

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 558

Display Date OCT - 9 2002

Publication Date OCT 10 2002

Certifier A. Corbin

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 15 approved new animal drug applications (NADAs) from Cyanamid Agricultural de Puerto Rico, Inc., to Fort Dodge Animal Health.

DATES: This rule is effective [insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Cyanamid Agricultural de Puerto Rico, Inc., P.O. Box 243, Manati, PR 00701, has informed FDA that it has transferred ownership of, and all rights and interest in, the following 15 approved NADAs to Fort Dodge Animal Health, A Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501:

NADA Number	Trade Name
039-356	RIPERCOL L Bolus; TRAMISOL Cattle Wormer Bolus
039-357	RIPERCOL L Soluble Drench Powder
042-740	RIPERCOL L; TRAMISOL Soluble Drench Powder for Sheep
042-837	RIPERCOL L Wormer Oblets; TRAMISOL Sheep Wormer Oblets
044-015	TRAMISOL Type A Medicated Article
045-455	TRAMISOL Type A Medicated Article

NADA Number	Trade Name
045-513	RIPERCOL L
049-553	RIPERCOL L
092-237	RIPERCOL L-Piperazine Soluble
093-688	RIPERCOL L-Piperazine
101-079	TRAMISOL 10% Pig Wormer; TRAMISOL Hog Wormer
102-437	TRAMISOL Injectable Solution
104-184	STYQUIN
107-085	TRAMISOL
126-237	TRAMISOL Gel

Accordingly, the agency is amending the regulations in 21 CFR 520.1242a, 520.1242b, 520.1242c, 520.1242e, 520.1242f, 522.234, 522.1244, and 558.315 to reflect the transfer of ownership and to reflect current format.

Following this change of sponsorship, Cyanamid Agricultural de Puerto Rico, Inc., is no longer the sponsor of any approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for Cyanamid Agricultural de Puerto Rico, Inc.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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 redelegated

to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 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: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

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 entry for “Cyanamid Agricultural de Puerto Rico, Inc.” and in the table in paragraph (c)(2) by removing the entry for “043781”.

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.

§ 520.1242a [Amended]

4. Section 520.1242a *Levamisole hydrochloride drench and drinking water* is amended in paragraph (b)(1) by removing “043781” and by adding in its place “No. 053501”.

§ 520.1242b [Amended]

5. Section 520.1242b *Levamisole hydrochloride tablet or oblet (bolus)* is amended in paragraph (c) by removing “043781” and by adding in its place “053501”.

§ 520.1242c [Amended]

6. Section 520.1242c *Levamisole hydrochloride and piperazine dihydrochloride* is amended in paragraph (b) by removing “043781” and by adding in its place “053501”.

§ 520.1242e [Amended]

7. Section 520.1242e *Levamisole hydrochloride effervescent tablets* is amended in paragraph (b) by removing “043781” and by adding in its place “053501”.

§ 520.1242f [Amended]

8. Section 520.1242f *Levamisole hydrochloride gel* is amended in paragraph (b) by removing “043781” and by adding in its place “053501”.

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: 21 U.S.C. 360b.

§ 522.234 [Amended]

10. Section 522.234 *Butamisolol hydrochloride* is amended in paragraph (b) by removing “043781” and by adding in its place “053501”.

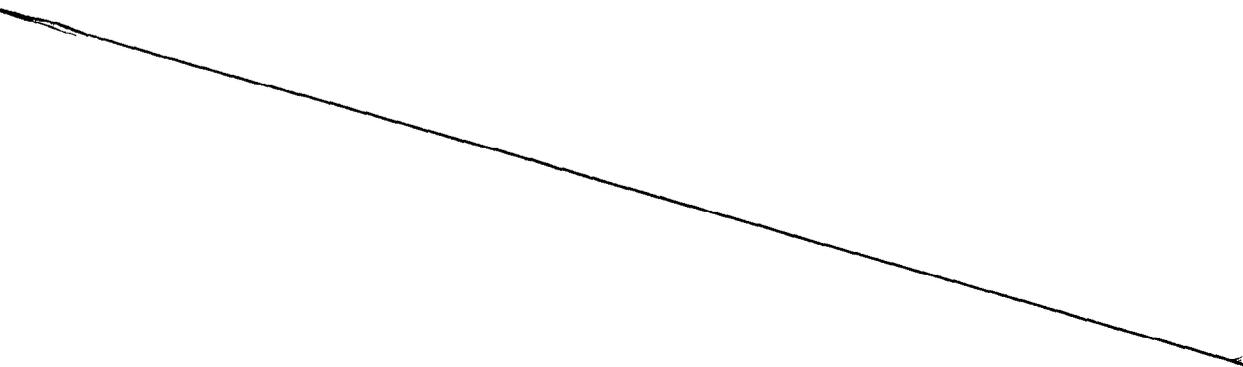
§ 522.1244 [Amended]

11. Section 522.1244 *Levamisole phosphate injection* is amended in paragraph (b) by removing “043781” and by adding in its place “053501”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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



§ 558.315 [Amended]

13. Section 558.315 *Levamisole hydrochloride (equivalent)* is amended in paragraph (a) by removing "043781" and by adding in its place "No. ⁰⁵³⁵⁰¹~~000856~~".

LB
10-7-02
✓

Dated: 9/26/02
September 26, 2002.



Andrew J. Beaulieu,
Acting Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.
[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

