

of information summary is provided to reflect the clarification.

List of Subjects 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

The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.905a is amended by removing paragraph (a); by redesignating paragraphs (b) and (c) as paragraphs (a) and (b); by adding paragraph (c); by revising the heading of paragraph (d)(2); by redesignating paragraph (d)(3) as paragraph (d)(4); by redesignating paragraphs (d)(2)(ii), (d)(2)(ii)(A), and (d)(2)(ii)(B) as paragraphs (d)(3)(i), (d)(3)(ii), and (d)(3)(iii); by adding a heading for newly redesignated paragraph (d)(3); by redesignating paragraphs (d)(2)(i)(A) and (d)(2)(i)(B) as paragraphs (d)(2)(ii) and (d)(2)(iii) to read as follows:

§ 520.905a Fenbendazole suspension.

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(c) *Related tolerances.* See § 556.275 of this chapter.

(d) * * *

(2) *Cattle including dairy cows of breeding age—** * *

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(3) *Beef cattle—** * *

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Dated: November 9, 1998.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 98-30750 Filed 11-17-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 806

[Docket No. 98N-0439]

Medical Devices: Reports of Corrections and Removals; Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) published in the **Federal Register** of August 7, 1998 (63 FR 42229), a direct final rule. The direct final rule notified the public of FDA's intention to amend the regulations that govern reports of corrections and removals of medical devices to eliminate the requirement for distributors to make such reports. This document delays the effective date of the direct final rule.

EFFECTIVE DATE: The effective date of the direct final published at 63 FR 42229 rule is delayed until February 22, 1999.

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20857, 301-827-2970.

SUPPLEMENTARY INFORMATION: FDA solicited comments concerning the direct final rule for a 75-day period ending October 21, 1998. FDA stated that the effective date of the direct final rule would be on December 21, 1998, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comment.

However, FDA has not yet received approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) of the information collection requirements in this rule. Therefore, FDA is revising the effective date of this rule to February 22, 1999. By that date, FDA expects to have received clearance from the Office of Management and Budget (OMB) for the information collection requirements in the rule. This document delays the effective date of the direct final rule.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, notice is given that no objections or requests for a hearing were filed in response to the August 7, 1998, final rule. Accordingly, the amendments issued thereby are effective February 22, 1999.

Dated: November 10, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-30876 Filed 11-17-98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AK 15-1703a; FRL-6188-7]

Approval and Promulgation of State Implementation Plans; Alaska

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Environmental Protection Agency (EPA) is approving in part and disapproving in part portions of the revisions to the State of Alaska Implementation Plan which were submitted to EPA by the Director of the Alaska Department of Environmental Conservation (ADEC) on January 8, 1997 and March 17, 1998. These revisions consist of certain changes to the ADEC rules for air quality control (18 AAC 50), updated Alaska statutes related to air pollution, and the "In Situ Burning Guideline for Alaska (revised 5/94)." These revisions were submitted in accordance with the requirements of section 110 and Part D of the Clean Air Act (hereinafter the Act).

DATES: This action is effective on January 19, 1999.

ADDRESSES: Copies of the State's request and other information supporting this proposed action are available for inspection during normal business hours at the following locations: EPA, Office of Air Quality (OAQ-107), 1200 Sixth Avenue, Seattle, Washington 98101, and State of Alaska, Department of Environmental Conservation, 410 Willoughby Avenue, Juneau, Alaska, 99801. Documents which are incorporated by reference are available for public inspection at the Air and Radiation Docket and Information Center, EPA, 401 M Street, SW, Washington, D.C. 20460, as well as the above addresses.

FOR FURTHER INFORMATION CONTACT: David C. Bray, Senior Air Pollution Scientist, Office of Air Quality (OAQ-107), EPA, Seattle, Washington, (206) 553-4253.

SUPPLEMENTARY INFORMATION:

I. Background

The Clean Air Act Amendments of 1990, Title V, require States to develop operating permit programs for most stationary sources. While Title V operating permit programs are not approved as part of the state implementation plan (SIP) under section 110 of the Act, many provisions of the SIP will interact closely with the Title V operating permit program. As