DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Robenidine and Bacitracin Zinc

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 using approved robenidine and bacitracin zinc Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis and increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: December 23, 1997.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV–28), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1602.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is the sponsor of ANADA 200–212 which provides for combining approved robenidine and bacitracin zinc Type A medicated articles to make Type C medicated broiler feeds containing robenidine hydrochloride 30 grams per ton (g/t) and bacitracin zinc 4 to 50 g/t for prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and with bacitracin zinc 4 to 30 g/t, for increased rate of weight gain, and with bacitracin zinc 27 to 50 g/t, for improved feed efficiency.

Alpharma Inc.'s ANADA 200–212 is approved as a generic copy of Hoffmann-La Roche, Inc.'s NADA 96–933. The ANADA is approved as of December 23, 1997, and the regulations are amended in 21 CFR 558.515(d)(1)(vi)(*b*) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of two single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, robenidine, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required to make Type C medicated feed from a Category II drug. Under section 512(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of robenidine and bacitracin zinc Type A medicated articles to make Type C medicated feeds as provided in NADA 200–212 is limited to manufacture in a licensed feed mill.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33 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.

§ 558.515 [Amended]

2. Section 558.515 *Robenidine hydrochloride* is amended in paragraph (d)(1)(vi)(*b*) by removing ''000004 and 000061'' and adding in its place ''000004, 000061, and 046573''.

Dated: October 30, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–33489 Filed 12–22–97; 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; Amprolium Plus Ethopabate With Bacitracin Zinc and Roxarsone

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 using approved amprolium plus ethopabate with bacitracin zinc and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds used as an aid in the prevention of coccidiosis and increased rate of weight gain in broiler chickens raised in floor pens.

EFFECTIVE DATE: December 23, 1997.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1602.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed ANADA 200–217 that provides for combining approved amprolium plus ethopabate with bacitracin zinc and roxarsone Type A medicated articles to make Type C medicated broiler feeds. The Type C medicated feed containing amprolium 113.5 grams per ton (g/t) plus ethopabate 36.3 g/t with bacitracin zinc 5 to 35 g/t and roxarsone 34 g/t, is used as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur, and for increased rate of weight gain in broiler chickens raised in floor pens.

Alpharma Inc.'s ANADA 200–217 provides for using approved AMPROL HI–E® (Merck's amprolium and ethopabate NADA 13–461), ALBAC® (Alpharma Inc.'s bacitracin zinc ANADA 200–223), and 3–NITRO® (Alpharma Inc.'s roxarsone NADA 7–891) Type A medicated articles to make the combination drug Type C medicated feeds.

Alpharma Inc.'s ANADA 200–217 is approved as a generic copy of Swisher Feed Div.'s NADA 39–284. The ANADA is approved as of December 23, 1997, and the regulations are amended in 21

CFR 558.58(d)(1)(iii) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of three Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, roxarsone, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required to make Type C medicated feed from a Category II drug. Under section 512(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of amprolium plus ethopabate, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated feeds as provided in ANADA 200–217 is limited to manufacture in a licensed feed mill.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 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.

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.

§ 558.58 [Amended]

2. Section 558.58 *Amprolium and ethopabate* is amended in paragraph (d)(1)(iii) in the table in the entry for ''Bacitracin 5 to 35 plus roxarsone 34 (0.00375%)'' in the column ''Limitations'' by removing ''No. 000004'' and adding in its place ''Nos. 000004 and 046573''.

Dated: October 30, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–33488 Filed 12–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 25 and 602

[TD 8743]

RIN 1545–AU12

Sale of Residence From Qualified Personal Residence Trust

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations permitting the reformation of a personal residence trust or a qualified personal residence trust in order to comply with the applicable requirements for such trusts. The final regulations also provide that the governing instruments of such trusts must prohibit the sale of a residence held in the trust to the grantor of the trust, the grantor's spouse, or an entity controlled by the grantor or the grantor's spouse.

DATES: The regulations are effective December 23, 1997.

FOR FURTHER INFORMATION CONTACT: Lane Damazo (202) 622–3090 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1485. Responses to this collection of information are required in order to ensure the proper collection of the gift tax.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The estimated annual burden per respondent/recordkeeper varies from 3 hours to 3.25 hours, depending on individual circumstances, with an estimated average of 3.1 hours.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer T:FP, Washington, DC 20224, and to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to this collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

On April 16, 1996, the IRS published in the **Federal Register** a notice of proposed rulemaking (formerly PS–004–96) at 61 FR 16623. The IRS received written and oral comments on the proposed regulations and held a public hearing on July 24, 1996. This document adopts final regulations with respect to this notice of proposed rulemaking.

Comments with respect to § 25.2702–5(a)(2) indicated that the procedure permitting reformation of trust instruments will be helpful to taxpayers and practitioners. It was suggested that an additional reformation period be made available for trusts for which the gift tax return due date had passed before the regulations became effective. Accordingly, under the final regulations, the trustees of trusts created before January 1, 1997, are granted a 90-day period after these regulations become final in which to reform the trust.

Some of the comments concerning the amendments to § 25.2702–5(b) and (c) agreed that the restrictions in the proposed regulations on the sale of the personal residence after the termination of the grantor's retained interest in a personal residence trust or a qualified personal residence trust further the intent of Congress in enacting section 2702(a)(3)(A)(ii). Other comments stated that the restrictions were not supported by the statute. Treasury and the IRS continue to believe that these regulations are consistent with the intent of Congress and carry out the purpose of the personal residence exception to section 2702.

Other comments suggested that the final regulations should contain an exception permitting the sale of the residence to the grantor if the need arises. Treasury and the IRS believe, however, that a rule of this nature is not necessary, since a grantor may lease the residence after the retained term from a trust or individual to which the