

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Parts 510,520,522, and 558

Animal Drugs, Feeds, and Related Products; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: **Final** rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is updating the animal drug regulations to reflect corrections of previously approved new animal drug applications (NADA 's). Several sponsors currently specified in the list of sponsors of approved applications and in the animal drug approval regulations are incorrect. This action is being taken to improve the accuracy of the regulations.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Judith M. O'Hare, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855,301-827-3664.

SUPPLEMENTARY INFORMATION: FDA has found several errors in the agency's regulations concerning approval of animal drugs, feeds, and related products including the list of sponsors of approved applications. To correct those errors, FDA is amending 21 CFR 510.600(C)(1) and (c)(2) to remove several sponsor names and drug labeler codes because the firms are no longer the holders of any approved NADA's. This document is also amending the animal drug approval regulations by correcting the nonsubstantive errors in 21 CFR 520.260, 520.2184, 520.2220b, 522.723,522.800,558.140, 558.485, and 558.635.

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 redelegate to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, and 558 are amended as follows:

PART 51 O-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 Names, *addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entries for “Affiliated Laboratories Division, **Whitmoyer** Laboratories, Inc.”, ‘ ‘**Albers** Milling Co.”, “Allied **Pharmacal**, Division of **K.C. Pharmacal**, Inc.”, ‘ ‘Ayerst Laboratories, Division of American Home Products, Corp.”, “Bristol Laboratories, Div. of Bristol-Myers Co.”, “Cooper U. S.A., Inc.”, “Cutter Laboratories, Inc.”, ‘ ‘Dawes Laboratories, Inc.”, “Feed Products, Inc.”, “H. Clay **Glover** Co., Inc.”, ‘ ‘**Gooch** Feed Mill Corp.”, “Grain Processing Corp.”, “ICI Americas, Inc.”, ‘ ‘**KASCO**–EFCO Laboratories, Inc.”, “Dr. LeGear, Inc.”, “McNeil Laboratories, Inc.”, “Triple “F”, Inc.”, “**Tutag** Pharmaceuticals, Inc.”, and “Western Serum Co.”; by alphabetically adding a new entry for ‘ ‘Equi Aid Products, Inc.”; and in the table in paragraph (c)(2) by removing **the** entries for

‘ 000015, 000045, 000046, 000124, 000 61,000794,010471,010616, 011398,011490,01 492, 011511,011825,011950, 012983,013959,017826, 021798,022591, and 024264’; and by numerically adding a new entry for “062240” 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
* * * Equi Aid Products, Inc., 1517 West Knudsen Dr., Phoenix, AZ 85027	062240

Drug labeler code	Firm name and address
062240	* * * Equi Aid Products, Inc., 1517 West Knudsen Dr., Phoenix, AZ 85027

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.

§ 520.260 [Amended]

4. Section 520.260 *n-Butyl chloride capsules* is amended in paragraph (b)(2) by removing “012983” and adding in its place “038782”.

§ 520.2184 [Amended]

5. Section 520.2184 *Sodium sulfachloropyrazine monohydrate* is amended in paragraph (b) by removing the phrase “Nos. 010042 and 053501” and adding in its place “No. 010042”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

6-7. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.723 [Amended]

8. Section 522.723 *Diprenorphine hydrochloride injection* is amended in paragraph (c) by removing “010042” and adding in its place “053923”.

§ 522.800 [Amended]

9. Section 522.800 *Droperidol and fentanyl citrate injection* is amended in paragraph (b) by removing “000045” and adding in its place “00006 1”.

PART 558-NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.140 [Amended]

11. Section 558.140 *Chlortetracycline and sulfamethazine* is amended in paragraph (a) by removing “000004” and adding in its place “063238”.

§ 558.485 [Amended]

12. Section 558.485 *Pyrantel tartrate* is amended by removing and reserving paragraph (a)(17).

§ 558.635 [Amended]

13. Section 558.635 *Virginiamycin* is amended in paragraph (b)(2) by removing “01 1490” and adding in its place “046573”.

Dated: March 23, 1999

March 23, 1999

Margaret Ann Miller

Margaret Ann Miller
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Center for Veterinary Medicine

[FR Doe. 99-???? Filed ??-??-99; 8:45 am]

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