(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

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 shall be submitted and shall 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 579

Animal feeds, Animal foods, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 579 is amended as follows:

PART 579—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD

1. The authority citation for 21 CFR part 579 continues to read as follows:

Authority: Secs. 201, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 348, 371).

2. New § 579.40 is added to read as follows:

§ 579.40 Ionizing radiation for the treatment of poultry feed and poultry feed ingredients.

Ionizing radiation for the treatment of complete poultry diets and poultry feed ingredients may be safely used as follows:

(a) *Energy sources.* Ionizing radiation is limited to gamma rays from sealed units of cobalt-60.

(b) *Limitation.* The ionizing radiation is used for feed or feed ingredients that do not contain drugs.

(c) *Use.* Ionizing radiation is used as a single treatment for rendering complete poultry diets or poultry feed ingredients salmonella negative as follows:

(1) Minimum dose 2.0 kiloGrays (kGy) (0.2 megarad (Mrad)); maximum dose 25 kGy (2.5 megarads Mrad). The absorbed dose of irradiation is to be based on initial concentration of salmonella using the relationship that 1.0 kGy (0.1 Mrad) reduces salmonella concentration by one log cycle (one decimal reduction).

(2) Feeds treated by irradiation should be formulated to account for nutritional loss.

(3) If an irradiated feed ingredient is less than 5 percent of the final product, the final product can be irradiated without being considered to be reirradiated.

Dated: September 21, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–24154 Filed 9–27–95; 8:45 am]

BILLING CODE 4160–01–U

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Federal Highway Administration

23 CFR Parts 192 and 1212

[Docket No. 91–17; Notice 4]

RIN 2127–AF93

Drug Offender's Driver's License Suspension

AGENCY: National Highway Traffic Safety Administration (NHTSA) and Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Final rule; technical amendment.

SUMMARY: The Drug Offender's Driver's License Suspension Law, 23 U.S.C. 159, requires the withholding of certain Federal-aid highway funds from States that do not enact either legislation requiring the revocation or suspension of an individual's driver's license upon conviction for any violation of the Controlled Substances Act or any drug offense, or a resolution opposing such legislation. The NHTSA and the FHWA had joint responsibility for administering the law. The statute's implementing regulation appeared in Chapter II of 23 CFR, which contains regulations jointly administered by the two agencies.

Responsibility for administering the law has since been redelegated to FHWA alone. This final rule removes the implementing regulation from Chapter II of 23 CFR, and places it in Chapter I of 23 CFR, which contains regulations administered only by FHWA.

EFFECTIVE DATE: September 28, 1995.

FOR FURTHER INFORMATION CONTACT: In FHWA: Ms. Mila Plosky, Office of Highway Safety, Room 3407, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590, telephone (202) 366–6902; or Mr. Paul L. Brennan, Office of Chief Counsel, Room 4217, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590, telephone (202) 366–0834.

In NHTSA: Mr. Gary Butler, Office of State and Community Services, National Highway Traffic Safety Administration, 400 7th Street, SW., Washington, D.C. 20590, telephone (202) 366–2121; or Ms. Sharon Y. Vaughn, Office of Chief Counsel, Room 5219, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, D.C. 20590, telephone (202) 366–1834.

SUPPLEMENTARY INFORMATION: The Department of Transportation and Related Agencies Appropriations Act for FY 1992, Pub. L. 102–143, added section 159 to title 23 of the United States Code. The new section required the withholding of certain Federal-aid highway funds from States that did not enact either legislation requiring the revocation or suspension of an individual's driver's license upon conviction for any violation of the Controlled Substances Act or any drug offense, or a resolution opposing such legislation.

On August 12, 1992 (57 FR 35989), NHTSA and FHWA published a final rule, promulgating a regulation to implement this requirement, 23 CFR 1212. The regulation appeared in Chapter II, Title 23 of the Code of Federal Regulations, which contains regulations administered jointly by NHTSA and FHWA.

The regulation required that each State certify by April 1, 1993, and by January 1 of each subsequent year, that it meets the requirements of 23 U.S.C. 159 and the implementing regulation.

NHTSA and FHWA had joint responsibility for administration of this program. NHTSA reviewed State laws and resolutions to determine compliance with the statutory provisions. FHWA administered the Act's penalty provisions.

All States have now submitted laws and resolutions that comply with 23 U.S.C. 159. Responsibility for administering this program has been redelegated to FHWA alone. This final rule removes the implementing regulation from Chapter II of 23 CFR, which contains regulations that are administered jointly by NHTSA and FHWA, and places it instead in Chapter I of 23 CFR, which contains regulations administered only by the FHWA.

Redelegating the entire responsibility for 23 U.S.C. 159 to FHWA will help in streamlining the certification process and eliminate the duplication of government efforts. This redelegation is also consistent with President Clinton's memorandum of March 4, 1995, titled