07083–1982, is sponsor of NADA 141–063 that provides for veterinary prescription use of Nuflor® Injectable Solution (florfenicol) for treatment of cattle for BRD. The firm filed a supplemental NADA that provides for veterinary prescription use of Nuflor® Injectable Solution (florfenicol) by a single subcutaneous injection for control of respiratory disease in cattle at high risk of developing BRD associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*. The supplemental NADA is approved as of December 17, 1998, and the regulations are amended by revising 21 CFR 522.955(d)(1) to reflect the approval. The basis of 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 supplement 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.

Under 21 U.S.C. 360b(c)(2)(F)(iii), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning December 17, 1998, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant. Three years marketing exclusivity is limited to subcutaneous use of the drug for control of respiratory disease in cattle at high risk of developing BRD associated with *P. haemolytica*, *P. multocida*, and *H. somnus*.

The agency has determined under 21 CFR 25.33(d)(5) 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 522

Animal drugs.

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.955 is amended by revising paragraph (d)(1)(i), by redesignating paragraph (d)(1)(ii) as paragraph (d)(1)(i)(B), and by adding paragraphs (d)(1)(ii)(A) and (d)(1)(ii)(B) to read as follows:

§ 522.955 Florfenicol solution.

* * * * *

(d) * * *

(1) * * *

(i) *Treatment of disease*—(A) *Amount.* 20 milligrams per kilogram of body weight (3 milliliters per 100 pounds) as an intramuscular injection. A second dose should be given 48 hours later. Alternatively, 40 milligrams per kilogram of body weight (6 milliliters per 100 pounds) as a single subcutaneous injection may be used.

(B) *Indications for use.* * * *

(ii) *Control of disease*—(A) *Amount.* 40 milligrams per kilogram of body weight (6 milliliters per 100 pounds) as a single subcutaneous injection.

(B) *Indications for use.* For control of respiratory disease in cattle at high risk of developing bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*.

* * * * *

Dated: January 13, 1999.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–2686 Filed 2–3–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Bacitracin Methylene Disalicylate and Roxarsone With Monensin

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. The supplemental NADA provides for using approved single ingredient bacitracin methylene disalicylate (BMD), monensin, and roxarsone Type A medicated articles to make an additional use level of BMD in Type C medicated broiler chicken feeds.

EFFECTIVE DATE: February 4, 1999.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7575.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed supplemental NADA 116–088 that provides for combining approved BMD® (10, 25, 30, 50, 60, or 75 grams per pound (g/lb) BMD), Coban® (45 or 60 g/lb monensin sodium), and 3–Nitro® (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to make Type C medicated broiler chicken feeds containing 100 to 200 g/ton(t) BMD, 90 to 110 g/t monensin sodium, and 22.7 to 45.4 g/t roxarsone. The BMD, monensin, and 22.7 to 34 g/t roxarsone Type C medicated feeds are used as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to BMD; as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain and improved feed efficiency. The BMD, monensin, and 22.7 to 45.4 g/t roxarsone Type C medicated feeds are used as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to BMD; as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain. The supplemental NADA is approved as of December 24, 1998, and the regulations are amended in 21 CFR 558.355 by revising paragraph (b)(11) and adding paragraphs (f)(1)(xxvi) and (f)(1)(xxvii) 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 the 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.

2. Section 558.355 is amended in paragraph (b)(11) by deleting ''and (xxv)'' and adding in its place ''(xxv), (xxvi), and (xxvii)'' and by adding paragraphs (f)(1)(xxvi) and (f)(1)(xxvii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(1) * * *

(xxvi) *Amount per ton.* Monensin 90 to 110 grams plus bacitracin 100 to 200 grams and roxarsone 22.7 to 34.0 grams.

(*a*) *Indications for use.* As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylene disalicylate; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*; for increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying hens. To control necrotic enteritis, start medication at first clinical signs of disease. The dosage range permitted provides for different levels based on the severity of infection. Use continuously for 5 to 7 days or as long as clinical signs persist, then reduce dosage to prevention level. Animals should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness. As roxarsone and bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.

(xxvii) *Amount per ton.* Monensin 90 to 110 grams plus bacitracin 100 to 200 grams and roxarsone 22.7 to 45.4 grams.

(*a*) *Indications for use.* As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylene disalicylate; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*; for increased rate of weight gain.

(*b*) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying hens. To control necrotic enteritis, start medication at first clinical signs of disease. The dosage range permitted provides for different levels based on the severity of infection. Use continuously for 5 to 7 days or as long as clinical signs persist, then reduce dosage to prevention level. Animals should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness. As roxarsone and bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.

* * * * *

Dated: January 13, 1999.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–2687 Filed 2–3–99; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8816]

RIN 1545–AW62

Roth IRAs

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to Roth IRAs under section 408A of the Internal Revenue Code (Code). Roth IRAs were created by the Taxpayer Relief Act of 1997 as a new type of IRA that individuals can use beginning in 1998. Section 408A was amended by the Internal Revenue Service Restructuring and Reform Act of 1998. On September 3, 1998, a notice of proposed rulemaking was published in the **Federal Register** (63 FR 46937) under Code section 408A. Written comments were received regarding the proposed regulations. On December 10, 1998, a public hearing was held on the proposed regulations. The final regulations affect individuals establishing Roth IRAs, beneficiaries under Roth IRAs, and trustees, custodians or issuers of Roth IRAs.

DATES: *Effective date:* The final regulations are effective on February 3, 1999.

Applicability date: The final regulations are applicable to taxable years beginning on or after January 1, 1998, the effective date for section 408A.

FOR FURTHER INFORMATION CONTACT: Cathy A. Vohs, (202) 622–6030 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in §§ 1.408A–2, 1.408A–4, 1.408A–5, and 1.408A–7 of the final regulations have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–1616. Responses to this collection of information are mandatory.

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

Estimated average annual burden per respondent/recordkeeper: 1 minute for designating an IRA as a Roth IRA and 30 minutes for recharacterizing an IRA contribution. The estimated burdens for the other reporting/recordkeeping requirements in the these final regulations are reflected in the burden of Forms 8606, 1040, 5498, and 1099R.

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

Books or records relating to a 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 September 3, 1998, a notice of proposed rulemaking was published in the **Federal Register** (63 FR 46937) under section 408A of the Internal