solvent vehicle. Each milliliter contains 100 milligrams of chloramphenicol. The chloramphenicol content is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of chloramphenicol that it is represented to contain. It is sterile. It is nonpyrogenic. It passes the safety test. Its pH is not less than 6.5 and not more than 8.5. The chloramphenicol used conforms to the standards prescribed by §455.10a(a)(1) of this chapter.

* * * * *

(4) * * *

(i) * * *

(*b*) The batch for potency, sterility, pyrogens, safety, and pH.

* * * * *

(b) * * *

(5) [Reserved]

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Any person who will be adversely affected by this regulation may file objections to it, request a hearing, and show reasonable grounds for the hearing. Any person who decides to seek a hearing must file (1) on or before October 30, 1980, a written notice of participation and request for hearing, and (2) on or before December 1, 1980, 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.

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 must be filed in four copies, identified with the docket number appearing in the heading of this order and filed with the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

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 office of the Hearing Clerk, between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This amendment shall become effective October 30, 1980.

(Secs. 507, 512(n), 59 Stat. 463 as amended, 82 Stat. 350-351 (21 U.S.C. 357, 360b(n)))

Dated: September 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-30032 Filed 9-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 440

[Docket No. 80N-0303]

Penicillin Antibiotic Drugs; Amoxicillin Trihydrate Chewable Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the antibiotic drug regulations to provide for the certification of a new antibiotic dosage form, amoxicillin trihydrate chewable tablets. The manufacturer has supplied sufficient data and information to establish the drug's safety and efficacy.

DATES: Effective September 30, 1980; comments by October 30, 1980.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joan Eckert, Bureau of Drugs (HFD-140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended with respect to providing for the certification of a new antibiotic dosage form, amoxicillin trihydrate chewable tablets. The agency concludes that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when the drug is used as directed in the labeling and that the regulations should be amended in Part 440 (21 CFR Part 440) to provide for its certification.

The agency has determined pursuant to 21 CFR 25.24(b) (22) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a sufficient impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 440 is amended by adding new § 440.103c to read as follows:

§ 440.103c Amoxicillin trihydrate chewable tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Amoxicillin trihydrate chewable tablets are composed of amoxicillin trihydrate with or without one or more suitable lubricants, diluents, preservatives, drying agents, flavorings, and colorings. Each tablet contains amoxicillin trihydrate equivalent to either 125 or 250 milligrams of amoxicillin. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of amoxicillin that it is represented to contain. Its moisture content is not more than 6.0 percent. It passes the identity test. The amoxicillin trihydrate used conforms to the standards prescribed by § 440.3(a)(1).

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5 of this chapter, this drug shall be labeled "amoxicillin tablets."

(3) *Requests for certification; samples.* In addition to the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assay on:

(*a*) The amoxicillin trihydrate used in making the batch for potency, safety, moisture, pH, amoxicillin content, concordance, crystallinity, and identity.

(*b*)The batch for potency, moisture, and identity.

(ii) Samples required:

(*a*) The amoxicillin trihydrate used in making the batch: 12 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 tablets.

(b) *Tests and methods of assay*—(1) *Potency.* Assay for potency by either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(i) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar with sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to obtain a stock solution of convenient concentration. Blend for 3 to

5 minutes. Remove an aliquot and dilute with solution 3 to the reference concentration of 0.1 microgram of amoxicillin per milliliter (estimated).

(ii) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, preparing the sample as follows: Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 5 minutes. Further dilute with solution 1 to the prescribed concentration.

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

(3) *Identity.* Proceed as directed in § 436.311 of this chapter, preparing the sample as follows: Using a mortar and pestle, grind a representative number of tablets into a fine powder. Dissolve an accurately weighed amount of this powder in 0.1*N* hydrochloric acid to give a solution containing 4 milligrams of amoxicillin per milliliter.

Because the conditions that must be met prior to providing for certification of this drug have been complied with, because the matter is noncontroversial, and because the marketing of this drug by other manufacturers would be delayed without good cause, the Food and Drug Administration finds that notice and public procedure and delayed effective date are unnecessary and impractical, and that the amendment may become effective upon the date of publication in the **Federal Register**. However, interested persons may, on or before October 30, 1980, submit to the Hearing Clerk (HFA–35), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this regulation. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the Hearing Clerk's office 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, request a hearing, and show reasonable grounds for the hearing. Any person who decides to seek a hearing must file (1) on or before October 30, 1980, a written notice of participation and request for hearing, and (2) on or before December 1, 1980, 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.

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 must be filed in four copies, identified with the docket number appearing in the heading of this order, with the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

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 office of the Hearing Clerk, between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall be effective September 30, 1980.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357))

Dated: September 22, 1980.

Mary A. McEniry,

Assistant Director for Regulatory Affairs, Bureau of Drugs.

[FR Doc. 80–30031 Filed 9–29–80; 8:45 am]

BILLING CODE 4110–03–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Pipradrol and SPA in Schedule IV; Schedules of Controlled Substances

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 pipradrol and SPA in Schedule IV of the Controlled Substances Act of 1970. This action is required in order for the United States to discharge its obligations under the Convention on Psychotropic Substances, 1971.

EFFECTIVE DATE OF CONTROL: December 1, 1980, except as otherwise provided in the "SUPPLEMENTARY INFORMATION" section of this Rule.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: 202–633–1366.

SUPPLEMENTARY INFORMATION: On April 15, 1980, the United States became a party to the Convention on Psychotropic Substances, 1971. In order to comply with the obligation imposed thereby, two substances, pipradrol and SPA, which are in Schedule IV of the treaty, must be controlled under the Comprehensive Drug Abuse Prevention and Control Act of 1970.

Section 102(c) of the Psychotropic Substances Act of 1978 (21 USC 812) states that "with respect to pipradrol and SPA (also known as (-)-1-dimethylamino-1,2-diphenylethane), the Attorney General shall by order, made without regard to sections 201 and 202 of the Controlled Substances Act, place such drugs in Schedule IV of such Act." These substances currently have no accepted medical use in the United States.

EFFECTIVE DATES: 1. Registration. Any person who manufactures, distributes, imports or exports pipradrol and SPA or who engages in research or conducts instructional activities with respect to these substances, 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 December 1, 1980.

2. Security. Pipradrol and SPA must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72 (b)–(d), 1301.73, 1301.74(a)–(f), 1301.75(b)–(c) and 1301.76 of Title 21 of the Code of Federal Regulations on or before December 29, 1980. In the event this effective date imposes 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 pipradrol and SPA, packaged after December 1, 1980, 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 Controlled

Substances Act (21 USC 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. Inventory. Every registrant required to keep records, who possesses any quantity of pipradrol or SPA, shall take an inventory, pursuant to §§ 1304.11–1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of these substances on hand on December 1, 1980.

5. 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 pipradrol and SPA commencing on the date on which the inventories of these substances are taken.

6. Importation and Exportation. All importation and exportation of pipradrol and SPA on and after December 1, 1980, shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

7. Criminal Liability. The Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to pipradrol and SPA not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, conducted after December 1, 1980, shall be unlawful, except that any person who is not now registered to handle these substances but who is entitled to registration under such Acts may continue to conduct normal business or professional practice with these substances between the date on which this Rule is published and the date which he obtains or is denied registration; provided, that the application for such registration is submitted on or before December 1, 1980.

Dated: September 19, 1980.

Peter B. Bensinger,

Administrator, Drug Enforcement Administration.

Under the authority vested in the Attorney General by Section 102(c) of the Psychotropic Substance Act of 1978 (21 U.S.C. 812), and delegated to the Administrator of the Drug Enforcement Administration pursuant to Sec. 0.100 of Title 28 of the Code of Federal Regulations, the Administrator hereby orders that Title 21 of the Code of Federal Regulations be amended by adding (e) (4) and (5) to § 1308.14:

§ 1308.14 Schedule IV.

* * * * *

(e) * * *

(4) pipradrol, 1750.

(5) SPA ((-)-1-dimethylamino-1,2-diphenylethane), 1635.

* * * * *

[FR Doc. 80-29726 Filed 9-29-80; 8:45 am]

BILLING CODE 4110-09-M

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21 CFR Part 1308

Placement of Sufentanil and Tilidine in Schedule I; Schedules of Controlled Substances

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 sufentanil and tilidine in Schedule I of the Controlled Substances Act of 1970. This action is required in order for the United States to discharge its obligations under the Single Convention on Narcotic Drugs, 1961.

DATE: EFFECTIVE DATE OF CONTROL: December 1, 1980, except as otherwise provided in the SUPPLEMENTARY INFORMATION section of this rule.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: 202–633–1366.

SUPPLEMENTARY INFORMATION: By a letter dated April 17, 1980, 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 drugs, sufentanil and tilidine, be added to Schedule I of the Single Convention on Narcotic Drugs, 1961.

Section 201(d)(1) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 USC 811(d)) states that, if control of a substance is required by United States obligations under the Single Convention on Narcotic Drugs, "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 USC 811 (a) and (b)) and section 202(b) (21 USC 812(b)) of the Act." This responsibility has been delegated to the Administrator of the Drug Enforcement Administration pursuant to § 0.100 of Title 28 of the Code of Federal Regulations.

In order to meet the obligations of the Single Convention on Narcotic Drugs and because sufentanil and tilidine have no currently accepted medical use, the Administrator of the Drug Enforcement Administration has determined that these substances should be placed in Schedule I of the Controlled Substances Act.

EFFECTIVE DATES: 1. Registration. Any person who manufactures, distributes, imports, or exports sufentanil or tilidine, or who engages in research or conducts instructional activities with respect to these substances, 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 December 1, 1980.

2. Security. Sufentanil and tilidine must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(a), 1301.72(c)–(d), 1301.73, 1301.74(a)–(c), 1301.74(e)–(f), 1301.75(a), 1301.75(c), and 1301.76 of Title 21 of the Code of Federal Regulations on or before December 29, 1980. In the event this effective date imposes 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 sufentanil and tilidine, packaged after December 1, 1980, 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 Controlled Substances Act (21 USC 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 sufentanil and tilidine shall submit applications for calendar year 1981 pursuant to §§ 1303.12 and 1303.22 of Title 21 of the Code of Federal Regulations on or before December 1, 1980.

5. Inventory. Every registrant required to keep records, who possesses any quantity of sufentanil or tilidine, shall take an inventory, pursuant to §§ 1304.11–1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of sufentanil and tilidine on hand on December 1, 1980.

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 sufentanil and tilidine commencing on the date on which the inventories of these substances are taken.