

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Chlortetracycline approximately 400, varying with body weight and food consumption to provide 10 milligrams per pound of body weight per day.	Swine; for increased rate of weight gain and improved feed efficiency; for treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.	Feed for not more than 14 days to provide 10 milligrams of chlortetracycline per pound of body weight per day; as chlortetracycline provided by Nos. 000004 and 046573 in § 510.600(c) of this chapter. Type C feed may be prepared from Type B feed containing 1 to 3 grams per pound BMD with 400 grams per pound CTC, to 046573 in § 510.600(c).	000004 and 046573
*	*	*	*	*

* * * * *

Dated: August 1, 1998.

Margaret Ann Miller,

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

[FR Doc. 98-22227 Filed 8-18-98; 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; Bambermycins****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 Hoechst Roussel Vet. The supplement provides revised limitations for using bambermycins Type A medicated articles to make a bambermycins Type B and Type C medicated feeds for feedlot cattle and for pasture cattle, including dairy and beef replacement heifers.

EFFECTIVE DATE: August 19, 1998.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0217.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed supplemental NADA 141-034 that provides for revised limitations for

using 10-grams-per-pound Gainpro® (bambermycins) Type A medicated articles to make Type B and Type C medicated feeds for feedlot cattle and for pasture cattle, including dairy and beef replacement heifers. The Type C medicated feeds are fed to provide 10 to 20 milligrams bambermycins per head per day to feedlot cattle for increased rate of weight gain and improved feed efficiency and to pasture cattle for increased rate of weight gain. The supplement is approved as of June 29, 1998, and the regulations are amended in § 558.95(d)(4) to reflect the approval by deleting the statement "Not for use in animals intended for breeding", and amending the phrase "slaughter, stocker, and feeder" to read "slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers."

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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning June 29, 1998, because the supplement contains substantial evidence of the effectiveness of the drug involved, 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 of the supplement

and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the use of bambermycins Type C medicated feeds for dairy and beef replacement heifers.

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.

§ 558.95 [Amended]

2. Section 558.95 *Bambermycins* is amended in paragraphs (d)(4)(i)(b), (d)(4)(ii)(b), (d)(4)(iii)(d), and (d)(4)(iv)(c) by removing the statement "Not for use in animals intended for breeding." and in paragraphs (d)(4)(ii)(b), (d)(4)(iii), and (d)(4)(iv), by removing the phrase "(slaughter, stocker, and feeder)" and by adding in its place the phrase "(slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers)."

Dated: August 1, 1998.

Margaret Ann Miller,

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

[FR Doc. 98-22225 Filed 8-18-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8778]

RIN 1545-AV67

Termination of Puerto Rico and Possession Tax Credit; New Lines of Business Prohibited

AGENCY: Internal Revenue Service (IRS),
Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations that provide guidance regarding the addition of a substantial new line of business by a possessions corporation that is an existing credit claimant. These temporary regulations reflect changes made by the Small Business Job Protection Act of 1996. The text of these temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rule section published elsewhere in this issue of the **Federal Register**.

DATES: These regulations are effective September 18, 1998.

Applicability: These regulations apply to taxable years of a possessions corporation beginning after August 19, 1998.

FOR FURTHER INFORMATION CONTACT: Patricia A. Bray or Elizabeth Beck, (202) 622-3880, or Jacob Feldman, (202) 622-3830 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Section 1601(a) of the Small Business Job Protection Act of 1996, Public Law 104-188, 110 Stat. 1755 (1996), amended the Internal Revenue Code by adding section 936(j). Section 936(j) generally repeals the Puerto Rico and possession tax credit for taxable years beginning after December 31, 1995. However, the section provides grandfather rules under which a corporation that is an existing credit claimant would be eligible to claim credits for a transition period. The Puerto Rico and possession tax credit will phase out for these existing credit

claimants ending with the last taxable year beginning before January 1, 2006.

For taxable years beginning after December 31, 1995 and before January 1, 2006, the Puerto Rico and possession tax credit applies only to a corporation that qualifies as an existing credit claimant (as defined in section 936(j)(9)(A)). The determination of whether a corporation is an existing credit claimant is made separately for each possession. A possessions corporation that adds a substantial new line of business (other than in a qualifying acquisition of all the assets of a trade or business of an existing credit claimant) after October 13, 1995, ceases to be an existing credit claimant as of the beginning of the taxable year during which such new line of business is added. Therefore, a possessions corporation that ceases to be an existing credit claimant either because it has added a substantial new line of business, or because a new line of business becomes substantial, during a taxable year may not claim the Puerto Rico and possessions tax credit for that taxable year or any subsequent taxable year.

Explanation of Provisions

This document provides temporary regulations that interpret section 936(j)(9)(B). In particular, temporary regulation § 1.936-11T adopts principles similar to those in § 1.7704-2(c) and (d) (transition rules for existing publicly traded partnerships) for determining whether a corporation has added a substantial new line of business.

Paragraph (a) of § 1.936-11T states the general rule that, if a possessions corporation that is an existing credit claimant, as defined in section 936(j)(9)(A), adds a substantial new line of business during a taxable year, it will cease to be an existing credit claimant as of the close of the taxable year ending before the date of such addition. The paragraph also generally describes the subjects discussed in the other paragraphs in § 1.936-11T.

Paragraph (b) addresses the meaning of the term *new line of business*. The temporary regulation generally follows the approach of § 1.7704-2(d)(1), providing the general rule derived from § 1.7704-2(d)(2) that explains when a business activity is a *pre-existing business*, and from § 1.7704-2(d)(3) that defines when that activity is *closely related* to a pre-existing business. Paragraph (b)(1) provides that a new line of business is any activity of the possessions corporation that is not closely related to a pre-existing business of the possessions corporation.

Paragraph (b)(2) explains that, except as provided in paragraph (b)(2)(ii), all the facts and circumstances (including factors A through H in paragraph (b)(2)(i)) must be considered to determine whether a new activity is closely related to a pre-existing business of the possessions corporation. Paragraph (b)(2)(i) applies the same eight factors considered in § 1.7704-2(d)(3), except that the temporary regulation provides that in applying factor H, the possessions corporation may use either the new North American Industry Classification System Code (NAICS code) or the Standard Industrial Classification Code (SIC code).

Factor (H) is whether the United States Bureau of the Census assigns the activity the same six-digit NAICS code (or four-digit SIC code) as the pre-existing business. In the case of a pre-existing business or activity that is listed under a NAICS code of 99999, Unclassified establishments, or under a miscellaneous category (most NAICS codes ending in a "9" are miscellaneous categories), the similarity in NAICS codes is ignored as a factor in determining whether the activity is closely related to the pre-existing business. The dissimilarity of the NAICS codes is considered in determining whether the activity is closely related to the pre-existing business. For purposes of this section, NAICS codes must be set forth in the North American Industry Classification System Manual, United States, that is in effect for the taxable year during which a new line of business is added.

Similarly, in the case of a pre-existing business or activity that is listed under a SIC code of 9999, Nonclassifiable Establishments, or under a miscellaneous category (most SIC codes ending in a "9" are miscellaneous categories), the similarity in SIC codes is ignored as a factor in determining whether the activity is closely related to the pre-existing business. The dissimilarity of the SIC codes is considered as a factor in determining whether the activity is closely related to the pre-existing business. The SIC codes are set forth in the Executive Office of the President, Office of Management and Budget, Standard Industrial Classification Manual, that is in effect for the taxable year during which a new line of business is added.

Paragraph (b)(2)(ii) provides safe harbors for determining whether an activity is closely related to a pre-existing business in three cases. First, an activity will be closely related to a pre-existing business if the activity is within the same six-digit NAICS code or four-digit SIC code as the pre-existing