PART 892—RADIOLOGY DEVICES

■ 10. The authority citation for part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 11. Amend § 892.2010 by revising paragraph (a) to read as follows:

§ 892.2010 Medical image storage device.

(a) *Identification:* A medical image storage device is a hardware device that provides electronic storage and retrieval functions for medical images. Examples include electronic hardware devices employing magnetic and optical discs, magnetic tapes, and digital memory.

* * * * *

■ 12. Amend § 892.2020 by revising paragraph (a) to read as follows:

§ 892.2020 Medical image communications device.

(a) *Identification.* A medical image communications device provides electronic transfer of medical image data between medical devices. It may include a physical communications medium, modems, and interfaces. It may provide simple image review software functionality for medical image processing and manipulation, such as grayscale window and level, zoom and pan, user delineated geometric measurements, compression, or user added image annotations. The device does not perform advanced image processing or complex quantitative functions. This does not include electronic transfer of medical image software functions.

* * * * *

■ 13. Amend § 892.2050 by revising the section heading and paragraph (a) to read as follows:

§ 892.2050 Medical image management and processing system.

(a) *Identification.* A medical image management and processing system is a device that provides one or more capabilities relating to the review and digital processing of medical images for the purposes of interpretation by a trained practitioner of disease detection, diagnosis, or patient management. The software components may provide advanced or complex image processing functions for image manipulation, enhancement, or quantification that are intended for use in the interpretation and analysis of medical images. Advanced image manipulation functions may include image segmentation, multimodality image registration, or 3D visualization. Complex quantitative functions may include semi-automated measurements or time-series measurements.

* * * * *

Dated: April 8, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: April 13, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–07860 Filed 4–16–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–665]

Schedules of Controlled Substances: Removal of Samidorphan From Control

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Acting Administrator of the Drug Enforcement Administration removes samidorphan (3-carboxamido-4-hydroxy naltrexone) and its salts from the schedules of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. Prior to the effective date of this rule, samidorphan was a schedule II controlled substance because it can be derived from opium alkaloids. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, conduct research, import, export, or conduct chemical analysis) or propose to handle samidorphan.

DATES: Effective April 19, 2021.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

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. 21 U.S.C. 812. 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 Acting Administrator of the Drug Enforcement Administration (DEA). 28 CFR 0.100.

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. 21 U.S.C. 811(a)(3). This action was initiated by one petition to remove samidorphan from the list of scheduled controlled substances of the CSA, and is supported by, *inter alia,* a recommendation from the Assistant Secretary of the 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 II controlled substances, on persons who handle or propose to handle samidorphan.

Background

Samidorphan (3-carboxamido-4-hydroxy naltrexone), is a chemical entity that is structurally similar to naltrexone, a mu (μ)-opioid receptor antagonist. Samidorphan (other developmental code names: RDC–0313 or ALKS 33) is a mu-opioid receptor antagonist with a weak partial agonist activity at the kappa- and delta-opioid receptors. According to HHS, products containing samidorphan are currently being developed for medical use. Samidorphan is currently controlled in schedule II of the CSA, as defined in 21 CFR 1308.12(b)(l), because it can be derived from opium alkaloids. On April 14, 2014, DEA received a petition to initiate proceedings to amend 21 CFR 1308.12(b)(1) so as to decontrol samidorphan from schedule II of the CSA. The petition complied with the requirements of 21 CFR 1308.43(b) and was accepted for filing. The petitioner contended that samidorphan has been characterized as an opioid receptor

antagonist, a class of drugs with no abuse potential.

DEA and HHS Eight Factor Analyses

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on samidorphan and forwarded the data, the sponsor's petition, and a request for scheduling recommendation on samidorphan to HHS on April 24, 2015.

On January 9, 2020, DEA received from HHS a scientific and medical evaluation (dated December 19, 2019) conducted by the Food and Drug Administration (FDA) [1] entitled ''Basis for the Recommendation to Remove Samidorphan (3-Carboxamido-4-Hydroxy Naltrexone) and its Salts from All Schedules of Control Under the Controlled Substances Act'' and a scheduling recommendation. Following consideration of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, HHS recommended that samidorphan and its salts be removed from all schedules of control of the CSA. In response, DEA conducted its own eight factor analysis of samidorphan pursuant to 21 U.S.C. 811(c). Both DEA and HHS analyses are available in their entirety in the public docket of this rule (Docket Number DEA–665) at *http://www.regulations.gov* under ''Supporting and Related Material.''

Determination To Decontrol Samidorphan

After a review of the available data, including the scientific and medical evaluation and the recommendation to decontrol samidorphan from HHS, the Acting Administrator of DEA published in the **Federal Register** a notice of proposed rulemaking (NPRM) entitled ''Schedules of Controlled Substances: Removal of Samidorphan from Control'' which proposed removal of samidorphan and its salts from the schedules of the CSA. 85 FR 79450, December 10, 2020. The proposed rule provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations by January 11, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before January 11, 2021.

Comments Received

DEA received two comments on the proposed rule to remove samidorphan from control. Both commenters supported decontrol of samidorphan.

Support

One commenter, a psychiatrist, clinical investigator and pain management expert, who participated as a principal investigator in clinical trials that examined the safety and efficacy of samidorphan and olanzapine combination product, stated that samidorphan counters weight gain associated with clinical use of olanzapine as antipsychotic medication and this combination product offers significant advancement relative to olanzapine alone, and thus supported this scheduling action.

Another commenter, on behalf of the sponsor of a samidorphan and olanzapine combination drug product currently under review by FDA for marketing approval, stated that samidorphan when combined with olanzapine has the potential to improve the safety profile of olanzapine by mitigating the weight gain associated with olanzapine treatment without altering its antipsychotic efficacy. This commenter agreed with DEA's conclusion that samidorphan lacks abuse or dependence potential and stated that samidorphan and its salts should be removed from the CSA schedules. This commenter further mentioned that the samidorphan and olanzapine combination product, which is currently under review by FDA for marketing approval, is an important new therapeutic option for patients and any delay in its availability for therapeutic use would negatively affect stakeholders, and therefore this final rule should be made effective immediately.

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

Scheduling Conclusion

Based on the consideration of all comments, the scientific and medical evaluation and accompanying recommendation of HHS, and based on DEA's consideration of its own eight-factor analysis, the Acting Administrator finds that these facts and all relevant data demonstrate that samidorphan does not meet the requirements for inclusion in any schedule, and will be removed from control under the CSA.

Regulatory Analyses

Executive Orders 12866 and 13563

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 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

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 Civil Justice Reform 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

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 Federal government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

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 Acting Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), 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 samidorphan from the list of schedules of the CSA. This action removes regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances for handlers and proposed handlers of samidorphan. Accordingly, it has the potential for some economic impact in the form of cost savings.

This rule will affect all persons who would handle, or propose to handle,

[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), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

samidorphan. Samidorphan is not currently available or marketed in any country. Due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the distribution and dispensing rates, if any, of samidorphan, DEA is unable to determine the number of entities and small entities which might handle samidorphan. In some instances where a controlled pharmaceutical drug is removed from the schedules of the CSA, DEA is able to quantify the estimated number of affected entities and small entities because the handling of the drug is expected to be limited to DEA registrants even after removal from the schedules. In such instances, DEA's knowledge of its registrant population forms the basis for estimating the number of affected entities and small entities. However, DEA does not have a basis to estimate whether samidorphan is expected to be handled by persons who hold DEA registrations, by persons who are not currently registered with DEA to handle controlled substances, or both. Therefore, DEA is unable to estimate the number of entities and small entities who plan to handle samidorphan.

Although DEA does not have a reliable basis to estimate the number of affected entities and quantify the economic impact of this final rule, a qualitative analysis indicates that this rule is likely to result in some cost savings. Any person planning to handle samidorphan 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

DEA finds that good cause exists for adopting this rule as a final rule with an immediate effective date under 5 U.S.C. 553(d) because this final rule relieves a restriction.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the RFA section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* 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 million or more (adjusted for inflation) in any one year. . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act

This action does not impose a new collection of information requirement under the Paperwork Reduction Act, 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.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, DEA is submitting a copy of this 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.

■ 2. In § 1308.12, revise paragraph (b)(1) introductory text to read as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, naldemedine, nalmefene, naloxegol, naloxone, 6β-naltrexol, naltrexone, and samidorphan, and their respective salts, but including the following:

* * * * *

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–07884 Filed 4–16–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 62

[Public Notice: 10818]

RIN 1400–AF03

Change to Certification Authority for the Alien Physician Category of the Exchange Visitor Program

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State (Department) is changing the certification authority for alien physicians from the American Board of Medical Specialties (ABMS) to the Accreditation Council for Graduate Medical Education (ACGME).

DATES: This rule is effective May 19, 2021.

FOR FURTHER INFORMATION CONTACT: G. Kevin Saba, Director, Office of Policy and Program Support, Office of Private Sector Exchange, Bureau of Educational and Cultural Affairs, U.S. Department of State, SA–4E, 2201 C Street NW, Washington, DC 20522; email at *JExchanges@state.gov*; or, (202) 634–4710.

SUPPLEMENTARY INFORMATION: In 22 CFR 62.27(e)(1) and (e)(4)(i), there is a reference to the ''American Board of Medical Specialties'' (ABMS). These provisions, last amended in 1993, state that ABMS will perform certain certification functions for the Secretary of State.

ABMS no longer produces the publication, *Marquis Who's Who,* referenced in 22 CFR part 62. Furthermore, ABMS has confirmed that it is also no longer the appropriate organization to comment on programs of graduate medical education. The Department has confirmed that the Accreditation Council for Graduate Medical Education (ACGME) has responsibility to accredit and recognize institutions offering programs of graduate medical education, and is replacing the reference to the ABMS with the ACGME in § 62.27.