

DMS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

Display Date 12-1-04  
Publication Date 12-2-04  
Certifier [Signature]

**New Animal Drugs for Use in Animal Feeds; Coumaphos**

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

**ACTION:** Final rule; technical amendment.

---

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to remove conditions of use in cattle and chickens for a coumaphos Type A medicated article for which approval was withdrawn in July 1996. This action is being taken to improve the accuracy of the agency's regulations.

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

**FOR FURTHER INFORMATION CONTACT:** George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4567, e-mail: [george.haibel@fda.gov](mailto:george.haibel@fda.gov).

**SUPPLEMENTARY INFORMATION:** FDA has found that parts 500 to 599 (21 CFR parts 500 to 599) of the Code of Federal Regulations reflect conditions of use in cattle for a coumaphos Type A medicated article for which approval was withdrawn by FDA, at the sponsors request, on July 3, 1996 (61 FR 34727). At this time, FDA is amending the regulations in § 558.185 to reflect the remaining approved uses of coumaphos in medicated cattle feeds.

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 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 558.185 is amended by redesignating paragraph (d) as paragraph (e); by revising paragraphs (a), (b), (d), and newly redesignated (e)(1); and by adding paragraph (d) to read as follows:

*Handwritten signature: P. B. Little*

**§ 558.185 Coumaphos.**

(a) *Specifications.* Type A medicated articles containing 1.12, 2.0, 11.2, or 50 percent coumaphos.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000859 for use of Type A medicated articles containing 1.12, 2.0, 11.2, or 50 percent coumaphos as in paragraphs (e)(2) and (e)(3) of this section.

(2) No. 017800 for use of Type A medicated articles containing 1.12 or 11.2 percent coumaphos as in paragraph (e)(1) of this section.

\* \* \* \* \*

(d) *Special considerations.* Labeling shall bear the following caution statement: “The active ingredient coumaphos is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before

or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.” Also, see § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Beef and dairy cattle*—(i) *Amount*. 0.0002 lb. (0.091 gram) per 100 lb. body weight per day for 6 consecutive days. Should conditions warrant, repeat treatment at 30-day intervals.

(ii) *Indications for use*. Control of gastrointestinal roundworms (*Haemonchus* spp., *Ostertagia* spp., *Cooperia* spp., *Nematodirus* spp., *Trichostrongylus* spp.).

(iii) *Limitations*. Feed in the normal grain ration to which the animals are accustomed, but not in rations containing more than 0.1 percent coumaphos. Do not feed to animals less than 3 months old. Do not feed to sick animals

or animals under stress, such as those just shipped, dehorned, castrated, or weaned within the last 3 weeks. Do not feed in conjunction with oral drenches or with feeds containing phenothiazine.

\* \* \* \* \*

Dated: 11/16/04

November 16, 2004.

SFS/A

Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

**BILLING CODE 4160-01-S**

*Roome*