(B) * * *

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

(C) * * *

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

* * * * *

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