



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 579

[Docket No. FDA-2012-F-0178]

Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food; Electron Beam and X-Ray Sources for Irradiation of Poultry Feed and Poultry Feed Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for irradiation of animal feed and pet food to provide for the safe use of electron beam and x-ray sources for irradiation of poultry feed and poultry feed ingredients. This action is in response to a food additive petition filed by Sadex Corp.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written objections and requests for a hearing by [INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA-2012-F-0178, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following ways:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

Mail/Hand delivery/Courier (For paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and [Docket Number] for this rulemaking. All objections received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting objections, see the “Objections” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register of February 29, 2012 (77 FR 12226), FDA announced that a food additive petition (animal use) (FAP 2272) had been filed by Sadex Corp., 2650 Murray St., Sioux City, IA 51111. The petition proposed to amend Title 21 of the Code of Federal Regulations (CFR) in part 579 Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food (21 CFR part 579) to provide for the safe use of electron beam and x-ray sources for irradiation of poultry feed and poultry feed ingredients. The notice of filing provided for a 30-day comment period on the petitioner's environmental assessment. One comment was received that was not substantive.

II. Conclusion

FDA concludes that the data establish the safety and utility of electron beam and x-ray sources for use as proposed with modification and that the regulations for irradiation of animal feed and pet food should be amended as set forth in this document.

III. Public Disclosure

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 this petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person (see FOR FURTHER INFORMATION CONTACT). As provided in § 571.1(h), the Agency will delete from the documents materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has determined under 21 CFR 25.32(j) that this action is of a 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.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections by (see DATES). Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision 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. It is only necessary to send one set of documents. It is no longer necessary to send three copies of all documents. Identify documents 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 Division of Dockets Management 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. In § 579.40, revise paragraph (a) to read as follows:

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

* * * * *

(a) Energy sources. Ionizing radiation is limited to:

(1) Gamma rays from sealed units of cobalt-60 or cesium-137;

(2) Electrons generated from machine sources at energy levels not to exceed 10 million electron volts;

(3) X-rays generated from machine sources at energies not to exceed 5 million electron volts, except as permitted by § 179.26(a)(4) of this chapter; or

(4) X-rays generated from machine sources using tantalum or gold as the target material and using energies not to exceed 7.5 (MeV).

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Dated: April 22, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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