

did not require testing for pyrogens at the bulk stage.

Bristol-Myers Squibb Co., the manufacturer of the innovator product, filed a petition for stay of action pursuant to 21 CFR 10.35, objecting to FDA's decision to promulgate the new regulation without notice and a prior opportunity for public comment. On November 9, 1994, FDA agreed to stay the effective date of the monograph for bleomycin sulfate bulk drug substance in order to reconsider the manner in which the agency promulgated the new monograph. A copy of FDA's letter notifying Bristol-Myers Squibb Co. of the stay is on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 450 is amended as follows:

**List of Subjects in 21 CFR Part 450**

Antibiotics.

**PART 450—ANTITUMOR ANTIBIOTIC DRUGS**

1. The authority citation for 21 CFR part 450 continues to read as follows:

**Authority:** Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

**§ 450.10 [Stayed]**

2. Section 450.10 *Bleomycin sulfate* is stayed effective November 9, 1994.

Dated: February 15, 1995.

**Murray M. Lumpkin,**

*Deputy Director, Center for Drug Evaluation and Research.*

[FR Doc. 95-5058 Filed 2-28-95; 8:45 am]

BILLING CODE 4160-01-F

**21 CFR Parts 510 and 558**

**Animal Drugs, Feeds, and Related Products; Change of Sponsor**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for nine new animal drug applications (NADA's) from Agri-Bio Corp. to Hoffman-LaRoche, Inc. This document also corrects an inadvertent error in the animal drug regulations.

**EFFECTIVE DATE:** March 1, 1995.

**FOR FURTHER INFORMATION CONTACT:**

Benjamin A. Puyot, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1646.

**SUPPLEMENTARY INFORMATION:** Agri-Bio Corp., 966 Dorsey St., Gainesville, GA 30501, has informed FDA that it has transferred the ownership of, and all rights and interests in, the following approved NADA's to Hoffmann-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110-1199:

NADA No.	Ingredient(s)	Trade name(s)
128-686 ...	Salinomycin .....	Bio-Cox.
132-447 ...	Salinomycin and Roxarsone .....	Bio-Cox and 3-Nitro.
134-284 ...	Salinomycin and Bambermycins .....	Bio-Cox and Flavomycins.
134-185 ...	Salinomycin and Roxarsone and Bambermycins .....	Bio-Cox and 3-Nitro Flavomycin.
135-321 ...	Salinomycin and Roxarsone and Bacitracin-MD .....	Bio-Cox and 3-Nitro and BMD.
135-746 ...	Salinomycin and Bacitracin-MD .....	Bio-Cox and BMD.
137-536 ...	Salinomycin and Roxarsone and Bacitracin Zn .....	Bio-Cox and 3-Nitro and Albac.
137-537 ...	Salinomycin and Lincomycin .....	Bio-Cox and Lincomix.
140-581 ...	Salinomycin and Roxarsone and Lincomycin .....	Bio-Cox and 3-Nitro and Lincomix.

Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) and 558.95(b)(1)(xi)(b) and (b)(1)(xii)(b) to reflect the change of sponsor.

In the **Federal Register** of January 13, 1995 (60 FR 3079 at 3080), FDA amended § 558.550; this amendment inadvertently failed to reflect a previous amendment published in the **Federal Register** of December 29, 1994 (59 FR 67185). The December 29, 1994, document amended § 558.550(a)(1) and (a)(2) to provide for specific levels of Type A articles approved for use for the specified sponsors. The January 13, 1995, document amended § 558.550(a)(2) to add approved referenced uses as stated in § 558.550(b). This document corrects the inadvertent error made in the final rule of January 13, 1995.

**List of Subjects**

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling,

Reporting and recordkeeping requirements.

**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 parts 510 and 558 are amended as follows:

**PART 510—NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

**§ 510.600 [Amended]**

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for "Agri-Bio Corp." and in the table in paragraph (c)(2) by removing the entry for "042835".

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

3. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

**§ 558.95 [Amended]**

4. Section 558.95 *Bambermycins* is amended in paragraphs (b)(1)(xi)(b) and (b)(1)(xii)(b) by removing "042835" and adding in its place "000004".

5. Section 558.550 is amended in paragraph (a)(1) by removing the number "042835" and adding in its place "000004", and by revising paragraph (a)(2) to read as follows:

**§ 558.550 Salinomycin.**

(a) \* \* \*

(2) To 012799 for use of 30 and 60 grams per pound as in paragraphs (b)(1)(i), (b)(1)(iii) through (b)(1)(xvi),

and (b)(3)(i) through (b)(3)(iii) of this section.

\* \* \* \* \*

Dated: February 9, 1995.

**Robert C. Livingston,**

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

[FR Doc. 95-4912 Filed 2-28-95; 8:45 am]

BILLING CODE 4160-01-F

**21 CFR Part 558**

**Animal Drugs, Feeds, and Related Products; Melengestrol Acetate and Tylosin**

**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 The Upjohn Co. The supplemental NADA provides for use of single ingredient Type A medicated articles containing melengestrol acetate (MGA) and tylosin to manufacture certain combination drug Type B and Type C medicated feeds for heifers fed in confinement for slaughter. The supplement provides for use of a dry MGA Type A article to make a dry Type B or Type C medicated feed.

**EFFECTIVE DATE:** March 1, 1995.

**FOR FURTHER INFORMATION CONTACT:** Jack Caldwell, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1638.

**SUPPLEMENTARY INFORMATION:** The Upjohn Co., Kalamazoo, MI 49001, filed supplemental NADA 138-995, MGA with Tylan (MGA with tylosin), which provides for use of approved MGA and tylosin Type A medicated articles to make Type B and Type C medicated feeds for heifers being fed in confinement for slaughter. The supplement removes the requirement for making dry pelleted Type B or C medicated feed. Therefore, dry MGA and tylosin Type A articles may be used to make a dry Type B or C medicated feed containing MGA and tylosin.

This supplement is approved as of January 13, 1995. Accordingly, 21 CFR 558.342(c)(4)(ii)(C) is amended by removing the existing reference to a pelleted medicated feed to reflect this approval.

This is a manufacturing supplement to an approved NADA. Approval of this supplement does not require added safety or efficacy data or information. Therefore, a freedom of information summary as provided in part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) is not required.

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 supplement for food-producing animals does not qualify for marketing exclusivity because the supplement does not contain new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(iii) 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:** Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

**§ 558.342 [Amended]**

2. Section 558.342 *Melengestrol acetate* is amended in paragraph (c)(4)(ii)(C) by removing the word "pelleted".

Dated: February 9, 1995.

**Robert C. Livingston,**

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

[FR Doc. 95-4913 Filed 2-28-95; 8:45 am]

BILLING CODE 4160-01-F

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[TD 8578]

**RIN 1545-AP23**

**Election Out of Subchapter K for Producers of Natural Gas; Correction**

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

**SUMMARY:** This document contains a correction to final regulations [TD 8578] which was published in the **Federal Register** for Friday, December 23, 1994 (59 FR 66181). The final regulations provide that the co-producers under a joint operating agreement must use one of two permissible methods described in the regulations in reporting income from gas sales and certain related deductions and credits.

**EFFECTIVE DATE:** January 1, 1995.

**FOR FURTHER INFORMATION CONTACT:** Grace Kim, (202) 622-3060 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Background**

The final regulations that are the subject of this correction are under section 761 of the Internal Revenue Code.

**Need for Correction**

As published, TD 8578 contains a typographical error that is in need of correction.

**Correction of Publication**

Accordingly, the publication of the final regulations which is the subject of FR Doc. 94-31291, is corrected as follows:

On page 66183, column 2, § 1.761-2, paragraph (d)(2)(i), ninth line from the bottom of the paragraph, regulation section "§ 1.4461(e)(3)" is corrected to read "§ 1.446-1(e)(3)".

**Cynthia E. Grigsby,**

*Chief, Regulations Unit, Assistant Chief Counsel (Corporate).*

[FR Doc. 95-4902 Filed 2-28-95; 8:45 am]

BILLING CODE 4830-01-P