

Paperwork Reduction Act

These regulations impose no reporting/recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Death benefits, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income (SSI), Reporting and recordkeeping requirements.

Dated: March 11, 1999.

Kenneth S. Apfel,

Commissioner of Social Security.

For the reasons set out in the preamble, subpart J of part 404 and subpart N of part 416 of chapter III of title 20 of the Code of Federal Regulations are amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

Subpart J is amended as follows:

1. The authority citation for subpart J of part 404 continues to read as follows:

Authority: Secs. 201(j), 204(f), 205(a), (b), (d)–(h), and (j), 221, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 404(f), 405(a), (b), (d)–(h), and (j), 421, 425, and 902(a)(5)); 31 U.S.C. 3720A; sec. 5, Pub. L. 97–455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6(c)–(e), and 15, Pub. L. 98–460, 98 Stat. 1802 (42 U.S.C. 421 note).

2. Section 404.942 is amended by revising paragraph (g), to read as follows:

§ 404.942 Prehearing proceedings and decisions by attorney advisors.

* * * * *

(g) Sunset provision. The provisions of this section will no longer be effective on April 1, 2000, unless they are extended by the Commissioner of Social Security by publication of a final rule in the Federal Register.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart N is amended as follows:

1. The authority citation for subpart N continues to read as follows:

Authority: Sec. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b); 31 U.S.C. 3720A.

2. Section 416.1442 is amended by revising paragraph (g), to read as follows:

§ 416.1442 Prehearing proceedings and decisions by attorney advisors.

* * * * *

(g) Sunset provision. The provisions of this section will no longer be effective on April 1, 2000, unless they are extended by the Commissioner of Social Security by publication of a final rule in the Federal Register.

[FR Doc. 99–6880 Filed 3–19–99; 8:45 am]

BILLING CODE 4190–29–P

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 two supplemental abbreviated new animal drug applications (ANADA's) filed by PennField Oil Co. The ANADA's provide for a zero-day withdrawal period for use of oxytetracycline hydrochloride (OTC HCl) soluble powder in the drinking water of turkeys and for an additional package size.

EFFECTIVE DATE: March 22, 1999.

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, filed two supplements to ANADA 200–026. One supplement provides for a zero-day withdrawal period for turkeys using PennField Oil Co.'s Oxytetracycline HCl–343 (oxytetracycline hydrochloride) treated drinking water. The other supplement provides for use of a package containing 512 grams of OTC HCl per 23.9 ounces

of soluble powder for making medicated drinking water for cattle, swine, sheep, chickens, and turkeys. The medicated drinking water is used for the control and treatment of bacterial infections caused by oxytetracycline susceptible organisms.

The supplemental ANADA's are approved as of February 5, 1999, and 21 CFR 520.1660d(a)(8) and (d)(1)(ii) are amended 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.

The agency 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.

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.

2. Section 520.1660d is amended in paragraphs (a)(8), (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), and (d)(1)(ii)(C)(3) by adding a sentence to the end of each paragraph to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

(a) * * *

(8) * * * Each 677.5-gram packet (23.9 ounce) contains 512 grams of OTC HCl.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(A) * * *

(3) * * * Zero-day withdrawal for those products sponsored by No. 053389.

(B) * * *
 (3) * * * Zero-day withdrawal for those products sponsored by No. 053389.

(C) * * *
 (3) * * * Zero-day withdrawal for those products sponsored by No. 053389.

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Dated: February 26, 1999.

Margaret Ann Miller,

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

[FR Doc. 99-6807 Filed 3-19-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs for Use in Animal Feeds; Tilmicosin

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 Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA for veterinary prescription use of tilmicosin Type C medicated swine feeds under a veterinary feed directive (VFD) provides a revised limitation to prevent accidental access by horses. Also, FDA amends the regulation to provide a swine muscle tolerance and an acceptable daily intake (ADI).

EFFECTIVE DATE: March 22, 1999.

FOR FURTHER INFORMATION CONTACT:

William T. Flynn, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7570.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, is sponsor of NADA 141-064 that provides for the use of Pulmotil® (tilmicosin) Type A medicated article to make Type B and Type C medicated swine feeds for control of swine respiratory disease. The drug is limited to use by or on the order of a licensed veterinarian under an approved VFD. The firm filed a supplemental NADA that provided for a revised limitation to prevent accidental access by horses. Also, FDA reviewed the information in the application and revised the regulation to provide an ADI

and a swine muscle tolerance. The supplemental NADA is approved as of February 2, 1999, and the regulations in 21 CFR 556.735 and 558.618 are amended 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 supplemental 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 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.

List of Subjects

21 CFR Part 556

Animal drugs, Food.

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 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.735 is revised to read as follows:

§ 556.735 Tilmicosin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of tilmicosin is 25 micrograms per kilogram of body weight per day.

(b) *Tolerances—(1) Cattle.* A tolerance is established for residues of parent tilmicosin (marker residue) in liver (target tissue) at 1.2 parts per million (ppm).

(2) *Swine.* A tolerance is established for residues of parent tilmicosin (marker residue) in liver (target tissue) at 7.5 ppm and in muscle at 0.1 ppm.

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.

4. Section 558.618 is amended in paragraph (d)(3) by adding a new sentence after the second sentence to read as follows:

§ 558.618 Tilmicosin

* * * * *

(d) * * *

(3) * * * Do not allow horses or other equine access to feeds containing tilmicosin. * * *

* * * * *

Dated: February 26, 1999.

Margaret Ann Miller,

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

[FR Doc. 99-6669 Filed 3-19-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF STATE

22 CFR Parts 121 and 124

[Public Notice 3011]

Amendments to the International Traffic in Arms Regulations (ITAR): Control of Commercial Communications Satellites on the United States Munitions List

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule amends the International Traffic in Arms Regulations (ITAR) by re-designating on the U.S. Munitions List (USML) commercial communications satellites. **EFFECTIVE DATE:** March 15, 1999.

FOR FURTHER INFORMATION CONTACT:

William J. Lowell, Director, Office of Defense Trade Controls, Bureau of Political-Military Affairs, Department of State, Telephone (703) 812-2564 or FAX (703) 875-6647 ATTN: Regulatory Change, Commercial Communications Satellites.

SUPPLEMENTARY INFORMATION: On October 17, 1998, the President signed Public Law 105-261, The Strom Thurmond National Defense Authorization Act for Fiscal Year 1999. This Act requires that, inter alia, effective March 15, 1999, communications satellites and related items (as defined in the Act) be controlled on the U.S. Munitions List, except with respect to export licenses for such satellites issued by the Department of Commerce before March 15, 1999 and export license applications