

Rules and Regulations

Federal Register

Vol. 81, No. 72

Thursday, April 14, 2016

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.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-432]

Schedules of Controlled Substances: Placement of AH-7921 Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration places the substance AH-7921 (Systematic IUPAC Name: 3,4-dichloro-*N*-(1dimethylamino)cyclohexylmethyl]benzamide), including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, into schedule I of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act and is required in order for the United States to discharge its obligations under the Single Convention on Narcotic Drugs, 1961. 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 or conduct instructional activities with, or possess), or propose to handle, AH-7921.

DATES: Effective May 16, 2016.

FOR FURTHER INFORMATION CONTACT: Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the

Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use in treatment in the United States, and the degree of dependence the 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.

Section 201(d)(1) of the CSA (21 U.S.C. 811(d)(1)) states that, if control of a substance is required “by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings and procedures required by section 201(a) and (b) (21 U.S.C. 811(a) and (b)) and section 202(b) (21 U.S.C. 812(b)) of the Act.” 21 U.S.C. 811(d)(1), 21 CFR 1308.46. If a substance is added to one of the schedules of the Single Convention on Narcotic Drugs, 1961, then, in accordance with article 3, paragraph 7 of the Convention, as a signatory Member State, the United States is obligated to control that substance under its national drug control legislation, the CSA. The Attorney General has delegated scheduling authority under 21 U.S.C.

811 to the Administrator of the DEA. 28 CFR 0.100.

Background

On May 8, 2015, the Secretary-General of the United Nations advised the Secretary of State of the United States, that during the 58th session of the Commission on Narcotic Drugs, AH-7921 was added to schedule I of the Single Convention on Narcotic Drugs, 1961. This letter was prompted by a decision at the 58th session of the Commission on Narcotic Drugs in March 2015 to schedule AH-7921 under schedule I of the Single Convention on Narcotic Drugs. As a signatory Member State to the Single Convention on Narcotic Drugs, the United States is obligated to control AH-7921 under its national drug control legislation, the CSA, in the schedule deemed most appropriate to carry out its international obligations. 21 U.S.C. 811(d)(1).

AH-7921

AH-7921 is an *N*-substituted cyclohexylmethyl benzamide developed in 1962 by Allen and Hanbury’s, Ltd., a pharmaceutical company in the United Kingdom. AH-7921 is a μ -opioid receptor agonist with analgesic activity similar to that of morphine. The DEA is not aware of any commercial or medical uses for this substance. In animals, withdrawal symptoms are observed following repeated administration of AH-7921. Currently, clinical studies evaluating the safety and pharmacological effects of AH-7921 in humans have not been reported in the scientific literature. Usage of AH-7921 for eliciting euphoria and relaxation has been documented. There have been several reports of overdoses and deaths from AH-7921 reported worldwide including at least one published case report of a death resulting from AH-7921 in the United States. Given the increasing abuse of opioid prescription drugs (e.g., oxycodone, hydrocodone and fentanyl) and increased use of heroin in the United States, there are legitimate concerns about an increased potential of abuse of AH-7921.

DEA is not aware of any claims or any medical or scientific literature suggesting that AH-7921 has a currently accepted medical use in treatment in the United States. Accordingly, DEA has not requested that HHS conduct a scientific and medical evaluation of the substance’s medical utility.

Furthermore, DEA is not required under 21 U.S.C. 811(d)(1) to make any findings required by 21 U.S.C. 811(a) or 812(b), and is not required to follow the procedures prescribed by 21 U.S.C. 811(a) and (b). Therefore, consistent with the framework of 21 U.S.C. 811(d), DEA concludes that AH-7921 has no currently accepted medical use in treatment in the United States and is most appropriately placed in schedule I of the CSA.

Conclusion

In order to meet the obligations of the Single Convention on Narcotic Drugs, 1961 and because AH-7921 has no currently accepted medical use in treatment in the United States, the Administrator of the Drug Enforcement Administration has determined that this substance should be placed in schedule I of the Controlled Substances Act.

Requirements for Handling

Upon the effective date of this final order, AH-7921 is subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, engagement in research, and conduct of instructional activities with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research or conducts instructional activities with, or possesses), or who desires to handle, AH-7921 must be registered with the 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, as of May 16, 2016. Any person who currently handles AH-7921, and is not registered with the DEA, must submit an application for registration and may not continue to handle AH-7921 as of May 16, 2016, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration must surrender all quantities of currently held AH-7921, or may transfer all quantities of currently held AH-7921 to a person registered with the DEA on or before May 16, 2016 in accordance with all applicable federal, state, local, and tribal laws. As of May 16, 2016, controlled substances must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* AH-7921 is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of May 16, 2016.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of AH-7921 must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302 as of May 16, 2016.

5. *Quota.* A quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 is required in order to manufacture AH-7921 as of May 16, 2016.

6. *Inventory.* Every DEA registrant who possesses any quantity of AH-7921 on the effective date of this order must take an inventory of all stocks of this substance on hand as of May 16, 2016, pursuant to 21 U.S.C. 827 and 958, and in accordance with §§ 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with the DEA after May 16, 2016 must take an initial inventory of all stocks of controlled substances (including AH-7921) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including AH-7921) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with §§ 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports with respect to AH-7921 pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* All DEA registrants who distribute AH-7921 must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of May 16, 2016.

9. *Importation and Exportation.* All importation and exportation of AH-7921 must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of May 16, 2016.

10. *Liability.* Any activity involving AH-7921 not authorized by, or in violation of the CSA, occurring as of May 16, 2016, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States obligations under international treaties, conventions, or protocols. 21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty, convention, or protocol, the Attorney General must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings or procedures otherwise required for scheduling actions. *Id.*

To the extent that 21 U.S.C. 811(d)(1) directs that if control is required by the United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, scheduling actions shall be issued by order (as compared to scheduling pursuant to 21 U.S.C. 811(a) by rule), the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action. In the alternative, even if this action does constitute “rule making” under 5 U.S.C. 551(5), this action is exempt from the notice and comment requirements of 5 U.S.C. 553 pursuant to 21 U.S.C. 553(a)(1) as an action involving a foreign affairs function of the United States given that this action is being done in accordance with 21 U.S.C. 811(d)(1)'s requirement that such action be taken to comply with the United States obligations under the specified international agreements.

Executive Order 12866

This action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 13132

This action does not have federalism implications warranting the application of Executive Order 13132. This action 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 Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 13175

This action does not have tribal implications warranting the application of Executive Order 13175. The action 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 Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. 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 action is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). However, the DEA has submitted a copy of this final order 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, Narcotics, Prescription drugs.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 2. Amend § 1308.11 by redesignating paragraphs (b)(3) through (55) as (b)(4) through (56) and adding a new (b)(3) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(3) AH-7921 (3,4-dichloro-N-[(1-dimethylamino) cyclohexylmethyl]benzamide 9551

* * * * *

Dated: April 8, 2016

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–08566 Filed 4–13–16; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA–HQ–OAR–2016–0098; FRL–9944–88–OAR]

Findings of Failure To Submit State Implementation Plans Required for Attainment of the 2010 1-Hour Primary Sulfur Dioxide National Ambient Air Quality Standard (NAAQS); Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) is correcting a final rule that appeared in the **Federal Register** on March 18, 2016 (81 FR 14736). The document included a listing of areas for which states had not submitted State Implementation Plans (SIPs) addressing nonattainment area SIP requirements for the 2010 1-hour primary sulfur dioxide (SO₂) NAAQS. This action corrects that listing to clarify that the Indiana, Pennsylvania nonattainment area for the 2010 SO₂ NAAQS consists of the entirety of Indiana County and part of Armstrong County.

DATES: The effective date of this document is April 18, 2016.

FOR FURTHER INFORMATION CONTACT: For questions regarding this correction, contact Dr. Larry Wallace, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Mail Code C539–01, Research Triangle Park, NC 27711, phone number (919) 541-0906 or by email at wallace.larry@epa.gov.

SUPPLEMENTARY INFORMATION:**Background**

The EPA issued the final rule, in FR Doc 2016–06063 on March 18, 2016 (81 FR 14736). That final rule establishes certain Clean Air Act deadlines for the EPA to impose sanctions if a state does not submit a SIP addressing nonattainment area SIP requirements to bring the affected areas into attainment of the 2010 1-hour primary SO₂ NAAQS and for the EPA to promulgate a Federal Implementation Plan to address any outstanding SIP requirements.

Need for Correction

As published, the final preamble contains an error in a table identifying areas subject to the findings of failure to submit related to the Indiana, Pennsylvania nonattainment area. The Indiana, Pennsylvania nonattainment area consists of the entirety of Indiana County and part of Armstrong County. See 78 FR 47191, August 5, 2013 codified at 40 CFR part 81, subpart C. The preamble table mistakenly lists Indiana County as a “partial” county that is part of the Indiana, Pennsylvania nonattainment area subject to a finding of failure to submit, when the full county should have been listed as subject to the finding. Additional notice and comment for this minor technical correction is unnecessary under 5 U.S.C. 553(b)(3)(B), and the EPA finds that good cause exists for this minor technical correction to become effective at the same time as the final rule. Accordingly, this correction is incorporated into the final rule and also becomes effective on April 18, 2016.

Correction of Publication

In FR Doc 2016–06063 appearing on page 14736 in the **Federal Register** of Friday, March 18, 2016, the following correction is made:

On page 14737, table entitled “STATES AND SO₂ NONATTAINMENT AREAS AFFECTED BY THESE FINDINGS OF FAILURE TO SUBMIT,” remove from the end of the fourth entry, under the column titled “Nonattainment area” the text “(p)”.

Dated: April 4, 2016.

Janet G. McCabe,

Acting Assistant Administrator.

[FR Doc. 2016–08509 Filed 4–13–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA–R09–OAR–2015–0204; FRL–9944–16–Region 9]

Partial Approval and Partial Disapproval of Air Quality State Implementation Plans; California; South Coast; Moderate Area Plan for the 2006 PM_{2.5} NAAQS

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving in part and disapproving in part State implementation plan (SIP) revisions