine (chemical name: *N*-ethyl-α-methyl-3-(trifluoromethyl)phenethylamine), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts is possible, from the schedules of the Controlled Substances Act. Prior to the effective date of this rule, fenfluramine was a

schedule IV controlled substance. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule IV controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, engage in research, import, export, conduct instructional activities or chemical analysis with, or possess) or propose to handle fenfluramine.

DATES: Effective December 23, 2022.

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

SUPPLEMENTARY INFORMATION:

Legal Authority

Under the Controlled Substances Act (CSA), each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause.[1] The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(2), the Attorney General may, by rule, ''remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.'' The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (DEA).[2]

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General on the petition of any interested party.[3] This action was initiated by a petition to remove fenfluramine from the list of scheduled controlled substances of the CSA, and is supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (HHS) and an evaluation of all relevant data by DEA. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule IV controlled substances, on persons who handle or propose to handle fenfluramine.

Background

Fenfluramine (chemical name: *N*-ethyl-α-methyl-3-(trifluoromethyl)phenethylamine), including its salts, isomers, and salts of such isomers, has been controlled under 21 CFR 1308.14(d) as a schedule IV substance of the CSA since June 15, 1973.[4] On September 25, 2019, Zogenix, Inc. (Zogenix; the Sponsor) submitted to the Food and Drug Administration (FDA) a New Drug Application (NDA) for Fintepla (fenfluramine), for the treatment of seizures associated with Dravet syndrome (DS) in patients two years of age and older. FDA approved the NDA on June 25, 2020, with the labelling listing fenfluramine as a schedule IV controlled substance.

On October 18, 2018, Zogenix submitted to DEA a petition requesting that fenfluramine be removed from schedule IV of the CSA. The petition complied with the requirements of 21 CFR 1308.43(b) and DEA accepted the petition for filing on November 13, 2018.

Notice of Proposed Rulemaking To Decontrol Fenfluramine

On July 19, 2022, DEA published a notice of proposed rulemaking (NPRM) to remove fenfluramine from the schedules of the CSA.[5] The NPRM provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations by August 18, 2022. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposal on or before August 18, 2022.

Comment Received

DEA received one comment on the NPRM to remove fenfluramine from control.

Opposition to rulemaking: One commenter opposed decontrol of fenfluramine, however the comment was at times ambiguous. The commenter seemed to be concerned about children using fenfluramine illicitly and the potential harm related to the combined use with a stimulant, specifically noting the fenfluramine-phentermine (''fen-phen'') combination and noting ''Stimulants+Psychedelics=Psychosis.''

DEA Response: DEA acknowledges the commenter's concerns about relative harm, especially related to children. DEA notes FDA approved Fintepla (fenfluramine) on June 25, 2020, for the treatment of DS in patients two years of age and older. Currently Fintepla is the only FDA-approved drug product with fenfluramine. HHS considered the harms the fenfluramine-phentermine combination produced in their April 2021 scientific and medical evaluation, which was provided to DEA as part of this rulemaking process, pursuant to 21 U.S.C. 811(b).

DEA notes that the combination historically produced serious cardiac effects, not psychological effects. The FDA-approved labeling for Fintepla indicates that patients must be enrolled in the Fintepla risk evaluation and mitigation strategy (REMS) program and undergo cardiac monitoring before, during, and after treatment with Fintepla to monitor for serious heart valve changes or high blood pressure in the arteries of the lungs. The FDA-required REMS program for Fintepla, including ongoing cardiac monitoring, would still be applicable under the FDA rules even after fenfluramine is decontrolled by DEA.

Based on FDA's scientific and medical review of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, HHS recommended that fenfluramine and its salts be removed from all schedules of the CSA. Pursuant to 21 U.S.C. 811(b), the recommendations of HHS shall be binding on DEA as to such scientific and medical matters and if the Secretary recommends that a drug or other substance not be controlled, DEA shall not control the drug or other substances. As stated in the NPRM, after careful review of all relevant data including HHS' scientific and medical evaluation and scheduling recommendation, DEA is therefore promulgating this final rule to remove fenfluramine, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible, from control under the CSA.

Determination To Decontrol Fenfluramine

Based on consideration of the comment, and the rationale set forth in the NPRM, the Administrator finds that fenfluramine does not meet the requirements for inclusion in any schedule. As such, DEA is removing fenfluramine, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible, from control under the CSA.

[1] 21 U.S.C. 812.

[2] 28 CFR 0.100.

[3] 21 U.S.C. 811(a).

[4] 38 FR 15719, May 9, 1973.

[5] 87 FR 42979.

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 scheduling action is subject to formal rulemaking procedures done ''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 removing a drug or other substance from the list of controlled substances. Such actions are exempt from review by the Office of Management and Budget 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. This rule does not have substantial direct effects on the States, on the relationship between the Federal 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. This rule 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 rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this rule is to remove fenfluramine from the list of schedules of the CSA. This action will remove regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances for handlers and proposed handlers of fenfluramine. Accordingly, it has the potential for some economic impact in the form of cost savings.

Fenfluramine as a pharmaceutical product (Fintepla) is currently available and marketed in the U.S. Because fenfluramine is currently a schedule IV drug, all legal handling of fenfluramine is currently done under appropriate DEA license. In such instances, DEA's knowledge of its registrant population forms the basis for estimating the number of affected entities and small entities that are affected by this rulemaking. There are currently 40 unique registrations authorized to handle fenfluramine specifically, as well as a number of registered analytical labs that are authorized to handle schedule IV controlled substances generally. From review of entity names, DEA estimates these 40 registrations represent 27 entities. Some of these entities are likely to be small entities. However, since DEA does not have information of registrant size and the majority of DEA registrants are small entities or are employed by small entities, DEA estimates a maximum of 27 entities are small entities. Therefore, DEA conservatively estimates as many as 27 small entities are affected by this final rule. However, because this rule would remove fenfluramine from regulatory controls of the CSA, it is likely to result in some cost savings. Any person planning to handle fenfluramine will realize cost savings in the form of saved DEA registration fees, and the elimination of physical security, recordkeeping, and reporting requirements. Because of these factors, DEA projects that this rule will not result in a significant economic impact on a substantial number of small entities.

Administrative Procedure Act

The Administrative Procedure Act requires the publication of a substantive rule to be made not less than 30 days before its effective date.[6] However, this requirement need not apply for ''a substantive rule which . . . relieves a restriction.'' [7] Therefore, DEA makes this rule effective immediately upon publication.

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 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 the final rule to both Houses of Congress and to the Comptroller General.

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 to read 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.

§ 1308.14 [Amended]

■ 2. In § 1308.14, remove and reserve paragraph (d).

Signing Authority

This document of the Drug Enforcement Administration was signed on December 12, 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**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–27400 Filed 12–22–22; 8:45 am]

BILLING CODE 4410–09–P

[6] 5 U.S.C. 553(d).

[7] 5 U.S.C. 553(d)(1).