

$$\text{Milligrams of ceforanide per vial} = \frac{A_u \times P_s \times d}{A_s \times 1,000}$$

where:

A_u = Area of the ceforanide sample peak (at a retention time equal to that observed for the standard);

A_s = Area of the ceforanide peak in the chromatogram of the ceforanide working standard;

P_s = Ceforanide activity in the ceforanide working standard solution in micrograms per milliliter; and

d = Dilution factor of the sample.

(2) *Sterility*. Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except reconstitute the vials with approximately 3.0 milliliters of diluting fluid A per each gram of antibiotic activity. Transfer approximately 1 milliliter from each of 20 vials into a sterile 500-milliliter Erlenmeyer flask containing 200 milliliters of diluting fluid A. Filter as described in paragraph (e)(1)(ii) of this section, except in lieu of filtering with three 100-milliliter quantities of diluting fluid A, rinse the filter membrane with three 100-milliliter portions of diluting fluid D followed by a final rinse with 100-milliliters of diluting fluid A.

(3) *Pyrogens*. Proceed as directed in § 436.32(b) of this chapter, using a solution containing 50 milligrams of ceforanide per milliliter.

(4) *Moisture*. Proceed as directed in § 436.201 of this chapter.

(5) *pH*. Proceed as directed in § 436.202 of this chapter, using the solution obtained when the product is reconstituted as directed in the labeling.

This regulation announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this regulation is not controversial and because when effective it provides notice of accepted standards, notice and comment procedure and delayed effective date are found to be unnecessary and not in the public interest. The amendment, therefore, is effective June 25, 1984. Interested persons may, however, on or before July 25, 1984, submit written comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number in brackets in the heading of this document. Received comments may be seen in the Dockets

Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before July 25, 1984, a written notice of participation and request for hearing, and (2) on or before August 24, 1984, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 430.20. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket number appearing in the heading of this order and filed with the Dockets Management Branch.

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 430.20.

All submissions under this order, except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall be effective June 25, 1984.

(Secs. 507, 701 (f) and (g), 52 Stat. 1055-1059 as amended, 59 Stat. 463 as amended (21 U.S.C. 357, 371 (f) and (g)))

Dated: June 13, 1984.

Daniel L. Michels,
Director, Office of Compliance, Center for
Drugs and Biologics.

[FR Doc. 84-16763 Filed 6-22-84; 8:45 am]
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DEPARTMENT OF JUSTICE
Drug Enforcement Administration
21 CFR Part 1308

Schedules of Controlled Substances;
Placement of Alfentanil in Schedule I

AGENCY: Drug Enforcement
Administration, Department of Justice.
ACTION: Final rule.

SUMMARY: This is a final rule issued by the Administrator of the Drug Enforcement Administration placing alfentanil into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). This action is required in order for the United States to discharge its obligations under the Single Convention on Narcotic Drugs, 1954.

EFFECTIVE DATE: August 24, 1984 except as otherwise provided in the SUPPLEMENTARY INFORMATION Section of this Rule.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: 202-633-1368.

SUPPLEMENTARY INFORMATION:
List of Subjects in 21 CFR Part 1308

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

By a letter dated March 27, 1984, the Secretary-General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs has decided that the narcotic drug, alfentanil, be added to Schedule I of the Single Convention on Narcotic Drugs, 1954.

Section 201(d)(1) of the CSA (21 U.S.C. 811(d)) states that, if control of a substance is required by United States obligations under the Single Convention on Narcotic Drugs, 1954, "the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings and procedures required by section 201 (a) and (b) (21 U.S.C. 811 (a) and (b)) and section 202(b) (21 U.S.C. 812(b)) of the Act." This responsibility has been delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR 0.100).

In order to meet the obligations of the United States as a Party to the Single Convention on Narcotic Drugs, 1954, and because alfentanil has no currently accepted medical use in the United

States, the Administrator of the Drug Enforcement Administration has determined that alfentanil should be placed into Schedule I of the CSA.

Effective Dates

1. *Registration.* Any person who manufactures, distributes, imports, exports, engages in research, or conducts instructional activities with respect to alfentanil, or who proposes to engage in such activities, shall submit an application for registration to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations on or before August 24, 1984.

2. *Security.* Alfentanil must be manufactured, distributed and stored in accordance with §§ 1301.71-1301.76 of Title 21 of the Code of Federal Regulations on or before September 24, 1984. In the event that the effective date should pose special hardships, the Drug Enforcement Administration will entertain any justified requests for extensions of time submitted to it on or before the required date of compliance.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of alfentanil, packaged after August 24, 1984, shall comply with the requirements of §§ 1302.03-1302.05 and 1302.07-1302.08 of Title 21 of the Code of Federal Regulations. In the event this effective date imposes special hardships on any "manufacturer," as defined in section 102(14) of the CSA (21 U.S.C. 802(14)), the Drug Enforcement Administration will entertain any justified requests for extensions of time submitted to it on or before the required date of compliance.

4. *Quotas.* All persons required to obtain quotas for alfentanil shall submit applications pursuant to §§ 1303.12 and 1303.22 of Title 21 of the Code of Federal Regulations on or before August 24, 1984.

5. *Inventory.* Every registrant required to keep records, who possesses any quantity of alfentanil, shall take an inventory, pursuant to §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of alfentanil on hand on August 24, 1984.

6. *Records.* All registrants required to keep records pursuant to §§ 1304.21-1304.27 of Title 21 of the Code of Federal Regulations shall maintain such records on alfentanil commencing on the date on which the inventories of these substances are taken.

7. *Reports.* All registrants required to submit reports on alfentanil to the Drug Enforcement Administration pursuant to §§ 1304.37-1304.41 of Title 21 of the Code of Federal Regulations shall report on the inventory taken under paragraph

5 above and on all subsequent transactions.

8. *Order Forms.* Each distribution of alfentanil on or after August 24, 1984, shall utilize an order form pursuant to Part 1305 of Title 21 of the Code of Federal Regulations.

9. *Importation and Exportation.* All importation and exportation of alfentanil on and after August 24, 1984, shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

10. *Criminal Liability.* The Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to alfentanil not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, conducted August 24, 1984, shall be unlawful, except that any person who is not now registered to handle alfentanil but who is entitled to registration under such Acts may continue to conduct normal business or professional practice with alfentanil between the date on which this rule is published and the date which he (she) obtains or is denied registration; provided, that the application for such registration is submitted on or before August 24, 1984.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the placement of alfentanil into Schedule I of the CSA will have no impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). This action involves the initial control of a substance with no legitimate medical use in the United States and must be carried out in order to fulfill United States international treaty obligations, in any event.

In accordance with the provisions of 21 U.S.C. 812(d)(1), this scheduling action is a formal rulemaking that is required by United States obligations under international convention, that is, the Single Convention on Narcotic Drugs, 1961. Such formal 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 12991 (46 FR 13193).

Dated: June 15, 1984.
Francis M. Mullen, Jr.,
Administrator, Drug Enforcement Administration.

PART 1308—[AMENDED]

Therefore, under the authority vested in the Attorney General by Section 201(d)(1) of the CSA (21 U.S.C. 812(d)) and delegated to the Administrator of

the Drug Enforcement Administration pursuant to 28 CFR 0.100, the Administrator hereby orders that:

(1) 21 CFR 1308.11(b)(2)-(45) is redesignated as 21 CFR 1308.11(b)(3)-(46); and

(2) A new § 1308.11(b)(2) is added to read as follows:

§1308.11 Schedule I.
* * * * *
(b) * * *

(2) Alfentanil 9737

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[FR Doc. 84-16335 Filed 6-22-84; 8:45 am]
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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 888

[Docket No. R-84-1137; FR-1864]

Section 8—Fair Market Rents for New Construction and Substantial Rehabilitation

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This rule amends the Section 8 Fair Market Rents (FMRs) applicable to New Construction and Substantial Rehabilitation for the State of Georgia, as well as for market areas within the States of New York, Ohio, and Texas. Section 8(c)(1) of the U.S. Housing Act of 1937 requires HUD to publish revised FMRs annually in the Federal Register. HUD published the last annual revision of the FMRs for New Construction and Substantial Rehabilitation on February 8, 1984 as an Interim Rule for effect on March 21, 1984. Many of the changes made in this rule are in response to comments submitted with respect to that annual revision. This rule revises FMR schedules for several of the nine market areas in the State of Georgia; it consolidates two market areas into one in the State of Texas; and it provides FMRs for efficiency (zero bedroom) units in eight other market areas in the States of New York and Ohio.

EFFECTIVE DATE: September 13, 1984.

FOR FURTHER INFORMATION CONTACT: Edward M. Winarski, Chief Appraiser, Valuation Branch, Technical Support