

DIPT occurred in 1999. Since then, law enforcement officials in Arizona, California, Colorado, Delaware, Florida, Idaho, Illinois, Iowa, New Jersey, Oregon, Texas, Virginia, Washington, Wisconsin and the District of Columbia have encountered these substances. According to the Florida Department of Law Enforcement (FDLE), 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. A gram of AMT or 5-MeO-DIPT as bulk powder costs less than \$150 from illicit sources on the Internet. DEA is not aware of any legitimate medical or scientific use of AMT and 5-MeO-DIPT. There is recent evidence suggesting the attempted clandestine production of AMT and 5-MeO-DIPT in Nevada, Virginia and Washington, DC.

Public Health Risks

AMT and 5-MeO-DIPT share substantial chemical and pharmacological similarities with other Schedule I tryptamine-based hallucinogens in Schedule I of the CSA (AET and DMT). This makes it likely that these drugs cause similar health hazards. 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). 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. Further, there have been several self-reports on Internet websites describing the reported abuse of these substances in combination with other controlled drugs, namely MDMA, marijuana, gamma hydroxybutyric acid (GHB) and 2,5-dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7). This practice of drug abuse involving combinations poses additional health risks to the users and the general public. Available information indicates that AMT and 5-MeO-DIPT lack any approved therapeutic use in the United States. The safety of these substances for use in humans has not been studied.

DEA has considered the three criteria for placing a substance into Schedule I of the CSA (21 U.S.C. 812). The data available and reviewed for AMT and 5-MeO-DIPT indicate that these

substances each have a high potential for abuse, no currently accepted medical use in treatment in the United States and are not safe for use under medical supervision.

Role of the Assistant Secretary for Health in Temporary Scheduling

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Deputy Administrator to notify the Assistant Secretary for Health, delegate of the Secretary of Health and Human Services, of his intention to temporarily place substances into Schedule I of the CSA. Comments submitted by the Assistant Secretary for Health in response to the notification regarding AMT and 5-MeO-DIPT, including whether there is an exemption or approval in effect for the substances in question under the Federal Food, Drug and Cosmetic Act, shall be taken into consideration before a final order is published.

Based on the above data, the continued uncontrolled distribution and abuse of AMT and 5-MeO-DIPT pose an imminent risk to the public safety. DEA is not aware of any recognized therapeutic uses of these substances in the United States.

In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, the Deputy Administrator has considered the available data and the three factors required for a determination to temporarily schedule AMT and 5-MeO-DIPT in Schedule I of the CSA and finds that placement of AMT and 5-MeO-DIPT into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

Because the Deputy Administrator finds that it is necessary to temporarily place AMT and 5-MeO-DIPT into Schedule I to avoid an imminent hazard to the public safety, the final order, if issued, will be effective on the date of publication of the **Federal Register**. AMT and 5-MeO-DIPT will be subject to the regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, possession, importing and exporting of a Schedule I controlled substance under the CSA. Further, it is the intention of the Deputy Administrator to issue such a final order as soon as possible after the expiration of thirty days from the date of publication of this notice and the date that notification was transmitted to the Assistant Secretary for Health.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This action provides a notice of intent to temporarily place AMT and 5-MeO-DIPT into Schedule I of the CSA. DEA is not aware of any legitimate uses of AMT and 5-MeO-DIPT in the United States.

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 Federalism

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

Unfunded Mandates Reform Act

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 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.