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 556.347 is revised to read as follows:

§ 556.347 Lasalocid.

(a) [Reserved]

(b) *Tolerances*—(1) *Chickens*. A tolerance is established for lasalocid residues of 0.3 part per million (ppm) parent lasalocid (marker residue) in skin with adhering fat (target tissue).

(2) *Cattle*. A tolerance is established for lasalocid residues of 0.7 ppm parent lasalocid (marker residue) in liver (target tissue).

(3) *Sheep*. A tolerance for residues of lasalocid is not needed.

(4) *Rabbits*. A tolerance is established for lasalocid residues of 0.7 ppm parent lasalocid (marker residue) in liver (target tissue).

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 558.311 is amended by revising paragraph (b)(4) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(b) * * *

(4) 15 percent activity to No. 063238 for use in Type C rabbit feeds as in paragraph (e)(1)(xvi) of this section and for use in ruminant free-choice Type C feeds as in paragraphs (e)(2) and (e)(3) of this section.

* * * * *

Dated: February 23, 1999.

Andrew J. Beaulieu,

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

[FR Doc. 99–6461 Filed 3–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Monensin and Virginiamycin

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 new animal drug application (NADA) filed by Elanco Animal Health, a Division of Eli Lilly and Co. The NADA provides for combining approved monensin and virginiamycin Type A medicated articles to make combination drug Type C medicated growing turkey feeds used for prevention of certain forms of coccidiosis and for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: March 17, 1999.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, a Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141–110 that provides for combining approved monensin and virginiamycin Type A medicated articles to make combination drug Type C medicated growing turkey feeds containing 54 to 90 grams per ton (g/t) monensin and 10 to 20 g/t virginiamycin. The Type C medicated growing turkey feed is used for the prevention of coccidiosis caused by *Eimeria meleagrimitis*, *E. adenoeides*, and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of January 29, 1999, and the regulations are amended in 21 CFR 558.355 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 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.

FDA has determined under 21 CFR 25.33(a)(2) 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 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.

2. Section 558.355 is amended by adding paragraph (f)(2)(iv) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(2) * * *

(iv) *Amount per ton*. Monensin, 54 to 90 grams, with virginiamycin, 10 to 20 grams.

(a) *Indications for use*. For the prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency in growing turkeys.

(b) *Limitations*. For growing turkeys only. Feed continuously as sole ration. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses, mature turkeys, and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Virginiamycin as provided by No. 000069 in § 510.600(c) of this chapter.

* * * * *

Dated: February 26, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–6460 Filed 3–16–99; 8:45 am]

BILLING CODE 4160–01–F