PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.1560 [Removed]

4. Section 520.1560 *Nitrofurantoin oral dosage forms* is removed.

§ 520.1560a [Removed]

5. Section 520.1560a *Nitrofurantoin oral suspension* is removed.

§ 520.1560b [Removed]

6. Section 520.1560b *Nitrofurantoin tablets and boluses* is removed.

§ 520.1801 [Removed]

7. Section 520.1801 *Piperazine adipate oral dosage forms* is removed.

§ 520.1801a [Removed]

8. Section 520.1801a *Piperazine adipate powder* is removed.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.723 [Amended]

10. Section 522.723 *Diprenorphine hydrochloride injection* is amended in paragraph (c) by removing the phrase ''Nos. 010042 and 000693'' and adding in its place the phrase ''No. 010042''.

§ 522.883 [Amended]

11. Section 522.883 *Etorphine hydrochloride injection* is amended in paragraph (c) by removing the phrase ''Nos. 010042 and 000693'' and adding in its place the phrase ''No. 010042''.

§ 522.1563 [Removed]

12. Section 522.1563 *Nitrofurantoin sodium injection* is removed.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

13. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.1580a [Removed]

14. Section 524.1580a *Nitrofurazone-nifuroxime-diperodon hydrochloride ear solution* is removed and reserved.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

15. 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).

§ 558.62 [Amended]

16. Section 558.62 *Arsanilic acid* is amended by removing paragraph (c)(2)(v) and by redesignating paragraph (c)(2)(vi) as paragraph (c)(2)(v).

§ 558.105 [Removed]

17. Section 558.105 *Buquinolate* is removed and reserved.

§ 558.128 [Amended]

18. Section 558.128 *Chlortetracycline* is amended by removing and reserving paragraph (c)(5)(iii).

§ 558.325 [Amended]

19. Section 558.325 *Lincomycin* is amended by removing and reserving paragraph (c)(3)(iv).

§ 558.460 [Amended]

20. Section 558.460 *Penicillin* is amended by removing and reserving paragraph (c)(2)(v).

§ 558.530 [Amended]

21. Section 558.530 *Roxarsone* is amended by removing and reserving paragraph (d)(3)(vii).

Dated: July 13, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–19091 Filed 8–3–95; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Ivermectin

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 Merck Research Laboratories, Division of Merck & Co., Inc. The original NADA provides for the use of a Type A medicated article containing ivermectin in manufacturing Type C medicated feed for production swine. The supplemental NADA expands use of the feed to breeding swine. The feed is intended for treatment and control of certain endo- and ectoparasites.

EFFECTIVE DATE: August 4, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, is the sponsor of approved NADA 140–974, which provides for the use of a Type A medicated article containing 0.6 percent ivermectin (2.72 grams per pound (g/lb)) in manufacturing Type C medicated feed containing 1.8 g of ivermectin per ton (t). The feed is indicated for the treatment and control of certain gastrointestinal roundworm, lungworm, kidney worm, lice, and mite infestations of growing swine (up to 220 lb in body weight) as in § 558.300 (21 CFR 558.300). The feed is administered so as to provide 0.1 milligram of ivermectin per kilogram (mg/kg) of body weight per animal per day. Merck has filed a supplemental NADA expanding use of the ivermectin-containing feed to include breeding swine. To achieve the same dosage level (i.e., 0.1 mg of ivermectin per kg of body weight) in the larger animals, the supplemental NADA provides for an ivermectin concentration up to 11.8 g/t of Type C medicated feed.

The supplemental NADA is approved as of August 4, 1995, and the regulations are amended in § 558.300 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Additionally, approval of the supplemental NADA increases the highest concentration of ivermectin permitted in Type C medicated feed from 1.8 to 11.8 g/t. The feed can be manufactured from either a Type A medicated article or a Type B medicated feed. Currently, the Category II table in § 558.4 (21 CFR 558.4) specifies that the maximum concentration of ivermectin permitted in a Type B feed is 182 g/t (i.e., 100 x the 1.8 g/t now approved for Type C feed). However, because the supplemental NADA increases the highest drug concentration permitted in the Type C feed to 11.8 g/t, this justifies a corresponding increase in the maximum ivermectin concentration in the Type B feed to 1,180 g/t (i.e., 100 x the 11.8 g/t). Accordingly, FDA is also amending the Category II table in § 558.4 to reflect this increase.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11 (e)(2)(ii) (21 CFR 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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, 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 approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning August 4, 1995, because the supplemental NADA contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the use for which the supplemental NADA is approved.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 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).

§ 558.4 [Amended]

2. Section 558.4 *Medicated feed applications* is amended in paragraph (d) in the ''Category II'' table in the entry for ''Ivermectin'' under the third column by removing ''182 g/ton (0.02%)'' and adding in its place ''1,180 g/ton (0.13%)''.

3. Section 558.300 is amended by revising paragraphs (c)(1)(i) and (iii) to read as follows:

§ 558.300 Ivermectin.

* * * * *

(c) * * *

(1) * * *

(i) *Amount.* For growing-finishing swine feed 1.8 grams of ivermectin per ton (to provide 0.1 milligram per kilogram of body weight per day). For mature and breeding swine feed 1.8 to 11.8 grams of ivermectin per ton (to provide 0.1 milligram per kilogram of body weight per day).

* * * * *

(iii) *Limitations.* Feed as the only feed for 7 consecutive days. For use in swine only. Withdraw 5 days before slaughter.

* * * * *

Dated: July 26, 1995.

Robert C. Livingston,

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

[FR Doc. 95–19281 Filed 8–3–95; 8:45 am]

BILLING CODE 4160–01–F

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 2606 and 2609

RIN 1212–AA72

Debt Collection Procedures—Tax Refund Offset

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation is adopting, as a final rule with change, amendments that it previously issued as an interim final rule. The procedures in this rule enable the PBGC to refer past-due, legally enforceable debts to the internal Revenue Service to be offset against federal tax refunds.

EFFECTIVE DATE: This rule is effective August 4, 1995.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Attorney, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026, 202–326–4024 (202–326–4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION: On December 6, 1994 (59 FR 62571), the Pension Benefit Guaranty Corporation published an interim final rule that amended its administrative review and debt collection regulations (29 CFR parts 2606 and 2609). As amended, the PBGC's regulations include the procedures required for participation in the federal tax refund offset program authorized by 31 U.S.C. 3720A. Section 3720A, and Internal Revenue Service regulations thereunder (26 CFR 301.6402–6), include requirements to ensure that debts referred for offset against amounts otherwise payable as tax refunds are past-due and legally enforceable and that the agency has made reasonable efforts (pursuant to regulations) to obtain payment.

The one comment on the interim final rule expressed concern about its effects on due process of law requirements under the Fifth Amendment to the United States Constitution. The PBGC believes that the commenter's concern is unwarranted. As noted above, the pre-referral procedures required by IRS regulations, which are included in the interim final rule, provide due process protections. Among other things, before the PBGC refers a debt for tax refund offset, the debtor has at least 60 days to present evidence that all or part of the debt is not past-due or not legally enforceable (§ 2609.33(b)(2)).

This final rule makes no changes in the rules of agency organization and procedure that wee prescribed by the interim final rule and have been in effect since January 5, 1995. Therefore, the Administrative Procedure Act does not require further notice and public procedure or a delayed effective date, and the PBGC for good cause finds that both such actions are unnecessary (5 U.S.C. 553 (b) and (d)).

E.O. 12866

The PBGC previously determined that the interim final rule was not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

List of Subjects

29 CFR Part 2606

Administrative practice and procedure, Organization and functions (Government agencies), Pension insurance, Pensions.

29 CFR Part 2609

Administrative practice and procedure, Claims.

Accordingly, the interim final rule amending 29 CFR parts 2606 and 2609 that was published at 59 FR 62571 on December 6, 1994, is adopted as a final rule without change.

Issued in Washington, DC this 31st day of July, 1995.

Martin Slate,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 95–19175 Filed 8–3–95; 8:45 am]

BILLING CODE 7708–01–M