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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 558

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Certifier A. Corbin

New Animal Drugs; Change of Sponsor's Drug Labeler Code

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's drug labeler code for ADM Alliance Nutrition, Inc. This action is being taken to improve the accuracy of the regulations.

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

FOR FURTHER INFORMATION CONTACT: Charise Kasser, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9069, e-mail: *charise.kasser@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115, has informed FDA that it has obtained a new drug labeler code (DLC) in 2007, which has not been reflected in the animal drug regulations. Accordingly, the regulations in 21 CFR 510.600, 520.445b, 520.2380a, 558.95, 558.128, 558.274, 558.311, 558.355, 558.485, 558.625, and 558.630 are amended to reflect this new DLC. This action is being taken to improve the accuracy of the regulations.

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 Part 520

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, 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. In § 510.600, in the table in paragraph (c)(1), revise the entry for “ADM Alliance Nutrition, Inc.”; and in the table in paragraph (c)(2), remove the entry for “021930” and in numerical sequence add an entry for “012286” 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
ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115	012286

(2) * * *

Drug labeler code	Firm name and address
012286	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115

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.

§ 520.445b [Amended]

- 4. In paragraph (b)(4) of § 520.445b, remove “021930” and in its place add “012286”.

§ 520.2380a [Amended]

- 5. In paragraph (c)(3) of § 520.2380a, remove “021930” and in its place add “012286”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.95 [Amended]

- 7. In paragraph (a)(4) of § 558.95, remove “016968, 017790, and 021930” and in its place add “012286, 016968, and 017790”.

§ 558.128 [Amended]

■ 8. In § 558.128, in paragraph (b)(2), remove “021930” and in its place add “012286”; and in the tables in paragraphs (e)(1) through (e)(4), in the “Sponsor” column, remove “021930” wherever it occurs and in its place add “012286”.

§ 558.274 [Amended]

■ 9. In § 558.274, in paragraph (a)(7), remove “021930” and in its place add “No. 012286”; and in the table in paragraphs (c)(1)(i) and (c)(1)(ii) in the “Sponsor” column, remove “021930” and in numerical sequence add “012286”.

§ 558.311 [Amended]

■ 10. In paragraph (b)(5) of § 558.311, remove “017800 and 021930” and in its place add “012286 and 017800”.

§ 558.355 [Amended]

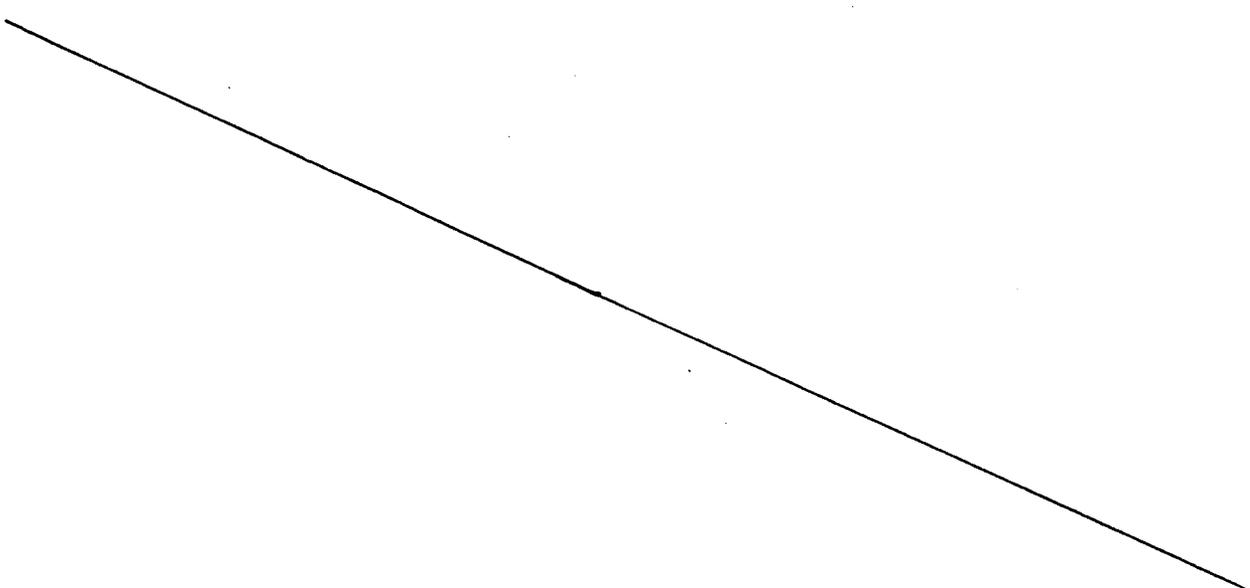
■ 11. In paragraph (b)(13) of § 558.355, remove “021930” and in its place add “No. 012286”.

§ 558.485 [Amended]

■ 12. In paragraph (b)(3) of § 558.485, remove “021930” and in numerical sequence add “012286”.

§ 558.625 [Amended]

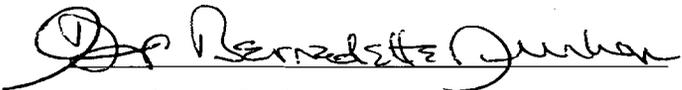
■ 13. In paragraphs (b)(10) and (b)(12) of § 558.625, remove “021930” and in its place add “No. 012286”.



§ 558.630 [Amended]

■ 14. In § 558.630, in paragraph (b)(2), remove “021930” and in its place add “012286; and in paragraph (b)(5), remove “021930” and in numerical sequence add “012286”.

Dated: 6/9/08
June 9, 2008.



Bernadette Dunham,
Director,
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