FR 64954, October 31, 2000). On November 29, 2000, Bayer Corp. (Bayer), the sponsor of enrofloxacin (sold under the trade name Baytril® 3.23% Concentrate Antimicrobial Solution), requested a hearing on the proposed withdrawal. On February 20, 2002, the FDA's then Acting Principal Deputy Commissioner published a notice of hearing granting Bayer's request and identifying the factual issues that would be the subject of the evidentiary hearing (67 FR 7700, February 20, 2002). On March 21, 2002, the Animal Health Institute submitted a notice of participation under 21 CFR 12.45. Oral hearing for the purposes of cross-examination of witnesses was held at FDA from April 28 through May 7, 2003. On March 16, 2004, an FDA Administrative Law Judge (ALJ) issued an initial decision under 21 CFR 12.120. The ALJ determined that enrofloxacin had not been ''shown to be safe under the conditions of use upon the basis of which the application was approved,'' as required under section 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(e)(1)(B)) and ordered that the approval of the NADA for Baytril be withdrawn. Bayer and CVM each filed exceptions to the initial decision on May 17, 2004.

In a notice published elsewhere in this issue of the **Federal Register**, FDA is announcing the final decision withdrawing approval of the NADA held by Bayer Corp., Agriculture Division, Animal Health, Shawnee Mission, KS 66201. NADA 140–828, Baytril® 3.23% Concentrate Antimicrobial Solution provides for use of enrofloxacin to treat poultry under § 520.813 (21 CFR 520.813). Relevant information concerning tolerances for residues of enrofloxacin in edible tissues of poultry is under § 556.228(a) (21 CFR 556.228(a)).

Therefore, in accordance with the final decision withdrawing approval and section 512(i) of the act (21 U.S.C. 360(b)(i)), FDA is amending the regulations to remove §§ 520.813 and 556.228(a).

The agency has determined under 21 CFR 25.33(g) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 520 and 556 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.813 [Removed]

■ 2. Section 520.813 is removed.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.228 [Amended]

■ 4. Section 556.228 is amended by removing paragraph (a), by redesignating paragraph (b) as paragraph (a), and by adding and reserving new paragraph (b).

Dated: July 27, 2005.

Lester M. Crawford,

Commissioner of Food and Drugs.

[FR Doc. 05–15223 Filed 7–28–05; 2:31 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; 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 a new animal drug application (NADA) from North American Nutrition Companies, Inc., to Elanco Animal Health, A Division of Eli Lilly & Co.

DATES: This rule is effective August 1, 2005.

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.gov*.

SUPPLEMENTARY INFORMATION: North American Nutrition Companies, Inc., C.S. 5002, 6531 St., Rt. 503, Lewisburg, OH 45338, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 127–507 for TYLAN SULFA G Type A Medicated Article to Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285. Accordingly, the agency is amending the regulations in 21 CFR 558.630 to reflect the transfer of ownership.

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 in 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 part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.630 [Amended]

■ 2. Section 558.630 is amended in paragraph (b)(10) by removing ''017790'' and by adding in numerical sequence ''000986''.

Dated: July 11, 2005.

Steven D. Vaughn,

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

[FR Doc. 05–15161 Filed 7–29–05; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

[Docket No. 2005–10]

Recordation of Documents

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of policy decision.