(a) The Director and Deputy Director, Center for Drugs and Biologics (CDB).

(b) For drugs assigned to their respective offices, the Directors and Deputy Directors of the Offices of: Drug Research and Review and Biologics Research and Review, CDB.

(c) For drugs assigned to their respective divisions, the Directors and Deputy Directors of the Divisions within the Offices of Drug Research and Review and Biologics Research and Review, CDB.

Dated: January 20, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-1502 Filed 1-22-87; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 357

[Docket No. 79N-0378]

Anthelmintic Drug Products for Over-the-Counter Human Use; Final Monograph; OMB Approval of Requirements

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Office of Management and Budget (OMB) has approved the collection of information requirement concerning its final rule on over-the-counter (OTC) anthelmintic drug products. The agency is amending that regulation to reflect OMB's approval.

EFFECTIVE DATE: February 2, 1987.

FOR FURTHER INFORMATION CONTACT: William E. Gilberton, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 1, 1986 (51 FR 27756), FDA issued a final rule in the form of a final monograph effective February 2, 1987 establishing conditions under which OTC anthelmintic drug products (products that destroy pinworms) are generally recognized as safe and effective and not misbranded. In that document (51 FR 27758-27759), FDA announced that it had submitted the final rule to the Office of Management and Budget (OMB) for approval of the collection of information requirement contained in § 357.152.

OMB has approved the collection of information requirement under OMB control number 0910-0232. This document announces OMB's approval and amends the regulation to reflect that approval.

Because this amendment is nonsubstantive, notice and public procedure are unnecessary (5 U.S.C. 553 (b)(B) and (d)).

List of Subjects in 21 CFR Part 357

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR Part 357 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

2. In § 357.152 by adding a parenthetical statement at the end of the section, to read as follows:

§ 357.152 Package inserts for anthelmintic drug products.

* * * * *

(Collection of information requirement approved by the Office of Management and Budget under number 0910-0232)

Dated: January 15, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-1501 Filed 1-22-87; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Placement of 1-Methyl-4-phenyl-4-propionoxypiperidine (MPPP) and 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP) 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 place the narcotic substances, 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP) and 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP) into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). This action is based on findings made by the DEA Administrator that both MPPP and PEPAP meet the statutory criteria for inclusion in Schedule I of the CSA. These findings are in agreement with the independent reviews and evaluations of relevant data conducted by both DEA and the Assistant Secretary for Health, Department of Health and Human Services. As a result of this final rule, the regulatory controls and criminal sanctions of Schedule I will be applicable to the manufacture, distribution, importation and exportation of MPPP and PEPAP.

EFFECTIVE DATE: January 23, 1987.

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

SUPPLEMENTARY INFORMATION: MPPP and PEPAP are potent analogs of meperidine, a Schedule II synthetic narcotic analgesic. Produced in clandestine laboratories, MPPP and PEPAP have been identified in the illicit drug traffic and MPPP in particular has been associated with the production of drug-induced Parkinson's disease in a number of users.

Based on the data available to him in 1985, the DEA Administrator determined that emergency scheduling of MPPP and PEPAP into Schedule I of the CSA was necessary to avoid an imminent hazard to the public safety. Therefore, in a **Federal Register** notice (50 FR 28098-100) dated July 10, 1985, the DEA Administrator, pursuant to the emergency scheduling provisions of 21 U.S.C. 811(h), placed MPPP and PEPAP into Schedule I of the CSA for one year effective on August 12, 1985. The temporary scheduling of MPPP and PEPAP was extended until February 12, 1987 in a subsequent **Federal Register** notice (51 FR 28695-6).

Following an independent review of the relevant data on MPPP and PEPAP by DEA and a scientific and medical evaluation of these substances by the Assistant Secretary for Health, the DEA Administrator, pursuant to 21 U.S.C. 811, proposed the permanent placement of MPPP and PEPAP into Schedule I of the CSA (August 11, 1986, 51 FR 28725-6). Interested parties were given until September 10, 1986 to submit comments or objections in writing regarding this proposal. During this 30-day period, DEA did not receive any comments or objections to the proposed scheduling action.

Based upon the investigations and review conducted by DEA and upon the scientific and medical evaluation and recommendation of the Assistant

Secretary for Health, the DEA Administrator, pursuant to the provisions of 21 U.S.C. 811 (a) and (b), finds that:

(1) MPPP and PEPAP have a high potential for abuse;

(2) MPPP and PEPAP have no currently accepted medical use in treatment in the United States; and

(3) MPPP and PEPAP lack accepted safety for use under medical supervision.

The above findings are consistent with the placement of MPPP and PEPAP into Schedule I of the CSA. The Administrator further finds that MPPP and PEPAP are opiates as defined in 21 U.S.C. 802(18) since both have an addiction-forming and addiction-sustaining liability similar to that of morphine. Consequently, MPPP and PEPAP are narcotics since the definition of narcotic, as stated in 21 U.S.C. 802(17)(A), includes: "Opium, opiates, derivatives of opium and opiates."

In accordance with 21 U.S.C. 811(h)(5) the emergency scheduling order for MPPP and PEPAP shall be vacated on the effective date of this final rule permanently placing MPPP and PEPAP into Schedule I of the CSA.

Since MPPP and PEPAP are already under temporary control in Schedule I, all regulations applicable to Schedule I narcotic substances will continue to be effective.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the placement of MPPP and PEPAP 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 permanent control of a substance with no legitimate medical use or manufacture in the United States.

In accordance with the provisions of 21 U.S.C. 811(a), this scheduling action is a formal rulemaking "on the record after opportunity for a hearing." 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 12291 (46 FR 13193).

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(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 orders that 21 CFR 1308.11 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. Section 1308.11 is amended by redesignating the existing paragraphs (b)(33) through (b)(36) and (b)(37) through (b)(47) as (b)(34) through (b)(37) and (b)(39) through (b)(49), respectively and by adding new paragraphs (b)(33) and (b)(38) to read as follows:

* * * * *

(b) * * *

(33) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine).....9661

* * * * *

(38) PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine.....9663

* * * * *

§ 1308.11 [Amended]

3. Section 1308.11 is amended by removing paragraphs (g)(2) and (g)(3) and redesignating the existing paragraphs (g)(4) through (g)(12) as (g)(2) through (g)(10).

Dated: January 16, 1987.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 87-1400 Filed 1-22-87; 8:45 am]

BILLING CODE 4410-09-M

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21 CFR Part 1308

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

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) in order to reschedule alfentanil, a narcotic substance, from Schedule I to Schedule II of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). This action follows final approval by the Food and Drug Administration (FDA) of a new drug application for alfentanil. Alfentanil is being moved into Schedule II because it has been approved by FDA as being safe and effective for indicated uses in medicine. As a result of this rule, the regulatory controls and criminal sanctions of a Schedule II narcotic substance under the CSA will be applicable to the manufacture, distribution, importation and exportation of alfentanil.

EFFECTIVE DATE: January 23, 1987.

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

SUPPLEMENTARY INFORMATION: A notice was published in the **Federal Register** on April 17, 1986 (51 FR 13025) proposing that alfentanil be transferred from Schedule I to Schedule II of the CSA. Interested persons were given until May 19, 1986, to submit comments or objections regarding the proposal. No correspondence of any kind was received regarding the proposal. Furthermore, according to the December 29, 1986 letter from Paula Botstein, M.D., Acting Deputy Director, Office of Drug Research and Review, Center for Drugs and Biologics, Food and Drug Administraion, the new drug application for alfentanil has been approved.

Based on the scientific and medical evaluation and recommendation contained in a January 31, 1986 letter from the Acting Assistant Secretary for Health, Department of Health and Human Services, the Administrator of the DEA, pursuant to the provisions of 21 U.S.C. 811(a) and (b), finds that:

(1) Alfentanil has a high potential for abuse;

(2) Alfentanil has a currently accepted medical use in treatment in the United States; and

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

The above findings are consistent with the placement of alfentanil into Schedule II of the CSA. The Administrator further finds that alfentanil is an opiate as defined in 21 U.S.C. 802(18) since it has an addiction-forming and addiction-sustaining liability similar to morphine. Consequently, alfentanil is a narcotic since the definition of narcotic, as stated in 21 U.S.C. 802(17)(A), includes: "Opium, opiates, derivatives of opium and opiates."

Regulations that are effective on January 23, 1987 and imposed on alfentanil are as follows:

1. *Registration.* Any person who manufactures, distributes, engages in research, imports or exports alfentanil or who proposes to engage in alfentanil's manufacture, distribution, importation, exportation or research shall obtain a registration to conduct that activity by (date of publication in Federal Register), pursuant to Part 1301 of Title 21 of the Code of Federal Regulations.

2. *Security.* Alfentanil must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(a)(c)(d), 1301.73, 1301.74, 1301.75(b)(c) and 1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and packaging.* All labels on commercial containers of, and all labeling of, alfentanil which is packaged after January 23, 1987 shall comply with the requirements of §§ 302.03–1302.05 and 1302.07–1302.08 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* Quotas for alfentanil are established pursuant to Part 1303 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Registrants possessing alfentanil are required to take inventories pursuant to §§ 1304.04 and 1304.11–1304.19 of Title 21 of the Code of Federal Regulations.

6. *Records.* All registrants must keep records pursuant to §§ 1304.04 and 1304.21–1304.29 of Title 21 of the Code of Federal Regulations.

7. *Reports.* All registrants are required to file reports pursuant to §§ 1304.31–1304.41 of Title 21 of the Code of Federal Regulations.

8. *Order Forms.* Each distribution of alfentanil requires the use of an order form pursuant to Part 1305 of Title 21 of the Code of Federal Regulations.

9. *Prescriptions.* As alfentanil has been approved by the FDA for use in medical treatment, the drug may be dispensed by prescription. Prescriptions for alfentanil are to be issued pursuant to §§ 1306.01–1306.07 and 1306.11–1306.15.

10. *Importation and Exportation.* All importation and exportation of alfentanil shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

11. *Criminal Liability.* Any activity with alfentanil not authorized by or in violation of the CSA or the Controlled Substances Import and Export Act continues to be unlawful. The applicable penalties before January 23, 1987 shall be those of a Schedule I narcotic controlled substance. On January 23, 1987, alfentanil for the purposes of criminal liability shall be treated as a Schedule II narcotic controlled substance. The penalties associated with Schedule I or II narcotic substances are the same.

12. *Other.* In all other respects, this order is effective on January 23, 1987.

Pursuant to Title 5, United States Code, section 605(b), the Administrator certifies that the rescheduling of alfentanil, as ordered herein, will not have a significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96–354). Most of the regulatory requirements imposed on Schedule II substances are the same as those imposed on Schedule I substances. Substances in Schedule II, however, may be prescribed by registered practitioners for use in medical treatment in the United States.

In accordance with the provisions of section 201(a) of the CSA (21 U.S.C. 811(a)), this scheduling action 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).

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(a) of the CSA (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 Part 0.100), the Administrator hereby orders that 21 CFR Part 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)(49) as (b)(2) through (b)(48).

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

§ 1308.12 Schedule II.

* * * * *

(c) * * *

(c)(1) alfentanil..... 9737

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Dated: January 16, 1987.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 87–1401 Filed 1–22–87; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Part 800

Equal Pay For Equal Work Under the Fair Labor Standards Act

AGENCY: Wage and Hour Division, Labor.

ACTION: Final rule; removal of interpretative regulations.

SUMMARY: The Department of Labor is issuing a final rule to remove the interpretative regulations found at 29 CFR Part 800, which was promulgated under the equal pay provisions of the Fair Labor Standards Act.

On August 20, 1986, the Equal Employment Opportunity Commission published final interpretative regulations under the Equal Pay Act at 29 CFR Part 1620, thereby rendering obsolete and of no legal effect 29 CFR Part 800. Therefore the latter interpretative regulations are being removed from the CFR.

EFFECTIVE DATE: January 23, 1987.

FOR FURTHER INFORMATION CONTACT: Paula V. Smith, Administrator, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue, NW., Washington, DC 20210, (202) 523–8305. This is not a toll free number.

SUPPLEMENTARY INFORMATION: Pursuant to Reorganization Plan No. 1 of 1978, 43 FR 19807 (May 9, 1978), and Executive Order No. 12144, 44 FR 37193 (June 26, 1979), responsibility and authority for enforcement of the Equal Pay Act of 1963 (EPA), 29 U.S.C. 206(d), was transferred from the Department of Labor (DOL) to the Equal Employment Opportunity Commission (EEOC) on July 1, 1979. At that time, the EEOC published a notice in the **Federal Register** stating that the EEOC was not adopting the EPA interpretations and opinions of DOL as its own, although employers could continue to rely on them to the extent they were consistent with statutory revisions and judicial interpretations until the EEOC issued its own interpretations. 44 FR 38671 (July 2, 1979).

On August 20, 1986, the EEOC published its final interpretative regulations under the EPA in the **Federal Register,** 51 FR 29816, stating that employers may no longer rely upon the DOL interpretations of EPA at 29 CFR Part 800.

Accordingly, 29 CFR Part 800 has now been rendered obsolete and of no legal