the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity for the new indications beginning August 16, 1995, because new clinical or field investigations (other than bioequivalence or residue studies) conducted by the sponsor were required for the approval.

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.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.1445 [Amended]

2. Section 520.1445 *Milbemycin oxime tablets* is amended in paragraph (c)(2) by adding the phrase ''and in puppies 4 weeks of age or greater and 2 pounds of body weight or greater.'' at the end of the paragraph and in paragraph (c)(3) by adding the sentence ''Do not use in puppies less than 4 weeks of age and less than 2 pounds in body weight.'' at the beginning of the paragraph.

Dated: September 15, 1995.

Robert C. Livingston,

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

[FR Doc. 95–24160 Filed 9–27–95; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

21 CFR Parts 520 and 556

Animal Drugs, Feeds, and Related Products; Sarafloxacin Hydrochloride

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 Abbott Laboratories. The NADA provides for use of sarafloxacin hydrochloride in turkey and broiler chicken drinking water for control of mortality associated with *Escherichia coli* organisms susceptible to sarafloxacin.

EFFECTIVE DATE: September 28, 1995.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Abbott Laboratories, 1401 Sheridan Rd., North Chicago, IL 60064–4000, filed NADA 141–017, which provides for use of sarafloxacin hydrochloride (SaraFlox® WSP) water soluble powder to make turkey and broiler chicken medicated drinking water used for control of mortality associated with *E. coli* organisms susceptible to sarafloxacin.

The NADA is approved as of August 18, 1995, and the regulations are amended by adding new § 520.2095 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, part 556 (21 CFR part 556) is amended by adding new § 556.594 to reflect that a tolerance for residues of sarafloxacin in edible turkey and broiler chicken tissues is not required. At zero withdrawal, the total residue of sarafloxacin HC1 in the target tissue (liver) is less than half the safe concentration (5.25 ppm). The marker compound, parent sarafloxacin HC1, represents 20 to 80 percent of the total residue in liver of turkeys and 60 to 80 percent of the total residue in liver of chickens, depending upon the extraction procedure.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning August 18, 1995, because no active ingredient (including any ester or salt thereof) has been previously approved in any other application filed under section 512(b)(1) of the act.

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.

List of Subjects

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, foods.

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 parts 520 and 556 are 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 520.2095 is added to read as follows:

§ 520.2095 Sarafloxacin soluble powder.

(a) *Specifications.* Each 145 grams (5.1 ounces) pouch contains sarafloxacin hydrochloride equivalent to 14.5 grams of sarafloxacin base.

(b) *Sponsor.* See No. 000074 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.594 of this chapter.

(d) *Conditions of use.* Used in drinking water as follows: (1) *Amount.* Chickens—20 to 40 parts per million for 5 consecutive days as the only source of drinking water. Turkeys—30 to 50 parts per million for 5 consecutive days as the only source of drinking water.

(2) *Indications for use.* For control of mortality in growing turkeys and broiler chickens associated with *Escherichia coli* organisms susceptible to sarafloxacin.

(3) *Limitations.* No preslaughter drug withdrawal period is required when the product is used as directed. Use in a manner other than that indicated or with a dose in excess of that recommended may result in drug residues in edible tissues. Do not use in laying hens producing eggs for human consumption. The effects of sarafloxacin on the reproductive function of treated fowl have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

4. New § 556.594 is added to subpart B to read as follows:

§ 556.594 Sarafloxacin.

A tolerance for residues of sarafloxacin in edible turkey and broiler chickens tissues is not required.

Dated: September 21, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–24159 Filed 9–27–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 579

[Docket No. 92F–0317]

Food Additives; Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food; Ionizing Radiation for Treatment of Poultry Feed or Poultry Feed Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations for irradiation in the production, processing, and handling of animal feed and pet food to provide for the safe use of gamma radiation from cobalt-60 in an absorbed dose range of 2 kiloGrays (kGy) (0.2 Megarads) (Mrad) to 25 kGy (2.5 Mrad), for rendering complete poultry feeds or poultry feed ingredients salmonella negative. This action is in response to a food additive petition filed by Nordion International, Inc.

DATES: Effective September 28, 1995; written objections and request for a hearing by October 30, 1995.

ADDRESSES: Submit written objections to Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sharon A. Benz, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1724.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of August 20, 1992 (57 FR 37825), FDA announced that a food additive petition (animal use) (FAP 2216) had been filed by Nordion International, Inc., 447 March Rd., P.O. Box 13500, Kanata, Ontario, Canada K2K 1X8. The petition proposed that the feed irradiation regulations be amended to provide for the safe use of gamma radiation from cobalt-60, not to exceed 25 kGy (2.5 Mrad), to control salmonella in complete poultry (chickens, turkeys, ducks, geese, cornish hens, pheasant, and quail) feeds or feed ingredients.

The notice of filing of FAP 2216 provided for a 60-day comment period. No comments have been received.

The use of irradiation was evaluated based on its ability to render feed salmonella negative. Salmonella is known to cause animal disease. The effect of subclinical cases of salmonella on animal production is difficult to quantitate. There are, however, substantial circumstantial data suggesting a potential link between the organisms in feed and organisms causing human and animal salmonellosis. For this reason, in 1990, FDA announced a goal of salmonella negative for animal feed and feed ingredients. FDA has defined salmonella negative as 10 samples testing negative for salmonella using the culture procedure described in the 7th edition of FDA's Bacteriological Analytical Manual (BAM).

Data submitted by the sponsor indicate that an irradiation dose of 1.0 kGy effectively reduces salmonella count by 1 log cycle (one decimal reduction). To ensure that irradiation achieves the intended purpose, all portions of the feed must receive at least the minimum absorbed dose. The minimum absorbed dose should be based on initial salmonella concentration using the relationship that 1 kGy reduces salmonella concentration by 1 log cycle. Based on the statistical power of the sampling plan, the minimum dose should be no less than 2 kGy in order to meet the salmonella negative definition.

Data submitted by the sponsor indicates that irradiation does have a minimal effect on the content of some nutrients such as water soluble vitamins and some amino acids. Feeds treated by irradiation should be formulated to account for such nutritional loss.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that irradiation of poultry feeds and poultry feed ingredients is safe when the feed is formulated to allow for nutritional loss, and that the regulations should be amended in part 579 (21 CFR part 579) by adding new § 579.40 as set forth below.

In accordance with § 571.1(h) (21 CFR 571.1(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 Veterinary Medicine by appointment with the information contact person listed above. As provided in 21 CFR 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

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 at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before October 30, 1995 file with the Dockets Management Branch (address above) written objections thereto. 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