

Dated: November 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-33637 Filed 12-18-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline and Monensin Sodium

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 an abbreviated new animal drug application (ANADA) filed by Alpharma Inc. The ANADA provides for the use of approved chlortetracycline Type A medicated articles and monensin sodium Type A medicated articles in making Type C medicated chicken feed used as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatments and as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* in broiler chickens.

EFFECTIVE DATE: December 21, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is the sponsor of ANADA 200-263 that provides for the use of approved ChlorMax™ Coban®, chlortetracycline Type A medicated articles and monensin sodium Type A medicated articles) in making Type C medicated chicken feed used as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatments, and as an aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* in broiler chickens. The ANADA is approved as a generic copy of Roche Vitamins, Inc.'s NADA 121-553, Aureomycin®-Coban®. ANADA 200-263 is approved as of September 21, 1998, and the regulations are amended in 21 CFR 558.355 to reflect the approval. The basis for approval is

discussed in the freedom of information summary.

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)(2) 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.

List of Subjects in 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 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.

§ 558.355 [Amended]

2. Section 558.355 *Monensin* is amended in paragraph (b)(11) by removing “(f)(1)(xviii)” and adding in its place “(f)(1)(xiv), (xviii),” and in paragraph (f)(1)(xiv)(b) by removing the phrase “No. 063238” and adding in its place “Nos. 046573 and 063238”.

Dated: November 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 31

[TD 8794]

RIN 1545-AW58

Increase in Cash-Out Limit Under Sections 411(a)(7), 411(a)(11), and 417(e)(1) for Qualified Retirement Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations providing guidance relating to the increase from \$3,500 to \$5,000 of the limit on distributions from qualified retirement plans that can be made without participant consent. This increase is contained in the Taxpayer Relief Act of 1997. In addition, these regulations eliminate, for most distributions, the “lookback rule” pursuant to which the qualified plan benefits of certain participants are deemed to exceed this limit on mandatory distributions. The final and temporary regulations affect sponsors and administrators of qualified retirement plans, and participants in those plans. The final regulations also amend the existing final regulations to cross-reference the temporary regulations. The text of the temporary regulations also serves, in part, as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of the **Federal Register**.

DATES: Effective Date: These regulations are effective December 21, 1998.

Applicability Date: These final and temporary regulations generally apply to distributions made on or after March 22, 1999. However, employers are permitted to apply the final regulations and the temporary regulations other than § 1.411(a)-11T(c)(3)(i) to plan years beginning on or after August 6, 1997.

FOR FURTHER INFORMATION CONTACT: Michael J. Karlan, (202) 622-6030 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations and the Employment Tax Regulations (26 CFR parts 1 and 31) under sections 411(a)(7), 411(a)(11), and 417(e)(1) regarding restrictions on involuntary distributions and joint and survivor annuity requirements for qualified plans. The final and temporary regulations change the existing regulations to take into account amendments made by the Taxpayer Relief Act of 1997 (TRA '97), Public Law 105-34, 111 Stat. 788 (1997).

Explanation of Provisions

A. Restrictions on Mandatory Distributions

Prior to the enactment of TRA '97, section 411(a)(11)(A) provided that if the present value of any nonforfeitable accrued benefit exceeded \$3,500, a plan met the requirements of section