

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.739 is revised to read as follows:

§ 556.739 Trenbolone.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of trenbolone is 0.4 microgram per kilogram of body weight per day.

(b) *Tolerances*. A tolerance for total trenbolone residues in uncooked edible tissues of cattle is not needed.

Dated: April 1, 1999.

Andrew J. Beaulieu,

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

[FR Doc. 99-9458 Filed 4-14-99; 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; Narasin and Nicarbazine With 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 using approved narasin and nicarbazine, bacitracin methylene disalicylate (BMD), and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds.

EFFECTIVE DATE: April 15, 1999.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Gilbert, 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 141-112 that provides for combining approved Maxiban™ (27 grams per pound (g/lb) each of narasin and nicarbazine), BMD® (10, 25, 30, 40, 50, 60, or 75 g/lb BMD), and 3-Nitro® (45.4, 90, or 227 g/lb roxarsone) Type A medicated articles to make Type C medicated broiler chicken feeds. The Type C feed contains 27 to 45 g/ton (t) each of narasin and nicarbazine, 50 g/t BMD, and 22.7 to 45.4 g/t roxarsone. The Type C feed is used for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation. The NADA is approved as of March 4, 1999, and the regulations are amended by adding 21 CFR 558.76(d)(3)(xxi), 558.363(d)(2)(iii), and 558.366(d)(5)(xxv), and by amending 21 CFR 558.366(c) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of Type A medicated articles to make combination drug Type C medicated feeds. Narasin with nicarbazine and roxarsone are Category II drugs 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 a Type C medicated feed from a Category II drug. Under 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 Type A medicated articles to make Type C medicated feeds as provided in NADA 141-112 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, 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 558.76 is amended by adding paragraph (d)(3)(xxi) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xxi) Narasin with nicarbazine and roxarsone as in § 558.366.

3. Section 558.363 is amended by adding paragraph (d)(2)(iii) to read as follows:

§ 558.363 Narasin.

* * * * *

(d) * * *

(2) * * *

(iii) Bacitracin methylene disalicylate, nicarbazine, and roxarsone as in § 558.366.

4. Section 558.366 is amended in the table in paragraph (c) under entry "27 to 45" by alphabetically adding an entry for "Naracin 27 to 45, bacitracin methylene disalicylate 50, and roxarsone 22.7 to 45.4" to read as follows:

§ 558.366 Nicarbazine.

* * * * *

(c) * * *

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27 to 45				

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	* * Narasin 27 to 45, bacitracin methylene disalicylate 50, and roxarsone 22.7 to 45.4.	* Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> , as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	* * Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Use as sole source of organic arsenic. Narasin and nicarbazin as provided by 000986, bacitracin methylene disalicylate and roxarsone by 046573.	* 046573
*	*	*	*	*

5. Section 558.530 is amended by adding paragraph (d)(5)(xxv) to read as follows:

§ 558.530 Roxarsone.

* * * * *

(d) * * *

(5) * * *

(xxv) Bacitracin methylene disalicylate, narasin, and nicarbazin as in § 558.366.

Dated: April 1, 1999.

George A. Mitchell,
Acting Director, Center for Veterinary Medicine.

[FR Doc. 99-9454 Filed 4-15-99; 8:45 am]

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans prescribes interest assumptions for valuing benefits under terminating single-employer plans. This final rule amends the regulation to adopt interest assumptions for plans with valuation dates in May 1999.

EFFECTIVE DATE: May 1, 1999.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202-326-4024. (For TTY/TDD

users, call the Federal relay service toll-free at 1-800-877-8339 and ask to be connected to 202-326-4024.)

SUPPLEMENTARY INFORMATION: The PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes actuarial assumptions for valuing plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974.

Among the actuarial assumptions prescribed in part 4044 are interest assumptions. These interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Two sets of interest assumptions are prescribed, one set for the valuation of benefits to be paid as annuities and one set for the valuation of benefits to be paid as lump sums. This amendment adds to appendix B to part 4044 the annuity and lump sum interest assumptions for valuing benefits in plans with valuation dates during May 1999.

For annuity benefits, the interest assumptions will be 5.70 percent for the first 20 years following the valuation date and 5.25 percent thereafter. The annuity interest assumptions represent an increase (from those in effect for April 1999) of 0.10 percent for the first 20 years following the valuation date and are otherwise unchanged. For benefits to be paid as lump sums, the interest assumptions to be used by the PBGC will be 4.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. The lump sum interest assumptions are unchanged from those in effect for April 1999.

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the

public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation of benefits in plans with valuation dates during May 1999, the PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4044

Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR part 4044 is amended as follows:

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

1. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

2. In appendix B, a new entry is added to Table I, and Rate Set 67 is added to Table II, as set forth below. The introductory text of each table is republished for the convenience of the reader and remains unchanged.

Appendix B to Part 4044—Interest Rates Used to Value Annuities and Lump Sums