(i) 135 days for fiscal years ending on or after December 15, 2002 and before December 15, 2003;

(ii) 130 days for fiscal years ending on or after December 15, 2003 and before December 15, 2004; and

(iii) 125 days for fiscal years ending on or after December 15, 2004; and

* * * * *

(i) * * *

(2) For purposes of paragraph (e) of this section, the number of days shall be:

(i) For accelerated filers (as defined in § 240.12b–2 of this chapter):

(A) 134 days subsequent to the end of the registrant's most recent fiscal year for fiscal years ending on or after December 15, 2002 and before December 15, 2003;

(B) 129 days subsequent to the end of the registrant's most recent fiscal year for fiscal years ending on or after December 15, 2003 and before December 15, 2004; and

(C) 124 days subsequent to the end of the registrant's most recent fiscal year for fiscal years ending on or after December 15, 2004; and

(ii) 134 days subsequent to the end of the registrant's most recent fiscal year for all other registrants.

■ 3. Section 210.3–12 is amended by revising paragraph (g)(1) to read as follows:

§ 210.3–12 Age of financial statements at effective date of registration statement or at mailing date of proxy statement.

* * * * *

(g)(1) For purposes of paragraph (a) of this section, the number of days shall be:

(i) For accelerated filers (as defined in § 240.12b–2 of this chapter):

(A) 135 days for fiscal years ending on or after December 15, 2002 and before December 15, 2003;

(B) 130 days for fiscal years ending on or after December 15, 2003 and before December 15, 2004; and

(C) 125 days for fiscal years ending on or after December 15, 2004; and

(ii) 135 days for all other registrants.

* * * * *

Dated: April 8, 2003.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–8998 Filed 4–11–03; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

[Docket No. 76N–052G]

RIN 0910–AA01

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for Combination Drug Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of December 23, 2002 (67 FR 78158). The document issued a final monograph that established conditions under which over-the-counter (OTC) cold, cough, allergy, bronchodilator, and antiasthmatic (cough-cold) combination drug products are generally recognized as safe and effective and not misbranded as part of its ongoing review of OTC drug products.

DATES: The regulation is effective December 23, 2004.

FOR FURTHER INFORMATION CONTACT: Cazemiro R. Martin or Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION: In FR Doc. 02–32158 appearing on page 78158 in the **Federal Register** of Monday, December 23, 2002, the following corrections are made:

§ 341.40 [Corrected]

1. On page 78168, in the second column, in Part 341 *Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use*, under the authority citation, in amendment 2, ''Section 341.40 is added to subpart C to read as follows:'' is corrected to read ''Section 341.40 is added to subpart B to read as follows:''

§ 341.70 [Corrected]

2. On page 78170, in the second column, in § 341.70 *Labeling of OTC drug products containing ingredients that are used for treating concurrent symptoms (in either a single-ingredient or combination drug product)*, in paragraph (b), ''Repeat every hour as needed or as directed by a doctor.'' is corrected to read ''Repeat every 2 hours as needed or as directed by a doctor.''

Dated: April 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–9067 Filed 4–11–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

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 seven approved new animal drug applications (NADAs) for clopidol Type A medicated articles and combination drug medicated chicken and turkey feeds from Aventis Animal Nutrition, Inc., to Merial Ltd.

DATES: This rule is effective April 14, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Aventis Animal Nutrition, Inc., 3480 Preston Ridge Rd., suite 650, Alpharetta, GA 30005–8891, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 34–393, 40–264, 41–541, 44–016, 46–209, 49–934, and 99–150 for clopidol Type A medicated articles and certain combination clearances for use in medicated feeds for chickens and turkeys to Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640. Accordingly, the agency is amending the regulations in § 558.175 (21 CFR 558.175) to reflect the transfer of ownership. Section 558.175 is also being changed to a table format.

Following the change of sponsor of these NADAs, Aventis Animal Nutrition, Inc., is no longer the sponsor of any approved applications. Therefore, 21 CFR 510.600(c) is being amended to remove the entries for this sponsor.

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 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 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 ''Aventis Animal Nutrition, Inc.'' and in the table in paragraph (c)(2) by removing the entry for ''011526''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 4. Section 558.175 is revised to read as follows:

§ 558.175 Clopidol.

(a) *Specifications.* Type A medicated article containing 25 percent clopidol.

(b) *Approvals.* See No. 050604 in § 510.600(c) of this chapter.

(c) [Reserved]

■ (d) *Conditions of use.* It is used as follows:

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 113.5		Broiler chickens and replacement chickens intended for use as caged layers: As an aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.	Do not feed to chickens over 16 weeks of age.	050604
(2) 113.5	Bacitracin methylene disalicylate 4 to 50	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain.	Feed continuously as the sole ration from the time chicks are placed in floor pens until slaughter. Do not feed to chickens over 16 weeks of age; bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.	050604
(3) 113.5	Bacitracin 4 to 25 plus roxarsone 45.4	Broiler chickens: As in paragraph (d)(1) of this section; for growth promotion, feed efficiency; improved pigmentation, and increased rate of weight gain.	Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicylate or bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter.	046573 050604
(4) 113.5	Bacitracin zinc 5 to 25	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter.	046573 050604
(5) 113.5	Chlortetracycline 100 to 200	Broiler and replacement chickens: As in paragraph (d)(1) of this section; for control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Feed continuously as sole ration from the time chicks are placed in floor pens for 7 to 14 days.	050604
(6) 113.5	Lincomycin 2 to 4	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain and improved feed efficiency.	Do not feed to chickens over 16 weeks of age; as lincomycin hydrochloride monohydrate.	000009
(7) 113.5	Roxarsone 45.4	Broiler and replacement chickens intended for use as caged layers: As in paragraph (d)(1) of this section; for growth promotion, feed efficiency; and improved pigmentation.	Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.	050604

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(8) 227		Broiler and replacement chickens intended for use as caged layers: As in paragraph (d)(1) of this section.	Feed continuously as the sole ration; feed up to 16 weeks of age if intended for use as caged layers; withdraw 5 days before slaughter if given at the level of 0.025 percent in feed or reduce level to 0.0125 percent 5 days before slaughter.	050604
(9) 113.5 or 227		Turkeys: As an aid in the prevention of leucocytozoonosis caused by *Leucocytozoon smithi*.	For turkeys grown for meat purposes only; feed continuously as the sole ration at 0.0125 or 0.025 percent clopidol depending on management practices, degree of exposure, and amount of feed eaten; withdraw 5 days before slaughter.	050604

Dated: March 25, 2003.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 03–9028 Filed 4–11–03; 8:45 am]

BILLING CO DE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[FL–094–200316a; FRL–7481–8]

Approval and Promulgation of State Plan for Designated Facilities and Pollutants: Florida

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving the sections 111(d)/129 plan submitted by the Florida Department of Environmental Protection (FDEP) for the State of Florida on November 29, 2001, for implementing and enforcing the Emissions Guidelines (EG) applicable to existing Commercial and Industrial Solid Waste Incineration (CISWI) units that commenced construction on or before November 30, 1999.

DATES: This direct final rule is effective June 13, 2003 without further notice, unless EPA receives adverse comments by May 14, 2003. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: All comments should be addressed to: Joydeb Majumder, EPA Region 4, Air Toxics and Management Branch, 61 Forsyth Street, SW., Atlanta, Georgia 30303–3104. Copies of materials submitted to EPA may be examined during normal business hours at the above listed Region 4 location. Anyone interested in examining this document should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Joydeb Majumder at (404) 562–9121 or Heidi LeSane at (404) 562–9035.

SUPPLEMENTARY INFORMATION:

I. Background

On December 1, 2000, pursuant to sections 111 and 129 of the Clean Air Act (Act), EPA promulgated new source performance standards (NSPS) applicable to new CISWIs and EG applicable to existing CISWIs. The NSPS and EG are codified at 40 CFR part 60, subparts CCCC and DDDD, respectively. Subparts CCCC and DDDD regulate the following: Particulate matter, opacity, sulfur dioxide, hydrogen chloride, oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins and dibenzofurans.

Section 129(b)(2) of the Act requires States to submit to EPA for approval State Plans that implement and enforce the EG. State Plans must be at least as protective as the EG, and become Federally enforceable upon approval by EPA. The procedures for adoption and submittal of State Plans are codified in 40 CFR part 60, subpart B. EPA originally promulgated the subpart B provisions on November 17, 1975. EPA amended subpart B on December 19, 1995, to allow the subparts developed under section 129 to include specifications that supersede the general provisions in subpart B regarding the schedule for submittal of State Plans, the stringency of the emission limitations, and the compliance schedules.

This action approves the State Plan submitted by FDEP for the State of Florida to implement and enforce subpart DDDD, as it applies to existing CISWI units only.

II. Discussion

FDEP submitted to EPA on November 29, 2001, the following in their 111(d)/129 State Plan for implementing and enforcing the EG for existing CISWIs under their direct jurisdiction in the State of Florida: Public Participation-Demonstration that the Public Had Adequate Notice and Opportunity to Submit Written Comments and Attend the Public Hearing; Legal Authority; Emission Limits and Standards; Compliance Schedule; Inventory of CISWI Plants/Units; CISWI Emissions Inventory; Source Surveillance, Compliance Assurance and Enforcement Procedures; Submittal of Progress Reports to EPA; and applicable State of Florida statutes and rules of the FDEP.

The approval of the Florida State Plan is based on finding that: (1) FDEP provided adequate public notice of public hearings for the EG for CISWIs, and (2) FDEP also demonstrated legal authority to adopt emission standards and compliance schedules; enforceable applicable laws, regulations, standards, and compliance schedules; the ability to seek injunctive relief; obtain information necessary to determine compliance; require record keeping; conduct inspections and tests; require the use of monitors; require emission reports of owners and operators; and make emission data publicly available.

FDEP cites the following references for the legal authority: The Florida Statues (F.S.), sections 403.031 definitions, 403.061 powers and duties, 403.0872 Title V air operating permits, and 403.8055 authority to adopt federal