

for increased rate of weight gain and improved feed efficiency in growing turkeys.

(b) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 012799 in § 510.600(c) of this chapter.

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Dated: August 23, 2000.

**Stephen F. Sundlof,**

Director, Center for Veterinary Medicine.

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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; Monensin, Bacitracin Methylene Disalicylate, 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 a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved, single-ingredient monensin, bacitracin methylene disalicylate (BMD), and roxarsone Type A medicated articles to make three-way combination drug Type C medicated feed used as an aid in the prevention of coccidiosis, as an aid in the prevention and control of necrotic enteritis, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

**DATES:** This rule is effective September 5, 2000.

**FOR FURTHER INFORMATION CONTACT:** Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

**SUPPLEMENTARY INFORMATION:** Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-138 that provides for use of Coban® (45 or 60 grams per pound (g/lb) of monensin as monensin sodium), BMD (10, 25, 30, 40, 50, 60, or 75 g/lb BMD), and 3-Nitro® (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to

make combination Type C medicated feeds for replacement chickens intended for use as caged layers. The Type C medicated feeds contain 90 to 110 g/ton monensin, 50 or 100 to 200 g/ton BMD, and 22.7 to 45.4 g/ton roxarsone and are used as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; as an aid in the prevention (at 50 g/ton BMD) or control (at 100 to 200 g/ton BMD) of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation. The NADA is approved as of June 28, 2000, and 21 CFR 558.355 is amended 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.

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 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 by redesignating paragraphs (f)(4)(ii) and (f)(4)(iii) as paragraphs (f)(4)(i)(a) and (f)(4)(i)(b), and by adding new

paragraphs (f)(4)(ii) and (f)(4)(iii) to read as follows:

#### § 558.355 Monensin.

\* \* \* \* \*

(f) \* \* \*

(4) \* \* \*

(ii) *Amount per ton.* Monensin, 90 to 110 grams; bacitracin methylene disalicylate, 50 grams; plus roxarsone, 22.7 to 45.4 grams.

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

(b) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens. Use as sole source of organic arsenic. Do not feed to chickens over 16 weeks of age. Poultry should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. As monensin sodium provided by 000986; bacitracin methylene disalicylate and roxarsone as provided by 046573 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Monensin, 90 to 110 grams; bacitracin methylene disalicylate, 100 to 200 grams; plus roxarsone, 22.7 to 45.4 grams.

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

(b) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams/ton). Do not feed to laying chickens. Use as sole source of organic arsenic. Do not feed to chickens over 16 weeks of age. Poultry should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. As monensin sodium provided by 000986; bacitracin methylene disalicylate and roxarsone as

provided by 046573 in § 510.600(c) of this chapter.

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Dated: August 24, 2000.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 00-22620 Filed 9-1-00; 8:45 am]

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Parts 1 and 602

[TD 8901]

RIN 1545-AW16

#### Qualified Lessee Construction Allowances for Short-Term Leases

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations concerning an exclusion from gross income for qualified lessee construction allowances provided by a lessor to a lessee for the purpose of constructing long-lived property to be used by the lessee pursuant to a short-term lease. The final regulations affect a lessor and a lessee paying and receiving, respectively, qualified lessee construction allowances that are depreciated by a lessor as nonresidential real property and excluded from the lessee's gross income. The final regulations provide guidance on the exclusion, the information required to be furnished by the lessor and the lessee, and the time and manner for providing that information to the IRS.

**DATES:** *Effective Date:* These regulations are effective October 5, 2000.

*Date of Applicability:* For date of applicability of § 1.110-1, see § 1.110-1(d).

**FOR FURTHER INFORMATION CONTACT:** Paul Handleman, (202) 622-3040 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Paperwork Reduction Act

The collections of information contained in these 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) under control number 1545-1661. Responses to these collections 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 the collection of information displays a valid control number.

The estimated annual burden per respondent varies from .5 hours to 1.5 hours, depending on individual circumstances, with an estimated average of 1 hour.

Comments concerning the accuracy of these burden estimates and suggestions for reducing these burdens should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, OP:FS:FP, Washington, DC 20224, and 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.

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 September 20, 1999, the IRS published proposed regulations (REG-106010-98) in the **Federal Register** (64 FR 50783) inviting comments under section 110. A public hearing was held January 19, 2000. Numerous comments have been received. After consideration of all the comments, the proposed regulations are adopted as revised by this Treasury decision.

#### Public Comments

In accordance with section 110(a), the proposed regulations provided that amounts provided to a lessee by a lessor for property to be constructed and used by the lessee pursuant to a lease are not includible in the lessee's gross income if the amount is a qualified lessee construction allowance. The proposed regulations defined a qualified lessee construction allowance as any amount received in cash (or treated as a rent reduction) by a lessee from a lessor under a short-term lease of retail space, provided the purpose and expenditure requirements are met.

#### Expenditure Requirement

The proposed regulations required that a qualified lessee construction allowance be expended by the lessee in the taxable year received on the construction or improvement of qualified long-term real property for use in the lessee's trade or business at the retail space. However, the proposed regulations deemed an amount to have been expended by a lessee in the taxable year in which the construction allowance was received by the lessee if

the amount is expended within 8½ months after the close of that taxable year.

Several commentators maintained that the proposed rule prescribing a time limit for making the expenditure is not required by the statute or the legislative history and should be eliminated. One commentator, for example, pointed out the absence of an explicit expenditure requirement in section 110 like the one found in section 118(c)(2)(B), which requires that an expenditure relating to a nontaxable contribution in aid of construction be made before the end of the second taxable year after the year in which such amount was received.

Section 110 does not provide an explicit expenditure time limit, but it also does not toll the statute of limitations until the taxpayer notifies the Secretary that the amount has been expended as does section 118. The lack of a statute of limitation tolling provision in section 110 would be troublesome if there was no limitation on the time period to make the qualified expenditure. In addition, section 110(a) provides that an amount may be excluded only to the extent that such amount does not exceed the amount expended by the lessee for the construction or improvement of qualified long-term real property.

The IRS and Treasury Department believe that the absence of an extension of the statute of limitations and use of the term "expended" in the past tense indicate that the amount must be expended by the end of the taxable year it is received. Accordingly, the final regulations retain the expenditure time limitation. However, in recognition that a lessee may not be able to expend the amount in the same taxable year the lessee receives the construction allowance from the lessor, the final regulations also retain the 8½ month rule provided in the proposed regulations. This 8½ month rule, which grants the lessee an additional 8½ months after the close of the taxable year in which the construction allowance was received to expend the amount, is consistent with the time period, including extensions, that a corporate taxpayer has to file its return for the taxable year in which the construction allowance is received.

Commentators requested that to the extent the final regulations retain the expenditure requirement, the requirement should be modified to include construction allowances used to reimburse lessee expenditures made in a prior year. In response to these comments, the final regulations clarify that, provided the lessee has not