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]

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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