

Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: [edubbin@cvm.fda.gov](mailto:edubbin@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141-221 that provides for use of OPTAFLEXX 45 (ractopamine hydrochloride) Type A medicated article to make dry and liquid Type B and dry Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 28 to 42 days on feed. The NADA is approved as of June 13, 2003, and the regulations in 21 CFR 556.570 and 558.500 are 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 21 CFR 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 Division of Dockets Management (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 carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental

assessment, may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning June 13, 2003.

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 revised to read as follows:

##### § 556.570 Ractopamine.

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

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue)*. The tolerance for ractopamine hydrochloride (the marker residue) is 0.09 parts per million (ppm).

(ii) *Muscle*. The tolerance for ractopamine hydrochloride (the marker residue) is 0.03 ppm.

(2) *Swine*—(i) *Liver (the target tissue)*. The tolerance for ractopamine hydrochloride (the marker residue) is 0.15 ppm.

(ii) *Muscle*. The tolerance for ractopamine hydrochloride (the marker residue) is 0.05 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 558.500 is amended by adding paragraphs (d)(3) and (e)(2) to read as follows:

##### § 558.500 Ractopamine.

\* \* \* \* \*

(d) \* \* \*

(3) Ractopamine liquid Type B cattle feeds may be manufactured from dry ractopamine Type A articles. The liquid Type B feeds must be maintained at a pH of 4.5 to 7.5. Mixing directions for liquid Type B feeds requiring recirculation or agitation: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(e) \* \* \*

(2) *Cattle*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8.2 to 24.6		Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding.	000986
(ii) 9.8 to 24.6		Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding.	000986