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 in 21 CFR Part 520

Animal drugs.

■ 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 520 is 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.

■ 2. Add § 520.2130 to read as follows:

§ 520.2130 Spinosad.

(a) *Specifications.* Each chewable tablet contains 140, 270, 560, 810, or 1620 milligrams (mg) spinosad.

(b) *Sponsor.* See No. 000986 in § 510.600 of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer tablets once a month at a recommended minimum dosage of 13.5 mg per pound (30 mg per kilogram) of body weight.

(2) *Indications for use.* To kill fleas and for the prevention and treatment of flea infestations (*Ctenocephalides felis*) on dogs for 1 month.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: October 17, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–21058 Filed 10–24–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 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 five approved new animal drug applications (NADAs) from Merial Ltd., to Huvepharma AD.

DATES: This rule is effective October 25, 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: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640 has informed FDA that it has transferred ownership of, and all rights and interest in, the following five approved NADAs to Huvepharma AD, 33 James Boucher Blvd., Sophia 1407, Bulgaria:

Application No.	Trade name(s)
012–350	AMPROVINE (amprolium) 25% Type A Medicated Article; CORID (amprolium) 25% Type A Medicated Article
013–149	AMPROVINE (amprolium) 9.6% Solution
013–461	Broiler PMX No. 1620 (amprolium/ethopabate)
033–165	AMPROVINE (amprolium) 20% Soluble Powder; CORID (amprolium) 20% Soluble Powder
034–393	COYDEN 25 (clopidol); Lerbek 25

Accordingly, the agency is amending the regulations in 21 CFR 520.100, 558.55, 558.58, and 558.175 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

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 520 and 558 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.

§ 520.100 [Amended]

■ 2. In paragraph (b)(1) of § 520.100, remove ''050604'' and in its place add ''016592''.

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.

§ 558.55 [Amended]

■ 4. In paragraph (a) of § 558.55, remove ''050604'' and in its place add ''No. 016592''.

■ 5. In § 558.58, in the table in paragraph (e)(1)(i), in the first entry, in the ''Sponsor'' column, add ''050604'' and ''016592''; add paragraph (a)(3); and revise paragraph (b) to read as follows:

§ 558.58 Amprolium and ethopabate.

(a) * * *

(3) 25 percent amprolium and 0.8 percent ethopabate.

(b) *Approvals.* See § 510.600(c) of this chapter.

(1) No. 050604 for products described in paragraph (a) of this section.

(2) No. 016592 for product described in paragraph (a)(3) of this section.

§ 558.175 [Amended]

■ 6. In § 558.175, in paragraph (b) and in the table in paragraph (d)(1) in the ''Sponsor'' column, remove ''050604'' and in its place add ''016592''.

Dated: October 17, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–21057 Filed 10–24–07; 8:45 am]

BILLING CODE 4160–01–S

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