

GUIDANCE FOR INDUSTRY

Implementation of Section 10809 of the Farm Security and Investment Act of 2002, Pub. L. No. 107-171, § 10809 (2002) regarding the Petition Process to Request Approval of Labeling for Foods that Have Been Treated by Irradiation.

OFFICE OF NUTRITIONAL PRODUCTS, LABELING, AND DIETARY SUPPLEMENTS

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

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This guidance represents the agency's current thinking on this subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

This guidance is part of FDA's implementation of section 10809 of the Farm Security and Investment Act of 2002, Pub. L. No. 101-171, § 10809 (2002). Section 10809, which was enacted on May 13, 2002, directs FDA to publish a proposed rule and, with due consideration to public comment, a final rule to revise, as appropriate, the current regulation governing the labeling of foods that have been treated by irradiation. This provision further states that "[p]ending promulgation of the final rule..., any person may petition the Secretary [FDA] for approval of labeling, which is not false or misleading in any material respect, of a food which has been treated by irradiation using radioactive isotope, electronic beam, or x-ray." Section 10809 also requires that, pending promulgation of the final rule, "[t]he Secretary [FDA] shall approve or deny such a petition within 180 days of receipt of the petition, or the petition shall be deemed denied, except to the extent additional agency review is mutually agreed upon by the Secretary

[FDA] and the petitioner.”

FDA is issuing this guidance to interested parties who wish to petition the agency for approval of labeling, which is not false or misleading in any material respect, of a food that has been treated by irradiation. FDA recommends that interested parties who wish to petition the agency should use the procedures set forth in § 10.30 (21 CFR 10.30) that outline the requirements for submitting a citizen petition to FDA, except that § 10.30(e)(2)(iii), regarding 180-day tentative responses, does not apply because section 10809 provides that the petition is deemed to be denied if the Secretary [FDA] fails to act on the petition within 180 days of receipt, unless an extension is mutually agreed upon by the parties. Section 10.30 requires the petitioner to submit to the agency all relevant information that supports the petition, including any data, e.g., qualitative or quantitative consumer research, that shows consumer understanding of the purpose and intent of the proposed labeling. Such information might include, but is not limited to, data on consumers’ prior assumptions about, and perceptions of, the product characteristics in light of the proposed labeling statements, and data on consumer acceptance of, and comprehension of, the proposed labeling statements in comparison to consumer acceptance of, and comprehension of, the irradiation statement required by the current regulation (21 CFR § 179.26(c)(1)).