Island, AK, Enroute Domestic Airspace Area (62 FR 7741). Interested parties were invited by the FAA to participate in the rulemaking effort by submitting written comments on the proposal. No comments were received. Except for editorial changes, this amendment is the same as proposed in the notice. Enroute domestic airspace areas are published in paragraph 6006 of FAA Order 7400.9D, dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The enroute domestic airspace area, as modified by this final rule, will be published subsequently in the Order.

The Rule

This amendment to part 71 of Title 14 of the Code of Federal Regulations (14 CFR part 71) modifies the Browerville/Barter Island, AK, Enroute Domestic Airspace Area by removing that portion of the area protected by controlled airspace known as V–438. This action also renames the airspace area as the Barter Island, AK, Enroute Domestic Airspace Area. Enroute domestic airspace areas provide controlled airspace in those areas where there is a requirement for enroute air traffic control services, but where the Federal airway segment is inadequate. The recent creation of V–438 eliminated the need for that portion of the enroute domestic airspace area removed by this final rule.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71, as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6006—Enroute Domestic Airspace Areas

* * * * *

Barter Island, AK [Revised]

From the Put River, AK, NDB 12 AGL to Barter Island, AK, NDB.

* * * * *

Issued in Washington, DC, on May 15, 1997.

Nancy B. Kalinowski,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 97–13265 Filed 5–20–97; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 558

Animal Drugs, Feeds, and Related Products; Drug Labeler Code; Technical Amendment

AGENCY: Food and Drug Administration, HHS

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the correct drug labeler code for the ADM Animal Health & Nutrition Division that is used in title 21 of the Code of Federal Regulations. This action is being taken to ensure the accuracy of the regulations.

EFFECTIVE DATE: May 21, 1997.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1737.

SUPPLEMENTARY INFORMATION: Parts 510, 520, and 558 (21 CFR parts 510, 520, and 558) contain references to the incorrect drug labeler code number for ADM Animal Health and Nutrition Division. FDA is correcting the regulations in §§ 510.600, 520.445b, 558.128, 558.274, 558.485, 558.625, and 558.630 by removing ''012286'' and adding in its place ''017519''.

List of Subjects

21 CFR Part 510

Administrative practice and procedures, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) in the entry for ''ADM Animal Health & Nutrition Div.'' and in paragraph (c)(2) in the entry for ''012286'' by removing ''012286'' and adding in its place ''017519'', and in paragraph (c)(2) placing the entry in alphanumeric order.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.445b [Amended]

4. Section 520.445b *Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate)* is amended in paragraph (b) by removing ''012286'' and adding in its place ''017519''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

5. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.128 [Amended]

6. Section 558.128 *Chlortetracycline* is amended in paragraph (a)(4) and in the table in paragraph (d)(1) in the ''sponsor'' column by removing ''012286'' each time it appears and adding in its place ''017519''.

§ 558.274 [Amended]

7. Section 558.274 *Hygromycin B* is amended in paragraph (a)(7) and in the table in paragraph (c)(1), under the ''sponsor''column, by removing ''012286'' each time it appears and adding in its place, ''017519''.

§ 558.485 [Amended]

8. Section 558.485 *Pyrantel tartrate* is amended in paragraph (a)(11) by removing ''012286'' and adding in its place''017519''.

§ 558.625 [Amended]

9. Section 558.625 *Tylosin* is amended in paragraphs (b)(10) and (b)(52) by removing ''012286'' and adding in its place ''017519''.

§ 558.630 [Amended]

10. 558.630 *Tylosin and sulfamethazine* is amended in paragraphs (b)(3), (b)(8), and (b)(10) by removing ''012286'' and adding in its place ''017519''.

Dated: May 7, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–13269 Filed 5–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation and Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer Animal Health. The supplemental NADA provides for subcutaneous use of oxytetracycline injection in addition to intramuscular and intravenous use in beef cattle and nonlactating dairy cattle, and calves including preruminating (veal) calves.

EFFECTIVE DATE: May 21, 1997.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 113–232 that provides for use of Liquamycin® LA–200® (oxytetracycline injection) for subcutaneous in addition to intramuscular and intravenous treatment of beef cattle, nonlactating dairy cattle, and calves including preruminating (veal) calves. The supplemental NADA is approved as of April 23, 1997, and the regulations are amended in § 522.1660 (21 CFR 522.1660) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 522.1660(c) is redesignated as paragraph (d) and new paragraph (c) is added to provide for more uniform regulations and future expansion.

Also § 522.1660 is amended in new paragraph (d)(1) to add the phrase ''and calves including preruminating (veal) calves'' after the phrase ''nonlactating cattle'' in the title and an additional sentence following the text of newly redesignated paragraph (d)(1)(iii) to provide for subcutaneous use for this sponsor.

Furthermore, § 522.1660 is amended to correct several typographical errors. The errors are: In § 522.1660(d)(1)(ii), *Haemophilis* is misspelled, *Staphylococcus* is not capitalized, and in § 522.1660(d)(2)(ii), *multocida* is misspelled.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning April 23, 1997, because the supplement contains substantial evidence of effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. Exclusivity applies only to the subcutaneous route of administration.

The agency has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 522

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, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1660 is amended by redesignating paragraph (c) as (d) and reserving paragraph (c), in newly redesignated paragraph (d)(1) by revising the heading, in newly redesignated paragraph (d)(1)(ii) by removing the word ''*Hemophilis*'' and adding in its place ''*Haemophilis*'' and by removing the word ''*staphylococcus*'' and adding in its place ''*Staphylococcus*'', in newly redesignated paragraph (d)(2)(ii) by removing the word ''*multicida*'' and adding in its place ''*multocida*'', and by adding a new sentence at the end of newly redesignated paragraph (d)(1)(iii) to read as follows:

§ 522.1660 Oxytetracycline injection.

* * * * *

(c) [Reserved]

(d) * * *

(1) *Beef cattle, nonlactating dairy cattle and calves including preruminating (veal) calves.* * * *

(iii) * * * For sponsor 000069, use subcutaneously with a maximum of 10 milliliters per injection site in adult cattle as well as intramuscularly and intravenously.

* * * * *