



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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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 USC 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 USC 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 USC 811(d)(1) to make any findings required by 21 USC 811(a) or 812(b), and is not required to follow the procedures prescribed by 21 USC 811(a) and (b). Therefore, consistent with the framework of 21 USC 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] in accordance with all applicable federal, state, local, and tribal laws. As of [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. .

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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL

REGISTER], 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

10. *Liability.* Any activity involving AH-7921 not authorized by, or in violation of the CSA, occurring as of [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE

FEDERAL REGISTER], 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.

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(b) * * *

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

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Dated: April 8, 2016

Chuck Rosenberg,
Acting Administrator.

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