■ 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.

§ 520.538 [Amended]

■ 2. In paragraph (a) of § 520.538, remove ''25, 75, or 100 milligrams'' and in its place add ''25, 50, 75, or 100 milligrams''.

Dated: June 4, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–13353 Filed 6–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin, Fenbendazole, and Praziquantel Tablets

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 an original new animal drug application (NADA) filed by Intervet, Inc. The NADA provides for the veterinary prescription use of chewable tablets containing ivermectin, fenbendazole, and praziquantel for the treatment and control of various internal parasites and for the prevention of canine heartworm disease in adult dogs.

DATES: This rule is effective June 13, 2008.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8337, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed NADA 141–286 that provides for the veterinary prescription use of PANACUR Plus (ivermectin, fenbendazole, and praziquantel) Soft Chews for the treatment and control of various internal parasites and for the prevention of canine heartworm disease in adult dogs. The NADA is approved as of May 9, 2008, and the regulations are amended in 21 CFR part 520 by adding § 520.1200 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33(d)(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 the 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 § 520.1200 to read as follows:

§ 520.1200 Ivermectin, fenbendazole, and praziquantel tablets.

(a) *Specifications*. Each chewable tablet contains either:

(1) 68 micrograms (µg) ivermectin, 1.134 grams fenbendazole, and 57 milligrams (mg) praziquantel; or

(2) 27 µg ivermectin, 454 mg fenbendazole, and 23 mg praziquantel.

(b) *Sponsor*. See No. 057926 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer tablets to provide 6 µg per kilogram (/kg) ivermectin, 100 mg/kg fenbendazole, and 5 mg/kg praziquantel.

(2) *Indications for use*. For the treatment and control of adult *Toxocara canis* (roundworm), *Ancylostoma caninum* (hookworm), *Trichuris vulpis* (whipworm), and *Dipylidium caninum* (tapeworm), and for the prevention of heartworm disease caused by *Dirofilaria immitis* in adult dogs.

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

Dated: June 4, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–13354 Filed 6–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

[Docket No. FDA–2008–N–0310]

Medical Devices; Medical Device Reporting; Baseline Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its medical device reporting regulations to remove a requirement for baseline reports that the agency deems no longer necessary. Currently, manufacturers provide baseline reports to FDA that include the FDA product code and the premarket approval or premarket notification number. Because most of the information in these baseline reports is also submitted to FDA in individual adverse event reports, FDA is removing the requirement for baseline reports. The removal of this requirement will eliminate unnecessary duplication and reduce the manufacturer's reporting burden. FDA is amending the regulation in accordance with its direct final rule procedures. Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event we receive a significant adverse comment and withdraw this direct final rule.

DATES: This rule is effective October 27, 2008. Submit written or electronic