

(b) The statement of identity for a drug composed of a single active ingredient shall be the statement of identity established for that ingredient in the statement of identity section of the applicable OTC drug monograph established under Part 330 of this chapter, unless otherwise stated in an approved new drug application. The statement of identity for a drug composed of a combination of active ingredients shall be the established name of the combination, if there is any, followed by the statement of the general pharmacological category(ies)/principal intended action(s) of each ingredient as identified in the statement of identity section of the applicable OTC drug monographs established under Part 330 of this chapter, unless otherwise stated in an approved new drug application. In either case, if the drug does not have an established name or if there is no monograph established under Part 330 of this chapter, then the statement of identity shall consist only of a prominent and conspicuous statement of the general pharmacological category(ies) or the principal intended action(s) of each ingredient. The statement of identity shall be placed in direct conjunction with the most prominent display of the proprietary name or designation of the drug.

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Dated: March 28, 1986.

M.D. Kinslow,
Acting Associate Commissioner for
Regulatory Affairs.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposed Rescheduling of Alfentanil From Schedule I to Schedule II

AGENCY: Drug Enforcement
Administration, Justice.

ACTION: Notice of Proposed rulemaking.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) proposes to reschedule the Schedule I narcotic drug, alfentanil, to Schedule II of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). This action is initiated upon DEA's receipt of a letter from the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), recommending

that alfentanil be rescheduled from Schedule I to Schedule II. According to the Food and Drug Administration, alfentanil is a narcotic drug with a high potential for abuse and a new drug application for alfentanil will be approved in the near future. DEA's final decision concerning the relative abuse potential of alfentanil will take into account the Acting Assistant Secretary's recommendation and any information received in response to this proposal. The effects of this rule would be to require that the manufacture, distribution, dispensing, security, registration, record keeping, inventory, exportation and importation of this drug be subject to controls for Schedule II narcotic substances.

DATE: Written comments and objections must be received on or before May 19, 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.

By Federal Register final rule (49 FR 25849; June 25, 1984), alfentanil was controlled under Schedule I of the CSA, effective August 24, 1984. On January 31, 1986, the Acting Assistant Secretary for Health, on behalf of the Secretary, Department of Health and Human Services, sent to the Administrator of the Drug Enforcement Administration a letter recommending that alfentanil be rescheduled into Schedule II once it is approved for marketing and that alfentanil continue to be defined as a narcotic. Enclosed with the letter was a document prepared by the Food and Drug Administration entitled "Basis for the Rescheduling of Alfentanil From Schedule I to Schedule II of the Controlled Substances Act." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)) and the summarized recommendations regarding the rescheduling of alfentanil.

The factors considered by the Acting Assistant Secretary for Health with respect to the drug alfentanil were:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effect, if known;

(3) The state of current scientific knowledge regarding the drug (or other substance);

(4) Its history and current pattern of abuse;

(5) The scope, duration and significance of abuse;

(6) What, if any, risk to the public health;

(7) Its psychic or physiological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled under this title.

Based on the scientific and medical evaluation of the Food and Drug Administration and the recommendation of the Acting Assistant Secretary for Health, the Administrator of the Drug Enforcement Administration, pursuant to 21 U.S.C. 811(a) and 811(b), finds that:

(1) Based on all available information, alfentanil has a high potential for abuse.

(2) Alfentanil, upon final approval of a new drug application by the Food and Drug Administration, will have a currently accepted medical use in treatment in the United States.

(3) Abuse of this substance may lead to severe psychological or physical dependence.

Therefore, under the authority vested in the Attorney General (21 U.S.C. 811(a)) and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR 0.100), the Administrator hereby proposes that 21 CFR 1308 be 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, 871(b).

§ 1308.11 [Amended]

2. Section 1308.11 is amended by removing paragraph (b)(2) and redesignating paragraphs (b)(3) through (b)(46) as (b)(2) through (b)(45).

3. Paragraph (c) of § 1308.12 is amended by adding a new paragraph (c)(1) and redesignating the existing paragraphs (c)(1) through (c)(23) as (c)(2) through (c)(24):

§ 1308.12 Schedule II

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(c) * * *
(c)(1) alfentanil..... 9737
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Interested persons are invited to submit their comments or objections in writing regarding this proposal. If a person believes that one or more issues warrant a hearing, the reasons for such belief should be so stated and summarized. Comments, objections, and requests for hearing should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, 1405 I Street, NW., Washington, DC 20537, Attention: DEA Federal Register Representative.

If the Administrator finds that the written responses to this proposal raise one or more issues that warrant a hearing, then the Administrator will order a public hearing. A notice of the hearing will be published in the *Federal Register* summarizing the issues to be heard and setting a time for the hearing that will be at least 30 days after publication of the notice.

If no objections presenting grounds for a hearing on this proposal are received within the time limitation or if interested parties waive or are deemed to have waived their opportunity for a hearing or to participate in a hearing, the Administrator, after giving consideration to written comments and objections, will issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the rescheduling of alfentanil, as proposed herein, will have no significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). Many of the regulatory requirements imposed on Schedule II substances are similar to those imposed on Schedule I substances. Additionally, substances in Schedule II may be used in medical treatment in the United States.

In accordance with the provisions of 21 U.S.C. 811(a), this proposal to reschedule alfentanil from Schedule I to Schedule II 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 10, 1986.

John C. Lawn,

Administrator, Drug Enforcement Administration.

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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Parts 1254 and 1260

Records Declassification

AGENCY: National Archives and Records Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would reorganize National Archives and Records Administration (NARA) regulations concerning the declassification of classified records for which NARA has declassification authority. The rule will remove material which is duplicative and extend the time NARA has to forward to the responsible agency requests for declassification of classified information less than 30 years old.

DATE: Comments must be received by May 19, 1986.

ADDRESS: Comments should be sent to Director, Program Policy and Evaluation Division (NAA), National Archives and Records Administration, Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT: Adrienne C. Thomas or Nancy Allard at 202-523-3214 (FTS 523-3214).

SUPPLEMENTARY INFORMATION: The regulations in 36 CFR Parts 1254 and 1260 were originally published at 49 FR 1349 (Part 1254) and 49 FR 1344 (Part 1260) on January 11, 1984 and codified in 41 CFR Chapters 101 and 105. After NARA became an independent agency on April 1, 1985, pursuant to Pub. L. 98-497, the subject regulations in Title 41 of the CFR were recodified in 36 CFR Parts 1254 and 1260.

This proposed rule removes from Part 1254 procedures for mandatory review of classified information which are already contained in Part 1260, and removes from Part 1260 procedures for public requests for mandatory review which are also found in § 1254.46. A reference to the procedures in § 1254.46 is added to § 1260.1. In addition, Subparts A and B of Part 1260 are combined because the procedures outlined in these subparts are the same for both classified U.S. originated information and foreign government information provided to the United States in confidence.

Section 1260.10(a) is further modified by changing the time limit from 20 days to 30 days for NARA to forward to the responsible agency mandatory review requests involving information less than 30 years old. The ISOO implementing directive allows an agency 30 days to respond to a mandatory review request.

Because of an increase in demand, the volume of records involved in many requests, and the decrease in personnel resources for this activity, NARA has difficulty in meeting the shorter deadline.

This rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981. As required by the Regulatory Flexibility Act, it is hereby certified that this proposed rule will not have a significant impact on small business entities.

List of Subjects in 36 CFR Parts 1254 and 1260

Archives and records, Classified information.

For the reasons set forth in the preamble, NARA proposes to amend Title 36 of the Code of Federal Regulations as follows:

PART 1254—AVAILABILITY OF RECORDS AND DONATED HISTORICAL MATERIALS

1. The authority citation for Part 1254 continues to read as follows:

Authority: 44 U.S.C. 2101-2118.

§§ 1254.42 and 1254.44 [Redesignated]

2. Section 1254.42 is redesignated as § 1254.44, § 1254.44 is redesignated as § 1254.42, and the internal reference in paragraph (c) of the redesignated § 1254.44 is amended to read "§ 1254.42."

§§ 1254.48 through 1254.54 [Removed]

3. Sections 1254.48, 1254.50, 1254.52, and 1254.54 are removed.

§ 1254.56 [Redesignated]

4. Section 1254.56 is redesignated as § 1254.48.

§ 1254.58 [Redesignated]

5. Section 1254.58 is redesignated as § 1254.50.

PART 1260—DECLASSIFICATION OF AND PUBLIC ACCESS TO NATIONAL SECURITY INFORMATION

6. The authority citation for Part 1260 continues to read as follows:

Authority: 44 U.S.C. 2104(a); Executive Order 12356 of April 2, 1982 (3 CFR 1982 Comp., p. 166).

7. Section 1260.1 is revised to read as follows:

§ 1260.1 Scope of part.

Declassification of and public access to national security information and material (hereafter referred to as "classified information" or collectively termed "information") is governed by