

(d) *Incentive-based rate treatments for transmission infrastructure investment.*

\* \* \* The applicant must demonstrate that the facilities for which it seeks incentives either ensure reliability or reduce the cost of delivered power by reducing transmission congestion consistent with the requirements of section 219, that the *total* package of incentives is tailored to address the demonstrable risks or challenges faced by the applicant in undertaking the project, and that resulting rates are just and reasonable. \* \* \*

(1) For purposes of this paragraph (d), incentive-based rate treatment means any of the following:

\* \* \* \* \*

(i) *Rebuttable presumption.* (1) The Commission will apply a rebuttable presumption that an applicant has demonstrated that its project is needed to ensure reliability or reduces the cost of delivered power by reducing congestion for:

(i) A transmission project that results from a fair and open regional planning process that considers and evaluates projects for reliability and/or congestion and is found to be acceptable to the Commission; or

(ii) A project that has received construction approval from an appropriate state commission or state siting authority.

(2) To the extent these approval processes do not require that a project ensures reliability or reduce the cost of delivered power by reducing congestion, the applicant bears the burden of demonstrating that its project satisfies these criteria.

(j) *Commission authorization to site electric transmission facilities in interstate commerce.* If the Commission pursuant to its authority under section 216 of the Federal Power Act and its regulations thereunder has issued one or more permits for the construction or modification of transmission facilities in a national interest electric transmission corridor designated by the Secretary, such facilities shall be deemed to either ensure reliability or reduce the cost of delivered power by reducing congestion for purposes of section 219(a).

**Note:** The following appendix will not appear in the Code of Federal Regulations.

## Appendix A

### Requests for Rehearing

American Public Power Association and National Rural Electric Cooperative Association (together, APPA/NRECA)  
Coalition of Midwest Transmission Customers, PJM Industrial Customer Coalition, NEPOOL Industrial Customer Coalition, Southeast Electricity Consumers

Association, and Southwest Industrial Customer Coalition (collectively, Industrial Consumers).

Connecticut Department of Public Utility Control, the Massachusetts Municipal Wholesale Electric Company, the Connecticut Municipal Electric Energy Cooperative, the New Hampshire Electric Cooperative, the Maine Public Utility Commission, and the New England Conference of Public Utility Commissioners (collectively, New England Commissions).

Edison Electric Institute (EEI).  
Energy Financing, Inc. (Energy Financing).  
Midwest ISO Transmission Owners (MISO TOs).

National Association of Regulatory Utility Commissioners (NARUC).

New England Consumer-Owned Entities (NECOE).

Public Utilities Commission of the State of California (California Commission).  
Sacramento Municipal Utility District (SMUD).

Southern California Edison Company (SoCal Edison).

Southern Company Services, Inc., on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, and Mississippi Power Company (collectively, Southern Companies).

Transmission Access Policy Study Group (TAPS).

Transmission Dependent Utility Systems (TDU Systems).

Xcel Energy Services, Inc. (Xcel).

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 510, 520, and 558

#### New Animal Drugs; Change of Sponsor

**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 for 14 approved new animal drug applications (NADAs) from ADM Animal Health & Nutrition Division to ADM Alliance Nutrition, Inc.

**DATES:** This rule is effective January 10, 2007.

**FOR FURTHER INFORMATION CONTACT:** David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: david.newkirk@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** ADM Animal Health & Nutrition Division, 1000 North 30th St., Box 1C, Quincy, IL 62305-3115 has informed FDA that it has transferred ownership of, and all rights and interest in, the following 14 approved NADAs to ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115:

Application No.	Trade name(s)
048-480	Chloratet 50
065-256	Chlortet-Soluble-O
091-582	Gilt Edge TYLAN Mix
107-957	TYLAN 20 Sulfa-G, TYLAN 40 Sulfa-G
108-484	HFA Tylosin-10 Plus Sulfa
110-045	Good-Life TYLAN 10 Premix
110-439	HFA Hygromix 2.4 Medicated Premix
118-877	Ban-A-Worm Pyrantel Tartrate Ton Pack
128-411	TYLAN 5 Sulfa Premix
131-956	TYLAN Sulfa-G
131-957	TYLAN 10, TYLAN 20, TYLAN 40, TYLAN 5
132-448	FLAVOMYCIN
133-490	Ban-D-Wormer II BANMINTH
140-842	Hygromix 2.4 Premix

Accordingly, the agency is amending the regulations in 21 CFR 520.445b, 558.95, 558.128, 558.274, 558.485, 558.625, and 558.630 to reflect the transfer of ownership and a current format.

In addition, ADM Animal Health & Nutrition Division is no longer a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove entries for the firm.

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), remove the entry for “ADM Animal Health & Nutrition Division”; and in the table in paragraph (c)(2), remove the entry for “017519”.

**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.

■ 4. In § 520.445b, revise the section heading, and paragraphs (b) and (d)(4)(iii)(C) to read as follows:

**§ 520.445b Chlortetracycline powder.**

\* \* \* \* \*

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 048164 for use as in paragraph (d) of this section.

(2) No. 053501 for use as in paragraph (d)(4) of this section.

(3) No. 000010 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) through (iv) of this section.

(4) Nos. 021930 and 059130 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), (d)(4)(ii), and (d)(4)(iii) of this section.

\* \* \* \* \*

(d) \* \* \*

(4) \* \* \*

(iii) \* \* \*

(C) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 5 days. For Nos. 000010 and 021930, do not slaughter animals for food within 5 days of treatment; for No. 053501, do not slaughter animals for food within 24 hours of treatment.

\* \* \* \* \*

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

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

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

**§ 558.95 [Amended]**

■ 6. In paragraph (a)(4) of § 558.95, remove “016968, 017519, and 017790” and in its place add “Nos. 016968, 017790, and 021930”.

**§ 558.128 [Amended]**

■ 7. In § 558.128, in paragraph (b)(2), remove “017519” and in its place add “021930”; and in the tables in paragraphs (e)(1) through (e)(4), in the “Sponsor” column remove “017519” wherever it occurs and in its place add “021930”.

**§ 558.274 [Amended]**

■ 8. In § 558.274, in paragraph (a)(7), remove “017519” and in its place add “021930”; and in the table in paragraphs (c)(1)(i) and (c)(1)(ii), in the “Sponsor” column remove “017519” and in numerical sequence add “021930”.

**§ 558.485 [Amended]**

■ 9. In paragraph (b)(3) of § 558.485, remove “017519” and in numerical sequence add “021930”.

**§ 558.625 [Amended]**

■ 10. In paragraph (b)(10) of § 558.625, remove “017519” and in its place add “021930”.

**§ 558.630 [Amended]**

■ 11. In § 558.630, remove and reserve paragraphs (b)(3) and (b)(8); and in paragraph (b)(10) remove “017519”.

Dated: December 29, 2006.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 866**

[Docket No. 2006N-0517]

**Medical Devices; Immunology and Microbiology Devices; Classification of Quality Control Material for Cystic Fibrosis Nucleic Acid Assays**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying quality control material for cystic fibrosis nucleic acid assays into class II (special controls). The special control

that will apply to the device is the guidance document entitled “Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays.” The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

**DATES:** This final rule is effective February 9, 2007. The classification was effective October 12, 2006.

**FOR FURTHER INFORMATION CONTACT:** Zivana Tezak, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0496, ext. 117.

**SUPPLEMENTARY INFORMATION:****I. What is the Background of this Rulemaking?**

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of FDA’s regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an