

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 558

New Animal Drugs; Correction of Sponsor's Drug Labeler Codes

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a correction of sponsor's drug labeler code for Pennfield Oil Co.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: david.newkirk@fda.gov.

SUPPLEMENTARY INFORMATION: FDA has found that the animal drug regulations do not reflect the correct sponsor's drug labeler code for Pennfield Oil Co. Accordingly, the agency is amending the regulations in 21 CFR 510.600, 520.445b, 520.1660d, 522.1660a, 558.76, 558.78, 558.128, 558.140, 558.145, 558.195, 558.355, 558.450, 558.550, 558.600, 558.625, and 558.630 to correct this error.

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 522

Animal drugs.

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, 520, 522, 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: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) in the entry for “Pennfield Oil Co.” by removing “053389” and by adding in its place “048164”; and in the table in paragraph (c)(2) by removing the entry for “053389” and by adding in numerical sequence an entry for “048164” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

| Firm name and address | Drug labeler code |
|--|--------------------------|
| * * * Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144 * * * | * * * 048164 * * * |

(2) * * *

| Drug labeler code | Firm name and address |
|--------------------------|--|
| * * * 048164 * * * | * * * Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144 * * * |

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.445b [Amended]

■ 4. Section 520.445b is amended in paragraph (b) by removing “053389” and by adding in its place “048164”.

§ 520.1660d [Amended]

■ 5. Section 520.1660d is amended in paragraph (b)(6) by removing “053389” and by adding in its place “048164”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 6. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1660a [Amended]

■ 7. Section 522.1660a is amended in paragraph (b) by removing “053389” and by adding in its place “048164”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.76 [Amended]

■ 9. Section 558.76 is amended in the table in paragraph (d)(1)(iv) in the “Limitations” and “Sponsor” columns by removing “053389” and by adding in its place “048164”.

■ 10. Section 558.78 is amended by revising paragraphs (a) and (b); in the table in paragraph (d)(1) by redesignating paragraphs (d)(1)(ii) through (d)(1)(vi) as paragraphs (d)(1)(iii) through (d)(1)(vii); and by revising paragraph (d)(1)(i); and by adding new paragraph (d)(1)(ii) to read as follows:

§ 558.78 Bacitracin zinc.

(a) *Specifications.* Type A medicated articles containing bacitracin zinc equivalent to 5, 10, 25, 40, or 50 grams per pound bacitracin.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for uses as follows:

(1) No. 046573: 10, 25, 40, and 50 grams per pound for uses as in paragraph (d) of this section.

(2) No. 048164: 5 and 50 grams per pound for use as in as in paragraph (d)(1)(i) of this section.

* * * * *

(d) * * *

(1) * * *

| Bacitracin zinc in grams per ton | Combinations in grams per ton | Indications for use | Limitations | Sponsor |
|----------------------------------|-------------------------------|---|-------------------------------|------------------|
| (i) 4 to 50 | | Chickens: for increased rate of weight gain and improved feed efficiency | Growing chickens | 046573 048164 |
| (ii) 4 to 50 | | Turkeys and pheasants: for increased rate of weight gain and improved feed efficiency | Growing turkeys and pheasants | 046573 |
| * | * | * | * | * |

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§ 558.128 [Amended]

■ 11. Section 558.128 is amended in paragraph (b)(1) by removing “053389” and by adding in its place “048164”; and in the tables in paragraphs (e)(1), (e)(2), (e)(3), (e)(4), and (e)(5) in the “Sponsor” column by removing “053389” wherever it appears and by adding in its place “048164”.

§ 558.140 [Amended]

■ 12. Section 558.140 is amended in paragraph (a) by removing “053389” and by adding in its place “048164”.

§ 558.145 [Amended]

■ 13. Section 558.145 is amended in paragraph (a)(2) by removing “053389” and by adding in its place “048164”.

§ 558.195 [Amended]

■ 14. Section 558.195 is amended in the table in paragraph (e)(2)(iii) in the “Limitations” and “Sponsor” columns by removing “053389” and by adding in its place “048164”.

§ 558.355 [Amended]

■ 15. Section 558.355 is amended in paragraph (f)(1)(xiv)(b) by removing “053389” and by adding in its place “048164”.

§ 558.450 [Amended]

■ 16. Section 558.450 is amended in paragraph (a)(2) by removing “053389” and by adding in its place “048164”; in the table in paragraphs (d)(1)(i), (d)(1)(v), (d)(1)(vii), and (d)(1)(viii) in the “Sponsor” column by removing “053389” wherever it appears and by adding in its place “048164”; and in the table in

paragraph (d)(1)(ix) in the “Limitations” column by removing “053389” wherever it appears and by adding in its place “048164”.

■ 17. Section 558.550 is amended in paragraphs (d)(1)(xv)(c) and (d)(1)(xvi)(c) by removing “053389” and by adding in its place “048164”; and by revising paragraph (a) and by adding paragraph (b) to read as follows:

§ 558.550 Salinomycin.

(a) *Specifications.* Type A medicated articles containing 30 or 60 grams of salinomycin activity per pound (as salinomycin sodium biomass).

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) No. 046573 for use as in paragraph (d) of this section.

(2) No. 057926 for use as in paragraphs (d)(1)(i), (d)(1)(iii) through (d)(1)(xvi), (d)(2)(i), and (d)(3)(i) of this section.

(3) No. 048164 for use as in paragraphs (d)(1)(xv) and (d)(1)(xvi) of this section.

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§ 558.600 [Amended]

■ 18. Section 558.600 is amended in the table in paragraph (e)(1)(iii) in the “Limitations” and “Sponsor” columns by removing “053389” and by adding in its place “048164”.

§ 558.625 [Amended]

■ 19. Section 558.625 is amended in paragraph (b)(89) by removing “053389” and by adding in its place “048164”.

§ 558.630 [Amended]

■ 20. Section 558.630 is amended in paragraph (b)(10) by removing “053389” and by adding in numerical sequence “048164”.

Dated: October 14, 2004.

Steven D. Vaughn,

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

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S