(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 FĂP 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