■ 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

comments by August 27, 2008. If we receive no significant adverse comments within the specified comment period, we intend to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If we receive any timely significant adverse comment, we will withdraw this final rule in part or in whole by publication of a document in the **Federal Register** within 30 days after the comment period ends.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0310, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see section IX of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Howard A. Press, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr, Rockville, MD 20850, 240–276–3457.

SUPPLEMENTARY INFORMATION:

I. What Is the Background of the Rule?

In the **Federal Register** of December 11, 1995 (60 FR 63578), FDA published a final rule revising part 803 (21 CFR part 803) and requiring medical device manufacturers to submit certain reports relating to adverse events, including a requirement under § 803.55 to submit baseline reports on FDA Form 3417 or an electronic equivalent. Section 803.55 requires manufacturers to submit baseline reports when the manufacturer submits the first adverse event report under § 803.50 for a device model. In addition, § 803.55 requires annual updates of each baseline report.

The baseline report includes address information for the reporting and manufacturing site for the device, device identifiers, the basis for marketing for the device (e.g., the 510(k) number or PMA number), the FDA product code, the shelf life of the device (if applicable) and the expected life of the device, the number of devices distributed each year, and the method used to calculate that number. In the **Federal Register** of July 31, 1996 (61 FR 39868), FDA stayed the requirement for manufacturers to submit information on the number of devices distributed each year and the method used to calculate that number, because of questions raised about the feasibility of obtaining such information and the usefulness of such information once submitted to FDA.

With the requirement for these two data elements stayed, the data submitted in baseline reports largely overlapped with the data submitted in individual adverse event reports. That is, FDA had access to much of the information included in baseline reports through the individual adverse event reports submitted on the MedWatch mandatory reporting form (FDA Form 3500A). Two notable exceptions were the basis for marketing and the FDA product code, data elements that were included in the baseline reports but were not included in the FDA Form 3500A and its instructions.

The basis for marketing and the FDA product code were, however, subsequently incorporated into the FDA Form 3500A and its instructions. In the **Federal Register** of December 27, 2004 (69 FR 77256), FDA announced proposed modifications to FDA Form 3500A, which included adding an entry for the basis for marketing (PMA or 510(k) number). In the **Federal Register** of December 7, 2005 (70 FR 72843), FDA announced that the Office of Management and Budget approved these modifications under the Paperwork Reduction Act of 1995. FDA also modified the instructions for FDA Form 3500A to state that manufacturers use the FDA product code when completing the entry for ''Common Device Name'' on FDA Form 3500A.

With the addition of these two data elements (basis for marketing and FDA product code) to FDA Form 3500A and its instructions, the information submitted in FDA Form 3500A largely replicates the information submitted in baseline reports. As a result, the agency deems the baseline reporting requirement in § 803.55 no longer necessary. The agency believes that removing § 803.55 will reduce the reporting burden for manufacturers without impairing the agency's receipt of device adverse event information.

II. What Does This Direct Final Rulemaking Do?

In this direct final rule, FDA is removing § 803.55, which requires manufacturers to submit a baseline report when they submit the first report under § 803.50 involving a device model and provide annual updates thereafter. In addition, this direct final rule makes conforming amendments to §§ 803.1(a), 803.10(c), and 803.58(b) to remove references to baseline reports and to § 803.55. Finally, this direct final rule removes the terms ''device family'' and ''shelf life'' from the definitions in § 803.3 because these terms are used only in the context of baseline reports.

III. What Are the Procedures for Issuing a Direct Final Rule?

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA announced the availability of the guidance document entitled ''Guidance for FDA and Industry: Direct Final Rule Procedures'' that described when and how FDA will employ direct final rulemaking. We believe that this rule is appropriate for direct final rulemaking because it is intended to make noncontroversial changes to existing regulations. We anticipate no significant adverse comment.

Consistent with FDA's procedures on direct final rulemaking, we are publishing elsewhere in this issue of the **Federal Register** a companion proposed rule that is identical to the direct final rule. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for this direct final rule runs concurrently with the comment period of the companion proposed rule. Any comments received in response to the companion proposed rule will also be considered as

comments regarding this direct final rule.

We are providing a comment period on the direct final rule of 75 days after the date of publication in the **Federal Register**. If we receive any significant adverse comment, we intend to withdraw this final rule before its effective date by publication of a notice in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether an adverse comment is significant and warrants withdrawing a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment recommending an additional change to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

If we withdraw the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule under the usual notice-and-comment procedures under the APA (5 U.S.C. 552a *et seq.*). If we receive no significant adverse comment during the specified comment period, we intend to publish a confirmation document in the **Federal Register** within 30 days after the comment period ends.

IV. What is the Legal Authority for This Rule?

FDA is issuing this direct final rule under the device and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 360i, 371, and 374).

V. What is the Environmental Impact of This Rule?

The agency has determined under 21 CFR 25.30(h) and (i) 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.

VI. What is the Economic Impact of This Rule?

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The direct final rule amends the existing medical device reporting regulation to remove § 803.55, which requires that manufacturers submit baseline reports, and makes conforming amendments to §§ 803.1(a), 803.3, 803.10(c), and 803.58(b) to remove references to baseline reports and to § 803.55 and to remove the terms ''device family'' and ''shelf life.'' This final rule does not impose any new requirements but instead removes a reporting requirement for manufacturers that FDA deems no longer necessary. The agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. How Does the Paperwork Reduction Act of 1995 Apply to This Rule?

This direct final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VIII. What are the Federalism Impacts of This Rule?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. How Do You Submit Comments on This Rule?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov.*

List of Subjects in 21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 803 is amended as follows:

PART 803—MEDICAL DEVICE REPORTING

■ 1. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

§ 803.1 [Amended]

■ 2. Section 803.1 is amended in paragraph (a), in the fourth sentence, by removing the phrase ''and baseline reports''.

§ 803.3 [Amended]

■ 3. Section 803.3 is amended by removing the definitions for ''Device family'' and ''Shelf life''.

§ 803.10 [Amended]

■ 4. Section 803.10 is amended by removing paragraph (c)(3) and redesignating paragraph (c)(4) as paragraph (c)(3).

§ 803.55 [Removed]

■ 5. Section 803.55 is removed.

§ 803.58 [Amended]

■ 6. Section 803.58 is amended in paragraph (b)(1) by removing ''803.55,''.

Dated: June 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–13350 Filed 6–12–08; 8:45 am]

BILLING CODE 4160–01–S

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans prescribe interest assumptions for valuing and paying benefits under terminating single-employer plans. This final rule amends the regulations to adopt interest assumptions for plans with valuation dates in July 2008. Interest assumptions are also published on the PBGC's Web site (*http://www.pbgc.gov*).

DATES: Effective July 1, 2008.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: The PBGC's regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Three sets of interest assumptions are prescribed: (1) A set for the valuation of benefits for allocation purposes under section 4044 (found in Appendix B to Part 4044), (2) a set for the PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by the PBGC (found in Appendix B to Part 4022), and (3) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology (found in Appendix C to Part 4022).

This amendment (1) adds to Appendix B to Part 4044 the interest assumptions for valuing benefits for allocation purposes in plans with valuation dates during July 2008, (2) adds to Appendix B to Part 4022 the interest assumptions for the PBGC to use for its own lump-sum payments in plans with valuation dates during July 2008, and (3) adds to Appendix C to Part 4022 the interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology for valuation dates during July 2008.

For valuation of benefits for allocation purposes, the interest assumptions that the PBGC will use (set forth in Appendix B to part 4044) will be 5.95 percent for the first 20 years following the valuation date and 5.02 percent thereafter. These interest assumptions represent an increase (from those in effect for June 2008) of 0.27 percent for the first 20 years following the valuation date and 0.27 percent for all years thereafter.

The interest assumptions that the PBGC will use for its own lump-sum payments (set forth in Appendix B to part 4022) will be 3.50 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. These interest assumptions represent an increase from those in effect for June 2008 of 0.25 percent in the immediate annuity rate and are otherwise unchanged. For private-sector payments, the interest assumptions (set forth in Appendix C to part 4022) will be the same as those used by the PBGC for determining and paying lump sums (set forth in Appendix B to part 4022).

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the valuation and payment of benefits in plans with valuation dates during July 2008, the PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

■ In consideration of the foregoing, 29 CFR parts 4022 and 4044 are amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 177, as set forth below, is added to the table.

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *