

(6) The Director and Deputy Director, Division of Scientific Investigations, Office of Compliance, CDER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 512(e) and 512 (m)(4)(B)(ii) and (m)(4)(B)(iii) of the act regarding the issuance of written notices.

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(3) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(4) Regional Food and Drug Directors.

(5) District Directors.

Dated: April 24, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 92-10191 Filed 4-30-92; 8:45 am]

BILLING CODE 4180-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances Temporary Placement of Methcathinone Into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to temporarily place methcathinone 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 by the DEA Administrator that the scheduling of methcathinone, at least on a temporary basis, is necessary to avoid an imminent hazard to the public safety. As a result of this rule, the regulatory controls and criminal sanctions imposed on Schedule I substances under the CSA will be applicable to the manufacture, distribution and possession of methcathinone.

EFFECTIVE DATE: May 1, 1992.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: The Comprehensive Crime Control Act 1984 amended section 201 of the CSA (21 U.S.C. 811 et seq.) to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA if it is found that such action is necessary to avoid an imminent hazard to the public safety. The Attorney General has delegated this authority under 21 U.S.C. 811 to the Administrator of the DEA (28 CFR 0.100). A substance may be temporarily scheduled pursuant to the emergency scheduling provisions of the CSA if that substance is not listed in any 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. 355 of the Food, Drug and Cosmetic Act for the substance.

A notice of intent to temporarily place methcathinone into Schedule I of the CSA was published in the *Federal Register* on March 16, 1992 (57 FR 9080). The Administrator transmitted notice of his intention to temporarily place methcathinone into Schedule I of the CSA to the Assistant Secretary for Health of the Department of Health and Human Services. In response to this notification, the Food and Drug Administration, by letter, 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 methcathinone. The letter further stated that the Department of Health and Human Services has no objections to DEA's intention to temporarily place methcathinone into Schedule I of the CSA. No other comments were received regarding this matter.

Methcathinone, also called ephedrone or 2-methylamino-1-phenylpropan-1-one, is an N-monomethylated phenylisopropylamine that has a chemical structure similar to that of methamphetamine. Limited pharmacological data indicate that methcathinone produces amphetamine-like, psychomotor stimulant activity in laboratory animals.

Five clandestine laboratories producing methcathinone have been encountered. Methcathinone is sold on the street as a "legal" stimulant under the street name, "cat." It is distributed as a powdered material and is administered via nasal inhalation.

In accordance with 21 U.S.C. 811(h)(3), the Administrator has considered the following factors regarding methcathinone: (1) Its history and current pattern of abuse; (2) the scope, duration and significance of abuse; and (3) what, if any, risk there is to the public health.

Based on methcathinone's structural similarity to amphetamine and

methamphetamine, its amphetamine-like central nervous system stimulant properties in animals, its clandestine production, distribution and abuse, the Administrator, pursuant to 21 U.S.C. 811(h) of the CSA and 28 CFR 0.100, finds that temporary placement of methcathinone into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

The following regulations are effective with respect to methcathinone on May 1, 1992, except that individuals registered with DEA in accordance with part 1301 or part 1311 of title 21 of the Code of Federal Regulations, who currently possess methcathinone may continue to do so pending DEA's receipt of an application for amended registration no later than June 1, 1992:

1. **Registration.** Any person who manufactures, distributes, engages in research, imports or exports methcathinone or who proposes to engage in the manufacture, distribution, importation or exportation of methcathinone or conduct research with methcathinone 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.** Methcathinone 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 of methcathinone must comply with the requirements of §§ 1302.03-1302.05, 1302.07 and 1302.08 of title 21 of the Code of Federal Regulations.

4. **Quotas.** All persons required to obtain quotas for methcathinone must submit applications pursuant to §§ 1303.12 and 1303.22 of title 21 of the Code of Federal Regulations.

5. **Inventory.** Registrants in possession of methcathinone are required to take inventories of all stocks of this substance on hand pursuant to §§ 1304.11-1304.19 of title 21 of the Code of Federal Regulations.

6. **Records.** All registrants required to keep records pursuant to §§ 1304.21-1304.27 of title 21 of the Code of Federal Regulations must do so regarding methcathinone.

7. **Reports.** All registrants engaged in the manufacture, packaging, labeling or distribution of methcathinone are required to submit reports in accordance with §§ 1304.35-1304.37 of title 21 of the Code of Federal Regulations.

8. **Order Forms.** Each distribution of methcathinone requires the use of an order form pursuant to §§ 1305.01-

1305.16 of title 21 of the Code of Federal Regulations.

9. Importation and Exportation. All importation and exportation of methcathinone must be in compliance with part 1312 of title 21 of the Code of Federal Regulations.

10. Criminal Liability. Any activity with methcathinone not authorized by or in violation of the CSA or the Controlled Substances Import and Export Act occurring on or after May 1, 1992 is unlawful.

The Administrator of the DEA hereby certifies that the temporary placement of methcathinone into Schedule I of the CSA will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This action involves the temporary control of a substance with no currently approved medical use or manufacture in the United States.

This final rule is not a major rule for the purposes of Executive Order 12291 (46 FR 13193) of February 17, 1981. It has been determined that drug scheduling matters are not subject to review by the Office of Management and Budget (OMB) pursuant to the provisions of Executive Order 12291. Accordingly, this emergency scheduling action is not subject to the provisions of Executive Order 12778 which are contingent upon review by OMB. This regulation both responds to an emergency situation posing an imminent danger to the public health and safety, and is essential to a criminal law enforcement function of the United States. Accordingly, it is not subject to the 90-day moratorium on regulations ordered by the President of the United States in his memorandum of January 28, 1992.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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(h) of the CSA (21 U.S.C. 811(h)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), the Administrator hereby amends 21 CFR part 1308 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. Paragraph (g)(3) is added to § 1308.11 to read as follows:

§ 1308.11 Schedule I

* * * * *

(g) * * *

(3) Methcathinone (Some other names: 2-Methylamino-1-Phenylpropan-1-one; Ephedrone; Monomethylpropion; UR 1431, its salts, optical isomers, and salts of optical isomers—1237.

Dated: April 23, 1992.

Robert C. Bonner,
Administrator, Drug Enforcement
Administration.

[FR Doc. 92-10282 Filed 4-30-92; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

CGD1 92-007

Safety Zone Regulations: Kill Van Kull, NY and NJ

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone in all waters in the area of Bergen Point in Newark Bay and the Kill Van Kull of New York and New Jersey. This zone will restrict traffic in the described area and prohibit traffic from transiting the work area in a portion of the channel at Bergen Point West Reach. In the work area, concentrated drilling and blasting will be conducted and no vessel is permitted to transit that section. In the remaining restricted area, vessel passage is permitted under the criteria set forth in this regulation. This action is necessary to protect the maritime community from the possible dangers and hazards to navigation associated with the extensive blasting and dredging operations which are being conducted in the work area of the channel.

EFFECTIVE DATE: This regulation becomes effective at 6 a.m., March 30, 1992. It terminates at 12 a.m., August 1, 1992, unless terminated sooner by Captain of the Port NY (COTP NY).

FOR FURTHER INFORMATION CONTACT: LTJG J. Peschel Captain of the Port, New York (212) 668-7934.

SUPPLEMENTARY INFORMATION: Drafting Information

The drafters of this notice are LTJG J. E. Peschel, Project Officer, Captain of the Port, New York and LCDR J. Astley, Project Attorney, First Coast Guard District, Legal Office.

Regulatory History

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after Federal Register publication. Publishing an NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to respond to any potential hazards. The request for this zone was not received until March 26, 1992. Therefore, there was not sufficient time to publish proposed rules in advance of the event or to provide for a delayed effective date.

On August 8, 1991 this office submitted for publication a final rule which would impose a regulated navigation area (RNA) over the entire Kill Van Kull for the duration of a three year deepening project which is occurring throughout the Kill. When that rule is published it will appear as Part 165.165 of this Title (CGD1 89-065). To safeguard users of this waterway from hazards involved with this ongoing project, this safety zone establishes additional temporary restrictions both within and slightly beyond the boundaries of the RNA. These additional requirements specify mandatory check-in points for vessels nearing the work area, and require the employment of tugs when conducting certain operations during this most difficult phase of the project.

Background and Purpose

In August 1991, the Army Corps of Engineers (A.C.O.E.) and the Port Authorities of New York and New Jersey commenced an extensive channel deepening project in the Kill Van Kull and the Bergen Point area. This project reduces the available channel width by one half in the area of the worksite, from approximately 800 feet to 400 feet for the duration of the project.

In order to minimize the burden on the maritime community during this important and necessary dredging operation, the project is divided into phases. During each phase, blasting and dredging operations occur in only a small portion of the navigable channel. Limiting the size of the work area allows vessels to continue navigating the waterway with few, if any, restrictions, while providing the necessary level of safety and allowing the A.C.O.E. to