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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-423]

Schedules of Controlled Substances: Placement of Three Synthetic Phenethylamines into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing three synthetic phenethylamines: 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; 2C-B-NBOMe; 25B; Cimbi-36) into schedule I of the Controlled Substances Act. This proposed scheduling action is pursuant to the Controlled Substance Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. If finalized, this action would impose 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, conduct instructional activities or chemical analysis, or possess), or propose to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe.

DATES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)," may file a request for hearing, notice of appearance, or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45, 1316.47, and/or 1316.48, as applicable. Requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-423" on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public

view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152.

- *Hearing requests:* All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA)

applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing, Notice of Appearance at Hearing, Waiver of an Opportunity for a Hearing or to Participate in a Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. In accordance with 21 CFR 1308.44(a)–(c), requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)." 21 CFR 1300.01. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and may include a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of a hearing is restricted to: "(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *." All requests for hearing and waivers of participation must be sent to the DEA using the address information provided above.

Legal Authority

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. 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 purposes 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, 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 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)(1), the Attorney General may, by rule, "add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of

this title for the schedule in which such drug is to be placed * * *." The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the 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 (1) on her own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS),[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Assistant Secretary of the HHS and an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles, or proposes to handle, 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe.

Background

On November 15, 2013, the DEA published a final order in the *Federal Register* amending 21 CFR 1308.11(h) to temporarily place 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe), 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe), and 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe) into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 78 FR 68716. That final order, which became effective on the date of publication, was based on findings by the Deputy

[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.

Administrator of the DEA that the temporary scheduling of these three synthetic phenethylamine substances was necessary to avoid an imminent hazard to public safety pursuant to 21 U.S.C. 811(h)(1). At the time the final order took effect, section 201(h)(2) of the CSA, 21 U.S.C. 811(h)(2), required that the temporary scheduling of a substance expire at the end of two years from the date of issuance of the scheduling order, and it provided that, during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, temporary scheduling of that substance could be extended for up to 1 year. Pursuant to 21 U.S.C. 811(h)(2), the temporary scheduling of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe expires on November 14, 2015, unless extended. An extension of the temporary order is being ordered by the DEA Administrator in a separate action.

As described in the final order published on November 15, 2013, 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are structurally and pharmacologically similar to 2,5-dimethoxy-4-iodophenethylamine (2C-I), 2,5-dimethoxy-4-chlorophenethylamine (2C-C), and 2,5-dimethoxy-4-bromophenthylamine (2C-B). While 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have been used as research chemicals and/or studied due to their misuse and abuse, based on the review of the scientific literature, there are no known medical uses for 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe. The Assistant Secretary of Health for the U.S. Department of Health and Human Services (HHS) has advised that there are no exemptions or approvals in effect for 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe under section 505 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 355. As stated by the HHS, 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have no known accepted medical use. They are not the subject of any approved

new drug applications (NDAs) or investigational new drug applications (INDs), and are not currently marketed as approved drug products.

Proposed Determination to Schedule 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe

Pursuant to 21 U.S.C. 811(a)(1), proceedings to add a drug or substance to those controlled under the CSA may be initiated by the Attorney General, or her delegate, the DEA Administrator. On July 23, 2014, the DEA requested a scientific and medical evaluation and scheduling recommendations from the Assistant Secretary of Health for the HHS for 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe pursuant to 21 U.S.C. 811(b). Upon receipt of the scientific and medical evaluation and scheduling recommendations from the HHS dated August 12, 2015, the DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe pursuant to 21 U.S.C. 811(c).

Included below is a brief summary of each of the eight factors as analyzed by the HHS and the DEA, and as considered by the DEA in this proposed action. Please note that both the DEA and the HHS analyses are available under "Supporting Documents" of the public docket for this proposed rule at *http://www.regulations.gov* under docket number DEA-423.

1. *The Drug's Actual or Relative Potential for Abuse*: As described by the HHS, the abuse potentials of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are associated with their abilities to produce psychoactive effects that are similar to those produced by other schedule I hallucinogens that have a high potential for abuse such as 2,5-dimethoxy-4-methylamphetamine (DOM), 2,5-dimethoxy-4-iodophenethylamine (2C-I), 2,5-

dimethoxy-4-chlorophenethylamine (2C-C), 2,5-dimethoxy-4-bromophenthylamine (2C-B), and lysergic acid diethylamide (LSD).

The legislative history of the CSA suggests the DEA consider the following factors when determining whether a particular drug or substance has a potential for abuse:[2]

> 1) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community;
>
> 2) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels;
>
> 3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or
>
> 4) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

The substances 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have no approved medical uses in the United States and they have been encountered on the illicit market with adverse outcomes on the public health and safety. Human use of these substances is due to the individual's own initiative and it has been established that they are being abused for their psychoactive properties. For these reasons, there are no legitimate drug

[2] COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT OF 1970, H.R. REP. NO. 91-1444, 91st Cong., Sess. 2 (1970); *reprinted in* 1970 U.S.C.C.A.N. 4566, 4601.

channels for NBOMEs as marketed drugs and these substances should be limited to scientific research. Reports from public health and law enforcement communicate that these substances are being abused and taken in amounts sufficient to create a hazard to one's own health as evidenced by the emergency department admissions and deaths and this misuse is also a significant safety issue for those in the community. Data from forensic databases are used as indicators of illicit activity with drugs and abuse[3] within the United States and include the System to Retrieve Information from Drug Evidence (STRIDE),[4] STARLiMS, and the National Forensic Laboratory Information System (NFLIS)[5]. From January 2011 through August 2015 (query dates: September 22 & 23, 2015), STRIDE, STARLiMS, and NFLIS databases registered a total of 4,868 reports containing the three NBOMes (25I-NBOMe – 2,714 reports; 25C-NBOMe – 1,291 reports; 25B-NBOMe – 863 reports). These drug reports represent NBOMe data reported to these databases by participating DEA, Customs and Border Protection (CBP), state, and local/municipal forensic laboratories in the United States. 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have been reported to produce hallucinogenic effects. There have been numerous anecdotal self-reports substantiating that 25I-NBOMe, 25C-NBOMe, and/or 25B-NBOMe and their products are abused by humans for their hallucinogenic effects, as well as published reports indicating an increase in the abuse of

3 While law enforcement data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011

4 STRIDE was a database that collected analyses of results from drug evidence sent to DEA laboratories. Evidence was submitted by the DEA, other Federal agencies, and select local law enforcement agencies. On October 1, 2014, STARLiMS replaced STRIDE as the DEA system of record for forensic laboratory drug evidence data.

5 NFLIS is a DEA program and a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. The NFLIS database also contains Federal data from CBP. NFLIS includes drug chemistry results from completed analyses only.

these substances. These reports of abuse are in agreement with the large number of encounters of these substances by law enforcement.

2. *Scientific Evidence of the Drug's Pharmacological Effects, If Known*: Studies show that 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are full agonists at the 5-HT_{2A} serotonin receptor based on the receptor binding and functional activity profiles in *in vitro* studies. *In vivo* experimental animal studies have reported that 25I-NBOMe and 25B-NBOMe significantly increase the head twitch response, a response associated with hallucinogens that act on the 5-HT_{2A} serotonin receptor. In addition, 25I-NBOMe was more potent than the schedule I hallucinogen 2C-I, and 25B-NBOMe was more potent than the hallucinogen DOI in eliciting the head twitch response

According to the HHS, there are no reported human clinical trials with 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe but there is evidence that these substances are abused for their hallucinogenic effects. Clinical case reports indicate that 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe produce a number of stimulant-like adverse effects. According to the HHS, adverse health effects associated with products containing synthetic phenethylamines include: hallucinations (open and closed eye visuals), nausea, excessive sweating, tachycardia, psychomotor agitation, prolonged seizures, rhabdomyolysis, and renal failure.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance*: 25I-NBOMe, 25C-NBOMe and 25B-NBOMe are classified as 2C compounds, a structural class with a phenethylamine core substituted with methoxy groups on the 2 and 5 positions of the phenyl ring. 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are structurally similar to the 2C-X compounds (2C-I, 2C-C, and 2C-B,

respectively) which are controlled as schedule I hallucinogenic substances under the CSA. Data indicate that 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are rapidly distributed from the blood into the brain, liver, and bile. Studies examining elimination of NBOMes have reported that 90% of the parent compound is eliminated from the plasma within 90 minutes and urine samples suggest that the corresponding 2C compounds (i.e., 2C-I, 2C-C, and 2C-B) may be metabolites of the NBOMes. According to the HHS, 25I-NBOMe, 25C-NBOMe and 25B-NBOMe are not U.S. Food and Drug Administration (FDA)-approved drug products. The DEA is not aware of any currently accepted medical use or NDAs for 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe. Furthermore, the Assistant Secretary of the HHS responded that there were no current INDs or NDAs for these synthetic phenethylamines in the scientific and medical evaluations and recommendations addressed to the DEA Deputy Administrator dated August 12, 2015.

4. *Its History and Current Pattern of Abuse*: Law enforcement has encountered 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe in the illicit drug market. These synthetic substances are available over the Internet and sold through illicit channels, often purported to be schedule I hallucinogens, like LSD. Market names for products found to contain NBOMe include, but are not limited to: "Smiles," "N-bomb," "Cimbi-5," "25I," and others. 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have been seized as powders, as solutions, on blotter paper, and laced on food items. According to the HHS, 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are abused in the same manner as schedule I hallucinogens such as LSD, DOM, 2C-I, 2C-B, and 2C-C. Furthermore, evidence indicates that youth appear to be the primary abusers of these synthetic substances.

5. *The Scope, Duration, and Significance of Abuse*: Evidence from law enforcement indicates that the abuse of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe is widespread. Law enforcement databases registered a total of 4,868 drug reports involving 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe (query date: September 22 & 23, 2015) spanning a time period from January 2011 through August 2015. Law enforcement encounters of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe have occurred in at least 43 states and the District of Columbia. As stated by the HHS, based on the pharmacological properties of the substances, it is reasonable to assume that, if uncontrolled, the scope, duration, and significance of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe abuse could be similar to that of LSD. Concerns over the abuse of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe have prompted state, military, and international control of these substances.

6. *What, if Any, Risk There is to the Public Health*: Law enforcement, medical community representatives, and public health officials have reported exposure incidents that demonstrate the dangers associated with the abuse of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe to individual abusers as well as to the public. Furthermore, the HHS stated that the NBOMe series of drugs have much narrower "therapeutic" ratios and much smaller margins of safety than most other known hallucinogens, and so carry greater risk of acute toxicity and death.

There have been numerous reports of deaths associated with the abuse of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe. Published case reports have also described deaths associated with the ingestion of the NBOMe substances. As of October 2013, the DEA has obtained medical examiner and postmortem toxicology reports implicating some combination of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe in the death of 17

individuals. The average age of these individuals is 20 years (range 15 to 29 years). The circumstances surrounding the deaths include acute toxicity (14) or unpredictable, violent behavior due to 25I-NBOMe toxicity ultimately leading to death (3). As detailed above, there are reported instances of emergency department admissions and deaths associated with the abuse of these synthetic substances. There is no accepted medical use of these substances in the United States.

7. *Its Psychic or Physiological Dependence Liability*: According to the HHS, the pharmacologic profiles of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe strongly suggest that they possess physiological and psychological dependence liability that is similar to that of schedule I hallucinogens such as LSD, 2C-I, 2C-C, 2C-B, and DOM, although there are no studies or case reports that document the psychic or physiological dependence potential of these substances. However, based on the structural similarity between the NBOMes (25I-NBOMe, 25C-NBOMe, and 25B-NBOMe) and other schedule I hallucinogens (2C-I, 2C-B, 2C-C) and the similarity in pharmacological actions and resulting effects in the hallucinogen drug class (e.g. LSD, psilocybin), it is expected that the NBOMes will share a similar psychic and psychological dependence liability.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA*: 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are not considered immediate precursors of any controlled substance of the CSA as defined by 21 U.S.C 802(23).

Conclusion: Based on consideration of the scientific and medical evaluations and accompanying recommendation of the HHS, and based on the DEA's considerations of

its own eight-factor analysis, the DEA finds that these facts and all other relevant data constitute substantial evidence of the potential for abuse of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe. As such, the DEA hereby proposes to schedule 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe as controlled substances under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(1), finds that:

(1) 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have a high potential for abuse that is comparable to other schedule I substances such as 2C-I, 2C-C, 2C-B, LSD and DOM;

(2) 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe have no currently accepted medical use in treatment in the United States; and

(3) There is a lack of accepted safety for use of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe under medical supervision.

Based on these findings, the Administrator of the DEA concludes that 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; 2C-B-NBOMe; 25B; Cimbi-36), including

their salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe

If this rule is finalized as proposed, persons who handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe would continue[6] to be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, possession, importing, and exporting of schedule I controlled substances, including those listed below:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe, or who desires to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe would be required to 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.

2. *Security.* 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe would be subject to schedule I security requirements and would need to be handled and stored pursuant to 21 U.S.C. 821, 823, and 871(b), and in accordance with 21 CFR 1301.71–1301.93.

3. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe would need to be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers would be permitted to manufacture 25I-

[6] 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 78 FR 68716.

NBOMe, 25C-NBOMe, or 25B-NBOMe in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person who becomes registered with the DEA on or after the effective date of the final rule must take an initial inventory of all stocks of controlled substances (including NBOMes) 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 a new inventory of all stocks of controlled substances (including NBOMes) on hand every two years pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports with respect to 25I-NBOMe, 25C-NBOMe, and/or 25B-NBOMe pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304 and 1312.

7. Order Forms. Every DEA registrant who distributes 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe would be required to comply with the order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305.

8. Importation and Exportation. All importation and exportation of 25I-NBOMe, 25C-NBOMe, and 25B-NBOMe would need to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. Liability. Any activity involving 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe not authorized by, or in violation of, the CSA or its implementing regulations would be unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this proposed 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 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 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

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It 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 (RFA), 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. On November 15, 2013, the DEA published a final order to temporarily place these three synthetic phenethylamines into schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The DEA estimates that all entities handling or planning to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe are currently registered to handle these substances. There are currently 18 registrations authorized to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 18 registrations represent 13 entities, of which 6 are small entities. Therefore, the DEA estimates six small entities are affected by this proposed rule.

A review of the 18 registrations indicates that all entities that currently handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe handle other schedule I controlled substances, and have established and implemented (or currently maintain) the systems and processes required to handle 25I-NBOMe, 25C-NBOMe, or 25B-NBOMe. Therefore, the DEA anticipates that this proposed rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the six

affected small entities. Therefore, the DEA has concluded that this proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the "Regulatory Flexibility Act" section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 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 $100,000,000 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 the UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 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.

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 proposed to be amended 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), unless otherwise noted.

2. In § 1308.11:

a. Add paragraphs (d)(48) through (50);

b. Remove paragraphs (h)(4), (5), and (6); and

c. Redesignate paragraphs (h)(7) through (24) as (h)(4) through (21).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(48) 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe or 2C-I-NBOMe)……..**....**(7538)

(49) 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe or 2C-C-NBOMe)……...……...(7537)

(50) 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe or 2C-B-NBOMe)……..**..**(7536)

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Dated: November 10, 2015.

Chuck Rosenberg,
Acting Administrator.

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