FDA Releases Proposed Rule Revising Regulations Governing Labeling of Foods That Have Been Treated By Irradiation

On April 4, 2007, FDA released a proposed rule¹ that would revise the Agency’s labeling regulations applicable to foods (including dietary supplements) for which irradiation has been approved by FDA.² In the proposed rule, FDA would require that only those irradiated foods in which the irradiation causes a material change in the food, or a material change in the consequences that may result from the use of the food, bear the radura logo and the term “irradiated,” or a derivative thereof, in conjunction with explicit language describing the change in the food or its conditions of use. FDA is also proposing to allow a firm to petition FDA for use of an alternate term to “irradiation” (other than “pasteurized”). In addition, FDA is proposing to allow a firm to use the term “pasteurized” in lieu of “irradiated,” provided it notifies the Agency that the irradiation process being used meets the statutory criteria for “pasteurized” and the Agency does not object to the notification. According to the Agency, the proposed rule, if finalized, will provide consumers with more useful information than the current regulation.

FDA is accepting comments on this proposed rule until July 3, 2007. Comments on the information collection provisions should be submitted by May 4, 2007 to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB).

I. Background

A. Current labeling requirements for irradiated foods

FDA regulates food irradiation as a food additive and must approve the use of irradiation on a food product.³ Currently, irradiation is approved for use on spices, fresh foods, eggs, molluscan shellfish, meat, and poultry for a variety of uses (e.g., control insects and microorganisms, delay maturation, and control disease-causing microorganisms).⁴

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¹ Irradiation in the Production, Processing, and Handling of Food, 72 Fed. Reg. 16291 (Apr. 4, 2007) (Proposed Rule), available at http://www.fda.gov/OHRMS/DOCKETS/98fr/07-1636.pdf. In the preamble to the proposed rule, the Agency states that “food” refers to conventional foods as well as dietary supplements.” id. at 16293 n. 1. Though FDA specifically includes dietary supplements in this proposed rule, the rule appears to have limited impact on dietary supplement manufacturers given the foods that may be irradiated under current FDA regulations (e.g., spices, fresh foods, eggs, molluscan shellfish, meat, and poultry).

² FDA issued the proposed rule in response to a mandate in the Farm Security and Rural Investment Act of 2002 (FSRIA), which 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 using radioactive isotope, electronic beam, or x-ray to reduce pest infestation or pathogens. Farm Security and Rural Investment Act of 2002, Public Law 107-171 (2002), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ171.107.pdf.

³ See 21 C.F.R. § 179.21 et seq.

⁴ Id. at § 179.26.
In the preamble to the final rule promulgating the current irradiation labeling regulation, FDA determined that food that has been irradiated must contain a specified statement on the label because irradiation has the potential to change a food product in a way that is not obvious, but may be important, to consumers.\(^5\) As such, 21 C.F.R. § 179.26(c) currently requires that the label and labeling of retail packages and displays of irradiated food bear both the radura logo and a radiation disclosure statement ("Treated with radiation" or "Treated by radiation"). FDA also stated in the preamble to the final rule that manufacturers may voluntarily include additional information on the label of irradiated products to describe the specific type of radiation (i.e., "treated with x-radiation" or "treated with ionizing radiation") and to describe the purpose of irradiation, such as "treated with radiation to control spoilage."\(^6\)

B. Other activity with respect to the labeling requirements for irradiated foods

Though the substance of the irradiation labeling regulation has remained unchanged since 1986, there has been some activity with respect to this topic since then. The Food and Drug Administration Modernization Act of 1997 (FDAMA)\(^7\) amended the Federal Food, Drug, and Cosmetic Act (the FDCA) by adding section 403C to the FDCA, 21 U.S.C. § 343-3, which addressed the prominence of the radiation disclosure statements. The FDAMA Joint Statement\(^8\) stated that FDA should seek public comment on whether additional changes should be made to current regulations relating to the labeling of foods treated with ionizing radiation. In response to this direction, FDA published an Advanced Notice of Proposed Rulemaking (ANPRM) in the Federal Register on February 17, 1999 seeking public comment on the meaning of the current irradiation labeling statement and soliciting suggestions for possible revisions.\(^9\) FDA received over 5,550 comments in response to this ANPRM.\(^10\)


\(^6\) Id. at 13387-8.


\(^10\) In addition to publishing the ANPRM, in June and July 2001, the Agency conducted focus group research in Maryland, Minnesota, and California to assist it in formulating specific revisions to the labeling regulations. 72 Fed. Reg. at 16292-3. According to the Agency, the focus group data "indicated that the majority of participants were uncertain about the safety, effectiveness, and appropriateness of irradiated food products and greatly desired more information." Id. at 16293.
Finally, in 2002, the Farm Security and Rural Investment Act of 2002 (FSRIA) was signed into law. The law included two provisions related to irradiation labeling. First, section 10808 of FSRIA included new criteria for use of the term “pasteurized” in labeling and revised section 403(h) of the FDCA to provide that a food may purport to be or be represented as pasteurized if the food has been subjected to a safe process or treatment that is prescribed for such food in a regulation issued under the Act or the food has been subjected to a safe process or treatment that meet certain criteria. Second, section 10809 of FSRIA 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. The section further stated that pending promulgation of the final rule, interested parties may petition FDA for the approval of labeling that may be used on irradiated foods as an alternative to the currently required irradiation disclosure statement. As part of FDA’s implementation of this section, it issued a guidance document to advise how interested parties could petition the Agency under this section. To date, the Agency has not received any petitions requesting the use of alternate labeling for irradiated foods.

II. Proposed Amendment

A. Material change

In promulgating the current irradiation labeling rule, FDA concluded that, “to prevent deception, the fact that the irradiated food is processed is material information that is required to be disclosed on the label.” As the Agency notes, however, in recent years, its policies on the labeling of foods have shifted from focusing on the processing itself to the results of the processing of the food. This shift is apparent in the proposed rule, which would require that only those irradiated foods in which the irradiation causes a material change in the food, or a material change in the consequences that may result from the use of the food, bear the radura logo and the term “irradiated,” or a derivative thereof, in conjunction with explicit language describing the change in the food or its conditions of use (e.g., “irradiated to inhibit sprouting”).

11 Public Law 107-171.
14 Id. at 16295.
15 Id.
16 Id. at 16294; proposed 21 C.F.R. § 179.26(c)(1). In the preamble to the proposed rule, FDA notes that it would not object to the use of additional terms to indicate that a food has been subjected to the process of irradiation, for example, “treated with radiation,” “treated by irradiation,” or “processed with radiation.” Id. at 16294. Under current organic standards, irradiation is an “excluded method,” and its intentional use disqualifies any agricultural product, raw or processed, from bearing any organic claim. 7 C.F.R. § 205.105(f). This proposed rule would not affect those standards nor the labeling of food certified as “organic” under the USDA program.
Under the proposed rule, labeling must include information about material changes in the characteristics of food or the labeling would be considered misleading under section 201(n) of the FDCA, and the food would be misbranded. The FDCA clarifies that in determining whether a food is misbranded because its labeling is misleading,

there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling . . . fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article . . . .

FDA's implementing regulations echo these statutory misbranding provisions. “Materiality” is not defined in the FDCA or by regulation.

FDA has historically interpreted materiality to refer to information about the attributes of the food itself. The Agency has found information to be “material” and therefore required in labeling where the absence of such information may pose special health risks, or in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles when in fact it does not (e.g., reduced fat margarine not suitable for frying).

18 Under section 403(a) of the FDCA, a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 343(a).
20 21 C.F.R. § 1.21(a).
21 See, e.g., 21 C.F.R. § 101.17(g) (warning statement required on the labels of juice that has not been pasteurized); 21 C.F.R. 172.804 (d)(2) (statement required on aspartame-containing products to alert phenylketonurics that the product contains phenylalanine).
22 72 Fed. Reg. at 16293. See also, FDA, Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (Jan. 2001) ("Draft Bioengineering Labeling Guidance"), available at http://www.cfsan.fda.gov/~dms/biolabgu.html; Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term, 58 Fed. Reg. 2431, 2437 (January 6, 1993) (Final Rule) ("Information disclosing differences in performance characteristics (e.g., physical properties, flavor characteristics, functional properties, and shelf life) is a material fact under section 201(n) of the act because it bears on the consequence of the use of the article. Accordingly, this information must be communicated to the consumer on the product label, or the labeling would be misleading, and the product would be misbranded under section 403(a) of the act.").
Consistent with this historical interpretation, the proposed rule would define the term “material change” to refer to a change in the organoleptic, nutritional, or functional properties of a food, caused by irradiation, that the consumer could not identify at the point of purchase in the absence of appropriate labeling.23 If these changes are not within the range of characteristics ordinarily found in such foods, they would be considered ‘material’ under this proposal.24

FDA uses bananas and spices as examples of irradiated foods and cites changes to shelf life as an example of a material change in a food’s characteristics.25 In the case of bananas, the Agency explains that the extended shelf life would be a material change because without appropriate labeling, a consumer may purchase a banana expecting the faster ripening schedule of unirradiated bananas and may not be able to use the irradiated bananas for his planned use.26 In contrast, in the case of irradiated spices, FDA “tentatively believes that the extension of shelf life in this case does not have the potential to be detrimental to the consumer (e.g., to prevent the consumer’s planned use of the food) because the irradiated spice can be used identically to an unirradiated spice.”27 Thus, the producer would not be required to declare this information on the spice label.

The proposed rule does not set a blanket standard for all products that have been irradiated. Rather, according to the Agency, because these changes are typically process specific and will vary with the food and the irradiation conditions, “the need for labeling must be determined on a case-by-case basis by appropriate testing of the food irradiated under specific conditions, e.g., time and dosage, because the effect of irradiation on the properties of concern depends on the particular food.”28

For foods that have been treated with irradiation but where the irradiation has not caused a material change in the food’s characteristics, FDA would not require a label statement but would not object to manufacturers voluntarily labeling their products to indicate that the food is irradiated.29

B. Alternate terms to “irradiated”

The proposed rule would allow the use of alternate terms to “irradiated” or any of its derivatives if use of the term has been approved by FDA in response to a citizen petition submitted in accordance with 21 C.F.R. § 10.30.30 The petition should include all relevant information and views on which the petitioner relies, including any data, e.g., qualitative or quantitative consumer research, that show consumer understanding of the purpose and intent of the alternative labeling.31

23 72 Fed. Reg. at 16291. FDA describes organoleptic properties as properties related to the taste, smell, or texture of a food. Id. at 16293. According to the Agency, it is not currently aware of any changes to the nutritional properties of any food it has approved for irradiation. Id. at 16293 n. 2. Finally, with respect to functional properties of a food, FDA refers to storage properties of a food. Id. at 16293.
24 Id. at 16293.
25 Id. at 16294.
26 Id.
27 Id.
28 Id.
29 Id. at 16294.
30 Id. at 16296; proposed 21 C.F.R. § 179.26(c)(2)(i).
31 Id.
C. Use of the term "pasteurized"

The proposed rule would allow the use of the term “pasteurized” in lieu of “irradiated” or any of its derivatives if the irradiation process meets the criteria of section 403(h)(3) of the FDCA, and the party seeking to label a food as “pasteurized” under this provision has notified FDA and provided effectiveness data regarding the process or treatment used. Provided that the Agency has not objected to the notification within 120 days after receipt of the notification, the notifier would be permitted to label a food as “pasteurized” in lieu of “irradiated.”

III. FDA’s Requests for Comments

FDA requests comments on a variety of topics addressed in the proposed rule. Listed below are key requests for comments related to the substantive parts of the proposed rule:

- on the utility, for purposes of labeling, of distinguishing between those changes to a food's functional properties from irradiation that may make a food unsuitable for a particular use (e.g., delayed ripening) and those changes that still allow for the food to be used identically to one that is not irradiated (e.g., extension of shelf life alone);

- on whether the control of food-borne pathogens changes the characteristics of the food in an unexpected way, i.e., outside of the normal variation for the food, and would therefore require additional labeling to inform the consumer of such change;

- on any specific changes that might be caused by irradiation that might constitute non-material changes;

- on the effect of irradiation on shelf life and the extent of any relationship between control of food-borne pathogens and extension of shelf life, and

- on whether the term that describes the process, e.g., “irradiated” or an alternate term such as “pasteurized,” is a necessary part of the label statement to ensure that consumers completely understand the statement.

32 21 U.S.C. § 343(h)(3). The criteria prescribed in the FDCA are that the food has been subjected to a safe process that (1) is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganisms of public health significance that are likely to occur in the food; (2) is at least as protective of the public health as a process or treatment prescribed by regulation as pasteurization; (3) is effective for a period that is at least as long as the shelf life of the food when stored under normal and moderate abuse conditions; and (4) is the subject of a notification to the Secretary (FDA) that includes effectiveness data regarding the process or treatment and at least 120 days have passed after receipt of such notification without the Secretary making a determination that the process or treatment has not been shown to meet the requirements. Id.


34 Id. at 16294.

35 Id. at 16295.

36 Id.

37 Id.

38 Id. at 16296.
There are other issues that food and dietary supplement manufacturers may wish to address. First, the proposed rule represents a reinterpretation of "material fact," under sections 403(a) and 201(n) of the FDCA. As discussed above, the current rule on irradiation labeling appears to consider that the irradiation itself is "material" information, despite the position that FDA has taken generally with respect to other food labeling issues, i.e., that the materiality of information depends on the consequences of use of the food. The proposed rule appears consistent with FDA's historical position regarding the standard for determining when information is material so that mandatory disclosure of this information is required in product labeling. Food and dietary supplement manufacturers should study the proposal carefully and address in comments any implications of this aspect of the proposed rule.

Second, the proposed rule may introduce inconsistency in the labeling requirements for food regulated by FDA and for meat and poultry products, which are under the authority of the U.S. Department of Agriculture (USDA's Food Safety and Inspection Service (FSIS). FDA and FSIS have entered into a memorandum of understanding establishing procedures to jointly respond to petitions to use food ingredients and sources of irradiation in the production of meat and poultry products. FSIS has issued regulations at 9 C.F.R. 424.22(c) regarding the irradiation of meat and poultry products, which include labeling requirements for these products. These labeling regulations are generally consistent with current FDA requirements. In light of FDA's proposed rule, meat and poultry producers should consider whether to encourage FSIS to make similar changes in current irradiation labeling requirements.

41 See id. at 72156.

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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