

SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

Country/Entity	License requirement	License review policy	Federal Register citation
The following Department of Atomic Energy entities:			
—Bhabha Atomic Research Center (BARC);	For all items subject to the EAR.	Case-by-case for all items listed on the CCL. Presumption of approval for EAR99 items.	63 FR 64322, 11/19/98; 65 FR 14444, 03/17/00; 66 FR 50090, 10/01/01; 69 FR 56694, 09/22/04.
—Indira Gandhi Atomic Research Center (IGCAR);			
—Indian Rare Earths;			
—Nuclear reactors (including power plants) not under International Atomic Energy Agency (IAEA) safeguards, fuel reprocessing and enrichment facilities, heavy water production facilities and their collocated ammonia plants.			
The following Department of Atomic Energy entities:			
—Nuclear reactors (including power plants) subject to International Atomic Energy Agency (IAEA) safeguards: Tarapur (TAPS 1 & 2), Rajasthan (RAPS 1 & 2).	For all items subject to the EAR.	Case-by-case for all items listed on the CCL. Presumption of approval for EAR99 items. Presumption of approval for all items not multilaterally controlled for Nuclear Proliferation (NPI) reasons for use in the “balance of plant” (non-reactor-related end uses) ¹ activities at nuclear facilities subject to International Atomic Energy Agency safeguards (Rajasthan 1 & 2 and Tarapur 1 & 2).	63 FR 64322, 11/19/98; 65 FR 14444, 03/17/00; 66 FR 50090, 10/01/01; 69 FR 56694, 09/22/04.
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¹ “Balance of Plant” refers to the part of a nuclear power plant used for power generation (e.g., turbines, controllers, or power distribution) to distinguish it from the nuclear reactor.

Eileen M. Albanese,
Director, Office of Exporter Services.
 [FR Doc. 04–21837 Filed 9–27–04; 11:43 am]
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DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1308**

[Docket No. DEA–252F]

**Schedules of Controlled Substances:
 Placement of Alpha-Methyltryptamine
 and 5-Methoxy-N,N-Diisopropyltryptamine Into Schedule I
 of the Controlled Substances Act**

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

ACTION: Final rule.

SUMMARY: This final rulemaking is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to place alpha-methyltryptamine (AMT) and 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DIPT) into Schedule I of the Controlled Substances Act (CSA). This action by the DEA Deputy Administrator is based on a scheduling recommendation by the

Department of Health and Human Services (DHHS) and a DEA review indicating that AMT and 5-MeO-DIPT meet the criteria for placement in Schedule I of the CSA. This final rule will continue to impose the regulatory controls and criminal sanctions of Schedule I substances on the manufacture, distribution, and possession of AMT and 5-MeO-DIPT.

EFFECTIVE DATE: September 29, 2004.

FOR FURTHER INFORMATION CONTACT: Christine Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION: On April 4, 2003, the Deputy Administrator of the DEA published a final rule in the **Federal Register** (68 FR 16427) amending § 1308.11(g) of Title 21 of the Code of Federal Regulations to temporarily place AMT and 5-MeO-DIPT into Schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). This final rule, which became effective on the date of publication, was based on findings by the Deputy Administrator that the temporary scheduling of AMT and 5-MeO-DIPT was necessary to avoid an imminent hazard to the public safety. Section 201(h)(2) of the CSA (21 U.S.C.

811(h)(2)) requires that the temporary scheduling of a substance expires at the end of one year from the effective date of the order. However, if proceedings to schedule a substance pursuant to 21 U.S.C. 811(a)(1) have been initiated and are pending, the temporary scheduling of a substance may be extended for up to six months. On March 31, 2004, the Acting Deputy Administrator published a notice of proposed rulemaking in the **Federal Register** (69 FR 16838) to place AMT and 5-MeO-DIPT into Schedule I of the CSA on a permanent basis. The temporary scheduling of AMT and 5-MeO-DIPT, which would have expired April 3, 2004, was extended to October 3, 2004 (69 FR 17034, April 1, 2004). One comment was received regarding the proposed placement of these substances into Schedule I of the CSA.

The DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for AMT and 5-MeO-DIPT. The Acting Deputy Administrator submitted these data to the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS). In accordance with 21 U.S.C. 811(b), the Acting Deputy Administrator also requested a scientific and medical evaluation and a

scheduling recommendation for AMT and 5-MeO-DIPT from the Acting Assistant Secretary of DHHS. On September 17, 2004, the Acting Assistant Secretary for Health recommended that AMT and 5-MeO-DIPT be permanently controlled in Schedule I of the CSA.

Alpha-methyltryptamine (AMT) and 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DIPT) are tryptamine (indoleethylamine) derivatives and share several similarities with the Schedule I tryptamine hallucinogens such as alpha-ethyltryptamine (AET) and N,N-dimethyltryptamine (DMT). Several other tryptamines also produce hallucinogenic/stimulant effects and are controlled as Schedule I substances under the CSA (bufotenine, diethyltryptamine, psilocybin and psilocyn). Although tryptamine itself appears to lack consistent hallucinogenic/stimulant effects, substitutions on the indole ring and the ethylamine side-chain of this molecule result in pharmacologically active substances (McKenna and Towers, J. Psychoactive Drugs, 16: 347–358, 1984). The chemical structures of AMT and 5-MeO-DIPT possess the critical features necessary for hallucinogenic/stimulant activity. In drug discrimination studies, both AMT and 5-MeO-DIPT substitute for 1-(2,5-dimethoxy-4-methylphenyl)-aminopropane (DOM), a phenethylamine-based hallucinogen in Schedule I of the CSA. The potencies of DOM-like discriminative stimulus effects of these and several other similar tryptamine derivatives correlate well with their hallucinogenic potencies in humans (Glennon *et al.*, Eur. J. Pharmacol. 86: 453–459, 1983).

AMT, besides its full generalization to DOM, also partially mimics amphetamine and 3,4-methylenedioxymethamphetamine (MDMA) in drug discrimination tests in experimental animals. AMT increases systolic and diastolic arterial blood pressures, dilates pupils and produces strong motor stimulant effects. The behavioral effects of orally administered AMT (20 mg) in humans are slow in onset, occurring after 3 to 4 hours, and gradually subsiding after 12 to 24 hours, but may last up to 2 days in some subjects. The majority of the subjects report euphoria, stimulation, muscle tension, muscle ache, nervous tension, irritability, restlessness, dizziness, impaired motor coordination, unsettled feeling in stomach, inability to relax and sleep, and visual effects such as blurry vision, apparent movement of objects, sharper outlines, brighter colors, longer after images, and visual hallucinations. The majority of the subjects equate the

effects of a 20 mg dose of AMT to those of 50 micrograms of lysergic acid diethylamide (LSD). AMT also produces dextroamphetamine-like mood elevating effects in humans (Hollister *et al.*, J. Nervous Ment. Dis., 131: 428–434, 1960; Murphree *et al.*, Clin. Pharmacol. Ther. 2: 722–726, 1961).

Similar to other classical hallucinogens, AMT binds to serotonin receptors. It also inhibits 5-HT uptake, induces catecholamine release and inhibits monoamine oxidase activity. The available experimental evidence suggests that both serotonergic and dopaminergic systems mediate behavioral effects of AMT.

5-MeO-DIPT produces pharmacological effects similar to those of several Schedule I hallucinogens. The synthesis and preliminary human psychopharmacology study on 5-MeO-DIPT was first published in 1981 (Shulgin and Carter, Comm. Psychopharmacol. 4: 363–369, 1981). According to this report, subjective effects of 5-MeO-DIPT are substantially similar to those of MDMA, 3,4-methylenedioxymphetamine (MDA) and 4-Bromo-2,5-dimethoxyphenethylamine (2C-B). 5-MeO-DIPT is an orally active hallucinogen. Following oral administration of 6–10 mg, 5-MeO-DIPT produces subjective effects with an onset of about 20–30 minutes, a peak at about 1–1.5 hours and duration of about 3–6 hours. Subjects who have been administered 5-MeO-DIPT are talkative and disinhibited. 5-MeO-DIPT dilates pupils. High doses of 5-MeO-DIPT produce nausea, jaw clenching, muscle tension and overt hallucinations with both auditory and visual distortions. As mentioned above, 5-MeO-DIPT fully mimics the discriminative stimulus effects of DOM, a Schedule I hallucinogen. According to the discriminative stimulus studies conducted by the Drug Evaluation Committee of the College on Problems of Drug Dependence, 5-MeO-DIPT dose-dependently (0.1–3 mg/kg, IP) generalizes to LSD with a maximal response of about 70% at doses (3 mg/kg) that severely disrupted responding.

The abuse of stimulant/hallucinogenic substances in popular all night dance parties (“raves”) and in other venues has been a major problem in Europe since the 1990s. In the past several years, this activity has spread to the United States. The Schedule I controlled substance MDMA and its analogues, collectively known as Ecstasy, are the most popular drugs abused at these raves. Their abuse has been associated with both acute and long-term public health and safety

problems. These raves have also become venues for the trafficking and abuse of other substances in place of or in addition to “Ecstasy.” AMT and 5-MeO-DIPT belong to such a group of substances.

The abuse of AMT and 5-MeO-DIPT began to spread in 1999. Since that time, these tryptamines have been encountered by law enforcement agencies in several states. These substances have been commonly encountered in tablet, capsule or powder forms. The tablet form often bears imprints commonly seen on MDMA tablets such as spider, alien head and “?” logos. These tablets also vary in colors such as pink, purple, red, and orange. The powder in capsule was also found to vary in colors such as white, off-white, gray, and burnt orange. Data from law enforcement officials indicate that 5-MeO-DIPT is often sold as “Foxy” or “Foxy Methoxy”, while AMT has been sold as “Spirals” at least in one case. Data gathered from published studies indicate that these are administered orally at doses ranging from 15–40 mg for AMT and 6–20 mg for 5-MeO-DIPT.

According to the Florida Department of Law Enforcement (FDLE) report issued in 2002, the abuse by teens and young adults of AMT and 5-MeO-DIPT is an emerging problem. There have been reports of abuse of AMT and 5-MeO-DIPT at clubs and raves in Arizona, California, Florida and New York. Many tryptamine-based substances are illicitly available from United States and foreign chemical companies and from individuals through the Internet. There is also evidence of attempted clandestine production of AMT and 5-MeO-DIPT in Nevada, Virginia and Washington, DC.

According to data from the System to Retrieve Information on Drug Evidence (STRIDE), since 1999 Federal law enforcement authorities seized 34 drug exhibits and filed 14 cases pertaining to the trafficking, distribution and abuse of AMT during 1999 to 2003. The corresponding STRIDE data for 5-MeO-DIPT included 63 drug exhibits pertaining to 32 cases. AMT drug seizures included 21 capsules and 1,011.8 grams of powder, while 5-MeO-DIPT drug seizures included 12,070 tablets, 560 capsules, and 6,532.3 grams of powder. Since 2001, the National Forensic Laboratory Information System (NFLIS) registered 10 and 12 cases of AMT and 5-MeO-DIPT, respectively. AMT drug exhibits included 17 dosage units and 7.53 grams of powder, while 5-MeO-DIPT drug exhibits included 24 capsules, 3 tablets and 14.42 grams of powder.

AMT and 5-MeO-DIPT share substantial chemical and pharmacological similarities with other Schedule I tryptamine-based hallucinogens in Schedule I of the CSA. AMT shares pharmacological effects of amphetamine, a stimulant, and DOM and LSD, the Schedule I hallucinogens. AMT acts as a stimulant, produces euphoria and increases heart rate and blood pressure. The evidence suggests that 5-MeO-DIPT mimics pharmacological effects of MDMA, MDA, and 2C-B, the Schedule I hallucinogens. It also partially mimics amphetamine effects. The risks to the public health associated with the above mentioned controlled substances are well known and documented. AMT and 5-MeO-DIPT, similar to other tryptamine- or phenethylamine-based hallucinogens, through the alteration of sensory perception and judgment can pose serious health risks to the user and the general public. Tryptamine, the parent molecule of AMT and 5-MeO-DIPT, is known to produce convulsions and death in animals (Tedeschi *et al.*, J. Pharmacol. Exp. Ther. 126: 223–232, 1959). Following extensive studies on AMT as a possible antidepressant drug in 1960s, The Upjohn Company concluded that AMT is a highly toxic substance and discontinued the clinical studies on this substance. In fact, there were two recent published case reports describing the instances of emergency department admissions resulting from abuse of AMT and 5-MeO-DIPT in 2003 (Long *et al.*, Vet. Human Toxicol., 45: 149, 2003; Meatherall and Sharma, J. Anal. Toxicol., 27: 313–317, 2003). There has been at least one confirmed death caused by the abuse of AMT in Florida in 2003. The above data show that the continued, uncontrolled tablet or capsule production, distribution and abuse of AMT and 5-MeO-DIPT pose hazards to the public health and safety. There are no recognized therapeutic uses of these substances in the United States.

The DEA received one comment from an organization in response to the proposed placement of AMT and 5-MeO-DIPT into Schedule I of the CSA. This organization did not support the proposed placement of these drugs into Schedule I on the following basis: (1) They believed insufficient data exists to support placement into Schedule I as the mere use of these substances was not abuse and (2) Prohibiting the possession of these substances is a substantial infringement of the fundamental right of adults to freedom of thought. Both the DEA and the DHHS have found that sufficient scientific,

trafficking and abuse data, as summarized herein, does exist to place AMT and 5-MeO-DIPT in Schedule I of the CSA on a permanent basis. As these substances have no legitimate medical use in the United States, the trafficking in, and use by individuals for the psychoactive effects they produce, is considered abuse. In addition, the control of these substances in Schedule I of the CSA does not violate any legally protected right.

Based on all the available information gathered and reviewed by the DEA and in consideration of the scientific and medical evaluation and scheduling recommendation by the Assistant Secretary of the DHHS, the Deputy Administrator has determined that sufficient data exist to support the placement of AMT and 5-MeO-DIPT into Schedule I of the CSA pursuant to 21 U.S.C. 811(a). The Deputy Administrator finds:

(1) AMT and 5-MeO-DIPT have a high potential for abuse.

(2) AMT and 5-MeO-DIPT have no currently accepted medical use in treatment in the United States.

(3) AMT and 5-MeO-DIPT lack accepted medical safety for use under medical supervision.

In accordance with 21 U.S.C. 811(h)(5), the Deputy Administrator hereby vacates the order temporarily placing AMT and 5-MeO-DIPT into Schedule I of the CSA published in the **Federal Register** on April 4, 2003.

Regulatory Requirements

With the issuance of this final order, AMT and 5-MeO-DIPT continue to be subject to regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, dispensing, importing and exporting of a Schedule I controlled substance, including the following:

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports AMT and 5-MeO-DIPT or who engages in research or conducts instructional activities with respect to AMT and 5-MeO-DIPT 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.

2. *Security.* AMT and 5-MeO-DIPT are 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.

3. *Labeling and Packaging.* All labels and labeling for commercial containers

of AMT and 5-MeO-DIPT which are distributed on or after October 29, 2004 shall comply with requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* Quotas for AMT and 5-MeO-DIPT are established pursuant to Part 1303 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of AMT and 5-MeO-DIPT is required to keep an inventory of all stocks of the substances 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 for AMT and 5-MeO-DIPT shall conduct an inventory of all stocks of AMT and 5-MeO-DIPT.

6. *Records.* All registrants are required to keep records pursuant to §§ 1304.03, 1304.04 and §§ 1304.21–1304.23 of Title 21 of the Code of Federal Regulations.

7. *Reports.* All registrants required to submit reports in accordance with § 1304.33 of Title 21 of the Code of Federal Regulations shall do so regarding AMT and 5-MeO-DIPT.

8. *Order Forms.* All registrants involved in the distribution of AMT and 5-MeO-DIPT must comply with the order form requirements of part 1305 of Title 21 of the Code of Federal Regulations.

9. *Importation and Exportation.* All importation and exportation of AMT and 5-MeO-DIPT must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations.

10. *Criminal Liability.* Any activity with AMT and 5-MeO-DIPT not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring on or after September 29, 2004 will continue to be unlawful.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Administrator of the DEA hereby certifies that the placement of AMT and 5-MeO-DIPT into Schedule I of the CSA will not have a significant economic impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This action involves the control of two substances with no currently accepted medical use in the United States.

Executive Order 12866

This final rule is not a significant regulatory action for the purposes of Executive Order 12866. Drug

Scheduling matters are not subject to review by the Office of Management and Budget pursuant to provisions of Executive Order 12866, section 3(d)(1).

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 final rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule will not have sufficient federalism implications to warrant the preparation of a federalism assessment.

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 \$114,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. 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, Reporting and recordkeeping requirements.

■ 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 the DEA by the Department of Justice regulations (28 CFR 0.100) and re-delegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator 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)(32) as paragraphs (d)(16) through (d)(33),

■ B. Adding a new paragraph (d)(15),

■ C. Further redesignating paragraphs (d)(19) through (d)(33) as paragraphs (d)(20) through (d)(34),

■ D. Adding a new paragraph (d)(19),

■ E. Removing paragraphs (g)(3) and (g)(4) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(15) Alpha-methyltryptamine (other name: AMT)—7432.

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(19) 5-methoxy-N,N-diisopropyltryptamine (other name: 5-MeO-DIPT) —7439.

* * * * *

Dated: September 23, 2004.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD13-04-039]

RIN 1625-AA08

Special Local Regulations for Marine Events, Strait Thunder Hydroplane Races, Port Angeles, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary special local regulations for the Strait Thunder Hydroplane Races held on the waters of Port Angeles Harbor, Port Angeles, Washington. These special local regulations limit the movement of non-participating vessels in the regulated race area and provide for a viewing area for spectator craft. This rule is needed to provide for the safety of life on navigable waters during the event.

DATES: This rule is effective from 9 a.m. on October 1, 2004 through 5 p.m. on October 3, 2004 Pacific Daylight Time.

ADDRESSES: Documents indicated in this preamble as being available in the docket are port of docket CGD13-04-039 and are available for inspection or copying at the U.S. Coast Guard Marine Safety Office Puget Sound, 1519 Alaskan Way South, Building 1, Seattle, Washington 98134 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Junior Grade Jessica Hagen at (206) 217-6231.

SUPPLEMENTARY INFORMATION:

Background and Purpose

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The hydroplane race poses several dangers to the public including excessive noise, objects falling from any accidents, and hydroplanes racing at high speeds in proximity to other vessels. Accordingly, prompt regulatory action is needed in order to provide for the safety of spectators and participants during the event. If normal notice and comment procedures were followed, this rule would not become effective until after the date of the event. The Coast Guard finds that good cause exists for not publishing an NPRM, because doing so would be contrary to the interests of public safety because immediate action is necessary to protect the public.

Under 5 U.S.C.(d)(3), for the same reasons cited above, the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**.

Discussion of Rule

This rule will create two regulated areas, a race area and a viewing area. These regulated areas restrict the movement of spectator, non-participant, vessels during hydroplane races. These regulated areas assist in minimizing the inherent dangers associated with hydroplane races. These dangers include, but are not limited to, excessive noise, race craft traveling at high speed in close proximity to one another and to spectator craft, and the risk of airborne objects from any accidents associated with hydroplanes. In the event that hydroplanes require emergency assistance, rescuers must have immediate and unencumbered access to the craft. The Coast Guard, through this action, intends to promote the safety of personnel, vessels, and facilities in the area. Due to these concerns, public safety requires these regulations to