DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA–226F]

Schedules of Controlled Substances: Temporary Placement of Benzylpiperazine and Trifluoromethylphenylpiperazine Into Schedule I

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

ACTION: Final rule.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this final rule to temporarily place N-benzylpiperazine (BZP) and 1-(3-trifluoromethylphenyl) piperazine (TFMPP) into Schedule I of the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of the CSA. This final action is based on a finding by the DEA Deputy Administrator that the placement of BZP and TFMPP into Schedule 1 of the CSA is necessary to avoid an imminent hazard to the public safety. As a result of this rule, the criminal sanctions and regulatory controls of Schedule I substances under the CSA will be applicable to the manufacture, distribution, and possession of BZP and TFMPP.

EFFECTIVE DATE: September 20, 2002.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Under What Authority Are BZP and TFMPPP Being Temporarily Scheduled?

The Comprehensive Crime Control Act of 1984 (Pub. L. 98–473), which was signed into law on October 12, 1984, amended section 201 of the Controlled Substances Act (CSA)(21 U.S.C. 811) to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA for one year without regard to the requirements of 21 U.S.C. 811 (b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. The Attorney General may extend the temporary scheduling up to 6 months. A substance may be temporarily scheduled under the emergency provisions of the CSA if that substance is not listed in any other schedule under section 202 of the CSA (21 U.S.C. 812) or if there is no exemption or approval in effect under 21 U.S.C. 355 for the substance. The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of DEA (28 CFR 0.100). The Administrator has redelgated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

A notice of intent to temporarily place BZP and TFMPP into Schedule I of the CSA was published in the **Federal Register** on July 18, 2002 (67 FR 47341). The Deputy Administrator transmitted notice of his intention to temporarily place BZP and TFMPP into Schedule I of the CSA to the Assistant Secretary for Health of the Department of Health and Human Services (HHS). In response to this notification, the Food and Drug Administration has advised DEA that there are no exemptions or approvals in effect under 21 U.S.C. 355 of the Food, Drug and Cosmetic Act for BZP and TFMPP and HHS has no objection to DEA's intention to temporarily place N. benzylpiperazine and 1-(3-trifluoromethylphenyl)piperazine into Schedule I of the CSA.

What Factors Were Considered in the Determination To Temporarily Schedule N-benzylpiperazine and 1-(3-trifluoromethylphenyl)piperazine?

The Deputy Administrator has considered the available data and the following three factors required for a determination to temporarily schedule a substance under the CSA (21 U.S.C. 811 (c)):

4. Its history and current pattern of abuse;

5. Scope, duration and significance of abuse; and

6. What, if any, risk there is to the public health.

Additionally, DEA has considered the three criteria for placing a substance into Schedule I of the CSA (21 USC 812). The data available and reviewed for BZP and TFMPP indicate that they have a high potential for abuse, no currently accepted medical use in treatment in the US and are not safe for use under medical supervision.

What Are BZP and TFMPP?

BZP and TFMPP are piperazine derivatives, BZP was first synthesized in 1944 as a potential antiparasitic agent. There are no therapeutic applications for BZP and TFMPP, BZP and TFMPP have no accepted medical use in treatment in the United States. The safety for use of these two substances has not been determined. They are available primarily as chemical intermediates in syntheses. These two substances are similar in chemical structure and are often found to be abused together in tablets or powder form.

Why Are BZP and TFMPP Being Controlled?

Abuse of BZP was first reported in late 1996 in California. BZP and TFMPP are being encountered in several regions of the United States and their abuse has spread rapidly from the states where they were initially encountered. Over the past few years, in the United States, BZP and TFMPP have increasingly been found in similar venues as the popular club drug 3,4-methylenedioxymethamphetamine (MDMA, also known as Ecstasy). BZP and TFMPP are also sold as MDMA and are targeted to the youth population. The tablet form often bears imprints commonly seen on MDMA tablets such as a fly, crown, heart, butterfly, or bull's head logos in pink, tan, white, or green. BZP and TFMPP have also been found in powder form or liquid form packaged in small convenience sizes sold on the Internet, Illicit distributions occur through smuggling of bulk powder through organizations with connections to overseas sources of supply. The bulk powder is then processed into capsule, tablet, or pill form and distributed through organized networks. These organizations also distribute other controlled substances such as MDMA, 2C–B, marijuana and anabolic steroids.

The increasing abuse of BZP and TFMPP in the United States is evidenced by increasing encounters by law enforcement agencies. DEA, State and local law enforcement agencies reported BZP and TFMPP in drug exhibits seized in the states of California, Connecticut, Florida, Illinois, Indiana, Iowa, Louisiana, Minnesota, Nevada, New York, Oregon, Rhode Island, South Carolina, Texas, Virginia, Washington and Wisconsin. Over fifty (50) seizures have been reported and amounted to over 39,000 tablets and 1000 pounds of powder. BZP and TFMPP are being promoted as legal alternatives to MDMA. They are often sold as ''Ecstasy'', or as ''BZP'', ''A^2'', ''legal E'' or ''legal X''. BZP and TFMPP, with their easy availability and their so-called legal status, are becoming drugs of abuse in the United States.

As with amphetamine and MDMA, the effects of BZP are stimulant-like and those of TFMPP are hallucinogen-like. The risks to the public health associated with MDMA and amphetamine, both substances with high potential for abuse, are well known and documented. BZP acts as a stimulant similar in effect to MDMA or amphetamine, producing euphoria and inducing cardiovascular

effects in humans, including increased heart rate, systolic blood pressure and pulse rate. TFMPP, at approximately 100 mg, produces hallucinogenic effects similar to those produced by MDMA. TFMPP is a serotonin releasing agent and binds to serotonin receptors in the brain. In 2001, a report from University Hospital in Zurich, Switzerland details the death of a young female which was attributed to the combined use of benzylpiperazine and MDMA.

What Is the Effect of This Final Rule?

With the issuance of this final order, BZP and TFMPP become 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.

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports BZP and TFMPP or who engages in research or conducts instructional activities with respect to BZP and TFMPP 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 (CFR) by October 21, 2002.

2. *Security.* BZP and TFMPP are subject to Schedule I security requirements and must be manufactured, distributed and stored in accordance with *§§ 1301.7, 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 BZP and TFMPP which are distributed on or after October 21, 2002 shall comply with requirements of *§§ 1302.02–1302.07* of Title 21 of the Code of Federal Regulations.

4. *Quotas.* Quotas for BZP and TFMPP 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 BZP and TFMPP 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 BZP and TFMPP shall conduct an inventory of all stocks of BZP and TFMPP on or before October 21, 2002.

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 § 1304.31 through *§ 1304.33* of Title 21 of the Code of Federal Regulations shall do so regarding BZP and TFMPP.

8. *Order Forms.* All registrants involved in the distribution of BZP and TFMPP 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 BZP and TFMPP must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations.

10. *Criminal Liability.* Any activity with BZP and TFMPP not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring on or after September 20, 2002 is unlawful.

Regulatory Certification

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 temporarily places BZP and TFMPP into Schedule I of the Controlled Substance 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 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 § 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, Narcotics, Prescription drugs, Reporting and Record keeping requirements.

Under the authority vested in the Attorney General by Section 201(h) of the CSA (21 U.S.C. 811 (h)), and delegated to the Administrator of the DEA by 28 CFR 0.100, and redelegated to the Deputy Administrator by 28 CFR 0.104, the Deputy Administrator hereby orders that 21 CFR Part 1308 is 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, 871b, unless otherwise noted.

2. Section 1308.11 is amended by adding paragraphs (g)(3) and (g)(4) to read as follows:

§ 1308.11 Schedule I.

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(g) * * *

(3) N-benzylpiperazine (some other names: BZP; 1-benzylpiperazine), its optical isomers, salts and salts of isomers—7493

(4) 1-(3-trifluoromethylphenyl)piperazine (other name: TFMPP), its optical isomers, salts and salts of isomers—7494

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Dated: September 5, 2002.

John B. Brown, III,

Deputy Administrator.

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