

**§ 3.8 Public Information and submittals.**

(See also § 1.36 of this chapter regarding public information and Freedom of Information Act requests.)

\* \* \* \* \*

5. Section 3.8(b) is amended in the eighth sentence by replacing the word "Secretary" with the word "Commission"

6. Section 3.8 is further amended by adding a new paragraph (k) at the end thereof to read as follows:

\* \* \* \* \*

(k) *Fees for Freedom of Information Act requests.*—(1) *Definitions.* For purposes of this paragraph the following definitions apply.

(i) "Freedom of Information Act request" means a written request for public records in the possession of the Commission, which request is filed pursuant to section 552(a)(3) of the Freedom of Information Act (5 U.S.C. 552) and in accordance with § 1.36 of this chapter.

(ii) "Professional employee" means an employee of the Commission whose official grade level is GS-10 or above.

(iii) "Clerical employee" means an employee of the Commission whose official grade level is GS-9 or below.

(2) *Search fees.* If Commission response to a Freedom of Information Act request requires search of Commission records, the requester will be charged for the search at the following rates:

(i) \$4.00 per quarter hour for search services performed by a professional employee; and

(ii) \$2.00 per quarter hour for search services performed by a clerical employee.

(3) *Duplication fees.* If Commission response to a Freedom of Information Act request requires the duplication of documents, and:

(i) If the duplication is done by Commission staff, the requester will be charged 10 cents per photocopy plus postage; or

(ii) If the duplication is done by an independent contractor, the requester will be charged in accordance with a uniform fee schedule for photocopies, and microfiche and microfilm duplication, plus postage. The uniform fee schedule is set by contract with the independent contractor and may be obtained in person, by telephone, or by mail from the Division of Public Information.

(4) *No fees charged below minimum.* If the total fees assessed for search and duplication services performed by Commission staff in response to a Freedom of Information Act requests, or to a series of related request, are \$5.00

or less, the Commission will not charge the requester for those services.

(5) *Waiver or reduction of fees.* At the time a Freedom of Information Act request is filed with the Commission, the requester may petition the Commission for waiver, or reduction, of the fees described in this paragraph. The requester should show that waiver or reduction of the fees is in the public interest, because the requester's receipt of the information primarily benefits the general public. If the Commission determines that waiver, or reduction, of fees is in the public interest, the requested information will be furnished without charge or at a reduced rate.

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

#### Schedules of Controlled Substances; Proposed Placement of Alpha- Methylfentanyl into Schedule I

**AGENCY:** Drug Enforcement Administration, Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This notice of proposed rulemaking is issued by the Acting Administrator of the Drug Enforcement Administration to place the substance, alpha-methylfentanyl, into Schedule I of the Controlled Substances Act (CSA). This action was initiated upon the receipt of a letter from the Assistant Secretary for Health, Department of Health and Human Services (DHHS), who recommended that alpha-methylfentanyl be placed into Schedule I of the CSA, and DEA's review of the abuse and trafficking of this substance. This proposed action would impose the control mechanisms and criminal sanctions of Schedule I on the manufacturing, distribution and possession of alpha-methylfentanyl.

**DATE:** Comments must be submitted on or before September 4, 1981.

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

**FOR FURTHER INFORMATION CONTACT:** Howard McClam, Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: (202) 633-1366.

**SUPPLEMENTARY INFORMATION:** On May 4, 1981, the Administrator of the Drug

Enforcement Administration, submitted information relevant to the abuse potential and illicit trafficking of N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionamide, or alpha-methylfentanyl to the Acting Assistant Secretary for Health. Briefly, the information documented that alpha-methylfentanyl, trafficked on the street as "China White" (1) is an analogue of the Schedule II narcotic, fentanyl, (2) has no legitimate medical use or manufacturer in the United States, (3) produces a typical morphine-like profile, with an analgesic potency roughly 100 times that of morphine, and (4) has been shown to suppress withdrawal symptoms in morphine-dependent monkeys. Additionally, forensic laboratories have identified alpha-methylfentanyl in over 25 drug evidence submissions since January 1980, Narcotic Treatment Program Directors report their clients use of alpha-methylfentanyl, and medical examiners have associated at least nine overdose deaths with the use of alpha-methylfentanyl.

In accordance with the provisions of 21 U.S.C. 811(b), the DEA Administrator requested a scientific and medical evaluation of the relevant information and a scheduling recommendation for alpha-methylfentanyl from the Assistant Secretary for Health. On July 28, 1981, the Acting Administrator of the Drug Enforcement Administration received a letter from the Assistant Secretary for Health, acting on behalf of the Secretary of the Department of Health and Human Services, recommending that alpha-methylfentanyl be placed into Schedule I of the Controlled Substances Act (21 U.S.C. 801 *et seq.*) without further delay. The letter of the Assistant Secretary is set forth below:

July 27, 1981.

Mr. Francis Mullen, Jr.,  
Acting Administrator, Drug Enforcement  
Administration, 1405 Eye Street, N.W.,  
Washington, D.C.

Dear Mr. Mullen: Pursuant to the Controlled Substances Act, 21 U.S.C., 811(c)(CSA), this letter is notification of DHHS' recommendation for control of alpha-methylfentanyl into Schedule I of the CSA.

Alpha-methylfentanyl is a substance with narcotic-like pharmacological activity on the central nervous system. It has no accepted medical use in treatment in the United States. The substance is clandestinely synthesized, illicitly sold and abused, and is known on the street as "China white." The Food and Drug Administration (FDA) reviewed the document entitled "Control Recommendation for Alpha-methylfentanyl," prepared by your scientific staff, and found it accurate, thorough, and complete.

The eight factors listed in CSA Section 201(c), 21 U.S.C. 811(c), were reviewed. Based

on this review, the findings required by Section 202(b) of the CSA, 21 U.S.C. 812(b) are as follows:

- A. Alpha-methylfentanyl has a high potential for abuse.
- B. Alpha-methylfentanyl has no currently accepted medical use in treatment in the United States.
- C. There is a lack of accepted safety for use of alpha-methylfentanyl under medical supervision.

The FDA considers your position scientifically sound and has recommended that alpha-methylfentanyl be scheduled into Schedule I of the CSA without further delay. I concur with that recommendation.

Should you have any questions concerning this issue, the FDA Drug Abuse Staff is prepared to respond.

Sincerely yours,  
Edward N. Brandt, Jr.,  
*Assistant Secretary for Health.*

Based upon the investigations and review of the Drug Enforcement Administration and relying on the scientific and medical evaluation and the recommendation of the Secretary of Health and Human Services in accordance with 21 U.S.C. 811(c), the Acting 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, alpha-methylfentanyl has high potential for abuse;
2. Alpha-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 alpha-methylfentanyl under medical supervision.

The Acting Administrator further finds that alpha-methylfentanyl is an opiate as defined in 21 U.S.C. 802(17) since it has addiction-forming and addiction-sustaining liabilities similar to those of morphine. Consequently, alpha-methylfentanyl is a narcotic since the definition of narcotic, as stated in 21 U.S.C. 802(16)(A) includes: " \* \* \* Opium, coca leaves and opiates."

Under the authority vested in the Attorney General by Section 201(a) of the Act (21 U.S.C. 811(a)), and delegated to the Administrator of the Drug Enforcement Administration by Department of Justice regulations (21 CFR 0.100), the Acting Administrator hereby proposes that 21 CFR 1308.11(b)(6) be revised to read:

**§ 1308.11 Schedule I.**  
\* \* \* \* \*  
(b) \* \* \*  
(6) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl]proprionanilide).....9814  
\* \* \* \* \*  
and that 21 CFR 1308.11(b)(6)-(45) be renumbered 21 CFR 1308.11(b)(7)-(46).

Interested persons are invited to submit their comments, objections or requests for hearing in writing with regard to this proposal. Request for 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 Acting Administrator, Drug Enforcement Administration, 1405 I Street, N.W., Washington, D.C. 20537, Attention: DEA Federal Register Representative.

In the event that comments, objections or requests for hearing raise one or more issues which the Acting Administrator finds warrant a hearing, the Acting 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.

If no objections presenting grounds for a hearing on this proposal are received within the time limitation, or interested parties waive or are deemed to waive their opportunity for a hearing or to participate in a hearing, the Acting Administrator, after giving consideration to written comments and objections, will issue his final order pursuant to 21 CFR 1308.48 without a hearing. This section provides for the final order to specify an effective date for control which shall not be less than 30 days from the date of publication in the Federal Register unless the Acting Administrator finds that conditions of public health or safety necessitate an earlier effective date. The Acting Administrator, noting that the Assistant Secretary for Health recommends that alpha-methylfentanyl be scheduled into Schedule I of the CSA without further delay and recognizing that the use and abuse of alpha-methylfentanyl, has resulted in several overdose deaths, considers the health consequences attendant to its use to be of a very serious nature. Therefore, when the final order for the control of alpha-methylfentanyl is issued, the effective date of control will be August 5, 1981, unless evidence showing why this should not be is presented.

Pursuant to 5 U.S.C. 605(b), the Acting Administrator certifies that the placement of alpha-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, alpha-methylfentanyl, proposed for control in this notice, has no legitimate use or manufacturer in the United States.

In accordance with the provisions of 21 U.S.C. 811(a), this proposal to place alpha-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: July 30, 1981.  
Francis M. Mullen, Jr.,  
*Acting Administrator, Drug Enforcement Administration.*  
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**DEPARTMENT OF THE TREASURY**

**Bureau of Alcohol, Tobacco and Firearms**  
**27 CFR Part 4**  
[Notice No. 378; Ref: Notice No. 357]

**Multi-Vintage Labeling for Wine Under the Federal Alcohol Administration Act**  
**AGENCY:** Bureau of Alcohol, Tobacco and Firearms, Department of the Treasury.  
**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Bureau of Alcohol, Tobacco and Firearms (ATF) is proposing amendments to the wine labeling and advertising regulations which would allow the stating of distinct vintages and percentages from each on wine labels and in wine advertisements for blended wine. The labeling of multi-vintage dates and percentages would provide to consumers information that is accurate, specific, and truthful concerning blended wines.

In accordance with Executive Order 12291, this notice of proposed rulemaking is not classified as a major rule.  
**DATE:** Comments must be received on or before November 3, 1981.  
**ADDRESS:** Send comments to: Chief, Regulations and Procedures Division, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 385, Washington, DC 20044.

**FOR FURTHER INFORMATION CONTACT:** Roger L. Bowling, Research and Regulations Branch, 202-566-7626.  
**SUPPLEMENTARY INFORMATION:**

**Background**  
ATF has not, as a matter of policy, allowed the labeling of distinct vintages and the percentages of each on labels of