information in the administrative record, including any submission made by the manufacturer or person. The decision of whether a cease and desist order should be issued shall be made within 30 days after receipt of any information and argument submitted by the manufacturer or person. The cease and desist order shall be final unless the affected manufacturer or person requests a reconsideration of the order to the Administrator, Agricultural Marketing Service, within 30 days after the date of the issuance of the order.

§ 1170.15 Appeals.

If the cease and desist order is confirmed by the Administrator, Agricultural Marketing Service, the manufacturer or person may appeal the order in the appropriate United States District Court not later than 30 days after the date of the confirmation of the order.

§ 1170.16 Enforcement.

(a) If a person subject to the Dairy Product Mandatory Reporting program fails to obey a cease and desist order after the order has become final and unappealable, or after the appropriate United States district court has entered a final judgment in favor of the Administrator, Agricultural Marketing Service, the United States may apply to the appropriate United States district court for enforcement of the order.

(b) If the court determines that the cease and desist order was lawfully made and duly served and that the manufacturer or person violated the order, the court shall enforce the order.

(c) If the court finds that the manufacturer or person violated the cease and desist order, the manufacturer or person shall be subject to a civil penalty of not more than $10,000 for each offense.

Dated: June 10, 2008.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E8–13550 Filed 6–16–08; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Paste

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The supplemental ANADA adds effectiveness claims against various species of internal parasites when horses are treated with ivermectin paste.

DATES: This rule is effective June 17, 2008.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed a supplement to ANADA 200–326 for BIMECTIN (ivermectin) Paste 1.87% adding effectiveness claims against various species of internal parasites of horses. The supplemental ANADA is approved as of May 23, 2008, and 21 CFR 520.1192 is amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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 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. In § 520.1192, remove paragraphs (b)(4) and (e)(1)(ii)(C) and revise paragraph (b)(3) to read as follows:

§ 520.1192 Ivermectin paste.

* * * * *

(b) * * *

(3) Nos. 051311, 054925, and 061623 for use of a 1.87 percent paste for use as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section.

* * * * *

Dated: June 9, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–13607 Filed 6–16–08; 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; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA provides for revision of an effectiveness claim and pathogen nomenclature for a tylosin phosphate and sulfamethazine Type A medicated article used to manufacture medicated swine feeds.

DATES: This rule is effective June 17, 2008.

FOR FURTHER INFORMATION CONTACT: Timothy Schell, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8116, e-mail: *timothy.schell@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 41–275 that provides for use of TYLAN 40 SULFA–G (tylosin phosphate and sulfamethazine) Elliptical Pellets, a Type A medicated article. The