

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 579

[Docket No. 99F-2799]

DMB

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**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 [*insert date of publication in the Federal Register*]. Submit written objections and request for a hearing by [*insert date 30 days after date of publication in the Federal Register*].

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 [*insert date 30 days after date of publication in the **Federal Register***]. 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.

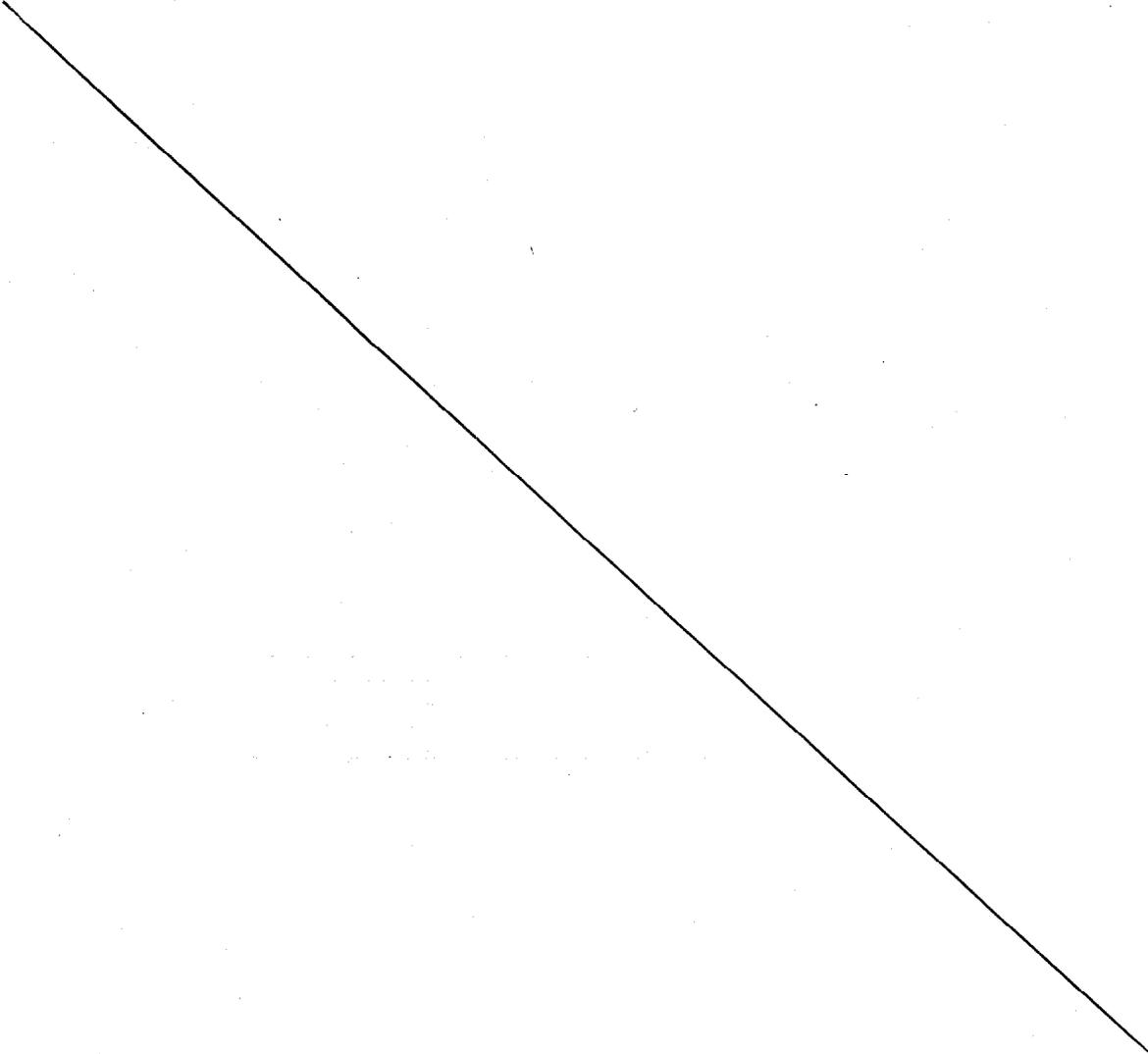
Ionizing radiation for treatment of complete diets for animals may be safely used under the following conditions:

* * * * *

(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: 3/31/01
March 31, 2001.

S F Sundlof

Stephen F. Sundlof,
Director
Center for Veterinary Medicine.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

[Signature]

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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