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 Intervet, Inc. The ANADA provides for use of butorphanol tartrate injection for horses for the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

EFFECTIVE DATE: December 2, 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: Intervet, Inc., 405 State St., P.O. Box 318, Millsboro, DE 19966–0318, filed ANADA 200–239 that provides for veterinary prescription use of Dolorex® (butorphanol tartrate) injection intravenously for horses for the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

ANADA 200–239 is approved as a generic copy of Fort Dodge Animal Health's NADA 135–780 for Torbugesic® for horses. The ANADA is approved as of September 28, 1998, and the regulations are amended in 21 CFR 522.246(b) 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)(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 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 522.246 is amended by revising paragraph (b) to read as follows:

§ 522.246 Butorphanol tartrate injection.

* * * * *

(b) *Sponsors.* Approval to firms identified in § 510.600(c) of this chapter for use as indicated:

(1) See No. 057926 for use as in paragraph (c)(2) of this section.

(2) See No. 000856 for use as in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

* * * * *

Dated: November 5, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–32022 Filed 12–1–98; 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; Chlortetracycline and Salinomycin

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 two abbreviated new animal drug applications (ANADA's) filed by Alpharma Inc. The ANADA's provide for using approved chlortetracycline and salinomycin Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis and as an aid in the reduction of mortality due to *E. coli* infections.

EFFECTIVE DATE: December 2, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20852, 301–827–0209.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of ANADA's 200–261 and 200–262 that provide for combining approved ChlorMax™ (50, 65, or 70 grams per pound (g/lb) chlortetracycline) and Sacox® or Bio–Cox® (30 or 60 g/lb salinomycin sodium) Type A medicated articles to make Type C medicated broiler feeds containing chlortetracycline 500 grams per ton (g/t) and salinomycin 40 to 60 g/t. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.

Alpharma Inc.'s ANADA 200–261 is approved as a generic copy of Roche Vitamins, Inc.'s NADA 140–859. Alpharma Inc.'s ANADA 200–262 is approved as a generic copy of Hoechst Roussel's ANADA 200–095. Alpharma Inc.'s ANADA's 200–261 and 200–262 are approved as of September 21, 1998, and 21 CFR 558.550(a)(3) is amended to reflect the approvals. The basis for approval is discussed in the freedom of information summaries.

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 these applications 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)(1) that these actions are of a type that do 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 558.550 is amended by revising paragraph (a)(3) to read as follows:

§ 558.550 Salinomycin.

(a) * * *

(3) To 046573 for use as in paragraphs (d)(1)(xv) and (d)(1)(xvi) of this section.

* * * * *

Dated: November 12, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–32141 Filed 12–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8790]

RIN 1545–AU38

Definition of Reasonable Basis

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the accuracy-related penalty. These amendments are necessary to define reasonable basis and to make conforming changes to existing regulations. These regulations affect any taxpayer that files a tax return.

DATES: Effective date. These regulations are effective December 2, 1998.

Applicability date. For dates of applicability, see §§ 1.6662–2(d) and 1.6664–1(b)(2).

FOR FURTHER INFORMATION CONTACT: Beverly A. Baughman, 202–622–4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On September 1, 1995, the IRS issued final regulations [TD 8617 (60 FR 45661)], relating to the accuracy-related penalty under chapter 1 of the Internal Revenue Code. Those regulations provided guidance concerning the reasonable basis standard for purposes of (1) the negligence penalty under section 6662(b)(1), and (2) the disclosure exception to the penalties for disregarding rules or regulations under section 6662(b)(1) and the substantial understatement of income tax under section 6662(b)(2). In the preamble to the final regulations, the IRS and Treasury Department requested comments and suggestions on providing further guidance on the reasonable basis standard. On November 12, 1996, proposed regulations [IA–42–95 (1996–49 I.R.B. 21) (see § 601.601(d)(2)(ii)(*b*) of this chapter)] defining reasonable basis and making conforming changes to the final regulations relating to the accuracy-related penalty were published in the **Federal Register** (61 FR 58020).

Written comments responding to the notice of proposed rulemaking were received. A public hearing was held on February 25, 1997. After consideration of all the comments, the proposed regulations under section 6662 relating to the definition of reasonable basis for purposes of the accuracy-related penalty are adopted as revised by this Treasury decision.

In addition, on August 5, 1997, the Taxpayer Relief Act (TRA) of 1997, Pub. L. 105–34 (111 Stat. 788), was enacted. The Act added a restriction regarding whether or not a corporation has a reasonable basis for its tax treatment of an item for purposes of reducing the amount of the substantial understatement penalty. This restriction has been incorporated into the final regulations.

Explanation of Provisions and Summary of Comments

These final regulations provide that a return position will have a reasonable basis for purposes of the accuracy-related penalties if it is reasonably based on one or more certain authorities. Also, if the return position does not satisfy the reasonable basis standard, a reasonable cause and good faith exception may still apply.

One commentator suggested that the substantial authority standard in § 1.6662–4(d)(3)(ii) of existing regulations and the reasonable basis standard in § 1.6662–3(b)(3) of the proposed regulations be expanded to include as authority a well-reasoned construction of the applicable regulatory provisions in addition to the statutory provisions. The substantial authority standard in § 1.6662–4(d)(3)(ii) has not been expanded to reflect this comment. However, the definition of reasonable basis in § 1.6662–3(b)(3) has been clarified to include an explicit cross-reference to the nature of the analysis discussion in § 1.6662–4(d)(3)(ii) of the substantial authority regulations.

Several commentators suggested that the final regulations explain where the reasonable basis standard ranks in the hierarchy of return position standards. This suggestion was not adopted. The final regulations do not rank the standards formally because such a comparison would change the focus of the reasonable basis regulations from the taxpayer's obligation to determine his or her tax liability in accordance with the internal revenue laws to the probability of the return position prevailing in litigation.

Several commentators supported the exclusion of a numerical qualification of the reasonable basis standard in the proposed regulations because they believed that such a qualification would encourage arbitrary and mechanical application of the standards and create bad precedent outside the scope of the reasonable basis standard. The final regulations do not include a numerical qualification.

One commentator requested that the final regulations refer specifically to Rev. Rul. 59–60 (1959–1 C.B. 237) (see § 601.601(d)(2)(ii)(*b*) of this chapter), which provides guidance regarding the valuation of stock of closely held corporations for estate and gift tax purposes. The final regulations do not adopt this suggestion. It is not necessary to include a reference to a specific revenue ruling because § 1.6662–4(d)(3)(iii) of the existing regulations already lists revenue rulings as an acceptable type of authority.

One commentator requested that the final regulations clarify the effect of the Omnibus Budget Reconciliation Act of 1993, Pub. L. 103–66 (107 Stat. 312), and the reasonable cause and good faith exception under section 6664 on a taxpayer's access to prepayment litigation in Tax Court. The final regulations do not adopt this suggestion. It is not necessary to clarify that a taxpayer has access to prepayment litigation in Tax Court because under section 6665 the Tax Court has jurisdiction to redetermine additions to tax in the same manner as the underlying tax.

Pursuant to the Taxpayer Relief Act of 1997, Pub. L. 105–34 (111 Stat. 788), § 1.6662–4(e)(3) has been added to the final regulations. That section provides that for purposes of reducing the amount of the substantial understatement penalty by making an adequate disclosure, a corporation will not be treated as having a reasonable basis for its tax treatment of an item attributable to a multi-party financing transaction entered into after August 5, 1997, if the treatment does not clearly reflect the income of the corporation.

The Chief Counsel for Advocacy of the Small Business Administration requested that the preamble to the regulations explain why the IRS has concluded that this regulation is not subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6). The Chief Counsel for Advocacy submits that the regulations tighten the definition of reasonable basis and, thus, impose a de facto recordkeeping requirement because they may require small businesses to keep and maintain records (such as the documents referred to in § 1.6662–4(d)(3)(iii)) to support tax reporting decisions.

After carefully considering these comments, the IRS and Treasury have