clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 10

Administrative practice and procedure, News media.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and 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. Section 10.75 is amended by redesignating paragraph (b) as paragraph (b)(1) and by adding paragraph (b)(2) to read as follows:

§ 10.75 Internal agency review of decisions.

* * * * *

(b)(1) * * *

(2) A sponsor, applicant, or manufacturer of a drug or device regulated under the act or the Public Health Service Act (42 U.S.C. 262), may request review of a scientific controversy by an appropriate scientific advisory panel as described in section 505(n) of the act, or an advisory committee as described in section 515(g)(2)(B) of the act. The reason(s) for any denial of a request for such review shall be briefly set forth in writing to the requester. Persons who receive a Center denial of their request under this section may submit a request for review of the denial. The request should be sent to the Chief Mediator and Ombudsman.

Dated: November 12, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–30812 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 97N–0524]

RIN 0910–AA43

Food Labeling: Warning and Notice Statement: Labeling of Juice Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration is correcting a final rule that appeared in the **Federal Register** of July 8, 1998 (63 FR 37030). The final rule revised the food labeling regulations to require a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. The document was published with several inadvertent editorial errors. This document corrects those errors.

DATES: The regulation is effective September 8, 1998; however, compliance for juice other than apple juice and apple cider is not required until November 5, 1998.

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

In FR Doc. No. 98–18287, appearing in the **Federal Register** of Wednesday, July 8, 1998, the following corrections are made:

1. On page 37038, in the third column, in the fourth full paragraph, in the sixth line, ''(Ref. 9)'' is corrected to read ''(Ref. 7)''.

2. On page 37040, in the first column, in the last line of the first full paragraph, ''(Ref. 10)'' is corrected to read ''(Ref. 8)''.

3. On page 37040, in the third column, in the second full paragraph, in the eleventh line, ''(Ref. 11)'' is corrected to read ''(Ref. 9)'' and in that same paragraph, in the fifteenth and eighteenth lines, ''(Ref. 12)'' is corrected to read ''(Ref. 10)''.

5. On page 37041, in the last line of the third column, ''(Ref. 13)'' is corrected to read ''(Ref. 11)''.

6. On page 37044, in the third column, in the fourth paragraph, in the twenty-fifth line, ''(Ref. 14)'' is corrected to read ''(Ref. 12)''.

7. On page 37047, in the second column, in the second full paragraph, in the twentieth line, ''(Ref. 15)'' is corrected to read ''(Ref. 13)''.

§ 101.17 [Corrected]

8. On page 37056, in the third column, in § 101.17(g)(7)(i)(B), beginning in the fourth line, ''Hazard Analysis Critical Control Points'' is corrected to read ''Hazard Analysis and Critical Control Point''.

Dated: November 10, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30814 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Fenbendazole Suspension; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulation concerning veterinary prescription use of Hoechst Roussel Vet's fenbendazole suspension for cattle. The amendment clarifies the oral dose of fenbendazole suspension used as a dewormer in cattle.

EFFECTIVE DATE: November 18, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7575.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, is sponsor of new animal drug application (NADA) 128–620 that provides for oral, veterinary prescription use of Panacur® (fenbendazole) 10 percent suspension. The drug is used as a dewormer in cattle, including dairy cattle of breeding age at 5 milligrams per kilogram (mg/kg) of body weight, and only in beef cattle at 10 mg/kg of body weight. The regulations are amended in 21 CFR 520.905a to clarify the approval.

The amendments clarify the drug dose used to treat various classes of animals and insert certain technical revisions. No additional safety or effectiveness data were required. A revised freedom

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.

* * * * *

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

(d) * * *

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

* * * * *

(3) *Beef cattle*—* * *

* * * * *

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]

BILLING CODE 4160–01–F

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]

BILLING CODE 4160–01–F

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