



JUN 6 2003

Mr. Chip Colonna  
President  
GUARDiON  
Post Office Box 17349  
Memphis, Tennessee 38187-0349

Dear Mr. Colonna:

This is in response to your letter of April 15, 2003, regarding your concerns about the labeling of irradiated food products. We hope that the following is helpful.

As noted in your letter, the Farm Bill of 2002 contains several provisions related to food irradiation labeling. Regarding pasteurization, the provision of the Farm Bill (Public Law 107-171), section 10808, sets out conditions for the use of the term "pasteurization" in labeling when treatments other than heat are used. The other provision, section 10809, directs the Food and Drug Administration (FDA) to engage in further rulemaking on the subject of irradiation labeling. During the interim of rulemaking, this provision further provides for any person to petition the agency for approval of alternate labeling, which is not false or misleading in any material respect, of a food that has been treated by irradiation. As directed by the Farm Bill, FDA intends to implement these provisions. Currently, FDA has issued a level 1 guidance document entitled "Guidance for Industry: Implementation of Section 10809 of the Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-101, § 10809 (2002) regarding the Petition Process to Request Approval of Labeling for Foods That Have Been Treated By Irradiation." We are enclosing a copy of the guidance.

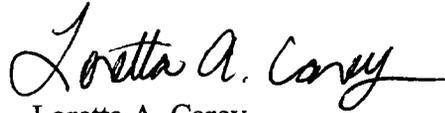
In addition, as you may be aware, irradiation labeling was identified as one of the Center for Food Safety and Applied Nutrition's 2003 program priorities. Consistent with the 2003 program priorities, we intend to develop a proposed rule to revise, as appropriate, the existing regulation that requires irradiated food to be labeled. As we continue to develop proposed rulemaking, we will consider how to most appropriately address the labeling of irradiated foods. We will forward a copy of your letter to our Dockets Management Branch. Please be assured that we will consider all comments before making a final decision on the labeling of irradiated foods.

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Thank you for your letter expressing your concerns about labeling regulations governing irradiated food products. If we can provide additional assistance, please don't hesitate to contact us.

Sincerely yours,

A handwritten signature in black ink that reads "Loretta A. Carey". The signature is written in a cursive style with a long horizontal flourish at the end.

Loretta A. Carey  
Consumer Safety Officer  
Division of Food Labeling, Standards  
and Compliance  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Enclosure

# 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  
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

OCTOBER 2002

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# GUIDANCE FOR INDUSTRY

Implementation of Section 10809 of the Farm Security and Investment Act of 2002, Pub. L. No. 101-171, § 10809 (2002) regarding the Petition Process to Request Approval of Labeling for Foods that Have Been Treated by Irradiation.

**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)).