Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: FDA is amending its administrative regulations in 21 CFR part 10. We are taking this action to ensure accuracy and clarity in the agency's regulations.

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because the amendments to the regulations provide only technical changes to correct inaccurate citations and to update terminology, and are nonsubstantive.

List of Subjects in 21 CFR Part 10

Administrative practice and procedure, News media.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 10 is amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

■ 1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

■ 2. In § 10.90, revise paragraphs (a) and (c) to read as follows:

§ 10.90 Food and Drug Administration regulations, recommendations, and agreements.

(a) *Regulations.* FDA regulations are issued in the **Federal Register** under § 10.40 or § 10.50 and codified in the Code of Federal Regulations. Regulations may contain provisions that will be enforced as legal requirements, or which are intended only as guidance documents and recommendations, or both. The dissemination of draft notices and regulations is subject to § 10.80.

* * * * *

(c) *Recommendations.* In addition to the guidance documents subject to § 10.115, FDA often formulates and disseminates recommendations about matters which are authorized by, but do not involve direct regulatory action under, the laws administered by the Commissioner, e.g., model State and local ordinances, or personnel practices for reducing radiation exposure, issued under 42 U.S.C. 243 and 21 U.S.C. 360ii. These recommendations may, in the discretion of the Commissioner, be handled under the procedures established in § 10.115, except that the recommendations will be included in a separate public file of recommendations established by the Division of Dockets Management and will be separated from the guidance documents in the notice of availability published in the **Federal Register**, or be published in the **Federal Register** as regulations under paragraph (a) of this section.

* * * * *

Dated: March 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–7286 Filed 3–31–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

[Docket No. FDA–2010–N–0002]

Ophthalmic and Topical Dosage Form New Animal Drugs; Orbifloxacin, Mometasone Furoate Monohydrate, and Posaconazole Suspension

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 new animal drug application (NADA) filed by Intervet, Inc. The NADA provides for the veterinary prescription use of a suspension containing orbifloxacin, mometasone furoate monohydrate, and posaconazole for the treatment of otitis externa in dogs.

DATES: This rule is effective April 1, 2010.

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, email: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068, filed NADA 141–266 that provides for veterinary prescription use of POSATEX (orbifloxacin, mometasone furoate monohydrate, and posaconazole) Otic Suspension for the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (coagulase-positive staphylococci, *Pseudomonas aeruginosa*, and *Enterococcus faecalis*). The NADA is approved as of February 18, 2010, and the regulations are amended in 21 CFR part 524 by adding § 524.1610 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.

FDA has determined under 21 CFR 25.33 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.

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.

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 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 2. Add § 524.1610 to read as follows:

§ 524.1610 Orbifloxacin, mometasone furoate monohydrate, and posaconazole suspension.

(a) *Specifications.* Each gram of suspension contains 10 milligrams (mg) orbifloxacin, mometasone furoate monohydrate equivalent to 1 mg mometasone furoate, and 1 mg posaconazole.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* For dogs weighing less than 30 lbs. instill 4 drops once daily into the ear canal. For dogs weighing 30 lbs. or more, instill 8 drops into the ear canal. Therapy should continue for 7 consecutive days.

(2) *Indications for use*. For the treatment of otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (coagulase-positive staphylococci, *Pseudomonas aeruginosa*, and *Enterococcus faecalis*).

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

Dated: March 24, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010–7163 Filed 3–31–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. FDA–2009–N–0458]

RIN 0910–AG29

Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended to Treat, Diagnose, or Cure; Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations on premarket approval of medical devices to include requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure. Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule under FDA's usual procedure for notice and comment to provide a procedural framework to finalize the rule in the event we receive significant adverse comment and withdraw this direct final rule.

DATES: This rule is effective August 16, 2010. Submit electronic or written comments on the direct final rule by June 15, 2010. Submit electronic or written comments on the information collection requirements by June 1, 2010. 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–2009–N–0458, 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.

Instructions: All submissions received must include the agency name and docket number and regulatory information number (RIN) 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 the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section 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: Robert Gatling, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1640, Silver Spring, MD 20993, 301–796–6560.

SUPPLEMENTARY INFORMATION:

I. What Is the Background of This Rule?

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA)[1] (Public Law 110–85) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding, among other things, a new section 515A of the act (21 U.S.C. 360e–1). Section 515A(a) of the act requires persons who submit certain medical device applications to include readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. This rule amends FDA's regulations to implement the requirements of section 515A(a) of the act.

Section 515A(c) of the act states that, for the purposes of that section, the term "pediatric subpopulation" has the meaning given the term in section 520(m)(6)(E)(ii) of the act (21 U.S.C. 360j(m)(6)(E)(ii)). Section 520(m)(6)(E)(ii) of the act defines the term "pediatric subpopulation" to mean one of the following populations:

- Neonates;
- Infants;
- Children; or
- Adolescents.

We have previously issued guidance recommending the age range for each of the populations included in the term "pediatric subpopulation." See *Premarket Assessment of Pediatric Medical Devices* (May 14, 2004); (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm*).

The term "pediatric patient" is defined, for purposes of section 520(m)(6)(E)(i) of the act as patients who are 21 years of age or younger at the time of the diagnosis or treatment. Because no other definition of "pediatric patient" is included in the Pediatric Medical Device Safety and Improvement Act of 2007, and because the definition in section 520(m)(6)(E)(i) of the act is consistent with the definition of pediatric subpopulations in section 520(m)(6)(E)(ii), FDA has concluded that the term "pediatric patient" in section 515A of the act refers to patients who are 21 years of age or younger at the time of the diagnosis or treatment.

The information submitted under section 515A(a) of the act will help FDA track the following information that it is required to report annually to Congress, in accordance with section 515A(a)(3) of the act:

- The number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;
- The number of approved devices labeled for use in pediatric patients;
- The number of approved pediatric devices that were exempted from a review fee under section 738(a)(2)(B)(v) of the act (21 U.S.C. 379j(a)(2)(B)(v)); and
- The review time for each such device.

[1] Title III of FDAAA, which includes new section 515A, is also known as the Pediatric Medical Device Safety and Improvement Act of 2007.