drug regulations in 21 CFR 312.1(a), Forms FD–1572 and FD–1573, to incorporate appropriate implementing provisions for, and cross-reference to, Part 50 (Protection of Human Subjects) and Part 56 (Institutional Review Boards). The agency inadvertently omitted a revision to item 6h in Form FD–1572 and item 4h in Form FD–1573 to incorporate appropriate references to Part 56. This document corrects that omission in Part 312 as follows:

PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

In § 312.1 by revising item 6h of Form FD–1572 in paragraph (a)(12) and item 4h of Form FD–1573 in paragraph (a)(13) to read as follows:

§ 312.1 Conditions for exemption of new drugs for investigational use.

(a) * * *

(12) * * *

6. * * *

h. The investigator is required to assure the sponsor that for investigations subject to an institutional review requirement under Part 56 of this chapter the studies will not be initiated until the institutional review board has reviewed and approved the study. (The organization and procedure requirements for such a board as set forth in Part 56 should be explained to the investigator by the sponsor.)

* * * * *

(13) * * *

4. * * *

h. The investigator is required to assure the sponsor that for investigations subject to an institutional review requirement under Part 56 of this chapter the studies will not be initiated until the institutional review board has reviewed and approved the study. (The organization and procedure requirements for such a board as set forth in Part 56 should be explained to the investigator by the sponsor.)

* * * * *

Dated: December 2, 1981.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-35039 Filed 12-7-81; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 555

Chloramphenicol Drugs for Animal Use; Chloramphenicol Oral Solution

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the animal drug regulations to reflect approval of a supplemental new drug application (NADA) filed by Philips Roxane, Inc., providing for safe and effective use of a chloramphenicol oral solution for treating dogs for certain bacterial infections.

EFFECTIVE DATE: December 8, 1981.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Bureau of Veterinary Medicine (HFV–114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3420.

SUPPLEMENTARY INFORMATION: Philips Roxane, Inc., 2621 North Belt Highway, St. Joseph, MO 64502, filed a supplement to NADA 65–477 providing for use of an oral solution containing 250 milligrams of chloramphenicol per milliliter for treating dogs for bacterial pulmonary infections, urinary tract infections, enteritis, and infections associated with canine distemper, caused by organisms susceptible to chloramphenicol.

This product conforms to the requirements for certification and conditions of marketing of chloramphenicol oral solution which are codified in 21 CFR 555.110c. Approval is based on submission of published literature and results of a crossover blood level study demonstrating bioequivalence to an oral solution for which certification has been approved. Under 21 CFR 514.1(b)(9), and exemption from the submission of some of the data as required by 21 CFR 514.1(b)(8) has been applied to this NADA. The supplemental NADA is approved and the regulations are amended to reflect the approval.

The Bureau of Veterinary Medicine 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. Therefore, an environmental impact statement will not be prepared. The Bureau's finding of no significant impact and the evidence supporting this finding, contained in an environmental impact analysis report (pursuant to 21 CFR 25.1(f)(2)(ii)), may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (address above).

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

PART 555—CHLORAMPHENICOL DRUGS FOR ANIMAL USE

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i) and (n), 82 Stat. 347, 350–351 (21 U.S.C. 360b(i) and (n))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 555 is amended in § 555.110c by revising paragraph (c)(2)(ii) to read as follows:

§ 555.110c Chloramphenicol oral solution.

* * * * *

(c) * * *

(2) * * *

(ii) For solutions containing 250 milligrams of chloramphenicol per milliliter see 000010 and 013983 in § 510.600(c) of this chapter.

* * * * *

Effective date. December 8, 1981.

(Sec. 512(i) and (n), 82 Stat. 347, 350–351 (21 U.S.C. 360b(i) and (n)))

Dated: November 30, 1981.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 81-35041 Filed 12-7-81; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Placement of N-ethylamphetamine into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This is a final rule placing the substance, N-ethylamphetamine, into Schedule I of the Controlled Substances Act. As a result of this rule, N-ethylamphetamine will be subject to the manufacture, distribution, security, registration, recordkeeping, quotas, inventory, order forms, criminal liability, exportation and importation control of Schedule I.

EFFECTIVE DATE: January 7, 1981.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Regulatory Control Division, Drug Enforcement

Administration, Washington, D.C. 20537, Telephone: (202) 633–1366.

SUPPLEMENTARY INFORMATION: A notice was published in the Federal Register on Thursday, September 10, 1981 (46 FR 45156) proposing that N-ethylamphetamine be placed into Schedule I of the Controlled Substances Act. All interested persons were given until November 9, 1981 to submit any comments or objections in writing regarding this proposal. No comments or objections were received in response to this proposal, nor were there any requests for a hearing.

Based upon the investigations and review conducted by the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Assistant Secretary for Health, Department of Health and Human Services, received in accordance with 21 U.S.C. 811(b), the Acting Administrator of the Drug Enforcement Administration, pursuant to 21 U.S.C. 811 (a) and (b), finds that:

(1) Based on information now available, N-ethylamphetamine has a high potential for abuse;

(2) N-ethylamphetamine has no currently accepted medical use in treatment in the United States; and,

(3) N-ethylamphetamine lacks accepted safety for use under medical supervision.

The above findings are consistent with the placement of N-ethylamphetamine in Schedule I of the Controlled Substances Act. All regulations applicable to Schedule I substances are effective on January 7, 1982.

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports N-ethylamphetamine, or who engages in research or conducts instructional activities with respect to this 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.* N-ethylamphetamine must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72 (a), (c), and (d), 1301.73, 1301.74 (a)–(f), 1301.75(a), and 1301.76 of Title 21 of the Code of Federal Regulations on or before January 7, 1982. In the event that this imposes special hardships, the Drug Enforcement Administration will entertain any justified requests for extensions of time.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of N-ethylamphetamine and all labeling of N-ethylamphetamine packaged after January 7, 1982, must comply with the requirements of §§ 1302.03–1302.05, 1302.07, and 1302.08 of Title 21 of the Code of Federal Regulations. In the event this imposes special hardships on any manufacturer, as defined in section 102(14) of the Controlled Substances Act (21 U.S.C. 802(14)), the Drug Enforcement Administration will entertain any justified request for an extension of time.

4. *Quotas.* All persons required to obtain quotas on N-ethylamphetamine 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 who possesses any quantity of N-ethylamphetamine shall take an inventory pursuant to §§ 1304.11–1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of N-ethylamphetamine on hand.

6. *Records.* All registrants required to keep records pursuant to §§ 1304.21–1304.27 of Title 21 of the Code of Federal Regulations shall do so regarding N-ethylamphetamine commencing on the date on which the inventory of N-ethylamphetamine is taken.

7. *Reports.* All registrants required to submit reports pursuant to §§ 1304.37–1304.41 of Title 21 of the Code of Federal Regulations shall do so regarding N-ethylamphetamine commencing on the date on which the inventory of N-ethylamphetamine is taken.

8. *Order Forms.* The order form requirements of §§ 1305.01–1305.16 of Title 21 of the Code of Federal Regulations shall be in effect on the date which the inventory of fenethylline is taken.

9. *Importation and Exportation.* All importation and exportation of N-ethylamphetamine shall be required to be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

10. *Criminal Liability.* The Acting Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to N-ethylamphetamine not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful, except that any person who is entitiled to registration under such Acts may continue to conduct normal business, research or professional practice with N-ethylamphetamine between the date on which this order is published and the date on which he obtains or is denied registration: *Provided,* That application for such registration is submitted on or before January 7, 1982.

11. *Other.* In all other respects, this order is effective January 7, 1982.

Pursuant to Title 5, United States Code, section 605(b), the Acting Administrator certifies that control of N-ethylamphetamine as ordered herein, will have no significant impact upon small business or other entities whose interests must be considered under the Regulatory Flexibility Act.

In accordance with the provisions of section 201(a) of the Controlled Substances Act (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 12991 and from the postponement of pending regulations under the President's memorandum of January 30, 1981.

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 regulations of the Department of Justice (28 CFR Part 0.100), the Acting Administrator hereby orders that Part 1308, Title 21, Code of Federal Regulations (CFR), be amended by revising paragraph (f) of § 1308.11 of Title 21, Code of Federal Regulations (CFR), to include N-ethylamphetamine therein as item (2), to read as follows:

§ 1308.11 Schedule I.

* * * * *

(f) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Fenethylline—1503

(2) N-ethylamphetamine—1475

Dated: December 1, 1981.

Francis M. Mullen, Jr.,

Acting Administrator, Drug Enforcement Administration.

[FR Doc. 81-35123 Filed 12-7-81; 8:45 am]

BILLING CODE 4410-09-M