

(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.

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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.

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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.