Medicine (HFV–170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532, filed ANADA 200–457 that provides for veterinary prescription use of Mupirocin Ointment USP, 2% for the treatment of bacterial skin infections in dogs. Taro Pharmaceuticals U.S.A., Inc.'s Mupirocin Ointment USP, 2% is approved as a generic copy of Pfizer, Inc.'s BACTODERM Ointment approved under NADA 140–839. The ANADA is approved as of November 29, 2010, and the regulations are amended in 21 CFR 524.1465 to reflect the approval.

In addition, Taro Pharmaceuticals U.S.A., Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. Accordingly, the tables in 21 CFR 510.600(c) are being amended to add entries for this firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1) alphabetically add an entry for "Taro Pharmaceuticals U.S.A., Inc."; and in the table in paragraph (c)(2) numerically add an entry for "051672" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532	051672
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
051672	Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532.
* * * * *	

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.1465 [Amended]

■ 4. In paragraph (b) of § 524.1465, remove "Nos. 000069 and 025463" and in its place add "Nos. 000069, 025463, and 051672".

Dated: December 10, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010–31870 Filed 12–17–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–331F]

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: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), including its salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule I of the Controlled Substances Act (CSA). This action by the DEA Deputy Administrator is based on a scheduling recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (DHHS) and a DEA review indicating that 5-MeO-DMT meets the criteria for placement in schedule I of the CSA. This final rule will 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: *Effective Date:* January 19, 2011.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, 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:

Background

In accordance with 21 U.S.C. 811(b) of the CSA, DEA gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse of 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT). On February 21, 2007, the Deputy Administrator of the DEA submitted these data to the 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 Assistant Secretary for Health.

5-MeO-DMT is related to the schedule I hallucinogens N,N-dimethyltryptamine (DMT), 2,5-dimethoxy-4-methylamphetamine (DOM), lysergic acid diethylamide (LSD) and mescaline in its pharmacological properties and hallucinogenic effects. 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 ($5\text{-}HT_2$) receptors. 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.

Evidence of 5-MeO-DMT trafficking was first reported in 1999 by Federal law enforcement officials. Though 5-MeO-DMT is likely to be underreported because it is not a controlled substance, from January 1999 to December 2009, law enforcement officials encountered 23 cases involving 35 drug exhibits pertaining to the trafficking, distribution and abuse of 5-MeO-DMT, according to the System to Retrieve Information from Drug Evidence (STRIDE), a Federal database of drug exhibits analyzed by DEA laboratories. The drug exhibits analyzed by DEA laboratories comprised 89 grams of powder and 10 milliliters of liquid containing 5-MeO-DMT. From January 2004 to December 2009, the National Forensic Laboratory Information System (NFLIS), a database of drug analyses conducted by State and local forensic laboratories, reported 27 State and local drug cases involving 32 drug exhibits identified as 5-MeO-DMT.

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. There have been reports of emergency room admissions and a death associated with the abuse of 5-MeO-DMT. 5-MeO-DMT has never been approved by the Food and Drug Administration (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.

Notice of Proposed Rulemaking

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)).

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from DHHS, the Deputy Administrator of the DEA published a Notice of Proposed Rulemaking entitled "Schedules of Controlled Substances: Placement of 5-Methoxy-Dimethyltryptamine into Schedule I of the Controlled Substances Act" on August 21, 2009 (74 FR 42217), which proposed placement of 5-MeO-DMT in schedule I of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments on or before September 21, 2009.

After the comment period closed on September 21, 2009, DEA discovered that the supporting documents referenced in the proposed rule were not posted to the electronic docket, thus not available for review. DEA reopened the public comment period (October 28, 2009, Notice of Proposed Rulemaking) (74FR55502) for an additional 30 days to ensure all interested members of the public had an opportunity to review all the materials and provide comments. Comments submitted on or before November 27, 2009, were considered.

Comments Received

The DEA received 22 comments in response to the August 21, 2009, and October 28, 2009, Notices of Proposed Rulemaking. Five comments were received in response to the first Notice of Proposed Rulemaking. An additional 17 comments were received during the 30-day reopening of the comment period. One of the comments submitted contained only supporting materials for another comment that was submitted. All commenters were concerned citizens, none of whom identified themselves as representing organizations.

Support for the rule as proposed: One commenter supported the proposal to schedule 5-MeO-DMT in schedule I. DEA appreciates the support of this commenter for this final rule.

Twenty of the comments were in opposition to the proposed scheduling of 5-MeO-DMT in schedule I of the CSA. Various reasons for the disapproval of the scheduling of 5-MeO-DMT were provided. Most comments can be grouped into the following general categories: (1) Those concerned that the comment or request for hearing period was inadequate and requesting an extension of the comment or request for hearing period, (2) those concerned that 5-MeO-DMT is a naturally occurring substance and thus should not be controlled, (3) those that questioned the pharmacological and abuse potential findings considered by DEA and DHHS for the purpose of scheduling 5-MeO-DMT, (4) those concerned that the proposed scheduling would limit access to 5-MeO-DMT for research, and (5) those that alleged violations of the Establishment Clause and/or the Free Exercise Clause of the First Amendment or raised other legal challenges.

Length of comment or request for hearing period: Several commenters felt that the length of the comment or request for hearing period was too short and requested that the comment or request for hearing period be extended, to as much as 24 months. Some commenters noted the need to research pharmacological, religious or other evidence regarding 5-MeO-DMT and prepare comments and stated there was not enough time before the comment period closed to obtain or prepare this information.

In response to these comments, DEA does not believe that a further extension or reopening of the comment or request for hearing period is necessary or warranted. Pharmacological and abuse data on 5-MeO-DMT are publicly available and easily retrievable. The period for comments and requests for hearings with regard to the Notices of Proposed Rulemaking was thirty (30) days from the date of publication of each Notice of Proposed Rulemaking. Interested persons who wished to submit written data, views or arguments have had ample opportunity to use the information in the medical and scientific literature, which are available to the public from various resources (*e.g.,* U.S. National Library of Medicine, public libraries, and Web sites of scientific journals), along with the supplemental information provided by DEA (*i.e.,* DEA's scheduling review document and FDA's scientific and medical evaluation and scheduling recommendation) as well as other sources of information such as publications by Federal agencies (*e.g.,* reports from DEA's NFLIS, National Institute on Drug Abuse's (NIDA) National Survey on Drug Use and Health, Substance Abuse and Mental

Health Services Administration's Drug Abuse Warning Network, and NIDA's Monitoring the Future) to submit meaningful comments on 5-MeO-DMT that can be supported by data or scientific arguments. These data are publicly available and easily retrievable. DEA has considered the amount of time needed to obtain and review documents and supporting materials relevant to the commenter's position, prepare the comment, and submit the comment and finds that a 30-day comment period provides a meaningful opportunity for interested persons to submit comments or request a hearing. While commenters indicated that an extension of the comment period would allow time for further research regarding 5-MeO-DMT, DEA notes that this scheduling action does not prevent such research from occurring. Any person wishing to conduct research using 5-MeO-DMT may do so provided that the person has obtained a schedule I researcher registration with DEA, has the appropriate research protocols in place with FDA, and meets all other requirements.

Use of *http://www.regulations.gov:* Several commenters discussed the use of *http://www.regulations.gov,* the government's online Federal Docket Management System (FDMS). Commenters stated that the document reopening the comment period was posted to the electronic docket on *http://www.regulations.gov* on October 28, 2009, but that certain supporting materials were not posted until November 3, 2009. In a related comment, a commenter objected to the "splitting" of the electronic docket for the reopening of the comment period from the electronic docket for the Notice of Proposed Rulemaking. The commenter indicated that "splitting" the dockets made it difficult to view all docket components and made it "extremely difficult to communicate to others where and how to locate, view, or comment on Docket No. DEA–331."

DEA disagrees with these comments. The supporting documents were posted to the electronic docket (Docket ID DEA 2009–0008) on September 30, 2009, and October 2, 2009. DEA acknowledges that the electronic docket for the Notice of Proposed Rulemaking was separate from the electronic docket for the reopening of the comment period. This electronic method of posting, however, merely supplemented the notice provisions required by the Administrative Procedure Act (5 U.S.C. 553). Both the Notice of Proposed Rulemaking and the extension of the comment period were published in the **Federal Register** (74 FR 42217, August 21, 2009, and 74 FR 55502, October 28, 2009, respectively), in accordance with administrative law requirements. Although not required to do so, DEA posted a Statement for the Record in the Federal Docket Management System (FDMS) Docket ID DEA–2009–0008 (the August 21, 2009, Notice of Proposed Rulemaking) to alert the public that the Notice of Proposed Rulemaking to reopen the comment period was located in FDMS Docket ID DEA–2009–0013.

5-MeO-DMT is a naturally occurring substance: Some commenters objected to the proposed scheduling of 5-MeO-DMT because 5-MeO-DMT is a naturally occurring substance. DEA has considered these comments and acknowledges the biological presence of 5-MeO-DMT in humans and in certain toads and plant species. However, DEA disagrees with the contention that the fact that 5-MeO-DMT is a naturally occurring substance prevents it from being controlled. DHHS and DEA have considered the eight factors determinative of control set out in 21 U.S.C. 811(c), and DEA has considered the recommendations of DHHS in making the findings under 21 U.S.C. 812 that warrant placement in schedule I of the CSA.

Insufficient data: Several commenters believed that insufficient data exist to support the placement of 5-MeO-DMT into schedule I. For example, a few commenters argued that 5-MeO-DMT does not have toxic effects or lead to addiction or harmful behavior. In addition, a commenter incorrectly stated that there were no reported deaths associated with the use of 5-MeO-DMT. Other commenters suggested that the scheduling of 5-MeO-DMT be postponed until more research could be done.

DEA does not agree with these statements. The studies used to assess abuse potential of 5-MeO-DMT are widely held as the standard methods of evaluation. Behavioral effects of 5-MeO-DMT in animals and humans were found to be similar to those of the schedule I hallucinogens. Preclinical studies indicated that 5-MeO-DMT has pharmacological effects at serotonin receptors. In humans, 5-MeO-DMT produced subjective responses similar to DMT and other schedule I hallucinogens. In addition, DEA finds that the abuse of 5-MeO-DMT presents a safety hazard to the health of individuals. There are reports of emergency room admissions and a death associated with the abuse of 5-MeO-DMT. After careful consideration of preclinical and clinical studies and in accordance with 21 U.S.C. 811(a) and (b) and considering the factors enumerated in 21 U.S.C. 811(c), the Deputy Administrator of the DEA finds that 5-MeO-DMT has high abuse potential supporting placement in schedule I under the CSA.

Control of DMT: One commenter questioned the evidence considered by DEA to make the findings to control "DMT." DEA finds that this comment is not relevant to the present scheduling action as this Final Rule pertains to the scheduling of 5-MeO-DMT. However, if the commenter intended to refer to 5-MeO-DMT and not DMT, the reasons for controlling 5-MeO-DMT have already been provided.

Prohibition or restriction of use in research: Commenters expressed concern that the proposed scheduling of 5-MeO-DMT will prohibit or significantly restrict the use of 5-MeO-DMT in research. The DEA does not agree. As noted previously, persons interested in using 5-MeO-DMT for research purposes can still use this substance provided that they have a DEA schedule I researcher registration and meet all other statutory and regulatory criteria. This registration can be obtained by submitting an application for schedule I registration in accordance with 21 CFR 1301.18.

Constitutional concerns: Several commenters raised concerns that the proposed rule would substantially impair religious liberty. The commenters raised two specific concerns with respect to religion. First, the commenters questioned the proposed rule on the ground that the CSA, which authorizes this rulemaking, violates both the Free Exercise Clause and the Establishment Clause of the First Amendment. DEA has fully considered these concerns, and does not believe any change in the rule is necessary. With respect to the Free Exercise Clause, one commenter claimed that the CSA is not a neutral law of general applicability under *Employment Division* v. *Smith,* 494 U.S. 872 (1990), because the CSA includes exemptions for the use of alcohol, certain research and medical uses of certain substances, and the sacramental use of peyote by the Native American Church. This concern has been raised previously in litigation, and courts have concluded that the CSA does not interfere with the free exercise of religion in violation of the First Amendment. *See Olsen* v. *Mukasey,* 541 F.3d 827 (8th Cir. 2008); *O Centro Espirita Beneficiente Uniao do Vegetal* v. *Mukasey,* No. 00–1647 (D. N. M. June 16, 2008). The commenter raised similar concerns about the CSA with respect to the Establishment Clause of the First Amendment. Once again, courts have

upheld the validity of the CSA in the face of related challenges and concluded that the statute does not represent an establishment of religion in contravention of the First Amendment. *Peyote Way Church of God* v. *Thornburgh,* 922 F.2d 1210 (5th Cir. 1991); *United States* v. *Valazquez,* 2009 WL 2823730 (W.D. Okla. Aug. 31, 2009).

Another commenter suggested that if the final rule scheduling 5-MeO-DMT is issued without change, DEA should consider "providing special exemption for religious use." The commenter did not provide any specific details about the kind of exemption that he believed would be appropriate. Accordingly, DEA lacks the information necessary to evaluate this comment.

Finally, one commenter questioned DEA's finding that the proposed rule does not have federalism implications warranting the application of Executive Order 13132. DEA has considered this concern and concurs with the conclusion that the placement of 5-MeO-DMT and its salts into schedule I of the CSA 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.

Scheduling of 5-MeO-DMT

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)), the independent review of the available data by DEA, and after a review of the comments received in response to the Notice of Proposed Rulemaking and the notice reopening the comment period, the Deputy Administrator, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(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.

Based on these findings, the Deputy Administrator of the DEA concludes that 5-MeO-DMT and its salts warrant control in schedule I of the CSA (21 U.S.C. 812 (b)(1)).

Regulatory Requirements

As noted below, 5-MeO-DMT will 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-MeO-DMT or who engages in research or conducts instructional activities with respect to 5-MeO-DMT, or who proposes to engage in such activities, must submit an application for schedule I registration in accordance with part 1301 of Title 21 of the Code of Federal Regulations. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before January 19, 2011 and may continue their activities until DEA has approved or denied that application.

Security. 5-MeO-DMT is 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 on or after January 19, 2011.

Labeling and Packaging. All labels and labeling for commercial containers of 5-MeO-DMT which are distributed on or after January 19, 2011 must comply with the requirements of §§ 1302.03 through 1302.07 of Title 21 of the Code of Federal Regulations on or after January 19, 2011.

Quotas. Quotas for 5-MeO-DMT must 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-MeO-DMT must keep an inventory of all stocks of 5-MeO-DMT on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations on or after January 19, 2011. Every registrant who desires registration in schedule I to handle 5-MeO-DMT must conduct an inventory of all stocks of the substance.

Records. All registrants who handle 5-MeO-DMT must keep records pursuant to §§ 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on or after January 19, 2011.

Reports. All registrants required to submit reports in accordance with § 1304.33 of Title 21 of the Code of Federal Regulations must do so regarding 5-MeO-DMT on and after January 19, 2011.

Order Forms. All registrants involved in the distribution of 5-MeO-DMT must comply with the order form requirements of part 1305 of Title 21 of the Code of Federal Regulations on and after January 19, 2011.

Importation and Exportation. All importation and exportation of 5-MeO-DMT must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations on or after January 19, 2011.

Criminal Liability. Any activity with 5-MeO-DMT not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful on or after January 19, 2011.

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 final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. This action involves the control of a substance with no currently accepted medical use in treatment in the United States. This final rule will place 5-MeO-DMT 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 $126,400,000 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 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. Section 1308.11 is amended by:

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

■ B. Adding a new paragraph (d)(15).

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(15) 5-methoxy-N,N-dimethyltryptamine 7431. Some trade or other names: 5-methoxy-3-[2-(dimethylamino)ethyl]indole; 5-MeO-DMT

* * * * *

Dated: December 13, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–31854 Filed 12–17–10; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2009–0041–201058; FRL–9241–1]

Approval and Promulgation of Implementation Plans; Mississippi; Prevention of Significant Deterioration Rules: Nitrogen Oxides as a Precursor to Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to approve a portion of a revision to the Mississippi State Implementation Plan (SIP), submitted by the Mississippi Department of Environmental Quality (MDEQ), to EPA on November 28, 2007. The revision amends Mississippi's prevention of significant deterioration (PSD) permitting regulations in the SIP to address permit requirements promulgated in the 1997 8-Hour Ozone National Ambient Air Quality Standards (NAAQS) Implementation Rule-Phase II (hereafter referred to as the "Ozone Implementation New Source Review (NSR) Update"). The Ozone Implementation NSR Update revised permit requirements relating to the implementation of the 1997 8-hour ozone NAAQS specifically incorporating nitrogen oxides (NO_X) as a precursor to ozone. EPA's approval of Mississippi's provisions to include NO_X as an ozone precursor into the Mississippi SIP is based on EPA's determination that Mississippi's SIP revision related to these provisions complies with Federal requirements.

DATES: *Effective Date:* This rule will be effective January 19, 2011.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2009–0041. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30 excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: For information regarding the Mississippi SIP, contact Ms. Twunjala Bradley, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Telephone number: (404) 562–9352; e-mail address: *bradley.twunjala@epa.gov.* For information regarding NSR/PSD, contact Ms. Yolanda Adams, Air Permits Section, at the same address above. Telephone number: (404) 562–9214; e-mail address: *adams.yolanda@epa.gov.* For information regarding 8-hour ozone NAAQS, contact Ms. Jane Spann, Regulatory Development Section, at the same address above. Telephone number: (404) 562–9029; e-mail address: *spann.jane@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

On July 18, 1997, EPA promulgated a revised 8-hour ozone NAAQS of 0.08 parts per million—also referred to as the 1997 8-hour ozone NAAQS. On April 30, 2004, EPA designated areas as attainment, nonattainment and unclassifiable for the 1997 8-hour ozone NAAQS. As part of the 2004 designations, EPA also promulgated an implementation rule for the 1997 8-hour ozone NAAQS in two phases. Phase I of EPA's 1997 8-hour ozone implementation rule (Phase 1 Rule), published on April 30, 2004, and effective on June 15, 2004, provided the implementation requirements for designating areas under subpart 1 and subpart 2 of the CAA. 69 FR 23857.

On November 29, 2005, EPA promulgated the second phase for implementation provisions related to the 1997 8-hour ozone NAAQS which finalized regulations to implement the 8-hour NAAQS for PSD permitting purposes—also known as the Phase II Rule. 70 FR 71612. The Phase II Rule addressed control and planning requirements as they applied to areas