

American Electric Power Service Corporation (AEP)
 DNV KEMA
 DR Supporters⁴⁷
 Edison Electric Institute (EEI)
 Efficiency Evaluation Organization (EVO)
 Electricity Consumers Resource Council (ELCON)
 Electric Power Supply Association (EPSA)
 Hess Corporation (HESS)
 Independent Market Monitor for PJM (PJM IMM)
 Industrial Energy Consumers of America (IECA)
 ISO/RTO Council (IRC)
 John Lynch (Mr. Lynch)
 North America Power Partners (NAPP)
 New England Conference of Public Utilities Commissioners (NECPUC)
 New York Transmission Owners (NYTOs)⁴⁸
 Northeast Energy Efficiency Partnerships, Inc. (NEEP)
 PSEG Companies (PSEG)⁴⁹
 Southern Company Services, Inc. (Southern)
 Viridity Energy, Inc.; EnergyConnect, Inc.; and PJM Industrial Customer Coalition (Viridity)
 Women's Energy Matters (WEM)
 [FR Doc. 2013-04433 Filed 3-6-13; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73, 172, 173, 176, 177, 178, 184, and 189

[Docket No. FDA-2012-N-0010]

Food and Color Additives; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending certain regulations regarding food and color additives to correct minor errors (such as misspelled chemical names) and to update office names and addresses. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

⁴⁷ DR Supporters include Comverge, Inc., Energy Connect, Inc., Energy Curtailment Specialists, Inc., EnerNOC, Inc., and Wal-Mart Stores, Inc.

⁴⁸ New York Transmission Owners includes Central Hudson Gas & Electric Corporation, Consolidated Edison Company of New York, Inc., Long Island Power Authority, New York Power Authority, New York State Electric & Gas Corporation, Orange and Rockland Utilities, Inc., and Rochester Gas and Electric Corporation.

⁴⁹ The PSEG Companies are: Public Service Electric and Gas Company (PSE&G), PSEG Power LLC (PSEG Power) and PSEG Energy Resources & Trade LLC (PSEG ER&T).

DATES: This rule is effective March 7, 2013.

FOR FURTHER INFORMATION CONTACT:

Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1200.

SUPPLEMENTARY INFORMATION: We are making technical amendments to our regulations under 21 CFR parts 73, 172, 173, 176, 177, 178, 184, and 189. In brief, these amendments are as follows:

- Correct misspelled chemical names in §§ 73.3129, 176.180, and 177.1210. For example, we are revising § 73.3129 to replace “Disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulphonatophenyl]amino]-9, 10-dihydro-9,10-dioxoanthracene-2-sulphonate” with “Disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulfonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulfonate”;
- Correct a table entry in § 177.1500 regarding the melting point of certain nylon 12T resins; and
- Amend §§ 172.712, 172.723, 172.809, 172.831, 172.833, 172.886, 173.25, 173.45, 173.325, 173.368, 177.1350, 177.1360, 177.1637, 177.2440, 177.2600, 178.1010, 178.3297, 184.1012, 184.1024, 184.1034, 184.1063, 184.1259, 184.1316, 184.1415, 184.1583, 184.1595, 184.1866, 184.1914, 184.1985, 189.110, and 189.180 to remove archaic or obsolete office names and replace them with the current Office name “Office of Food Additive Safety.” Where appropriate, we also are updating the street address to reflect our present location at 5100 Paint Branch Parkway, College Park, MD 20740, and contact information to reflect our new telephone number, 240-402-1200. The final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required. Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). These amendments are merely correcting nonsubstantive errors. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

List of Subjects

21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

21 CFR Part 173

Food additives.

21 CFR Parts 176, 177, and 178

Food additives, Food packaging.

21 CFR Part 184

Food additives, Substances generally recognized as safe.

21 CFR Part 189

Food additives, Food packaging, Substances prohibited from use in human food.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR parts 73, 172, 173, 176, 177, 178, 184, and 189 are amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

- 1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

- 2. Amend § 73.3129 as follows:

- a. Revise the section heading to read as set forth below.

- b. In paragraph (a), remove “disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulphonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate” and in its place add “disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulfonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulfonate”.

§ 73.3129 Disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulfonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulfonate.

* * * * *

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

- 3. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

§ 172.712 [Amended]

- 4. In § 172.712, in paragraph (b), remove “the Office of Premarket Approval, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition,

5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 172.723 [Amended]

■ 5. In § 172.723, in paragraph (b)(1), remove “Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., suite 1200, Washington, DC” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 172.809 [Amended]

■ 6. In § 172.809, in paragraph (b), remove “Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 172.831 [Amended]

■ 7. In § 172.831, in paragraph (b), remove “Division of Product Policy (HFS-206), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 172.833 [Amended]

■ 8. In § 172.833, in paragraph (b)(2), remove “Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 172.886 [Amended]

■ 9. In § 172.886, in paragraph (c)(2)(iii), remove “Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and

Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

■ 10. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

§ 173.25 [Amended]

■ 11. In § 173.25, in paragraph (b)(2)(ii)(B), remove “Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 173.45 [Amended]

■ 12. In § 173.45, in paragraph (a), remove “Division of Product Policy, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 173.325 [Amended]

■ 13. In § 173.325, in paragraph (h), remove “Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 173.368 [Amended]

■ 14. In § 173.368, in paragraph (c), remove “Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

■ 15. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

§ 176.180 [Amended]

■ 16. In § 176.180, in the table in paragraph (b)(2), in the first column, remove “Methyl naphthalene sulfonic acid-formaldehyde condensate, sodium salt” and in its place add “Methyl naphthalene sulfonic acid-formaldehyde condensate, sodium salt”; and remove “Naphthalene sulfonic acid-formaldehyde condensate, sodium salt” and in its place add “Naphthalene sulfonic acid-formaldehyde condensate, sodium salt”.

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

■ 17. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 177.1210 [Amended]

■ 18. In § 177.1210, in table 1 in paragraph (b)(5), in the first column, remove “Naphthalene sulfonic acid-formaldehyde condensate, sodium salt” and in its place add “Naphthalene sulfonic acid-formaldehyde condensate, sodium salt”; and remove “Sodium salt of trisopropyl naphthalenesulfonic acid” and in its place add “Sodium salt of trisopropyl naphthalenesulfonic acid”.

§ 177.1350 [Amended]

■ 19. In § 177.1350, in paragraph (b)(2), remove “Division of Petition Control (HFS-215) Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 177.1360 [Amended]

■ 20. In § 177.1360, in paragraph (d), remove “Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200”.

§ 177.1500 [Amended]

■ 21. In § 177.1500, in table 1 in paragraph (b), in the third column of the entry for “11. Nylon 12T resins for use in contact with all types of food except those containing more than 8 percent alcohol,” remove “290–310” and in its place add “N/A”.

§ 177.1637 [Amended]

■ 22. In § 177.1637, in paragraph (b)(2), remove “Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 177.2440 [Amended]

■ 23. In § 177.2440, in paragraph (a)(3), remove “Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, 1110 Vermont Ave. NW., Suite 1200, Washington, DC” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 177.2600 [Amended]

■ 24. In § 177.2600, in paragraph (c)(4)(i), remove “Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

■ 25. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 178.1010 [Amended]

■ 26. In § 178.1010, in paragraph (c)(40), remove “Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and

Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 178.3297 [Amended]

■ 27. Amend § 178.3297 as follows:

- a. In paragraph (c), remove “Center for Food Safety and Applied Nutrition, (HFS–200) Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740,” and in its place add “Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.
- b. In paragraph (e), in the entry for “High-purity furnace black,” remove “Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

■ 28. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

§ 184.1012 [Amended]

■ 29. In § 184.1012, in paragraph (b), remove “Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., Suite 1200, Washington, DC” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 184.1024 [Amended]

■ 30. In § 184.1024, in paragraph (b), remove “Office of Premarket Approval (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 184.1034 [Amended]

■ 31. In § 184.1034, in paragraph (b), remove “Office of Premarket Approval (HFS–200), Food and Drug

Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 184.1063 [Amended]

■ 32. In § 184.1063, in paragraph (b)(8), remove “Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 184.1259 [Amended]

■ 33. In § 184.1259, in paragraph (b)(8), remove “Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 184.1316 [Amended]

■ 34. In § 184.1316, in paragraph (b), remove “Office of Premarket Approval (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 184.1415 [Amended]

■ 35. In § 184.1415, in paragraph (b), remove “Office of Premarket Approval (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 184.1583 [Amended]

■ 36. In § 184.1583, in paragraph (b), remove “Office of Premarket Approval (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in

its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 184.1595 [Amended]

■ 37. In § 184.1595, in paragraph (b), remove “Office of Premarket Approval (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 184.1866 [Amended]

■ 38. In § 184.1866, in paragraph (b), remove “Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 184.1914 [Amended]

■ 39. In § 184.1914, in paragraph (b), remove “Office of Premarket Approval (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 184.1985 [Amended]

■ 40. In § 184.1985, in paragraph (b), remove “Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., Suite 1200, Washington, DC” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100

Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

■ 41. The authority citation for 21 CFR part 189 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371, 381.

§ 189.110 [Amended]

■ 42. In § 189.110, in paragraph (c), remove “Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

§ 189.180 [Amended]

■ 43. In § 189.180, in paragraph (c), remove “Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740” and in its place add “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200”.

Dated: February 1, 2013.

Susan M. Bernard,

Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

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BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 529, and 558

[Docket No. FDA–2012–N–1167]

New Animal Drug Applications; Alfaprostol; Bicyclohexylammonium Fumagillin; N-Butyl Chloride; Competitive Exclusion Culture; Dichlorophene and Toluene; Flurogestone Acetate; Isoflurane; Pyrantel; Tylosin; Tylosin and Sulfamethazine

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 the withdrawal approval of 19 new animal drug applications (NADAs) and one abbreviated new animal drug application (ANADA). The applications are being withdrawn for lack of compliance with the reporting requirements in an FDA regulation.

DATES: This rule is effective March 18, 2013.

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; 240–453–6843; david.alterman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of the 19 NADAs and one ANADA listed in table 1, and all supplements and amendments thereto, is withdrawn, effective March 18, 2013, for lack of compliance with reporting requirements in 21 CFR 514.80. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect withdrawal of approval of the following applications and a current format. Withdrawal of approval of some applications did not require amending the regulations.

TABLE 1—NADAS AND ANADA FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Trade name (drug)	Applicant	Citation in 21 CFR
NADA 009–252	FUMIDIL B (bicyclohexylammonium fumagillin) ..	Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214	520.182
NADA 034–601	SYNCHRO–MATE (flurogestone acetate)	G. D. Searle LLC, Pharmacia Corp., 4901 Searle Pkwy., Skokie, IL 60077	529.1003