therapy must not exceed 25 micrograms per liter (µg/L).

(b) The package insert of LVP's used in TPN therapy must state that the drug product contains no more than 25 µg/L of aluminum. This information must be contained in the ''Precautions'' section of the labeling of all large volume parenterals used in TPN therapy.

(c) The maximum level of aluminum present at expiry must be stated on the immediate container label of all small volume parenteral (SVP) drug products and pharmacy bulk packages (PBP's) used in the preparation of TPN solutions. The aluminum content must be stated as follows: ''Contains no more than—— µg/L of aluminum.'' The immediate container label of all SVP's and PBP's that are lyophilized powders used in the preparation of TPN solutions must contain the following statement: ''When reconstituted in accordance with the package insert instructions, the concentration of aluminum will be no more than —— µg/L.'' This maximum level of aluminum must be stated as the highest of:

(1) The highest level for the batches produced during the last 3 years;

(2) The highest level for the latest five batches, or

(3) The maximum historical level, but only until completion of production of the first five batches after January 26, 2001.

(d) The package insert for all LVP's, all SVP's, and PBP's used in TPN must contain a warning statement. This warning must be contained in the ''Warnings'' section of the labeling. The warning must state:

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 µg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

(e) Applicants and manufacturers must use validated assay methods to determine the aluminum content in parenteral drug products. The assay methods must comply with current good manufacturing practice requirements. Applicants must submit to the Food and Drug Administration validation of the method used and release data for several batches. Manufacturers of parenteral drug products not subject to an approved application must make assay methodology available to FDA during inspections. Holders of pending applications must submit an amendment under § 314.60 or § 314.96 of this chapter.

Dated: December 29, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–1788 Filed 1–25–00; 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; Ractopamine Hydrochloride

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 use of a ractopamine hydrochloride Type A medicated article to make Type B and Type C medicated swine feeds. The Type C medicated finishing swine feeds are used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness. The regulations are also amended to provide for an acceptable daily intake (ADI) for ractopamine and tolerances for drug residues in edible products derived from treated swine.

DATES: This rule is effective January 26, 2000.

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 140–863 that provides for use of Paylean® (ractopamine hydrochloride) Type A medicated article to make Type B and Type C medicated swine feeds. The Type C medicated finishing swine feeds must contain at least 16 percent crude protein. Feeds containing 4.5 grams per ton (g/t) ractopamine hydrochloride are used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness. Feeds containing 4.5 to 18 g/t ractopamine hydrochloride are used for improved feed efficiency and increased carcass leanness. The NADA is approved as of December 22, 1999, and the regulations in part 558 (21 CFR part 558) are amended by adding § 558.500 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Furthermore, § 558.4(d) is amended in the ''Category I'' table by adding an entry for ''ractopamine'' to provide for the assay limits for Type A medicated articles and Type B/C medicated feeds and the maximum Type B medicated feed level.

In addition, part 556 (21 CFR part 556) is amended by adding § 556.570 to establish an ADI for total ractopamine and tolerances for residues of ractopamine in edible tissues of treated swine.

In accordance with the freedom of information provisions of 21 CFR part 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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval for food-producing animals qualifies for 5 years of marketing exclusivity beginning December 22, 1999, because no active ingredient (including any ester or salt of the active ingredient) has been previously approved for any other application filed under section 512(b)(1).

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 556

Animal drugs, Foods.

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 556.570 is added to subpart B to read as follows:

§ 556.570 Ractopamine.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of ractopamine is 1.25 micrograms ractopamine hydrochloride per kilogram of body weight per day.

(b) *Tolerances.* Swine—Tolerances are established for residues of ractopamine hydrochloride parent (marker residue) in edible swine tissues of 0.05 part per million (ppm) in muscle, and 0.15 ppm in liver (target tissue). Residues of ractopamine in swine muscle are not indicative of the safety of residues in other edible 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 558.4 is amended in paragraph (d) in the ''Category I'' table by adding an entry alphabetically for ''Ractopamine'' to read as follows:

§ 558.4 Medicated feed applications.

* * * * *

(d) * * *

CATEGORY I

Drug	Assay limits percent [1] type A	Type B maximum (200x)	Assay limits percent [1] type B/C [2]
* *	*	* *	* *
Ractopamine	85–105	1.8 g/lb (0.4%)	80–110
* *	*	* *	* *

[1] Percent of labeled amount.

[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

* * * * *

5. Section 558.500 is added to subpart B to read as follows:

§ 558.500 Ractopamine.

(a) *Approvals.* Type A medicated articles: 9 grams of ractopamine hydrochloride per pound to 000986 in § 510.600(c) of this chapter.

(b) [Reserved]

(c) *Related tolerances.* See § 556.570 of this chapter.

(d) *Conditions of use.* (1) *Swine*—(i) *Amount.* 4.5 grams of ractopamine hydrochloride per ton of Type C feed for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; 4.5 to 18 grams per ton for improved feed efficiency and increased carcass leanness; fed in a complete ration containing at least 16 percent crude protein to finishing swine from 150 to 240 pounds body weight.

(ii) *Limitations.* Feed continuously as sole ration. Not for use in breeding swine.

(2) [Reserved]

Dated: January 13, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–1789 Filed 1–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803 and 804

[Docket No. 98N–0170]

Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, Distributor Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing reporting by manufacturers, importers, distributors and health care (user) facilities of adverse events related to medical devices. Amendments are being made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: March 27, 2000.

FOR FURTHER INFORMATION CONTACT: Susan E. Bounds, Center for Devices and Radiological Health (HFZ–500), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2735.

SUPPLEMENTARY INFORMATION:

I. General

In the **Federal Register** of September 14, 1984 (49 FR 36326), FDA issued medical device reporting regulations for manufacturers and importers under the act and the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295). To correct weaknesses noted in the 1976 amendments, and to better protect the public health by increasing reports of device-related adverse events, Congress enacted the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), which required medical device user facilities and distributors to report certain device-related adverse events.

Distributor reporting requirements became effective on May 28, 1992, following the November 26, 1991 (56 FR 60024), the publication of those provisions in a tentative final rule. In the **Federal Register** of September 1, 1993 (58 FR 46514), FDA published a notice announcing that the proposed distributor reporting regulations had become final by operation of law and were now codified in part 804 (21 CFR part 804).