(e) Reporting information for all manufacturers (Form 3500A, Block G). You must submit the following:

(1) Your reporting office's contact name and address and device manufacturing site;

(2) The contact's telephone number;

(3) Your report sources;

(4) Date received by you (month, day, year);

(5) PMA/510k Number and whether or not the product is a combination product;

(6) Type of report being submitted (e.g., 5–day, initial, followup); and

(7) Your report number.

* * * * *

18. Revise the introductory text of § 803.53 to read as follows:

§ 803.53 If I am a manufacturer, in which circumstances must I submit a 5-day report?

You must submit a 5-day report to us with the information required by § 803.52 in accordance with the requirements of § 803.12(a) no later than 5 work days after the day that you become aware that:

* * * * *

19. Amend § 803.56 by revising the introductory text and paragraphs (a) and (c) to read as follows:

§ 803.56 If I am a manufacturer, in what circumstances must I submit a supplemental or followup report and what are the requirements for such reports?

If you are a manufacturer, when you obtain information required under this part that you did not provide because it was not known or was not available when you submitted the initial report, you must submit the supplemental information to us within 30 calendar days of the day that you receive this information. You must submit the supplemental or followup report in accordance with the requirements of § 803.12(a). On a supplemental or followup report, you must:

(a) Indicate that the report being submitted is a supplemental or followup report;

* * * * *

(c) Include only the new, changed, or corrected information.

Dated: August 11, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–19683 Filed 8–20–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–331]

Schedules of Controlled Substances: Placement of 5-Methoxy-N,N-Dimethyltryptamine Into Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this notice of proposed rulemaking to place the substance 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT) and its salts into schedule I of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Acting Assistant Secretary for Health of the Department of Health and Human Services (DHHS) and on an evaluation of the relevant data by DEA. If finalized as proposed, this action would impose the criminal sanctions and regulatory controls of schedule I substances under the CSA on the manufacture, distribution, dispensing, importation, exportation, and possession of 5-MeO-DMT.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before September 21, 2009. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–331'' on all written and electronic correspondence. Written comments being sent via regular or express mail should be sent to the Drug Enforcement Administration, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be sent to DEA by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept electronic comments containing Microsoft Word, WordPerfect, Adobe PDF, or Excel files only. DEA will not accept any file format other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern time on the day the comment period closes because *http://www.regulations.gov* terminates the public's ability to submit comments at midnight Eastern time on the day the comment period closes. Commenters in time zones other than Eastern time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152, *Telephone:* (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Comments and Requests for Hearing

In accordance with the provisions of the CSA (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 (5 U.S.C. 556 and 557). All persons are invited to submit their comments or objections with regard to this proposal. Requests for a hearing may be submitted by interested persons and must conform to the requirements of 21 CFR 1308.44 and 1316.47. The request should state, with particularity, the issues concerning which the person desires to be heard and the requestor's interest in the proceeding. Only interested persons, defined in the regulations 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 request a hearing.

21 CFR 1308.42. Please note that DEA may grant a hearing only ''for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable'' pursuant to 21 U.S.C. 811(a). All correspondence regarding this matter should be submitted to the DEA using the address information provided above.

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug

Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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 posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket 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 posted online or made available in the public docket, 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. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

Background

Explanation of 5-methoxy-N,N-dimethyltryptamine

5-MeO-DMT is related to the schedule I hallucinogen, N,N-dimethyltryptamine (DMT), in its chemical structure and pharmacological properties. 5-MeO-DMT also shares pharmacological similarities with several other schedule I hallucinogens such as 2,5-dimethoxy-4-methylamphetamine (DOM), lysergic acid diethylamide (LSD) and mescaline. In animal drug discrimination studies, DOM, LSD, mescaline, DMT, and alpha-methyltryptamine (AMT) fully substitute for the discriminative stimulus cue of 5-MeO-DMT. In *in vitro* receptor binding studies, 5-MeO-DMT, similar to DMT and other schedule I hallucinogens, binds to central serotonin 2 (5-HT_2) receptors.

Studies show that the potencies of hallucinogens in humans correlate with their drug affinities for the 5-HT_2 receptor and discriminative stimulus potencies. Accordingly, 5-MeO-DMT produces psychoactive effects in humans following inhalation (~6–20 mg), intravenous injection (~0.7–3.1 mg), sublingual (~10 mg), intranasal insufflation (~10 mg) and oral (~30 mg) (if encapsulated or taken with a monoamine oxidase inhibitor) routes of administration. Anecdotal reports from humans who have used 5-MeO-DMT describe hallucinogenic effects similar to those produced by DMT. 5-MeO-DMT, however, is reported to be 4 to 5-fold more potent than DMT when administered by inhalation, sublingual or oral (if encapsulated) routes of administration.

Control of 5-methoxy-N,N-dimethyltryptamine

Evidence of the abuse of 5-MeO-DMT was first reported in 1999 by federal law enforcement personnel. According to the System to Retrieve Information on Drug Evidence (STRIDE), a federal database for seized drug exhibits analyzed by DEA laboratories, from January 1999 to December 2008, law enforcement seized 33 drug exhibits and filed 23 cases pertaining to the trafficking, distribution and abuse of 5-MeO-DMT. The seized drug exhibits comprised 89 grams of powder and 10 milliliters of liquid containing 5-MeO-DMT. Since 2004, National Forensic Laboratory Information System (NFLIS), a database for drug cases analyzed by federal, state and local forensic laboratories, registered 23 state and local cases involving 27 analyzed items containing 5-MeO-DMT.

There is evidence of clandestine laboratory operations to synthesize 5-MeO-DMT. 5-MeO-DMT has been encountered in powder, capsule, and liquid forms. 5-MeO-DMT is typically abused either by smoking or insufflating the powder. Investigations by federal law enforcement indicate that individuals, especially youths and young adults, are purchasing 5-MeO-DMT from Internet-based chemical suppliers. In addition, there are several instances where 5-MeO-DMT was sold as a counterfeit of MDMA.

The risks to the public health associated with the abuse of 5-MeO-DMT are similar to the risks associated with those of schedule I hallucinogens. 5-MeO-DMT can pose serious health risks to the user and general public through its ability to induce hallucinogenic effects and other sensory distortions and impaired judgment. Self-reports that are posted on Internet Web sites describe the abuse of this substance in combination with other controlled drugs such as DMT, N,N-diethyltryptamine (DET), LSD, marijuana, ecstasy, or mushrooms (contains psilocybin and psilocin). This practice of drug abuse involving combinations can pose additional health risks to the users and the general public. These data show that the continued trafficking and abuse of 5-MeO-DMT pose hazards to the public health and safety. Indeed, there have been reports of emergency room admissions and death associated with the abuse of 5-MeO-DMT.

There are no FDA-approved drug products. 5-MeO-DMT has never been approved by the FDA for marketing as a human drug product in the United States and there are no recognized therapeutic uses of 5-MeO-DMT in the United States.

References to the above studies and data may be found in the Health and Human Services scheduling recommendation and DEA's independent analysis, both of which are available on the electronic docket associated with this rulemaking.

Placement of 5-MeO-DMT Into Schedule I

In accordance with 21 U.S.C. 811(b) of the CSA, DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse of 5-MeO-DMT. On February 21, 2007, the Deputy Administrator of the DEA submitted these data to the Acting Assistant Secretary for Health, Department of Health and Human Services. In accordance with 21 U.S.C. 811(b), the Deputy Administrator also requested a scientific and medical evaluation and a scheduling recommendation for 5-MeO-DMT from the Acting Assistant Secretary for Health. On December 18, 2008, the Principal Deputy Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of the DEA a scientific and medical evaluation and a letter recommending that 5-MeO-DMT and its salts be placed into schedule I of the CSA. Enclosed with the letter was a document prepared by FDA entitled, ''Basis for the Recommendation to Control 5-Methoxy-Dimethyltryptamine (5-MeO-DMT) in Schedule I of the Controlled Substances Act.'' The document contained a review of the factors which the CSA requires the

Secretary to consider (21 U.S.C. 811(b)). The factors considered by the Assistant Secretary of Health and DEA with respect to 5-MeO-DMT were:

(1) Actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effects, if known;

(3) The state of current scientific knowledge regarding the drug;

(4) History and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) What, if any, risk there is to the public health;

(7) Psychic or physiological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled under the CSA.

Based on the recommendation of the Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, the Deputy Administrator finds that sufficient data exist to support the placement of 5-MeO-DMT into schedule I of the CSA pursuant to 21 U.S.C. 811(a). The specific findings required pursuant to 21 U.S.C. 811 and 812 for 5-MeO-DMT to be placed into schedule I are as follows:

(1) 5-MeO-DMT has a high potential for abuse.

(2)5-MeO-DMT has no currently accepted medical use in treatment in the United States.

(3) There is a lack of accepted safety for use of 5-MeO-DMT under medical supervision.

Regulatory Requirements

If this rule is finalized as proposed, 5-methoxy-N,N-dimethyltryptamine would be subject to regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, dispensing, importation and exportation of a schedule I controlled substance, including the following:

Registration. Any person who manufactures, distributes, dispenses, imports or exports 5-methoxy-N,N-dimethyltryptamine or who engages in research or conducts instructional activities with respect to 5-methoxy-N,N-dimethyltryptamine, or who proposes to engage in such activities, would be required to submit an application for schedule I registration in accordance with part 1301 of Title 21 of the Code of Federal Regulations.

Security. 5-methoxy-N,N-dimethyltryptamine would be subject to schedule I security requirements and must be manufactured, distributed and stored in accordance with §§ 1301.71; 1301.72(a), (c), and (d); 1301.73; 1301.74; 1301.75(a) and (c); and 1301.76 of Title 21 of the Code of Federal Regulations.

Labeling and Packaging. All labels and labeling for commercial containers of 5-methoxy-N,N-dimethyltryptamine which are distributed on or after the effective date of a Final Rule finalizing this regulation would be required to comply with requirements of §§ 1302.03 through 1302.07 of Title 21 of the Code of Federal Regulations.

Quotas. Quotas for 5-methoxy-N,N-dimethyltryptamine would be established pursuant to the requirements of part 1303 of Title 21 of the Code of Federal Regulations.

Inventory. Every registrant required to keep records and who possesses any quantity of 5-methoxy-N,N-dimethyltryptamine upon the effective date of any Final Rule finalizing these regulations would be required to keep an inventory of all stocks of the substance on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations. Every registrant who desires registration in schedule I to handle 5-methoxy-N,N-dimethyltryptamine would be required to conduct an inventory of all stocks of the substance.

Records. All registrants who handle 5-methoxy-N,N-dimethyltryptamine would be required to keep records pursuant to §§ 1304.03, 1304.04 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations.

Reports. All registrants required to submit reports in accordance with § 1304.33 of Title 21 of the Code of Federal Regulations would be required to do so regarding 5-methoxy-N,N-dimethyltryptamine.

Order Forms. All registrants involved in the distribution of 5-methoxy-N,N-dimethyltryptamine would be required to comply with the order form requirements of part 1305 of Title 21 of the Code of Federal Regulations.

Importation and Exportation. All importation and exportation of 5-methoxy-N,N-dimethyltryptamine would be required to be in compliance with part 1312 of Title 21 of the Code of Federal Regulations.

Criminal Liability. Any activity with 5-methoxy-N,N-dimethyltryptamine not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring on or after the effective date of any Final Rule finalizing these regulations would be unlawful.

Regulatory Certifications

Executive Order 12866

In accordance with the provisions of the CSA (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 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), 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. This proposed rule, if finalized, would place 5-methoxy-N,N-dimethyltryptamine into schedule I of the Controlled Substances Act.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices: or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign

based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby proposes that 21 CFR part 1308 be amended 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. Section 1308.11 is amended by:

A. Redesignating existing paragraphs (d)(15) through (d)(34) as paragraphs (d)(16) through (d)(35).

B. Adding a new paragraph (d)(15).

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(15) 5-methoxy-N,N-dimethyltryptamine, its isomers, salts and salts of isomers—7431.

Some trade or other names: 5-methoxy-3-[2-(dimethylamino)ethyl]indole; 5-MeO-DMT.

* * * * *

Dated: August 12, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9–20204 Filed 8–20–09; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2009–0720]

RIN 1625–AA00

Safety Zone; Ocean City Beachfront Air Show, Ocean City, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone for the Ocean City Beachfront Air Show, an aerial demonstration to be held over the waters of the Atlantic Ocean adjacent to Ocean City, New Jersey. This Safety Zone is necessary to provide for the safety of life on navigable waters during the event. This proposed action would temporarily restrict vessel traffic in portions of the Atlantic Ocean adjacent to Ocean City, New Jersey during the aerial demonstration.

DATES: Comments and related material must be received by the Coast Guard on or before September 21, 2009 Requests for public meetings must be received by the Coast Guard on or before August 28, 2009.

ADDRESSES: You may submit comments identified by docket number USCG–2009–0720 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. *See* the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Lieutenant Rebecca Walthour, Chief of Waterways Management Branch, Coast Guard Sector Delaware Bay, at 215–271–4889, e-mail *Rebecca.A.Walthour@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2009–0720), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu, select ''Notices'' and insert ''USCG–2009–0720'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the Actions column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½; by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box, insert USCG–2009–0720 and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with