Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposed Placement of 3-Methylfentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice of proposed rulemaking is issued by the Administrator of the Drug Enforcement Administration (DEA) to place the narcotic substance, 3-methylfentanyl into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). This proposed action by the DEA Administrator is based on data gathered and reviewed by DEA and independently evaluated by the Acting Assistant Secretary for Health, Department of Health and Human Services. If finalized, this proposed action would impose the regulatory control mechanisms and criminal sanctions of Schedule I on the manufacture, distribution and possession of 3-methylfentanyl.

DATE: Comments must be submitted on or before May 27, 1986.

ADDRESS: Comments and objections should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, 1405 I Street NW., Washington, DC 20537, Attention: DEA Federal Register Representative.

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

SUPPLEMENTARY INFORMATION:

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

On March 25, 1985, the Administrator of the Drug Enforcement Administration issued a final rule in the **Federal Register** temporarily placing 3-methylfentanyl into Schedule I of the Controlled Substances Act pursuant to the emergency scheduling provisions of 21 U.S.C. 811(h). This action which became effective on April 25, 1985 was based on a finding by the Administrator that the emergency scheduling of 3-methylfentanyl was necessary to avoid an imminent hazard to the public safety. Section 201(h)(2) of the GSA (21 U.S.C. 811(h)(2)) provides that the emergency scheduling of a substance expires at the end of 1 year from the effective date of the order. However, if a rulemaking proceeding to schedule the substance has been initiated pursuant to section 201(a)(1) of the GSA (21 U.S.C. 811(a)(1)), the temporary scheduling may be extended for up to 6 months. Under this provision, the tempoary scheduling of 3-methylfentanyl which would expire on April 25, 1986, may be extended until October 25, 1986. This extension is being ordered by the Administrator of DEA in a separate action.

Since the temporary scheduing of 3-methylfentanyl, DEA has continued to gather information regarding the abuse and abuse potential of 3-methylfentanyl and the clandestine manufacture, distribution and trafficking of this substance. By letter dated February 24, 1986, the DEA Administrator submitted the data which DEA had gathered regarding 3-methylfentanyl to the Acting Assistant Secretary for Health, Department of Health and Human Services. In accordance with the provisions of 21 U.S.C. 811(b), the DEA Administrator also requested a scientific and medical evaluation of the relevant information and a scheduling recommendation for 3-methylfentanyl from the Acting Assistant Secretary for Health. On April 7, 1986, the DEA Administrator received a reply from the Acting Assistant Secretary for Health recommending that 3-methylfentanyl be placed into Schedule I of the Controlled Substance Act. A portion of the letter is set forth below:

> Pursuant to the requirements of the Controlled Substances Act, 21 U.S.C. 801 et seq., the Food and Drug Administration (FDA) has conducted a scientific and medical evaluation of the drug 3-methylfentanyl. FDA has performed the eight factor evaluation required by 21 U.S.C. 811 and recommends that 3-methylfentanyl be placed in Schedule I of the Controlled Substances Act. I concur with FDA's recommendation to place 3-methylfentanyl in Schedule I. You will find enclosed a document that supports this recommendation and provides the required eight factor evaluation.

Briefly, the information gathered and reviewed by DEA and the scientific and medical evaluation by the Acting Assistant Secretary for Health shows that 3-methylfentanyl: (1) Is a very potent analog of fentanyl, a Schedule II narcotic substance, (2) produces the narcotic effects of a typical morphine-like compound including physical dependence after chronic administation, (3) is not approved for marketing by the Food and Drug Administration or commercially available in the United States, (4) is manufactured in clandestine laboratories, (5) has been identified by forensic laboratories in submissions of drug evidence from the East and West Coasts, (6) has been responsible for a least a portion of the narcotic overdose deaths attributed to fentanyl-like substances, and (7) continues to pose a threat to the public health and safety.

Based on the information gathered and reviewed by DEA and relying on the scientific and medical evaluation and scheduling recommendation of the Assistant Secretary for Health in accordance with 21 U.S.C. 811(c), the Administrator of the Drug Enforcement Administration, pursuant to the provisions of 21 U.S.C. 811(a), finds that:

1. Based on information now available, 3-methylfentanyl has a high potential for abuse;

2. 3-Methylfentanyl has no currently accepted medical use in treatment in the United States; and

3. There is a lack of accepted safety for use of 3-methylfentanyl under medical supervision.

The Administrator further finds that 3-methylfentanyl is an opiate as defined in 21 U.S.C. 802(18) since it has an addiction-forming and addiction-sustaining liability similar to that of morphine. Consequently, 3-methylfentanyl is a narcotic since the definition of a narcotic, as stated in 21 U.S.C. 802(17)(A) includes: "Opium, opiates, derivatives of opium and opiates."

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 DEA by Department of Justice Regulations (28 CFR 0.100), the Administrator hereby

proposes that 21 CFR 1308 be amended as follows:

PART 1308—[AMENDED]

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

Authority: 21 U.S.C. 811, 812, 871(b).

2. Paragraph (b) of § 1308.11 is revised by adding a new subparagraph (b)(31) and redesignating the existing subparagraphs (b)(31) through (b)(46) as (b)(32) through (b)(47):

§ 1308.11 Schedule I

* * * * *

(b) * * *

(31) 3-Methylfentanyl (N-[3-methyl-1-(2-phenethyl)-4-piperidyl]-N-phenyl-propanamide)—9813.

* * * * *

Interested persons are invited to submit their comments, objections or requests for hearing in writing with regard to this proposal. Requests for a hearing should state with particularity the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, 1405 I Street NW., Washington, DC 20537, Attention: DEA Federal Register Representative.

In the event that comments, objections or requests for a hearing raise one or more issues which the Administrator finds warrant a hearing, the Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the issues to be heard and setting the time for the hearing which will not be less than 30 days after the date of the notice.

Pursuant to Title 5, United States Code, section 605(b), the Administrator certifies that the proposed placement of 3-methylfentanyl into Schedule I of the Controlled Substances Act will have no impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). The substance, 3-methylfentanyl, proposed for control in this notice, has no legitimate use or manufacturer in the United States. In accordance with the provisions of Title 21, United States Code, section 811(a), this proposal to place 3-methylfentanyl into Schedule I, is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557, and as such, have been exempted from the consultation requirements of Executive Order 12291 (46 FR 13193).

Dated: April 21, 1986.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 86-9126 Filed 4-23-86; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

Oil and Gas and Sulphur Operations in the Outer Continental Shelf

AGENCY: Minerals Management Service, Interior.

ACTION: Proposed rule.

SUMMARY: The proposed rule would establish procedures to obtain testimony from witnesses or persons who have knowledge of serious accidents, fires, blowouts, or spills that occurred during oil, gas, or sulphur operations in the Outer Continental Shelf (OCS).

The testimony is needed by accident investigative panels to determine the cause or probable cause of an accident under investigation. These procedures would facilitate meetings of the investigative panels.

DATE: Comments must be hand-delivered or postmarked no later than May 27, 1986.

ADDRESS: Written Comments must be mailed or hand-delivered to the Department of the Interior; Minerals Management Service; 12203 Sunrise Valley Drive, Mail Stop 646; Reston, Virginia 22091; Attention: David A. Schuenke.

FOR FURTHER INFORMATION CONTACT: David A. Schuenke, telephone: (703) 648-7816, (FTS) 959-7816.

SUPPLEMENTARY INFORMATION: Section 22(d) of the Outer Continental Shelf Lands Act (OCSLA) provides that the Secretary of the Interior, or the Secretary of the Department in which the U.S. Coast Guard (USCG) is operating, shall make an investigation and public report on major fires, oil spills, deaths, and serious injuries occurring as a result of operations conducted pursuant to the OCSLA.

For any given spill or accident, the decision as to whether the Minerals Management Service (MMS) or the USCG will be the lead Agency in the investigation is determined by the provisions of a Memorandum of Understanding (MOU) between the U.S. Geological Survey and the USCG published in the **Federal Register** on January 8, 1981 (46 FR 2199). The MMS is party to the MOU after it succeeded to the authority of the U.S. Geological Survey's Conservation Division concerning activity in the OCS by direction of Secretarial Order 3071 dated January 19, 1982.

When MMS is the lead Agency in the investigation of a major accident, an investigative panel may be appointed by the Regional Director in whose Region the accident occurred. The panel may convene a meeting to take testimony from persons who have witnessed or are knowledgeable of the accident under investigation. Since such meetings affect persons other than MMS personnel, MMS has concluded that rules pertaining to the conduct of such meetings should be proposed.

The purpose of the meetings is to provide the investigative panel a forum by which to obtain information to aid in determining the cause or probable cause of the accident under investigation. Such meetings are not intended to be adversarial proceedings, and the proposed rule would preclude cross-examination of the persons giving testimony or interference with the meeting's progress.

Inasmuch as it is recognized that the meeting transcripts may be subject to other proceedings of an adversarial nature and further that the investigative panel's report on the accident may document lapses in compliance with regulations and Order, provisions are included to allow the presence of legal counsel during the questioning of witnesses.

Provisions pertaining to location, testimony under oath, verbatim transcripts, subpoena power, and travel expenses are also included.

Executive Order 12291

The purpose of this proposal is to provide procedures for accident investigative panels. These procedures would not increase prices for consumers nor would they result in major cost increases for individual industries, Federal, State, or local government agencies, or geopraphic regions. Based on this assessment, the Department of the Interior (DOI) has determined that this document does not constitute a major rule under Executive Order 12291; therefore, a Regulatory Impact Analysis is not required.

Regulatory Flexibility Act

The DOI has also determined that since this rule is procedural in nature, it would not have a significant economic effect on a substantial number of small entities.