DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Schedule I Temporary Placement of Three Synthetic Phenethylamines Into Schedule I]

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this final order to temporarily schedule three synthetic phenethylamines into the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The substances are 2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I–NBOMe); 2C–I–NBOMe; 25I; Cimbi-5; 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C–NBOMe); 2C–C–NBOMe; 25C; Cimbi-82, and 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B–NBOMe). The Assistant Administrator for Diversion Control, Drug Enforcement Administration, has determined that it is necessary to place these three synthetic phenethylamines in schedule I of the CSA to protect the public health and safety.

DATES: This final order is effective November 15, 2013.

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Chief, Policy Evaluation and Analysis Section, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The 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, but they 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), parts 1300 to 1321. 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 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 current accepted medical use, 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 all scheduled substances is published at 21 CFR part 1308. Section 201 of the CSA, 21 U.S.C. 201, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years, without regard to the requirements of 21 U.S.C. 811(b), if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year, 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355, for the substance. 21 U.S.C. 811(h)(1). Pursuant to 21 U.S.C. 871(a), the Attorney General has delegated his scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA, who in turn has delegated her authority to the Deputy Administrator of the DEA. 28 CFR 0.100, 0.104.

Background

Section 201(b)(4) of the CSA, 21 U.S.C. 811(b)(4), requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I of the CSA. The Deputy Administrator transmitted notice of his intention to place 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe in schedule I on a temporary basis to the Assistant Secretary by letter dated September 3, 2013. The Assistant Secretary responded to this notice by letter dated October 1, 2013 (received by the DEA on October 8, 2013), and advised that based on review by the FDA, there are currently no investigational new drug applications or approved new drug applications for 25I–NBOMe, 25C–NBOMe, or 25B–NBOMe. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of 25I–NBOMe, 25C–NBOMe, or 25B–NBOMe in schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary’s comments as required by 21 U.S.C. 811(h)(4). As 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe are not currently listed in any schedule under the CSA, and as no exemptions or approvals are in effect for 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe under section 505 of the FD&C Act, 21 U.S.C. 355, the conditions of 21 U.S.C. 811(h)(1) have been satisfied. As required by 21 U.S.C. 811(h)(1)[a], a notice of intent to temporarily schedule these three synthetic phenethylamines was published in the Federal Register on October 10, 2013. 78 FR 61991.

To make a finding that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Deputy Administrator is required to consider three of the eight factors set forth in section 201(b) of the CSA, 21 U.S.C. 811(c): The substance’s history and current pattern of abuse; the scope, duration, and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(c)(4)–(6).

Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I.
U.S.C. 811(b)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe indicate that these three synthetic phenethylamines have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

Synthetic Phenethylamines

The 2-methoxybenzyl series of 2C phenethylamine substances, such as 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe, has been developed over the last 10 years for use in mapping and investigating the serotonin receptors in the mammalian brain. 25I–NBOMe and 25B–NBOMe were first described by legitimate research laboratories in 2003. Subsequent studies involving these two substances appeared in the scientific literature starting in 2006. 25C–NBOMe first appeared in the scientific literature in 2011. No approved medical use has been identified for these synthetic phenethylamines, nor have they been approved by the FDA for human consumption. Synthetic 2C phenethylamine substances, of which 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe are representative, are termed for the two-carbon ethylene group between the phenyl ring and the amino group of the phenethylamine and are substituted with methoxy groups at the 2 and 5 positions of the phenyl ring. Numerous blotter papers and food items have been analyzed, and combinations of one or more of 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe have been identified as adulterants. Bulk quantities of these substances have been encountered as powders and liquid solutions.

From November 2011 through June 2013, according to the System to Retrieve Information from Drug Evidence (STRIDE) data, there are 54 exhibits involving 25I–NBOMe; 27 exhibits involving 25C–NBOMe; and 25B–NBOMe involving 12 cases for 25C–NBOMe; and 4 exhibits involving 25B–NBOMe. From June 2011 through June 2013, the National Forensic Laboratory Information System (NFLIS) registered 959 reports containing these synthetic phenethylamines (25I–NBOMe—795 reports; 25C–NBOMe—144 reports; 25B–NBOMe—20 reports) across 35 States. No instances involving 25I–NBOMe, 25C–NBOMe, or 25B–NBOMe were reported in NFLIS prior to June 2011.

Factor 4. History and Current Pattern of Abuse

One or more 2-methoxybenzyl analogues of the 2C compounds described here have been available over the Internet since 2010. The first identified domestic law enforcement encounter with 25I–NBOMe occurred in June 2011 in Milwaukee, Wisconsin. Information from published studies and law enforcement reports, supplemented with discussions on Internet Web sites and personal communications, document abuse of 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe by nasal insufflation of powders, intravenous injection or nasal absorption of liquid solutions, sublingual or buccal administration of blotter papers, and consumption of food items laced with these substances. These sources also report that 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe are often purported to be schedule I hallucinogens like lysergic acid diethylamide (LSD). Reports document that the abuse of these substances can cause severe toxic reactions, including death.

According to United States Customs and Border Protection data, bulk quantities of powdered 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe have been seized from shipments originating overseas, particularly from Asia. Given the relatively small quantity of these substances predicted to produce a hallucinogenic effect in humans, single seizures of these substances are capable of producing hundreds to thousands to millions of dosage units. Large seizures of these substances prepared on blotter papers have also been reported. Abuse of 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe has been characterized with acute public health and safety issues domestically and abroad. In response, a number of States and foreign governments have controlled these substances.

Factor 5. Scope, Duration, and Significance of Abuse

According to forensic laboratory reports, the first law enforcement encounter with 25I–NBOMe in the United States occurred in June 2011. According to NFLIS, 959 exhibits involving 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe were submitted to forensic laboratories between June 2011 and June 2013 from a number of States including Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming. The number of reports submitted to NFLIS involving 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe has increased in each of the last five quarters where complete data is available. According to STRIDE, there are 85 records that identify 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe in evidence submitted to DEA laboratories between November 2011 and June 2013.

Factor 6. What, If Any, Risk There Is to the Public Health

In 2012 and 2013, emergency department physicians and toxicologists published and presented numerous case reports of patients treated for exposure to 25I–NBOMe. The adverse health effects reported include tachycardia, hypertension, agitation, aggression, visual and auditory hallucinations, seizures, hyperpyrexia, clonus, elevated white cell count, elevated creatine kinase, metabolic acidosis, rhabdomyolysis, and acute kidney injury.

Medical examiner and postmortem toxicology reports from 11 States implicate some combination of 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe in the death of at least 17 individuals. These reports suggest that 14 individuals died of acute toxicity, and 3 individuals died of unpredictable or violent behavior due to 25I–NBOMe toxicity. 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe have each been detected in postmortem blood toxicology for cases of acute toxicity.

Since abusers obtain these drugs through unknown sources, the identity, purity, and quantity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users. There are no recognized therapeutic uses for these substances in the United States and possible deadly drug interactions between 25I–NBOMe and FDA-approved medications have been noted.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

Based on the above data and information, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe pose an...
The DEA is not aware of any currently accepted medical uses for these synthetic phenethylamines in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe indicate that these three synthetic phenethylamines have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Deputy Administrator through a letter dated September 3, 2013, notified the Assistant Secretary of the intention to temporarily place these three synthetic phenethylamines in schedule I.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Deputy Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule three synthetic phenethylamines, 2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I–NBOMe); 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C–NBOMe); 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B–NBOMe); 2C–I–NBOMe; 25I–NBOMe; 25C–NBOMe; and 25B–NBOMe. Current DEA registrants shall do so as of November 15, 2013.

Regulatory Requirements

Upon the effective date of this Final Order, 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe will become subject to the CSA’s schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, research, conduct of instructional activities, and possession including the following:

1. Registration. Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, conducts instructional activities, or possesses), or desires to handle, 25I–NBOMe, 25C–NBOMe, or 25B–NBOMe 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. Any person who currently handles 25I–NBOMe, 25C–NBOMe, or 25B–NBOMe and is not registered with the DEA must submit an application for registration and may not continue his/her activities until the DEA has approved that application. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA.


3. Labeling and packaging. All labeling and packaging requirements for controlled substances set forth in part 1302 of title 21 of the CFR shall apply to commercial containers of 25I–NBOMe, 25C–NBOMe, and 25B–NBOMe. Current DEA registrants shall have 30 calendar days from November 15, 2013 to comply with all labeling and packaging requirements.

4. Grant and quota applications. DEAs grant and quota applications received pursuant to part 1303 of title 21 of the CFR are granted and quota applications received pursuant to part 1303 of title 21 of the CFR.

5. Inventory. Every DEA registrant who possesses any quantity of 25I–NBOMe, 25C–NBOMe, or 25B–NBOMe on the effective date of this order will be required to take an inventory of all stocks of these substances on hand as of the effective date of this order, pursuant to 21 U.S.C. 827, 956(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements.

6. Records. All registrants who are authorized to handle 25I–NBOMe, 25C–NBOMe, or 25B–NBOMe are required to keep records pursuant to 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of title 21 of the CFR. Current DEA registrants authorized to handle 25I–NBOMe, 25C–NBOMe, or 25B–NBOMe shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. Reports. All registrants are required to submit reports in accordance with 1304.33 of title 21 of the CFR. DEA registrants who manufacture or distribute 25I–NBOMe, 25C–NBOMe, or 25B–NBOMe are required to comply with these reporting requirements and shall do so as of November 15, 2013.


10. Criminal Liability. Any activity involving 25I–NBOMe, 25C–NBOMe, or 25B–NBOMe not authorized by, or in violation of the CSA, occurring as of November 15, 2013 is unlawful, and may subject the person to administrative, civil, and criminal proceedings.

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order,
schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of a proposed temporary scheduling order is transmitted to the Assistant Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, 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 temporary scheduling action. In the alternative, even assuming that this action might be subject to section 553 of the APA, the Deputy Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuing temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Further, the DEA believes that this temporary scheduling action final order is not a “rule” as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(f) are not applicable where, as here, the DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking. Additionally, 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).

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. Pursuant to section 808(2) of the Congressional Review Act (CRA), “any rule by which an agency for good cause finds... that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines.” It is in the public interest to schedule these substances immediately because they pose a public health risk. This temporary scheduling action is taken pursuant to section 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety from new or designer drugs or abuse of those drugs. Section 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie section 811(h), that is, the DEA’s need to move quickly to place these substances into schedule I because they pose a threat to public health, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, in accordance with section 808(2) of the CRA, this order shall take effect immediately upon its publication.

List of Subjects in 21 CFR Part 1308

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

Under the authority vested in the Attorney General by section 201(h) of the CSA, 21 U.S.C. 811(h), and delegated to the Deputy Administrator of the DEA by Department of Justice regulations, 28 CFR 0.100, Appendix to Subpart R, the Deputy Administrator hereby intends to order that 21 CFR part 1308 be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

§ 1308.11 Schedule I.

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. Section 1308.11 is amended by adding paragraphs (h)(12), (13), and (14) to read as follows:

(h) 12 2-(4-iodo-2,5-dimethoxyphenyl)N-(2-methoxybenzyl)ethanamine, its optical, positional, and geometric isomers, salts and salts of isomers—7538 (Other names: 25B–NBOMe; 2C–B–NBOMe; 25B; Cimbi-36)

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 50, 55, and 58

Docket No. FR–5423–F–02

RIN 2501–AD51

Floodplain Management and Protection of Wetlands

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: This final rule revises HUD’s regulations governing the protection of wetlands and floodplains. With respect to wetlands, the rule codifies existing procedures for Executive Order 11990 (E.O. 11990), Protection of Wetlands. HUD’s policy has been to require the use of the 8-Step Process for floodplains for wetlands actions performed by HUD or actions performed with HUD financial assistance. This rule codifies this wetlands policy and improves consistency and increases transparency by placing the E.O. 11990 requirements in regulation. In certain instances, the new wetlands procedures will allow recipients of HUD assistance to use individual permits issued under section 404 of the Clean Water Act (Section 404 permits) in lieu of 5 steps of the E.O. 11990’s 8-Step Process, streamlining the wetlands decisionmaking processes. With respect to floodplains, with some exceptions, the rule prohibits HUD funding (e.g., Community Development Block Grants, HOME Investment Partnerships Program, Choice Neighborhoods, and others) or Federal Housing Administration (FHA) mortgage insurance for construction in Coastal High Hazard Areas. In order to ensure maximum protection for communities and wise investment of Federal resources in the face of current and future risk, this final rule also requires the use of preliminary flood maps and advisory base flood elevations where the Federal Emergency