Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: DEC International, Inc., 1919 South Stoughton Rd., P.O. Box 8050, Madison WI 53708–8050, has informed FDA that it has transferred ownership of, and all rights and interests in, NADA 141–200 for EAZI–BREED CIDR Progesterone Intravaginal Inserts to Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199. Accordingly, the agency is amending the regulations in 21 CFR 529.1940 to reflect the transfer of ownership.

Following this change of sponsorship, DEC International, Inc., is no longer the sponsor of any approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for DEC International, Inc.

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

21 CFR Part 510

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

21 CFR Part 529

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 529 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.

§ 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) by removing the entry for ''DEC International, Inc.'' and in the table in paragraph (c)(2) by removing the entry for ''067080''.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 529 continues to read as follows:

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

§ 529.1940 [Amended]

4. Section 529.1940 *Progesterone intravaginal inserts* is amended in paragraph (b) by removing ''067080'' and by adding in its place ''000009''.

Dated: July 17, 2002.

Alan Rudman,

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

[FR Doc. 02–19862 Filed 8–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved abbreviated new animal drug application (ANADA) from Equi Aid Products, Inc., to Farnam Companies, Inc.

DATES: This rule is effective August 7, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Equi Aid Products, Inc., 1517 West Knudsen Dr., Phoenix, AZ 85027, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200–168 for CW 48 (pyrantel tartrate) Type A medicated article to Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928. Accordingly, the agency is amending the regulations in § 558.485 (21 CFR 558.485) to reflect the transfer of ownership.

Following this change of sponsorship, Equi Aid Products, Inc., is no longer the sponsor of any approved application. Accordingly, § 510.600(c) is amended to remove the entries for Equi Aid Products, Inc.

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

21 CFR Part 510

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

21 CFR Part 558

Animal drugs, Animal feeds.

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 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: 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) by removing the entry for ''Equi Aid Products, Inc.'' and in the table in paragraph (c)(2) by removing the entry for ''062240''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: 21 U.S.C. 360b, 371.

§ 558.485 [Amended]

4. Section 558.485 *Pyrantel tartrate* is amended in paragraph (b)(7) by removing '', 017135, and 062240'' and by adding in its place ''and 017135''.

Dated: July 17, 2002.

Alan Rudman,

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

[FR Doc. 02–19861 Filed 8–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble 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 abbreviated new animal drug application (ANADA) filed by Pennfield Oil Co. The supplemental ANADA provides for a zero-day preslaughter withdrawal time for use of oxytetracycline hydrochloride (HCl) soluble powder in the drinking water of swine.

DATES: This rule is effective August 7, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137, filed a supplement to ANADA 200–026 that provides for use of PENNOX 343 (oxytetracycline HCl) soluble powder for making medicated drinking water for the treatment of various bacterial diseases of livestock. The supplemental ANADA provides for a zero-day preslaughter withdrawal time after the use of the product in the drinking water of swine. The supplemental ANADA is approved as of April 10, 2002, and 21 CFR 520.1660d is amended to reflect the approval. The basis of 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.

The agency had 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 Subject 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.

2. Section 520.1660d is amended by revising the last sentence in paragraph (d)(1)(iii)(C) to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(C) * * * Administer up to 5 days; do not use for more than 5 consecutive days; withdraw zero days prior to slaughter those products sponsored by Nos. 046573, 053389, 057561, and 061133.

* * * * *

Dated: July 17, 2002.

Alan Rudman,

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

[FR Doc. 02–19864 Filed 8–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Oxytetracycline

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 two supplemental new animal drug applications (NADAs) filed by Phibro Animal Health, Inc., which provide for a zero-day preslaughter withdrawal time for use of oxytetracycline in swine feed.

DATES: This rule is effective August 7, 2002.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7580, e-mail: *svaughn@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Phibro Animal Health, 710 Rte. 46 East, suite 401, Fairfield, NJ 07004, filed supplements to NADA 8–804 for TM–50, TM–50D, TM–100, and TM–100D (oxytetracycline) Type A medicated articles and NADA 95–143 for OXTC (oxytetracycline) Type A medicated articles used for making medicated feeds for the treatment of various bacterial diseases of livestock. The supplemental NADAs provide for a zero-day withdrawal time prior to slaughter when Type C medicated feeds containing oxytetracycline are fed continuously to swine at a dosage of 10 milligrams per pound (mg/lb) of body weight for up to 14 days. The supplemental NADAs are approved as of April 29, 2002, and the regulations are amended in 21 CFR 558.450 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: 21 U.S.C. 360b, 371.

§ 558.450 [Amended]

2. Section 558.450 *Oxytetracycline* is amended in the table in paragraph (d)(1)(ix), in entries 4 and 5, under the ''Limitations'' column, by removing