a. In paragraph (g)(1) remove the words ''A child may become'' and add, in their place ''There is a risk of a child becoming''.

b. In paragraph (g)(2)(iv) remove the first word ''If'' and add, in its place ''In the event''.

c. In paragraph (g)(2)(iv) add a second sentence to read ''For products not having an emergency release use instead 'In the event a person is trapped under the door, push the control button' ''.

d. In paragraph (g)(3)(i) in the second sentence, remove the word ''If'' and add it its place ''In the event''.

e. In paragraph (i) remove the initial word ''A'' and add, in its place ''Except for door operators complying with § 1211.9(b), a''.

Dated: November 20, 2000.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 00–30041 Filed 11–24–00; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 00F–1332]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on red meat carcasses. This action is in response to a petition filed by Ecolab, Inc.

DATES: This rule is effective November 27, 2000. Submit written objections and requests for a hearing by December 27, 2000. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 173.370, as of November 27, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 13, 2000 (65 FR 37155), FDA announced that a food additive petition (FAP 0A4720) had been filed by Ecolab Inc., Ecolab Center, 370 Wabasha St., St. Paul, MN 55102. The petition proposed to amend the food additive regulations in part 173 (21 CFR part 173) to provide for the safe use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on red meat carcasses.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe and the additive will achieve its intended technical effect as an antimicrobial agent on red meat carcasses. The agency also concludes that the regulation approving the additive should be entitled ''Peroxyacids.'' Reaction of hydrogen peroxide with acetic acid and octanoic acid results in partial conversion to peroxyacetic acid and peroxyoctanoic acid, respectively. Therefore, part 173 is amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by December 27, 2000. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.370 is added to subpart D to read as follows:

§ 173.370 Peroxyacids.

Peroxyacids may be safely used in accordance with the following prescribed conditions:

(a) The additive is a mixture of peroxyacetic acid, octanoic acid, acetic

acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid.

(b) The additive is used as an antimicrobial agent on red meat carcasses in accordance with current industry practice where the maximum concentration of peroxyacids is 220 parts per million (ppm) as peroxyacetic acid and the maximum concentration of hydrogen peroxide is 75 ppm.

(c) The concentrations of peroxyacids and hydrogen peroxide in the additive are determined by a method entitled ''Hydrogen Peroxide and Peracid (as Peracetic Acid) Content,'' dated July 26, 2000, developed by Ecolab, Inc., which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of this method from the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

Dated: November 14, 2000.

L. Robert Lake,

Director of Regulations Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–30050 Filed 11–24–00; 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; 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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of ivermectin oral paste for the treatment and control of various species of harmful gastrointestinal parasites in horses.

DATES: This rule is effective November 27, 2000.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–286 that provides for use of PHOENECTIN™ (ivermectin) Paste 1.87%. The ANADA provides for oral use of ivermectin paste for the treatment and control of various species of harmful gastrointestinal parasites in horses. The ANADA is approved as a generic copy of Merial Ltd.'s NADA 134–314 for EQVALAN® (ivermectin) Paste for Horses. ANADA 200–286 is approved as of September 20, 2000, and the regulations are amended in 21 CFR 520.1192 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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 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

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

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

2. Section 520.1192 is amended by revising paragraphs (a) and (b), by redesignating paragraph (c) as paragraph (d), and by adding new paragraph (c) to read as follows.

§ 520.1192 Ivermectin paste.

(a) *Specifications.* Each milligram of paste contains 0.0187 milligram (1.87 percent) or 0.00153 milligram (0.153 percent) of ivermectin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter, as follows:

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

(2) No. 059130 for use of a 1.87 percent paste as in paragraph (d)(1) of this section.

(c) *Related tolerances.* See § 556.344 of this chapter.

* * * * *

Dated: October 16, 2000.

Stephen S. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–30048 Filed 11–24–00; 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; Nitenpyram Tablets

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 Novartis Animal Health US, Inc. The NADA provides for the oral use of nitenpyram tablets for the treatment of flea infestations in dogs, puppies, cats, and kittens that are 4 weeks of age and older and 2 pounds (lb) of body weight or greater.

DATES: This rule is effective November 27, 2000.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed NADA 141–175 that provides for the over-the-counter use of CAPSTAR™ (nitenpyram) tablets for the oral treatment of flea infestations on dogs,