'd) Prior sanctions for this ingredient ferent from the uses established in his section do not exist or have been waived.

Dated: September 17, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-21565 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 433

[Docket No. 894N-0373]

Antibiotic Drug Products for Over-the-Counter Human Use; Exemption From Certification; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that amended the antibiotic drug regulations to specifically exempt from batch certification antibiotic drug products for over-the-counter (OTC) human use (51 FR 25523; July 15, 1986). This document corrects a typographical error.

FOR FURTHER INFORMATION CONTACT: Robert J. Meyer, Center for Drugs and Biologics (HFN-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049.

SUPPLEMENTARY INFORMATION: In FR Doc. 86-15850 appearing on page 25523, in the issue of Tuesday, July 15, 1986, the following correction is made on page 25523: In the second column, under "Background", the second paragraph, line 2, "(21 CFR 443.1)" is corrected to read "(21 CFR 433.1)".

Dated: September 17, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-21557 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 510 and 558

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

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two new animal drug applications (NADA's) from Abbott Laboratories to Fleming Laboratories, Inc.

EFFECTIVE DATE: September 24, 1986.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV-238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6243.

SUPPLEMENTARY INFORMATION: Fleming Laboratories, Inc. P.O. Box 34384, Charlotte, NC 28234, informed FDA of acquiring two NADA's from Abbott Laboratories. Fleming is now sponsor of NADA's 8-019 (Pro-Gen Arsanilic Acid) and 8-966 (Pro-Gen Sodium Arsanilate). Abbott confirmed the change. Fleming will assume all responsibilities for the cited NADA's as required by 21 CFR 510.300 and 21 CFR Part 514. The NADA's and the regulations are amended to reflect the new sponsor.

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, 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. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)); 21 CFR 5.10 and 5.83.

2. Section 510.600 is amended by adding a new entry alphabetically in paragraph (c)(1) and numerically in paragraph (c)(2), 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
* * * * *	
Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234	015565
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
015565	Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234.
* * * * *	

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: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10 and 5.83.

§ 558.60 [Amended]

4. Section 558.60 *Arsanilate sodium* is amended in paragraph (a) by removing the sponsor number "043731" and replacing it with "015565."

§ 558.62 [Amended]

5. Section 558.62 *Arsanilic acid* is amended in paragraph (a) by removing the sponsor number "043731" and replacing it with "015565."

Dated: September 18, 1986.

Marvin A. Norcross,

Associate Director for New Animal Drug Evaluation.

[FR Doc. 86-21558 Filed 9-23-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Pyrantel Tartrate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed for Furst-McNess Co., providing for the use of a 48-gram-per-pound pyrantel tartrate Type A medicated article in making 9.6- and 19.2-gram-per-pound pyrantel tartrate Type A medicated articles. The pyrantel tartrate Type A medicated articles subject to this approval are subsequently used to make Type C medicated feeds for swine.

EFFECTIVE DATE: September 24, 1986.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1414.

SUPPLEMENTARY INFORMATION: Furst-McNess Co., Freeport, IL 61032, is sponsor of NADA 140-825 submitted on