

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.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. WHO, "Food safety aspects relating to the application of X-ray surveillance equipment: Memorandum from a WHO meeting," Bulletin of the World Health Organization, vol. 31, pp. 297-301, 1990.

2. Wakeford, C. A. and R. Blackburn, "Induction and Detection of Radioactivity in Foodstuffs Irradiated with 10 MeV Electrons and X-rays," *Radiation Physics and Chemistry*, vol. 38, No. 1, pp. 29-38, 1991.

3. Findley, D. J. S., T.V. Parson, and M. R. Sene, "Experimental Electron Beam Irradiation of Food and the Induction of Radioactivity," *Applied Radiation and Isotopes*, vol. 43, pp. 567-575, 1992.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

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 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

2. Section 179.21 is amended by adding paragraphs (a)(4), (b)(1)(iii), and (b)(2)(iv) to read as follows:

§ 179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.

* * * * *

(a) * * *

(4) Machine sources producing X-radiation at energies no greater than 10 million electron volts (MeV).

(b) * * *

(1) * * *

(iii) The maximum energy of X-radiation emitted by machine source.

(2) * * *

(iv) A statement that no food shall be exposed to a radiation source listed in paragraph (a)(4) of this section so as to receive a dose in excess of 0.5 gray (Gy).

Dated: April 3, 2001.

L. Robert Lake,

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

[FR Doc. 01-8755 Filed 4-9-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 579

[Docket No. 99F-2799]

Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food; Irradiation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to reflect approval of a food additive petition (FAP) filed by Sterigenics International, Inc. (now IBA Food Safety Division) that provides for irradiation of various animal feeds and feed ingredients for microbial control.

DATES: This rule is effective April 10, 2001. Submit written objections and request for a hearing by May 10, 2001.

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: John D. McCurdy, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0171.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of September 3, 1999 (64 FR 48409), FDA announced that a food additive petition

(FAP 2243) had been filed by SteriGenics International, Inc., 4020 Clipper Ct., Fremont, CA 94538-6540. The petition proposed to amend the food additive regulations in part 21 CFR part 579 Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food to provide for the irradiation of various animal feeds and feed ingredients to control microbial contaminants. The notice of filing provided for a 60-day comment period. The agency received no comments.

FDA has evaluated data submitted by the sponsor of the petition and concludes that the data establish the safety and functionality of irradiation for use as proposed.

This final rule extends the ability to irradiate all animal feeds for the purpose of microbial disinfection, therefore, references to laboratory animals have been deleted from the regulation. Also, paragraph (b)(2) has been added to § 579.22 to make clear that as long as an irradiated feed ingredient is less than 5 percent of the final product, the final product may be irradiated without conflicting with the statement in § 579.22(b)(1) that the ionizing radiation is used or intended for use in single treatment.

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 § 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.

FDA has determined under 21 CFR 25.32(j) that this action is of 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.

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 May 10, 2001. 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 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 and redelegated to the Center for Veterinary Medicine, 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: 21 U.S.C. 321, 342, 343, 348, 371.

2. Section 579.22 is amended by revising the section heading, the introductory paragraph, and paragraph (b) to read as follows:

§ 579.22 Ionizing radiation for treatment of animal diets.

Ionizing radiation for treatment of complete diets for animals may be safely used under the following conditions:

* * * * *

(b) *Uses.* (1) The ionizing radiation is used or intended for use in single treatment as follows:

Food for irradiation	Limitations	Use
Bagged complete diets, packaged feeds, feed ingredients, bulk feeds, animal treats and chews.	Absorbed dose: Not to exceed 50 kiloGrays. Feeds and feed ingredients treated by irradiation should be formulated to account for nutritional loss.	Microbial disinfection, control or elimination

(2) 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 re-irradiated.

Dated: March 31, 2001.

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.
 [FR Doc. 01-8719 Filed 4-9-01; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 870 and 886

[Docket No. 99N-0035]

Medical Devices; Reclassification of Six Cardiovascular Preamendments Class III Devices into Class II

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying six cardiovascular preamendments devices from class III (premarket approval) into class II (special controls). FDA is also identifying the special controls that the agency believes will reasonably ensure the safety and effectiveness of the devices. This reclassification is being undertaken on the agency's own initiative based on new information under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices

Act of 1990 and the Food and Drug Administration Modernization Act of 1997. The agency is also revising the identification of one of the devices subject to this rule to simplify the classification regulation and is correcting a typographical error that was incorporated into the regulations.

DATES: This rule is effective May 10, 2001.

FOR FURTHER INFORMATION CONTACT:

Bette L. Lemperle, Center for Devices and Radiological Health (HFZ-453), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8262.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 15, 1999 (64 FR 12774), FDA published a proposed rule to reclassify 38 preamendments class III devices into class II and to establish special controls for these devices (the March 1999 proposal). FDA invited interested persons to comment on the proposed rule by June 14, 1999. FDA received one request to reopen the comment period for six cardiovascular devices. The request noted that FDA had not made the guidance documents that were proposed as special controls for these six devices available for comment through FDA's good guidance practices (GGP's). The requestor asked that FDA extend the comment period until at least 90 days after the guidance documents were publicly available. In the **Federal Register** of April 19, 2000 (65 FR 20995), FDA announced the availability

of six guidance documents for these devices and reopened the comment period on the reclassification of the six devices (65 FR 20933) until July 18, 2000.

FDA received two comments on the vascular graft prosthesis of less than 6 millimeters diameter (§ 870.3450 (21 CFR 870.3450)). These comments are summarized and addressed in section II of this document. FDA received no comments on the other five devices. In this final rule, FDA is reclassifying the six devices into class II with guidance documents as special controls.

The devices that are being reclassified in this final rule are:

- Vascular graft prosthesis of less than 6 millimeters diameter (§ 870.3450) (combined with vascular graft prosthesis of 6 millimeters and greater diameter (§ 870.3460 (21 CFR 870.3460)) and renamed vascular graft prosthesis)
- Pacemaker lead adaptor (21 CFR 870.3620)
- Annuloplasty ring (21 CFR 870.3800)
- Cardiopulmonary bypass defoamer (21 CFR 870.4230)
- Cardiopulmonary bypass arterial blood line filter (21 CFR 870.4260)
- Cardiopulmonary bypass oxygenator (21 CFR 870.4350)

In the **Federal Register** of March 31, 2000 (65 FR 17138), FDA published a final rule to reclassify 28 other preamendments class III devices that were included in the March 1999 proposal. That final rule included an error in the classification of aqueous shunts (21 CFR 886.3920). The word "neurovascular" was incorrectly used