send it to the Manager, Los Angeles Aircraft Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Los Angeles Aircraft Certification Office.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

(e) This amendment becomes effective on September 5, 1995.

Issued in Burlington, Massachusetts, on July 26, 1995.

James C. Jones,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 95–19230 Filed 8–1–95; 2:30 pm]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, and 558

Animal Drugs, Feeds, and Related Products; Piperazine Adipate Powder, Diprenorphine Hydrochloride Injection, Etorphine Hydrochloride Injection, and Certain Nitrofuran and Buquinolate Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions reflecting approval of 16 new animal drug applications (NADA's) held by Proctor & Gamble Pharmaceuticals, Inc., Happy Jack, Inc., and Lemmon Co. The NADA's provide for the use of piperazine adipate powder, diprenorphine hydrochloride (diprenorphine HCl) injection, etorphine HCl injection, certain nitrofuran dosage form products, and separately approved Type A medicated articles containing buquinolate or certain other drugs in manufacturing several Type C medicated feeds for chickens. In a notice published in the July 21, 1995, issue of the **Federal Register**, FDA is withdrawing approval of the NADA's.

EFFECTIVE DATE: August 14, 1995.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1722.

SUPPLEMENTARY INFORMATION: In a notice published in the July 21, 1995, issue of the **Federal Register** (60 FR 37651), FDA is withdrawing approval of the following NADA's:

NADA No.	Drug name	Sponsor name and address
10–158	Furamazone, bismuth subsalicylate bolus	Proctor & Gamble Pharmaceuticals, Inc., P.O. Box 191, Norwich, NY 13815.
10–358	Nitrofurantoin tablets and boluses	Do.
12–291	Nitrofurantoin oral suspension	Do.
12–612	Nitrofurazone, nifuroxime, diperodon HCl ear solution	Do.
34–716	Buquinolate	Do.
35–314	Buquinolate and bacitracin zinc	Do.
35–315	Buquinolate, bacitracin zinc, and penicillin	Do.
35–317	Buquinolate and penicillin	Do.
35–327	Buquinolate, bacitracin methylene disalicylate (bacitracin MD), and penicillin.	Do.
35–329	Buquinolate and bacitracin MD	Do.
38–657	Buquinolate and chlortetracycline	Do.
39–925	Buquinolate and roxarsone combination	Do.
39–926	Buquinolate and roxarsone	Do.
41–744	Nitrofurantoin sodium injection	Do.
95–017	Etorphine HCl injection and diprenorphine HCl injection	Lemmon Co., Sellersville, PA 18960.
115–580	Piperazine adipate powder	Happy Jack, Snow Hill, NC 28580.

The sponsors requested withdrawal of approval of the NADA's. This final rule removes 21 CFR 520.1560, 520.1560a, 520.1560b, 520.1801, 520.1801a, and 522.1563; amends 21 CFR 522.723 and 522.883 to reflect the withdrawal of approval of these NADA's; removes and reserves 21 CFR 524.1580a and 558.105; and amends 21 CFR 558.62, 558.128, 558.325, 558.460, and 558.530.

In addition, 21 CFR 510.600(c) is amended to remove the entries for Proctor & Gamble Pharmaceuticals, Inc., from the list of approved drug sponsors because it no longer holds any approved NADA's.

List of Subjects

21 CFR Part 510

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

21 CFR Parts 520, 522, and 524

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, 524, 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 ''Proctor & Gamble Pharmaceuticals, Inc.'' and in the table in paragraph (c)(2) by removing the entry for ''000149''.

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