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 August 30, 1984.

(Secs. 507, 701 (f) and (g), 52 Stat. 1055–1056 as amended, 59 Stat. 463 as amended (21 U.S.C. 357, 371 (f) and (g)))

Dated: August 23, 1984.

Daniel L. Michels,

Director, Office of Compliance, Center for Drugs and Biologics.

[FR Doc. 84-22881 Filed 8-29-84; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 430, 436, 442, 444, and 448

[Docket No. 84N-0258]

Antibiotic Drugs; Updating and Technical Changes

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations by making updatings, minor noncontroversial technical changes, and revocations in certain regulations providing for accepted standards of antibiotic and antibiotic-containing drugs for human use. These changes will result in more accurate and usable regulation.

DATES: Effective August 30, 1984; comments, notice of participation, and request for hearing by October 1, 1984; data, information, and analyses to justify a hearing by October 29, 1984.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joan M. Eckert, Center for Drugs and Biologics (HFN–815), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4290.

SUPPLEMENTARY INFORMATION: FDA is amending the antibiotic drug regulations by making updatings, minor noncontroversial technical changes, and revocations in certain antibiotic drug regulations that provide for accepted standards of antibiotic and antibiotic-containing drugs intended for human use. In one instance, the need for a change was called to FDA's attention by an industry representative. To aid the reader in understanding the types of amendments in this document, the amendments are grouped into three general classes for discussion in this preamble: updating, technical changes, and revocation.

Updating

In § 444.542b (21 CFR 444.542b), paragraph (a)(1)(vii) is revised and paragraph (a)(1)(viii), (ix), and (x) is added to provide public standards for three drug products containing neomycin in combination with a corticosteriod. In a Drug Efficacy Study Implementation notice published in the **Federal Register** of March 28, 1984 (49 FR 11888), FDA reclassified these drug products as effective for the indication stated in that notice.

Technical Changes

1. In §§ 444.542a(a)(1)(i)(*a*) and 444.542c(a)(1)(vi), the name "flurandrenolone" is changed to read "flurandrenolide" to be in agreement with the United States Adopted Names (USAN) designation.

2. In §§ 444.342d(b)(1) (i) and (ii), 448.313a(a)(1), 448.513a(a)(1), 448.513d(a)(1), and 448.513e(a)(1), the upper potency limits are raised from 120 percent to 130 percent. The sole manufacturer has submitted adequate data to support the higher limit.

Revocation

Sections 442.19 *Cephacetrile sodium*, 442.219 *Cephacetrile sodium for injection*, and 444.542d *Neomycin sulfate aerosol* are removed. These drugs are no longer manufactured. Also, conforming amendments are made to Parts 430 and 436 where applicable.

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 significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 430

Administrative practice and procedure; Antibiotics

21 CFR Part 436

Antibiotics.

21 CFR Part 442

Antibiotics, cepha.

21 CFR Part 444

Antibiotics, oligosaccharide.

21 CFR Part 448

Antibiotics, peptide.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 507, 701(f) and (g), 52 Stat. 1055–1056 as amended, 59 Stat. 463 as amended (21 U.S.C. 357, 371(f) and (g)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 430, 436, 442, 444, and 448 are amended as follows:

PART 430—ANTIBIOTIC DRUGS; GENERAL

1. Part 430 is amended:

§§ 430.5 and 430.6 [Amended]

a. In § 430.5 *Definitions of master and working standards*, by removing and reserving paragraphs (a)(54) and (b)(54).

b. In § 430.6 *Definitions of the terms "unit" and "microgram" as applied to antibiotic substances*, by removing and reserving paragraph (b)(57).

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

2. Part 436 is amended:

§§ 436.33, 436.105, and 436.205 [Amended]

a. In § 436.33 *Safety test*, by removing "Cephacetrile sodium" from the table in paragraph (b).

b. In § 436.105 *Microbiological agar diffusion assay*, by removing "Cephacetrile" from the tables in paragraphs (a) and (b).

c. In § 436.205 *Hydroxylamine colorimetric assay*, by removing "Cephacetrile" from the table in paragraph (b) and by removing "Cephacetrile sodium" from the table in paragraph (c).

§ 436.313 [Removed]

d. By removing § 436.313 *Thin layer chromatographic identity test for cephacetrile sodium.*

PART 442—CEPHA ANTIBIOTIC DRUGS

3. Part 442 is amended:

§§ 442.19 and 442.219 [Removed]

a. By removing § 442.19 *Cephacetrile sodium.*

b. By removing § 442.219 *Cephacetrile sodium for injection.*

PART 444—OLIGOSACCHARIDE ANTIBIOTIC DRUGS

4. Part 444 is amended:

a. In § 442.342d, by revising the last sentence in paragraph (b)(1) (i) and (ii) to read as follows:

§ 444.342d Neomycin sulfate-polymyxin B Sulfate————————ophthalmic suspension (the blank being filled in with the established name(s) of the other active ingredient(s) present in accordance with paragraph (a)(1) of this section).

* * * * *

(b) * * *

(1) * * *

(i) * * * Its content of neomycin is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of neomycin that it is represented to contain.

(ii) * * * Its content of polymyxin is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin that it is represented to contain.

* * * * *

b. In § 444.542a, by revising paragraph (a)(1)(i)(*a*) to read as follows:

§ 444.542a Neomycin sulfate ointment; neomycin sulfate————————ointment (the blank being filled in with the established name(s) of the other active ingredient(s) present in accordance with paragraph (a)(1) of this section.

(a) * * *

(1) * * *

(i) * * *

(*a*) 0.5 milligram of flurandrenolide; or

* * * * *

c. In § 444.542b, paragraph (a)(1)(vii) is revised and paragraph (a)(1) (viii), (ix), and (x) is added to read as follows:

§ 444.542b Neomycin sulfate———————— cream (the blank being filled in with the established name(s) of the other active ingredient(s) present in accordance with paragraph (a)(1) of this section).

(a) * * *

(1) * * *

(vii) 1 milligram of triamcinolone acetonide; or

(viii) 2.5 milligrams, 5.0 milligrams, or 10.0 milligrams of hydrocortisone; or

(ix) 10.0 milligrams or 25.0 milligrams of hydrocortisone acetate; or

(x) 0.5 milligram of flurandrenolide.

* * * * *

d. In § 444.542c, by revising the sentence in paragraph (a)(1)(vi) to read as follows:

§ 444.542c Neomycin sulfate———————— lotion (the blank being filled in with the established name(s) of the other active ingredient(s) present in accordance with paragraph (a)(1) of this section).

(a) * * *

(1) * * *

(vi) 0.5 milligram of flurandrenolide.

* * * * *

§ 444.542d [Removed]

e. By removing § 444.542d *Neomycin sulfate aerosol.*

PART 448—PEPTIDE ANTIBIOTIC DRUGS

5. Part 448 is amended:

a. In § 448.313a, by revising the second and third sentences in paragraph (a)(1) to read as follows:

§ 448.313a Bacitracin zinc-polymyxin B sulfate ophthalmic ointment.

(a) * * *

(1) * * * Its bacitracin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of bacitracin that it is represented to contain. Its polymyxin B content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain.* * *

* * * * *

b. In § 448.513a, by revising the third and fourth sentences in paragraph (a)(1) to read as follows:

§ 448.513a Bacitracin zinc-polymyxin B sulfate ointment.

(a) * * *

(1) * * * Its bacitracin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of bacitracin that it is represented to contain. Its polymyxin B content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. * * *

* * * * *

c. In § 448.513d, by revising the third, fourth, and fifth sentences in paragraph (a)(1) to read as follows:

§ 448.513d Bacitracin zinc-neomycin sulfate-polymyxin B sulfate topical powder.

(a) * * *

(1) * * * Its bacitracin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of bacitracin that it is represented to contain. Its neomycin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of neomycin that it is represented to contain. Its polymyxin B content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. * * *

* * * * *

d. In § 448.513e, by revising the third, fourth, and fifth sentences in paragraph (a)(1) to read as follows:

§ 448.513e Bacitracin zinc-neomycin sulfate-polymyxin B sulfate topical aerosol.

(a) * * *

(1) * * * Its bacitracin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of bacitracin that it is represented to contain. Its neomycin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of neomycin that it is represented to contain. Its polymyxin B content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. * * *

* * * * *

These amendments institute changes that are corrective, editorial, or of a minor substantive nature. Because the amendments are not controversial and because when effective they provide notice of accepted standards, FDA finds that notice, public procedure, and delayed effective date are unnecessary and not in the public interest. The amendments, therefore, shall become effective August 30, 1984. However, interested persons may, on or before October 1, 1984, submit written comments on this regulation 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 found 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 October 1, 1984 a written notice of participation and request for hearing, and (2) on or before October 29, 1984, the data, information, and analyses on which the person relies to justify a hearing, as specifed 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 office of the Dockets Management Branch, between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall be effective August 30, 1984.

(Secs. 507, 701 (f) and (g), 52 Stat. 1055–1056 as amended, 59 Stat. 463 as amended (21 U.S.C. 357, 371 (f) and (g)))

Dated: August 23, 1984.

Daniel L. Michels,

Director, Office of Compliance, Center for Drugs and Biologics.

[FR Doc. 84–22882 Filed 8–29–84; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs Not Subject to Certification; Famphur

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to codify a previously approved new animal drug application (NADA) sponsored by Ralston-Purina Co. The NADA provides for the use of famphur as a pour-on formulation for use on cattle to control grubs and to reduce lice infestations.

EFFECTIVE DATE: August 30, 1984.

FOR FURTHER INFORMATION CONTACT: Ben Puyot, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1414.

SUPPLEMENTARY INFORMATION: Ralston-Purina Co., Checkerboard Square, St. Louis, MO 63164, is the sponsor of NADA 43–215 which provides for use of famphur 13.2 percent. The drug is used as a pour-on formulation for the control of cattle grubs and to reduce cattle lice infestations. The drug was approved by letter dated June 4, 1970.

This action codifies the previously approved NADA but does not change the approved use of the drug. Because the application was approved before July 1, 1975, the sponsor is not required to submit a summary of the safety and effectiveness data and information under the Freedom of Information provisions of the animal drug regulations in 21 CFR 514.11(e)(2)(ii). However, a summary of the basis for approval is available upon request in accordance with 21 CFR 514.11(e)(2)(i).

The Center for Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in Part 524

Animal drugs, topical.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of the Center for Veterinary Medicine (21 CFR 5.83), Part 524 is amended in § 524.900 by revising paragraph (c), to read as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

§ 524.900 Famphur.

* * * * *

(c) *Sponsor.* See Nos. 010042 and 017800 in § 510.600(c) of this chapter.

* * * * *

Effective date. August 30, 1984.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: August 23, 1984.

Lester M. Crawford,

Director, Center for Veterinary Medicine.

[FR Doc. 84–22997 Filed 8–29–84; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 540

Penicillin Antibiotic Drugs for Animal Use; Ticarcillin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Beecham Laboratories, providing for intrauterine use of a ticarcillin infusion for treating mares for endometritis caused by beta-hemolytic streptococci.

EFFECTIVE DATE: August 30, 1984.

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

SUPPLEMENTARY INFORMATION: Beecham Laboratories, Division of Beecham, Inc., Bristol, TN 37620, filed NADA 55–095 providing for use of Ticillin® (sterile ticarcillin disodium) intrauterine infusion for horses for treating infections of beta-hemolytic streptococci. The NADA is approved and the regulations are amended to reflect the approval. The basis of this approval is discussed in the freedom of information summary.

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 (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Center for 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 and that an enviromental impact statement therefore will not be prepared. The Center's finding of no significant impact and the evidence supporting this finding, contained in a statement of exemption (pursuant to 21 CFR 25.1(f)(1)(ii) (*a*) and (*e*)) may be seen in the Dockets Management Branch (address above).

List of Subjects in 21 CFR Part 540

Animal drugs; Antibiotics, penicillin.

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) and redelegated to the Center for Veterinary Medicine (21 CFR 5.83), Part 540 is amended by adding new Subpart I consisting of § 540.680 to read as follows:

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

Subpart I—Certain Other Dosage Forms

§ 540.680 Ticarcillin.

(a) *Requirements for certification.* See § 440.90a of this chapter.

(b) *Tests and methods of assay.* See § 440.90a of this chapter.

(c) *Conditions of marketing*—(1) *Specifications.* Each vial contains the equivalent of 6 grams of ticarcillin (as ticarcillin disodium) to be reconstituted with 25 milliliters of sterile water for injection or sterile physiological saline, and diluted to desired volume of use.

(2) *Sponsor.* See No. 000029 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) *Indications for use.* For intrauterine use in horses for treatment of endometritis caused by beta-hemolytic streptococci.

(ii) *Amount.* 6 grams per day, intrauterine, for 3 consecutive days during estrus.

(iii) *Limitations.* For intrauterine use in horses only. Infuse aseptically. Not for use in horses raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date. August 30, 1984.

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

Dated: August 23, 1984.

Lester M. Crawford,

Director, Center for Veterinary Medicine.

[FR Doc. 84–22996 Filed 8–29–84; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[T.D. ATF–181; Re: Notice No. 497]

Mississippi Delta Viticultural Area

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Final rule (Treasury Decision).

SUMMARY: This final rule establishes a viticultural area in the States of Mississippi, Tennessee, and Louisiana to be known as "Mississippi Delta." The Bureau of Alcohol, Tobacco and Firearms believes that the establishment of the Mississippi Delta viticultural area and the subsequent use of its name as an appellation of origin in wine labeling and advertising will enable industry to label wines more precisely, and will help consumers to better identify the wines from this area.

EFFECTIVE DATE: October 1, 1984.

FOR FURTHER INFORMATION CONTACT: Steve Simon, FAA, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, 1200 Pennsylvania Avenue NW, Washington, DC 20226 (202–566–7626).

SUPPLEMENTARY INFORMATION:

Background

ATF regulations in 27 CFR Part 4 provide for the establishment of definite viticultural areas. The regulations also allow the name of an approved viticultural area to be used as an appellation of origin on wine labels and in wine advertisements.

Part 9 of 27 CFR provides for the listing of approved American viticultural areas, the names of which may be used as appellations of origin.

Section 4.25a(e)(1), Title 27, CFR, defines an American viticultural area as a delimited grape growing region distinguishable by geographical features. Section 4.25a(e)(2) outlines the procedure for proposing an American viticultural area. Any interested person may petition ATF to establish a grape growing region as a viticultural area.

Notice of Proposed Rulemaking

ATF received a petition from Mr. Samuel H. Rushing of The Winery Rushing, for the establishment of a viticultural area in northwestern Mississippi (with minute segments in Tennessee and Louisiana), to be known as "Mississippi Delta." In response, ATF published a notice of proposed ruelmaking, Notice No. 497, in the **Federal Register** on December 23, 1983 (48 FR 56799). That notice solicited public comment with respect to the proposed viticultural area. Five public comments were received, all of them endorsing the area as proposed. Therefore, this Treasury decision establishes the Mississippi Delta viticultural area with boundaries as proposed in Notice No. 497.

General Description of the Viticultural Area

The Mississippi Delta viticultural area is leaf-shaped and extends for a length of about 180 miles with a maximum width of about 65 miles. It comprises approximately 6,000 square miles.

The area is a flat, alluvial plain with extremely rich soil. Topsoil in the area is often 35 feet deep. The area is one of the more highly productive agricultural regions in the United States. Growing conditions are favorable to a wide variety of crops. Major crops are cotton, soybeans, grain sorghum, and rice. To a much lesser extent, the area is also a grape-producing region.

In the early part of this century, before Prohibition, grape growing was profitable in the area. Recently, the State of Mississippi has invested millions of dollars in Mississippi State University's Enology Laboratory, located at Stoneville in the heart of the Delta region. This expenditure is based upon belief that the region will someday become "the grape producing area of the Southeast," according to a letter of support form the head of that Laboratory. Estimates of current vineyard acreage range from 50 to 250 acres. There are vineyards dispersed through the area, and one winery is operating.

Name of the Area

The term "delta" is commonly understood to mean a triangular area by the mouth of a river, formed by alluvial deposits. The Mississippi Delta is an exception to this, in that it is an area of alluvial deposits located several hundred miles above the mouth of the Mississippi River. However, according to the evidence the area is a true delta, for its deposits were first laid down in an era of pre-history when the mouth of the Mississippi was much farther north. In more recent times, prior to the construction of the Mississippi River levee system, the area received periodic additional deposits whenever the Mississippi and/or Yazoo River flooded.

Geologists sometimes call the area the "Yazoo Basin," since the area is primarily drained by the Yazoo River, but locally and in literature it is most commonly called the "Mississippi Delta," or just "The Delta."

Author David Cohn's famous statement that the Mississippi Delta "begins in the lobby of the Peabody Hotel in Memphis and ends on Catfish Row in Vicksburg" has been quoted numerous times in histories of Mississippi. In particular, this statement appears in *Mississippi: A History,* by John K. Bettersworth, and *Mississippi,* by the Federal Writers' Project of the Works Progress Administration. (Memphis and Vicksburg are the approximate northern and southern boundaries of the Mississippi Delta viticultural area.)

Because of the danger of flooding, the Mississippi Delta was sparsely settled until about 100 years ago, when the levee system began to make agriculture feasible there. Nevertheless, within this century, the area has developed a considerable distinctive history and reputation.

Geographical Features; Boundaries

The western boundary of the area is the levee system of the Mississippi River. West of that, the land is not suitable for agriculture because it is subject to unpredictable, periodic floods. The land that is not protected by the levee system is used primarily for sporting purposes, such as hunting and fishing.