

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

DMB

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Certifier	<i>JHJ</i>

Tolerances for Residues of New Animal Drugs in Food; Lasalocid

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 Alpharma, Inc., which provides for establishing tolerances for residues of lasalocid in edible tissues of poultry.

DATES: This rule is effective [*insert date of publication* in the **Federal Register**].

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: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 96-298 that provides for the use of Avatec® (lasalocid sodium) Premix, a Type A medicated article. The supplement provides for establishing tolerances for residues of lasalocid in edible tissues of chickens and turkeys. The supplement is approved as of February 20, 2001, and the regulations in § 556.347 (21 CFR 556.347) are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, the agency is taking the opportunity to codify the acceptable daily intake (ADI) for total residues of lasalocid which was previously established, and to establish a tolerance for residues of lasalocid in sheep liver. The regulations are further amended in § 556.347 to reflect these actions.

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.

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 in 21 CFR Part 556

Animal drugs, Foods.

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 556 is 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) *Acceptable daily intake (ADI)*. The ADI for total residues of lasalocid is 10 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*. The tolerance for parent lasalocid (the marker residue) in liver (the target tissue) is 0.7 part per million (ppm).

(2) *Chickens*—(i) *Skin with adhering fat (the target tissue)*. The tolerance for parent lasalocid (the marker residue) is 1.2 ppm.

(ii) *Liver*. The tolerance for parent lasalocid (the marker residue) is 0.4 ppm.

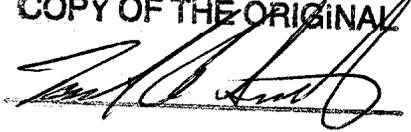
(3) *Turkeys*—(i) *Liver (the target tissue)*. The tolerance for parent lasalocid (the marker residue) is 0.4 ppm.

(ii) *Skin with adhering fat*. The tolerance for parent lasalocid (the marker residue) is 0.4 ppm.

(4) *Rabbits*. The tolerance for parent lasalocid (the marker residue) in liver (the target tissue) is 0.7 ppm.

(5) *Sheep*. The tolerance for parent lasalocid (the marker residue) in liver (the target tissue) is 1.0 ppm.

Dated: 4/9/01
April 9, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL


SF Sundlof
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Director,
Center for Veterinary Medicine.

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