Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857 from 9 a.m. to 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Under FDA s regulations implementing the National Environmental Policy Act (21 CFR Part 25), an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(4).

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 520 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

2. Part 520 is amended by adding new § 520.1193 *Ivermectin Tablets* to read as follows:

§ 520.1193 Ivermectin Tablets.

(a) *Specifications.* Each tablet contains 68, 136, or 272 micrograms of ivermectin.

(b) *Sponsor.* See 000006 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 6.0 micrograms per kilogram body weight (2.72 micrograms per pound), minimum. For dogs up to 25 pounds, 68 micrograms; dogs 26 to 50 pounds, 136 micrograms; dogs 51 to 100 pounds, 272 micrograms; dogs over 100 pounds, a combination of the appropriate tablets. The drug is administered at monthly dosing intervals.

(2) *Indications for use.* To prevent canine heartworm disease (*Dirofilaria immitis* infection) by eliminating the tissue stage of larvae.

(3) *Limitations.* Use once-a-month. Not for use in dogs under 6 weeks old. Initial use within a month after first exposure to mosquitoes. Final use within a month after last exposure to mosquitoes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: March 30, 1987

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 87–7578 Filed 4–6–87; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Placement of Nabilone Into 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) to place nabilone into Schedule II of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). Nabilone is a synthetic substance which is chemically and pharmacologically similar to the tetrahydrocannabinols. This action is based on a finding that nabilone fits the statutory criteria for inclusion in Schedule II of the CSA. As a result of this rule, the regulatory controls and criminal sanctions of Schedule II of the CSA will be applicable to the manufacture, distribution, importation and exportation of nabilone.

EFFECTIVE DATE: April 7 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 proposed rule was published in the **Federal Register** on June 18, 1986 (51 FR 22085–22086), proposing that nabilone be placed into Schedule II of the Controlled Substances Act (21 U.S.C. 801 *et seq.*). All persons were given until July 18, 1986 to submit any comments or objections in writing regarding the proposal.

Two comments, objections or requests for an administrative hearing were filed. Eli Lilly and Company, the manufacturer and developer of the drug supported the action. The other, Unimed, Inc., requested a hearing. Unimed, Inc. stated that it desired a hearing on its contention that a cautionary Statement Policy in DEA's final order controlling Unimed's product Marinol ought, likewise, to apply to nabilone.

DEA's Statement of Policy in the Marinol (dronabinol) order was included to satisfy United States obligations regarding the Schedule I classification of the substance under the Convention on Psychotropic Substances, 1971. Eli Lilly and Company, the manufacturer of nabilone, has advised DEA that it has no objection to the inclusion of a similar statement with respect to its product. However, since nabilone is not controlled under any of the international treaties to which the United States is a party, DEA does not believe that a similar Statement of Policy is required with respect to nabilone. To attach the Statement to substances not controlled under the Psychotropic Convention is not justified in this case. Additionally, DEA has no statutory obligation under the CSA to publish such a Statement regarding initial control measures; nor does the Statement of Policy have any relation to the issue at hand, that is, the listing of nabilone in Schedule II of the CSA

As with any Schedule II drug, the manufacture, distribution and dispensing of nabilone will be closely monitored by DEA. Scheduling II drugs are often subject to diversion into the illicit market, in many cases by DEA registrants. DEA will take action to revoke the registration of any registrant whose diversion of this, or any controlled substance, constitutes a threat to the public health and safety, and in addition will pursue any criminal sanctions which may be warranted under 21 U.S.C. 841(a)(1). See *United States* v. *Moore*, 423 U.S. 122 (1975).

The Unimed, Inc. request for a hearing for the singular purpose of seeking a cautionary Statement of Policy with respect to nabilone is denied. The Administrator finds that the scheduling of nabilone may continue without the need for a time-consuming hearing.

Having considered the comments and objections presented by the above listed parties, the requirements of the CSA, the Food and Drug Administration's conclusion that nabilone is a safe and effective drug under the provisions of the Federal Food, Drug and Cosmetic Act, the scientific and medical evaluation and the recommendation of the Acting Assistant Secretary for Health, acting on behalf of the Secretary of the Department of Health and Human Services, in accordance with 21 U.S.C. 811(b), the Administrator of the Drug Enforcement Administration, pursuant to the provisions of 21 U.S.C. 811(a) and 811(b), finds that:

(1) Based on available information, nabilone has a high potential for abuse

(2) Nabilone, with final approval of a new drug application by the Food and Drug Administration, has a currently accepted medical use in treatment in the United States.

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

The above findings are consistent with the placement of nabilone into Schedule II of the CSA. In order to avoid further delays in the initial marketing of nabilone, the control of nabilone in Schedule II will be effective on April 7 1987 In the event that the regulations impose special hardships on any registrant, the Drug Enforcement Administration will entertain any justified request for an extension of time to comply with the Schedule II regulations. The applicable regulations are as follows:

1. Registration. Any person who manufactures, distributes, delivers, imports or exports nabilone, or who engages in research or conducts instructional activities with the substance, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations.

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

3. Labeling and Packaging. All labels and labeling for commercial containers of nabilone must comply with the requirements of §§ 1302.03 through 1302.05 and 1302.07–1302.08 of Title 21 of the Code of Federal Regulations.

4. Quotas. All persons required to obtain quotas for nabilone shall submit applications pursuant to §§ 1303.12 and 1303.22 of Title 21 of the Code of Federal Regulations.

5. Inventory. Every registrant required to keep records and who possesses any quantity of nabilone shall take an inventory, pursuant to §§1304.04 and 1304.11 through 1304.19 of Title 21 of the Code of Federal Regulations, of all stocks on hand.

6. Records. All registrants required to keep records pursuant to §§1304.21 through 1304.27 of Title 21 of the Code of Federal Regulations shall do so regarding nabilone.

7 Reports. All registrants required to submit reports pursuant to §§ 1304.34 through 1304.37 of Title 21 of the Code of Federal Regulations shall do so regarding nabilone.

8. Order Forms. All registrants involved in the distribution of nabilone shall comply with the order form requirements of Part 1305 of Title 21 of the Code of Federal Regulations.

9. Prescriptions. FDA approved nabilone drug products may be used in medical treatment and may be dispensed by prescription. All prescriptions for FDA approved nabilone drug products shall comply with §§ 1306.11 through 1306.15 of Title 21 of the Code of Federal Regulations.

10. Importation and Exportation. All importation and exportation of nabilone shall be in compliance with Parts 1311 and 1312 of Title 21 of the Code of Federal Regulations.

11. Criminal Liability. Any activity with respect to nabilone not authorized by or in violation of the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful. The applicable penalties after April 7 1987 shall be those of a Schedule II substance.

12. Other. In all other respects, this orders is effective on April 7 1987

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the control of nabilone, 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, September 19, 1980). This action will allow the initial marketing of a drug product which has been approved by the FDA.

In accordance with the provisions of 21 U.S.C. 811(a) (section 201(a) of the CSA), this order to place nabilone into Schedule II 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.

List of Subjects in 21 CFR Part 1308

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

Pursuant to the authority vested in the Attorney General by 21 U.S.C. 811(a) (section 201(a) of the CSA) and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR 0.100), the Administrator hereby orders that 21 CFR 1308.12(f) be amended as follows by the addition of nabilone:

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. 21 CFR 1308.12(f) is amended by the addition of a new paragraph (f)(2) to read as follows:

§ 1308.12 Schedule II.

(f)

(2) Nabilone.....7379

[Another name for nabilone: (+)-*trans*-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[b,d]pyran-9-one].

Dated: March 31, 1987.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 87-7533 Filed 4-6-87; 8:45 am]

BILLING CODE 4410-09-M

Office of the Attorney General

28 CFR Part 0

[Order No. 1176-87]

Asylum Policy and Review

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: This order reflects the creation of the Asylum Policy and Review Unit within the Office of Legal Policy. This change to the Department's regulations is being made in order to reflect accurately the agency's internal management structure.

EFFECTIVE DATE: March 30, 1987

FOR FURTHER INFORMATION CONTACT: Ralph Thomas, Deputy Assistant Commissioner for Refugee, Asylum and Parole, Immigration and Naturalization Service, 425 Eye Street NW Washington, DC 20536 Telephone (202) 633–5463.

SUPPLEMENTARY INFORMATION: The Asylum Policy and Review Unit, located within the Office of Legal Policy, advises the Attorney General and the Deputy Attorney General on matters related to asylum policy. It will compile information relevant to asylum decisions and assist the Attorney General, the Deputy Attorney General, and the Immigration and Naturalization Service in coordinating related matters.

This order has been issued to increase efficiency within the Department and is a matter of internal Department management. It does not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). It is not a major rule within the meaning of Executive Order No. 12291.