NADA No.	Product name
6–019	Zuco Poultry Tabs
6–081	Korum
6–776	10% Sulfaquinoxaline
6–860	Ruco Tablets
6–891	Liquid Sul-Q-Nox
8–902	Hepasol
100–094	Poultry Sulfa
100–175	20% Sulfaquinoxaline
100–176	34% Sulfaquinoxaline
130–435	Oxytet Soluble
200–106	R–Pen
200–189	Lincomycin Soluble
200–274	Lincomycin Injectable 30%

The agency is amending parts 510 and 520 (21 CFR parts 510 and 520) to reflect the change of sponsor. The agency is amending § 510.600(c)(1) and (c)(2) to remove the sponsor name for I. D. Russell Co., Laboratories because the firm no longer is the holder of any approved NADA's.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to congressional review requirements in 5 U.S.C 801–808.

List of Subjects

21 CFR Part 510

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

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, 21 CFR parts 510 and 520 are amended as follows:

PART 510 NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 *Names, addresses, and drug labeler codes* of sponsors of approved applications is amended in the table in paragraphs (c)(1) by removing the entry for ''I. D. Russell Co., Laboratories'' and in the table in paragraph (c)(2) by removing the entry for ''017144''.

PART 520 ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 360b.

§ 520.1263c [Amended]

4. Section 520.1263c *Lincomycin hydrochloride soluble powder* is amended in paragraph (b) by removing ''017144'' and adding in its place ''046573''.

§ 520.1660d [Amended]

5. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraphs (b)(2), (d)(1)(ii)(A)(*3*), (d)(1)(ii)(B)(*3*), (d)(1)(ii)(C)(*3*), and (d)(1)(iii)(C) by removing ''017144'' and adding in its place ''046573''.

§ 520.1696b [Amended]

6. Section 520.1696b *Penicillin G potassium in drinking water* is amended in paragraph (b) by removing ''017144,''.

§ 520.2088 [Amended]

7. Section 520.2088 *Roxarsone tablets* is amended in paragraph (c)(2) by removing ''017144'' and adding in its place ''046573''.

§ 520.2089 [Amended]

8. Section 520.2089 *Roxarsone liquid* is amended in paragraph (b) by removing ''017144'' and adding in its place ''046573''.

§ 520.2325a [Amended]

9. Section 520.2325a *Sulfaquinoxaline drinking water* is amended in paragraph (a)(3) by removing ''017144'' and adding in its place ''046573''.

Dated: February 16, 2000.

Claire M. Lathers,

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

[FR Doc. 00–4668 Filed 2–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Chlortetracycline Powder

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 Pennfield Oil Co. The supplemental NADA provides for a revised withdrawal time for use of chlortetracycline (CTC) powder in swine drinking water.

DATES: This rule is effective February 29, 2000.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, is sponsor of NADA 65–480 that provides for use of CTC hydrochloride soluble powder for making medicated drinking water for swine and cattle for treatment and control of bacterial enteritis and bacterial pneumonia. The firm filed a supplemental NADA that provides for a zero-day slaughter withdrawal period after use of the product for treatment

and control of disease in swine. The supplemental NADA is approved as of December 22, 1999, and 21 CFR 520.445b(d)(1)(i)(A)(2) is amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to congressional review requirements in 5 U.S.C. 801–808.

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, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 360b.

§ 520.445b [Amended]

2. Section 520.445b *Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate)* is amended in paragraph (d)(1)(i)(A)(*2*) by removing the phrase ''; do not slaughter animals for food within 5 days of treatment''.

Dated: January 28, 2000.

Claire M. Lathers,

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

[FR Doc. 00–4731 Filed 2–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone Acetate and Estradiol

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 Hoechst Roussel Vet. The supplemental NADA provides for use of a higher dose ear implant containing trenbolone acetate and estradiol for steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: February 29, 2000.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed supplemental NADA 140–992 that provides for use of Revalor®-200, an ear implant containing 200 milligrams (mg) of trenbolone acetate and 20 mg of estradiol in 10 pellets. The implant is used for steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. The supplemental NADA is approved as of November 29, 1999, and the regulations are amended in 21 CFR 522.2477 by revising paragraph (b), the heading in paragraph (d)(1), and by adding paragraph (d)(1)(i)(C) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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 approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning on November 29, 1999, because the supplemental application contains substantial evidence of the 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 the approval and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use of the ear implant containing 200 mg trenbolone acetate and 20 mg estradiol for increased rate of weight gain and improved feed efficiency in steers fed in confinement for slaughter.

FDA has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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: 21 U.S.C. 360b.

2. Section 522.2477 is amended by revising paragraph (b), by removing in paragraph (d)(1) the heading ''Feedlot steers'' and by adding in its place ''Steers fed in confinement for slaughter'', and by adding paragraph (d)(1)(i)(C) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(b) *Sponsors.* See 012799 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(ii), (d)(1)(iii), (d)(2), and (d)(3) of this section. See 021641 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(ii), and (d)(1)(iii) of this section.

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