significantly affect regulated entities or the general public.

List of Subjects in 18 CFR Part 375

Authority delegations (Government agencies), Seals and insignia, Sunshine Act.

By the Commission. Commissioner Kelliher is not participating.

Kimberly D. Bose,

Secretary.

■ In consideration of the foregoing, the Commission amends part 375, chapter I, title 18, Code of Federal Regulations, as follows.

PART 375—THE COMMISSION

■ 1. The authority citation for part 375 continues to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 791–825r, 2601–2645; 42 U.S.C. 7101–7352.

■ 2. Part 375 is amended by removing § 375.303 and redesignating § 375.314 as § 375.303.

■ 3. Section 375.311 is amended by adding paragraphs (m) through (t) as follows:

§ 375.311 Delegations to the Director of the Office of Enforcement.

* * * * *

(m) Sign all correspondence with respect to financial accounting and reporting matters on behalf of the Commission.

(n) Pass upon actual legitimate original cost and depreciation thereon and the net investment in jurisdictional companies and revisions thereof.

(o) Issue interpretations of the Uniform Systems of Accounts for public utilities and licensees, centralized service companies, natural gas companies and oil pipeline companies.

(p) Pass upon any proposed accounting matters submitted by or on behalf of jurisdictional companies that require Commission approval under the Uniform Systems of Accounts, except that if the proposed accounting matters involve unusually large transactions or unique or controversial features, the Director of the Office of Enforcement must present the matters to the Commission for consideration.

(q) Pass upon applications to increase the size or combine property units of jurisdictional companies.

(r) Deny or grant, in whole or in part, motions for extension of time to file, or requests for waiver of the requirements of the following forms, data collections, and reports: Annual Reports (Form Nos. 1, 1–F, 2, 2–A, and 6); Quarterly Reports (Form Nos. 3–Q and 6–Q); Annual Report of Centralized Service Companies (Form No. 60); Narrative Description of Service Company Functions (FERC–61); Report of Transmission Investment Activity (FERC–730); and Electric Quarterly Reports, as well as, where required, the electronic filing of such information (§ 385.2011 of this chapter, Procedures for filing on electronic media, paragraphs (a)(6), (c), and (e)).

(s) Provide notification if a submitted Annual Report (Form Nos. 1, 1–F, 2, 2–A, and 6), Quarterly Report (Form Nos. 3–Q and 6–Q), Annual Report of Centralized Service Companies (Form No. 60), Narrative Description of Service Company Functions (FERC–61), Report of Transmission Investment Activity (FERC–730), or Electric Quarterly Report fails to comply with applicable statutory requirements, and with all applicable Commission rules, regulations, and orders for which a waiver has not been granted, or, when appropriate, notify a party that a submission is acceptable.

(t) Deny or grant, in whole or in part, requests for waiver of the requirements of parts 352, 356, 367 and 368 of this chapter, except that, if the matters involve unusually large transactions or unique or controversial features, the Director of the Office of Enforcement must present the matters to the Commission for consideration.

[FR Doc. E9–2686 Filed 2–9–09; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. FDA–2008–N–0341]

Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published in the **Federal Register** of September 29, 2008 (73 FR 56487), a direct final rule amending its regulations to require that the holder of a new drug application (NDA) submit certain information regarding authorized generic drugs in an annual report to a central office in the agency. The comment period closed December 15, 2008. FDA is withdrawing the direct final rule because the agency received significant adverse comment.

DATES: The direct final rule published at 73 FR 56487 on September 29, 2008, is withdrawn as of February 10, 2009.

FOR FURTHER INFORMATION CONTACT: Michelle D.D. Bernstein, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6362, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: FDA published a direct final rule on September 29, 2008 (73 FR 56487), that was intended to amend its regulations to require that the holder of an NDA submit certain information regarding authorized generic drugs in an annual report to a central office in the agency. In response to the direct final rule, the agency received significant adverse comments about the proposed revisions to the rule.

Under FDA's direct final rules procedures, the receipt of any significant adverse comment will result in the withdrawal of the direct final rule. Thus, this direct final rule is being withdrawn, effective immediately. Comments received by the agency regarding the withdrawn rule will be considered in developing a final rule using the usual Administrative Procedure Act notice-and-comment procedures.

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on September 29, 2008 (73 FR 56487), is withdrawn.

Dated: February 5, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–2746 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2008–N–0039]

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 IVX Animal Health, Inc. The supplemental ANADA provides for use of ivermectin oral paste for the treatment and control of additional species of gastrointestinal parasites in horses.

DATES: This rule is effective February 10, 2009.

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: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200–286 that provides for oral use of PHOENECTIN (ivermectin) Paste 1.87 percent for the treatment and control of additional species of gastrointestinal parasites in horses. The supplemental ANADA is approved as of December 18, 2008, and the regulations are amended in 21 CFR 520.1192 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 Subject 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)(3), (e)(1)(ii)(A), and (e)(1)(ii)(B); and revise paragraphs (b)(1), (b)(2), and (e)(1)(ii) to read as follows:

§ 520.1192 Ivermectin paste.

* * * * *

(b) * * *

(1) No. 050604 for use of a 1.87 percent paste as in (e)(1) of this section and a 0.153 percent paste for use as in paragraph (e)(2) of this section.

(2) Nos. 051311, 054925, 059130, and 061623 for use of a 1.87 percent paste for use as in paragraph (e)(1) of this section.

* * * * *

(e) * * *

(1) * * *

(ii) *Indications for use.* For treatment and control of Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth-stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages): *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults): *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

* * * * *

Dated: February 3, 2009.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. E9–2749 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WV102–6039; FRL–8750–1]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Update to Materials Incorporated by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; administrative change.

SUMMARY: EPA is updating the materials submitted by West Virginia that are incorporated by reference (IBR) into the State Implementation Plan (SIP). The regulations affected by this update have been previously submitted by the West Virginia Department of Environmental Protection and approved by EPA. This update affects the SIP materials that are available for public inspection at the National Archives and Records Administration (NARA), the Air and Radiation Docket and Information Center located at EPA Headquarters in Washington, DC, and the Regional Office.

DATES: *Effective Date:* This action is effective February 10, 2009.

ADDRESSES: SIP materials which are incorporated by reference into 40 CFR part 52 are available for inspection at the following locations: Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; the Air and Radiation Docket and Information Center, EPA Headquarters Library, Room Number 3334, EPA West Building, 1301 Constitution Ave., NW., Washington, DC 20460, and the National Archives and Records Administration. If you wish to obtain materials from a docket in the EPA Headquarters Library, please call the Office of Air and Radiation (OAR) Docket/Telephone number: (202) 566–1742; or the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

FOR FURTHER INFORMATION CONTACT: Harold A. Frankford, (215) 814–2108 or by e-mail at *frankford.harold@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The SIP is a living document which the State revises as necessary to address the unique air pollution problems.