unincorporated association, including any method specified in paragraph (a)(1), except that civil investigative demands may only be served in the manner provided by section 20(c)(7) of the FTC Act (in the case of service on a partnership, corporation, association, or other legal entity) or section 20(c)(8) of the FTC Act (in the case of a natural person). Service under this provision is complete upon delivery by the Post Office or upon personal delivery.

(3) All documents served in adjudicative proceedings under Part III of the Commission’s Rules of Practice other than complaints and initial, interlocutory, and final decisions and orders may be served by personal delivery or by first-class mail and shall be deemed served on the day of personal delivery or the day of mailing.

(4) When a party has appeared in a proceeding by an attorney, service on that individual of any document pertaining to the proceeding other than a complaint shall be deemed service upon the party. However, service of those documents specified in paragraph (a)(1) of this section shall first be attempted in accordance with the provision of paragraphs (a)(1)(i), (ii), and (iii) of this section.

(b) By other parties. Service of documents by parties other than the Commission shall be by delivering copies thereof as follows: Upon the Commission, by personal delivery or delivery by first-class mail to the Office of the Secretary of the Commission and, in adjudicative proceedings under Part III of the Commission’s Rules of Practice, to the Assistant Director in the Bureau of Competition and, the Associate Director in the Bureau of Consumer Protection, or the Director of the Regional Office of complaint counsel. Upon a party other than the Commission or Commission counsel, service shall be by personal delivery or delivery by first-class mail. If the party is an individual or partnership, delivery shall be to such individual or a member of the partnership; if a corporation or unincorporated association, to an officer or agent authorized to accept service of process therefor. Personal service includes handling the document to be served to the individual, partner, officer, or agent; leaving it at his or her office with a person in charge thereof; or, if there is no one in charge or if the office is closed or if the party has no office, leaving it at his or her dwelling house or usual place of abode with some person of suitable age and discretion then residing therein. Documents served in adjudicative proceedings under Part III of the Commission’s Rules of Practice shall be deemed served on the day of personal service or the day of mailing. All other documents shall be deemed served on the day of personal service or on the day of delivery by the Post Office.

(c) Proof of service. In an adjudicative proceeding under Part III of the Commission’s Rules of Practice, papers presented for filing by a party respondent or intervenor shall contain an acknowledgment of service by the person served or proof of service in the form of a statement of the date and manner of service and of the names of the person served, certified by the person who made service. Proof of service may appear on or be affixed to the papers filed.

By direction of the Commission, dated July 1, 1985.

Emily H. Rock,
Secretary.

[FR Doc. 85–18149 Filed 7–9–85; 8:45 am]
BILLING CODE 6750–01–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Temporary Placement of 1-Methyl-4-Phenyl-4-Propionoxyphenylidine (MPPP) and 1-(2-Phenylethyl)-4-Phenyl-4-Acetoxypyridine (P PapaP)) Into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration (DEA) is issuing this notice to temporarily place 1-methyl-4-phenyl-4-propionoxyphenylidine (MPPP) and 1-(2-phenylethyl)-4-phenyl-4-acetoxypyridine (P PapaP) into Schedule I of the Controlled Substances Act (CSA) pursuant to the emergency scheduling provisions of the CSA. This action is based on a finding that the scheduling of MPPP and P PapaP in Schedule I is necessary to avoid an imminent hazard to the public safety and on a recommendation from the Acting Assistant Secretary for Health, Department of Health and Human Services. This action will impose the criminal sanctions and regulatory controls of Schedule I on the manufacture, distribution and possession of MPPP and P PapaP.

EFFECTIVE DATE: On August 12, 1985 MPPP and P PapaP will be subject to Schedule I control.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, D.C. 20537; Telephone: (202) 633–1366.

SUPPLEMENTARY INFORMATION:

List of Subjects in 21 CFR Part 1308


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 CSA (21 U.S.C. 811) to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA if he finds that such action is necessary to avoid an imminent hazard to the public safety. A substance may be 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 approval or exemption in effect under 21 U.S.C. 835 for the substance. The Attorney General has delegated his authority under 21 U.S.C. 811 to the Acting Administrator of the Drug Enforcement Administration (28 CFR 0.100(b)).

As required by section 201(h)(4) of the CSA (21 U.S.C. 811(m)(4)), the Acting Administrator has notified the Secretary of Health and Human Services of his intention to place MPPP and P PapaP into Schedule I pursuant to the emergency scheduling provisions. Such action may not take effect until the expiration of thirty days after DEA notifies the Secretary and after a notification is published by DEA in the Federal Register.

In making a finding of an imminent hazard to the public safety, the Attorney General is required to consider only those factors set forth in paragraphs (4) the history and current pattern of abuse, (5) the scope, duration and significance of abuse, and (6) what, if any risk there is to the public health, of section 201(c) of the CSA (21 U.S.C. 811(c)).

House Report 98–835 which accompanied Public Law 98–473 states that “This new procedure [emergency scheduling] is intended by the Committee to apply to what has been called ‘designer drugs,’ new chemical analogs or variations of existing controlled substances, or other new substances, which have a psychoactive, stimulant or depressant effect and have high potential for abuse.” The report specifies that MPPP, which is similar to meperidine (Demerol), is an example of such a substance. This report goes on to
say that "... The ability to establish controls on MPPP, if its production for drug abuse were to be encountered more often, would be important to protect the public health and to prosecute those who wantonly risk the public health." Clearly, a situation envisioned by Congress has occurred. Analogues of the synthetic narcotic analgesic, meperidine (Demerol), including MPPP and PEPPAP, are examples of the "designer drugs" which Congress intended to subject to the emergency scheduling authority as imminent hazards to the public safety.

1-Methyl-4-phenyl-4-propionoxyperidine (MPPP) and 1-(2-phenethyl)-1-phenyl-4-acetylxyloperidine (PEPPAP) are reversed ester analogs of the Schedule II synthetic narcotic analgesic, meperidine (pethidine, Demerol). Analgesic screening tests in rats and mice indicate that MPPP and PEPPAP are meperidine-like opiate analgesics. The analgesic potency of MPPP, as measured after intravenous and subcutaneous administration in rats and mice, ranged from 5 to 30 times that of meperidine on a molar basis. Toxicity studies using subcutaneous administration in mice yielded an LD₅₀ for MPPP of 40 mg/kg compared to an LD₅₀ for meperidine of 196 mg/kg. The analgesic potency of PEPPAP, as measured after subcutaneous administration in mice and rats, ranged from 12 to 72 times that of meperidine on a molar basis. DEA is unaware of any legitimate medical use or manufacture of MPPP and PEPPAP in the United States.

MPPP and PEPPAP can be synthesized via the appropriate piperidinal intermediates. These intermediates are very susceptible to dehydration to the corresponding 1-alkyl-4-phenyl-1,2,5,6-tetrahydropridine (MPTP); in the case of the MPPP synthesis, the by-product, 1-methyl-4-phenyl-1,2,5,6-tetrahydropridine (MPTP), is also formed unless reaction conditions are carefully controlled: the PEPPAP synthesis also yields 1-(2-phenethyl)-4-phenyl-1,2,5,6-tetrahydropridine (PEPPT). It has been determined that MPTP is a neurotoxic substance which induces a permanent Parkinsonian syndrome in man and nonhuman primates. This Parkinsonian syndrome has been identified in individuals who were exposed to MPTP as an impurity in the narcotic substance MPPP or accidentally in an industrial setting. It is not known at this time whether PEPTP produces a similar neurotoxicity. Although careful synthetic procedures could eliminate the unwanted byproducts, MPPP and PEPTP, the samples of clandestinely produced MPPP and PEPPAP analyzed by forensic laboratories have invariably contained quantities of MPTP and PEPTP.

The abuse of MPPP was first reported in 1976 in the Washington, D.C. area when a 23 year old male was referred to the National Institute of Mental Health (NIMH) for evaluation after exhibiting symptoms of Parkinson's Disease. He was a known drug abuser and had used the meperidine analog, MPPP. This individual synthesized MPPP and reported that intravenous and intramuscular use of MPPP produced an opiate-like high and other subjective effects similar to those of meperidine. He subsequently produced more MPPP but altered the reaction conditions. Intravenous use of MPPP from these later batches resulted in hospitalization with Parkinsonian symptoms. Duplication of his synthesis by researchers produced MPPP, MPH (N-methyl-4-phenyl-4-hydroxy-piperidine) and MPTP (1-methyl-4-phenyl-1,2,5,6-tetrahydropridine). Subsequent studies showed that MPTP was responsible for the production of the Parkinsonian syndrome.

DEA laboratories analyzed six exhibits of MPPP in 1982 from Monterey and Santa Clara Counties in California. All exhibits had been produced, contained MPTP and were obtained from individuals who were hospitalized with a Parkinsonian syndrome. By the summer of 1983, neurologists at the Santa Clara Valley Medical Center reported that they were treating seven individuals for a Parkinsonian syndrome after their intravenous use of MPPP contaminated with MPTP. Scientists at the National Institute of Mental Health (NIMH) succeeded in producing Parkinsonism in these animals. MPPP has been sold on the street as synthetic heroin. Interviews with narcotics users indicate that many may have been unknowingly exposed to MPPP/MPTP or other meperidine analogs. Not all of these individuals immediately developed Parkinsonian symptoms. Parkinsonian's Disease is associated with a decrease in the number of dopaminergic neurons in the substantia nigra greater than that accompanying normal aging. Since MPTP also decreases the number of dopaminergic neurons in the substantia nigra, it is unlikely that more MPTP exposed individuals may develop Parkinsonism as their dopaminergic neurons further decrease with age.

Physicians at the University of British Columbia in Vancouver, Canada reported another case of MPTP-induced Parkinsonism after abuse of MPPP. An individual has prepared MPPP and snorted it daily for seven days prior to developing Parkinsonian symptoms.

Analysis of the material which he had taken revealed the presence of MPPP, MPTP and the piperidinol intermediate. Although forensic laboratories have not detected MPPP/MPTP in the illicit drug traffic since 1982, there is considerable evidence that MPPP/MPTP or other meperidine analogs have been available since that time and are currently available. Raids of clandestine laboratories producing methamphetamine near Jamal, California in September, 1984 and April, 1985 by DEA yielded copies of the typewritten synthesis of MPPP, literature references to the synthesis of meperidine analogs and, at the 1985 laboratory, precursors to produce MPPP. Additionally, in October, 1984, DEA seized a large-scale PCP laboratory in Brownsville, Texas which was in the process of making an intermediate which could have been converted into PEPPAP. Analysis of the reaction mixture found at the laboratory showed that 1-(2-phenethyl)-4-phenyl-piperidinol (intermediate in the synthesis of PEPPAP) and 1-(2-phenethyl)-4-phenyl-1,2,5,6-tetrahydropridine (PEPTP, dehydrolization by-product) were present. In March, 1985 a DEA laboratory reported the identification of PEPPAP and PEPTP in a sample confiscated by the Hayward Police Department in Alameda County, California.

In January, 1985, the Centers for Disease Control (CDC), Department of Health and Human Services, in conjunction with the State of California and the Santa Clara Valley Medical Center in San Jose, California, began an interview program to locate persons who may have used MPPP/MPTP. By letter dated April 12, 1985, DEA Acting Administrator John C. Lawn requested that Dr. James Mason, Acting Assistant Secretary for Health, provide DEA with the results of the CDC study and an evaluation of the study data relevant to a determination of the current or recent availability of MPPP/MPTP. Dr. Mason responded by letter dated May 28, 1985, that the evidence available suggests that meperidine analogs are currently available in California. The CDC found that a number of interviewees reported the use of a substance after 1982 which produced symptoms identical to those produced by acute MPPP/MPTP exposure. Specifically, 24 interviewees reported the use of such a substance in 1983, 91 in 1984 and 9 in 1985. Additionally, the CDC reports that trained staff at drug treatment clinics in Los Angeles, San Diego, and Fresno, California have reported seeing classical
signs and symptoms of meperidine analog use in clients. Narcotic users interviewed in San Francisco, Oakland and Selinas, California also report that meperidine analgesics are currently available. In his letter, Dr. Mason stated that "We believe that . . . meperidine analogs are currently available in California. Due to the known severe, irreversible toxic effect of MPTP/MPPP and total lack of any known health benefit associated with these substances, I encourage you to consider exercising whatever authorities are available to you to control these substances, including your Emergency Scheduling authority to place them in Schedule I of the Controlled Substances Act."

The intravenous use of clandestinely produced narcotics in general, and the meperidine analogs, MPPP and PEPAP in particular, pose substantial risks to the public health and safety. The presence of the neurotoxin, MPTP, as a by-product in clandestinely produced MPPP, multiplies the public health and safety hazards attendant to the use of MPPP. The continued availability, use and possible spread of the use of meperidine analogs, particularly MPPP, will undoubtedly result in the development of a chronic irreversible and progressive parkinsonian syndrome in many more individuals either immediately after use or some later time. Although PEPAP, the PEPAP by-product, has a chemical structure similar to that of MPTP, it is not yet known whether PEPAP will produce toxic effects similar to those produced by MPTP. Nevertheless, the current availability and use of PEPAP as a drug of abuse, its lack of any known accepted medical use and its possible toxicity, warrant immediate action to prevent further risk to the public health and safety.

The data described above show that the production, distribution and use of meperidine analogs, specifically MPPP and PEPAP analogs, pose a very serious hazard to the public health and safety. The use of MPPP in Washington, D.C., California and British Columbia, Canada as well as the attempted synthesis of PEPAP in Texas and its identification in California indicates that the use of MPPP and PEPAP is not an isolated phenomenon. There is a potential for the production, distribution and use of these substances along with their attendant health and safety hazards, to spread to other areas of 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 Acting Administrator has considered the following factors described in section 201(c) of the CSA (21 U.S.C. 811(c)) relative to making a determination of whether MPPP and PEPAP each pose an imminent hazard to the public safety: (4) Its 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.

Based on a consideration of these factors, the recommendation of the Acting Assistant Secretary for Health, and in light of the current availability and abuse of MPPP, PEPAP and their by-products MPTP and PEPAP, the neurotoxicity of MPTP, and the possible neurotoxicity of PEPAP, the Acting Administrator, pursuant to section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, finds that scheduling MPPP and PEPAP in Schedule I of the CSA, at least on a temporary basis, is necessary to avoid an imminent hazard to the public safety.

The Acting Administrator has transmitted notice of his intention to temporarily place MPPP and PEPAP into Schedule I of the CSA to the Secretary of Health and Human Services. Comments submitted by the Secretary in response to the notification, including whether there is an exemption or approval in effect for MPPP or PEPAP under the Federal Food, Drug and Cosmetic Act, shall be taken into consideration by the Acting Administrator before the notice becomes effective.

Pursuant to the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, the Acting Administrator hereby orders that on August 12, 1985 1-methyl-4-phenyl-4-propanonoxypiperidine (MPPP), its optical isomers, salts and salts of isomers, and 1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (PEPAP), its optical isomers, salts and salts of isomers, be placed into Schedule I of the CSA (21 U.S.C. 801 et seq.) unless the Acting Administrator gives notice in the Federal Register that this order is rescinded prior to August 12, 1985.

PART 1308—(AMENDED)

List of Subjects in 21 CFR Part 1308

Prescription drugs.

For the reasons set forth above, 21 CFR 1308.11(g) is amended as follows:

1. The authority citation for 21 CFR Part 1308 continues to read as follows:


2. Sections 1308.11(g)(3) and (4) are added to read as follows:

   §1308.11 Schedule I.

   (g) . . .

   (3) 1-methyl-4-phenyl-4-
        propanonoxypiperidine (MPPP), its
        optical isomers, salts and salts of
        isomers................................................. 9661

   (4) 1-(2-phenylethyl)-4-phenyl-4-
        acetyloxypiperidine (PEPAP), its
        optical isomers, salts and salts of
        isomers................................................. 9663

   . . .

The temporary placement of MPPP and PEPAP in Schedule I under section 201(h) of the CSA (21 U.S.C. 811(h)) will expire at the end of one year from the effective date of this order. If a rulemaking proceeding to schedule MPPP or PEPAP under the CSA has been initiated pursuant to section 201(a) of the CSA (21 U.S.C. 811(a)) and is pending, the temporary scheduling of MPPP or PEPAP may be extended for up to six months.

This action is not a formal rulemaking procedure as set forth in the Administrative Procedures Act (5 U.S.C. 551-559) and the opportunity for a hearing on the record is not required. Nevertheless, the Acting Administrator affords the opportunity for comments to be submitted concerning this matter. Comments should be submitted in quintuplicate to the Acting Administrator, Drug Enforcement Administration, 1405 I Street, N.W., Washington, D.C. 20537, Attention: Federal Register Representative.

All regulations and criminal sanctions applicable to Schedule I substances are effective on August 12, 1985 with respect to MPPP and PEPAP. However, individuals registered with DEA in accordance with Part 1301 or 1311 of Title 21 of the Code of Federal Regulations and who currently possess MPPP or PEPAP may continue to do so pending DEA's receipt of an amended registration application no later than September 8, 1985.

1. Registration. Any person who manufactures, distributes, delivers, imports or exports MPPP or PEPAP, or who engages in research or conducts instructional activities with respect to this substance, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations.

2. Security. MPPP and PEPAP must be manufactured, distributed and stored in accordance with §§ 1301.71—1301.76 of Title 21 of the Code of Federal Regulations.

3. Labeling and Packaging. All labels and labeling for commercial containers
Modification of the release conditions may be made by the Commission, or a member thereof, on its own motion, pursuant to 28 CFR 2.40(b). Requests for modification may be made by the U.S. Probation Officer supervising the parolee, also pursuant to 28 CFR 2.40(b), or by the parolee himself, pursuant to 28 CFR 2.40(e). The Commission has determined that these rules that provide generally for modification are sufficient to govern the exceptional circumstances where a parolee can secure permission to possess a firearm or other dangerous weapon. Any details concerning such a modification can be added, as necessary, to the procedures that accompany the rules.

This rule change will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

List of Subjects in 28 CFR Part 2

Administrative practice and procedures, Prisoners, Probation and parole.

PART 2—[AMENDED]

1. The authority citation for 28 CFR Part 2 is revised to read:

Authority: 18 U.S.C. 4203(a)(1) and 4204(a)(6).

2. 28 CFR 2.40, Conditions of Release, is amended by revising paragraph (a)(11) to read as follows:

§ 2.40 Conditions of release.

(a) * * *

(11) The parolee shall not possess a firearm or other dangerous weapon.

* * * * *


Benjamin F. Baer.
Chairman, U.S. Parole Commission.

[FR Doc. 85-16362 Filed 7-9-85; 8:45 am]

DEPARTMENT OF EDUCATION

Office of Inspector General

34 CFR Part 19

National Security Information; Handling Classified Information

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the existing regulations in 34 CFR Part 19—National Security Information Procedures to comply with the procedural requirements of Executive