

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