

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**Food and Drug Administration**

**21 CFR Part 556**

**Tolerances for Residues of New Animal Drugs in Food; Clorsulon**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**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 Merial Ltd. The supplemental NADA provides for establishing a tolerance for residues of clorsulon in the muscle tissue of cattle.

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

**FOR FURTHER INFORMATION CONTACT:** Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

**SUPPLEMENTARY INFORMATION:** Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077, filed a supplement to NADA 136-742 that provides for the use of Curatrem® (clorsulon) Drench in cattle for the treatment of liver fluke infestations. The supplement provides for establishing a tolerance for residues of clorsulon in the muscle tissue of cattle. The supplement is approved as of May 16, 2001, and § 556.163 (21 CFR 556.163) is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 556.163 is further amended by deleting references to safe concentrations and by adding the previously established acceptable daily intake of total residues of clorsulon.

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 556.163 is revised to read as follows:

#### **§ 556.163 Clorsulon.**

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of clorsulon is 8 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Kidney (the target tissue)*. The tolerance for parent clorsulon (the marker residue) is 1.0 part per million.

(ii) *Muscle*. The tolerance for parent clorsulon (the marker residue) is 0.1 part per million.

(2) [Reserved]

Dated: June 25, 2001  
June 25, 2001.

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

Monica Oliver

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