airplanes, certificated in any category; serial numbers 4001 and 4003 and subsequent.

Unsafe Condition

(d) This AD results from reports of fluid loss in the No. 2 hydraulic system, causing the power transfer unit to overspeed, increasing the fluid flow within the No. 1 hydraulic system. We are issuing this AD to prevent possible loss of both the No. 1 and No. 2 hydraulic systems, resulting in the potential loss of several functions essential for safe flight and landing of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Airplane Flight Manual (AFM) Revision

(f) Within 14 days after the effective date of this AD, revise the Limitations section of the applicable AFM to include the information in the applicable Bombardier temporary amendment specified in Table 1 of this AD, as specified in the temporary amendment. These temporary amendments introduce procedures for pulling the ''HYD PWR XFER'' circuit breaker in the event of the loss of all hydraulic fluid in the No. 1 or No. 2 hydraulic system. Operate the airplane according to the limitations and procedures in the applicable temporary amendment.

TABLE 1.—AFM TEMPORARY AMENDMENTS

For Model—	Use Bombardier Temporary Amendment—	Issue—	Dated—	To Bombardier Dash 8 Q400 Airplane Flight Manual—
–400 airplanes	13	1	July 14, 2005	PSM 1–84–1A.
–401 airplanes	13	1	July 14, 2005	PSM 1–84–1A.
–402 airplanes	13	1	July 14, 2005	PSM 1–84–1A.

Note 1: This may be done by inserting a copy of the applicable temporary amendment into the applicable AFM. When the applicable temporary amendment has been included in general revisions of the AFM, the general revisions may be inserted into the AFM, provided the relevant information in the general revisions is identical to that in the temporary amendment.

Alternative Methods of Compliance (AMOCs)

(g)(1) The Manager, New York Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(h) Canadian airworthiness directive CF–2006–08, dated April 26, 2006, also addresses the subject of this AD.

Issued in Renton, Washington, on March 26, 2007.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–6267 Filed 4–3–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 2005N–0272]

RIN 0910–ZA29

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise its labeling regulations applicable to foods (including dietary supplements) for which irradiation has been approved by FDA. FDA is proposing 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. For purposes of this rulemaking, we are using 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. 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 permit a firm to use the term ''pasteurized'' in lieu of ''irradiated,'' provided it notifies the agency that the irradiation process being used meets the criteria specified for use of the term ''pasteurized'' in the Federal Food, Drug, and Cosmetic Act (the act) and the agency does not object to the notification. This proposed action is in response to the Farm Security and Rural Investment Act of 2002 (FSRIA) and, if finalized, will provide consumers with more useful information than the current regulation.

DATES: Submit written or electronic comments on the proposed rule by July 3, 2007. Submit comments regarding information collection by May 4, 2007 to OMB (see **ADDRESSES**).

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0272 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- 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.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the

Electronic Submissions portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No. 2005N–0272 or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* 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.

Information Collection Provisions: Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB).To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION:

I. Background

A. Current Labeling Requirements for Irradiated Foods

In the **Federal Register** of February 14, 1984 (49 FR 5714), FDA published a proposed rule (the 1984 proposal) to approve the use of ionizing radiation on several foods. The 1984 proposal did not include a requirement for labeling disclosing the use of ionizing radiation. FDA received over 5,000 comments on this proposal, including numerous comments on the issue of labeling irradiated foods. Based on the comments and information received in response to the 1984 proposal and on further analysis, FDA published a final rule in the **Federal Register** on April 18, 1986 (51 FR 13376) (the 1986 final rule). The 1986 final rule required 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 irradiation''). FDA concluded that labeling indicating treatment of food with radiation was necessary to prevent misbranding of irradiated foods because irradiation may not visually change the food and in the absence of a label statement, the implied representation to consumers is that the food has not been processed. We stated in the preamble to the 1986 final rule that, in addition to the mandatory language, the manufacturer may also state on the wholesale or retail label the purpose of the treatment process or further describe the kind of treatment used (51 FR 13376 at 13387). That is, the manufacturer may include in the labeling any phrase such as ''treated with radiation to control spoilage,'' ''treated with radiation to extend shelf life,'' or ''treated with radiation to inhibit maturation,'' as long as the phrase truthfully describes the primary purpose of the treatment. Similarly, the manufacturer may choose to state more specifically the type of radiation used in the treatment, i.e., ''treated with x-radiation,'' ''treated with ionizing radiation,'' or ''treated with gamma radiation,'' if more specific description is applicable.

B. The 1999 Advanced Notice of Proposed Rulemaking (ANPRM) on the Labeling of Irradiated Foods

On November 21, 1997, the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115) was enacted. Section 306 of FDAMA amended the act by adding section 403C (21 U.S.C. 343–3). Section 403C of the act addressed the disclosure of irradiation on the labeling of foods as follows:

''(a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

(b) In this section, the term ''radiation disclosure statement'' means a written statement that discloses that a food has been intentionally subject to radiation.''

Although section 403C of the act addressed only the prominence of the radiation disclosure statements, the language in the FDAMA Joint Statement (H. Rep. 105–399, 105th Cong., 1st sess., at 98–99) 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. Specifically, the Joint Statement stated that ''the public comment process should be utilized by the Secretary to provide an opportunity to comment on whether the regulations should be amended to revise the prescribed nomenclature for the labeling of irradiated foods and on whether such labeling requirements should expire at a specified date in the future.'' The FDAMA Joint Statement also indicated that ''The conferees intend for any required irradiation disclosure to be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate anxiety'' (Ref. 1).

In response to the conferees' report, FDA published an ANPRM in the **Federal Register** of February 17, 1999 (64 FR 7834) seeking public comment on the meaning of the current irradiation labeling statement and soliciting suggestions for possible revisions. The 1999 ANPRM described the intent of the conference report, cited several documents related to irradiation labeling, and asked for comment on how the current label is perceived by consumers. The 1999 ANPRM also described whether other labeling would more accurately convey that the food was irradiated without implying a warning or causing inappropriate consumer anxiety.

FDA received over 5,550 comments in response to the 1999 ANPRM on the meaning of the current irradiation labeling statement and suggestions for possible revisions. The majority of comments urged FDA to retain the current labeling for irradiated foods. Some comments suggested alternate wording, such as ''cold pasteurization,'' or ''electronic pasteurization,'' while other comments contended that these terms serve only to obscure information and confuse consumers. A few comments stated that additional labeling, such as ''irradiated to kill harmful bacteria,'' was helpful.

C. Consumer Research

To better assist FDA in formulating specific revisions that would accomplish the objectives outlined in the FDAMA Joint Statement and also satisfy the requirements of the act, the agency, in addition to publishing the ANPRM, conducted focus group research in Maryland, Minnesota, and California, during June and July 2001. The primary focus of the research was to ascertain from focus group participants how they viewed the current irradiation disclosure statement. We were particularly interested in whether the focus group participants perceived the current irradiation disclosure statement as a warning. 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. Most of the participants viewed alternate terms, such as ''cold pasteurization'' and ''electronic pasteurization,'' as misleading, because such terms appeared to conceal rather than to disclose information. Participants did not see the current disclosure labeling as a warning, per se, because knowledgeable participants considered irradiation to be a positive safety attribute. Less knowledgeable participants, such as those who associated irradiation with things such as x-ray or radiation, wanted more information about the appropriateness of food irradiation. All participants agreed that irradiated foods should be labeled ''honestly.''

D. Farm Security and Rural Investment Act of 2002 (FSRIA) (Public Law 107–171)

On May 13, 2002, the President signed into law the FSRIA. The law included two provisions that relate to irradiation labeling. One of these provisions, section 10808, as discussed in the following paragraph, includes new criteria for use of the term ''pasteurization'' in labeling. The other provision, section 10809, directed FDA to publish for public comment proposed changes to the current regulations relating to the labeling of foods that have been treated by irradiation using radioactive isotope, electronic beam, or x-ray to reduce pest infestation or pathogens. The provision further stated 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 issuance 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.''

Section 10808 of the FSRIA, which includes new criteria for use of the term ''pasteurized'' in labeling, revised section 403(h) of the act 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 as pasteurization 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. The criteria prescribed in section 10808 of the FSRIA 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 micro-organisms 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 involved has not been shown to meet the requirements.

As part of FDA's implementation of section 10809 of the FSRIA, FDA issued a guidance document entitled ''Guidance; Implementation of Section 10809 of the Farm Security and Rural Investment Act of 2002, Public Law No. 107–171, section 10809 (2002) Regarding the Petition Process to Request Approval of Labeling for Foods That Have Been Treated by Irradiation'' (the 2002 Guidance). The 2002 Guidance was issued in accordance with FDA's Good Guidance Practices regulation in 21 CFR 10.115. The 2002 Guidance also advised how interested parties may petition the agency for the approval of labeling that may be used on irradiated food as an alternative to the currently required irradiation disclosure statement. FDA noted that this was an interim process and that it could be used until FDA published any final regulation on this issue. FDA published a notice in the **Federal Register** announcing the availability of the 2002 Guidance document on October 7, 2002 (67 FR 62487). To date, FDA has not received any petitions requesting the use of alternative labeling for irradiated foods.

II. The Proposal

A. Legal Authority/Statutory Directive

FDA's authority to require labeling of all foods[1], including irradiated foods, derives from sections 201(n) and 403(a)(1) of the act (21 U.S.C. 321(n) and 343(a)(1)). In addition, section 701(a) of the act (21 U.S.C. 371(a)) authorizes FDA to issue regulations for the efficient enforcement of the act. Under section 403(a)(1) of the act, a food is misbranded if ''its labeling is false or misleading in any particular.'' Section 201(n) of the act mandates that, in determining whether labeling is misleading, FDA take into account, among other things, whether the labeling fails to reveal facts that are material in the light of representations made or suggested or with respect to consequences that may result from the use of the product to which the labeling relates under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual.

Historically, the agency has generally interpreted the scope of the materiality concept to mean information about the characteristics of the food. FDA has required special labeling on the basis of it being ''material'' information in cases where the absence of such information leads the consumer to assume that a food, because of its similarity to another food, has nutritional[2], organoleptic (e.g., taste, smell, or texture), or functional (e.g., storage)[3] properties of the food it resembles when in fact it does not. For example, the labeling of margarine that has been processed in a way that results in it no longer being suitable for frying must disclose this difference from regular margarine.

Irradiation has various effects on foods that may cause changes in the characteristics of the food. Such changes may occur in the food's organoleptic, nutritional, or functional properties that would not be noticeable at the point of purchase but could be apparent when consumed or cooked. If these changes are not within the range of characteristics ordinarily found in such foods, they would be considered ''material'' under this proposal. In the absence of appropriate labeling disclosing these changes in the characteristics of the food, consumers would not have all of the necessary information needed to make a purchase decision or properly use the food. Thus, in the absence of information about these changes in the characteristics of the food, the labeling would be misleading under 201(n) of the act and the food would be misbranded. These

[1] Food refers to conventional foods as well as dietary supplements.

[2] Currently, we are not aware of any changes to the nutritional properties of any food FDA has approved for irradiation.

[3] The statutory phrase ''the consequences that may result from the use of the food'' (section 201(n) of the act) generally can also be described as changes in a food's functional properties. For brevity and clarity, we use the latter terminology in this document.

changes are typically process specific and will vary with the food and the irradiation conditions. In addition, these changes and the degree of the changes may be measurable and of consequence to consumers. Thus, a blanket statement on when labeling would be required due to irradiation causing material changes cannot be made in advance for all products. Rather, 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.

Under the proposal, the fact that a food has been irradiated would not by itself require disclosure on the label. FDA is proposing to require that only those irradiated foods in which irradiation causes a material change in a food's characteristics (e.g., organoleptic, nutritional, or functional properties) under the conditions of use prescribed in the label and labeling or under customary or usual conditions of use bear the radura logo. Those irradiated foods must also bear the term ''irradiated'' or any derivative thereof (e.g., ''irradiate,'' ''irradiation,'' ''radiation,'' etc.) in conjunction with language describing the material change. Additionally, FDA will not object to the use of additional terms to indicate that a food has been subjected to the process of irradiation, e.g., ''treated with radiation,'' ''treated by irradiation,'' or ''processed with radiation.'' However, in the absence of a material change, under the proposal, the fact that the food has been irradiated is not considered a material fact and, therefore, no logo or label statement would be needed. For such foods, FDA would not object to manufacturers voluntarily labeling their products to indicate that the food is irradiated. FDA is also proposing to 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 § 10.30 (21 CFR 10.30).

As discussed in more detail in section I of this document, the FSRIA amended section 403(h) of the act to include new criteria for the use of the term ''pasteurized'' in labeling. This section gives FDA authority to determine for labeling purposes whether alternate processes, e.g., irradiation, are equivalent to pasteurization in destroying pathogens. Therefore, FDA is also proposing to require that anyone seeking to label a food as ''pasteurized'' under this provision in lieu of referring to irradiation must notify FDA and provide supportive data. Provided the agency has not objected to the notification within 120 days after receipt of the notification, the notifier would be able to label a food as ''pasteurized'' in lieu of ''irradiated.''

Under section 409 of the act, no food may be irradiated without approval by FDA. Currently, FDA has approved irradiation for a number of foods, including spices, shell eggs and fruits and vegetables, although only a small fraction of these foods are actually irradiated. According to a report by the U.S. General Accounting Office[4] (2000), only 0.005 percent of fruits and vegetables consumed in the United States (about 1.5 million pounds), and 9.5 percent of all spices consumed in the United States (about 95 million pounds of spices and dry or dehydrated aromatic vegetable substances) are irradiated annually. See the following Web site for a listing of all foods that have been approved for irradiation: *http://a257.g.akamaitech.net/7/257/2422/10apr20061500/edocket.access.gpo.gov/cfr_2006/aprqtr/21cfr179.26.htm*.

B. Proposed Amendment

As previously discussed in section II.A of this document, irradiation has various effects on foods that may change a food's characteristics. For example, as with other forms of processing, the effects of irradiation that kill or weaken insects and microorganisms may also cause some changes in the food itself. Many of these changes are of little significance, as the composition of the food will remain within normal variations of unirradiated foods. However, other changes to organoleptic, nutritional, and functional properties may occur. Changes to shelf life are likely to be among the most common of these changes. Bananas and spices are illustrative of irradiated foods that may have an extended shelf life and are discussed in the following paragraph.

Bananas may be irradiated to delay ripening and extend shelf life. This is an example of a material change. Consumers have a general idea of the shelf life and ripening time of unirradiated bananas based upon their appearance and make purchase decisions based at least in part on the bananas' appearance (i.e., ripeness) and intended use. If irradiated bananas were not labeled to indicate the material change, e.g., delayed ripening, consumers would purchase the bananas expecting the faster ripening schedule of unirradiated bananas. A consumer who wanted to make a food that required very ripe bananas (e.g., banana bread) would not know, without labeling, that the irradiated bananas would not be ripe enough to make the banana bread when he wanted to do so. Thus, if the irradiated bananas are not labeled, the consumer might purchase the bananas and then discover later that they are unsuitable for the consumer's planned use.

In contrast, there are instances where treatment with irradiation may extend a food's shelf life without changing any of its functional characteristics in a way that may require using the food differently than its unirradiated counterpart. For example, while spices that are irradiated to control microbial growth will likely have their shelf life extended, FDA tentatively believes that the extension in 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. That is, in addition to possibly benefiting from the extended shelf life, a consumer buying the irradiated spice can use the irradiated spice the same as he would the unirradiated spice. Unlike the consumer of irradiated bananas described above, the spice consumer does not need additional information to prevent the potential for a detrimental consequence from using the irradiated food the same as its unirradiated counterpart. Thus, FDA tentatively believes that the extension of a spice's shelf life due to irradiation would not be material information that consumers need to know; therefore the producer would not be required to declare this information on the spice label. We request comment 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).

One of the goals of food science research on irradiation is to determine irradiation conditions that would minimize those unexpected effects that would be material to consumers. In a review article on the effects of irradiation on fresh-cut fruits and vegetables, Prakash and Foley (Ref. 1a) cite research illustrating how effects can vary depending on the food, irradiation conditions, and mitigating steps that can be taken. They report that in some cases low doses can cause significant loss in firmness; however, in other fruits and vegetables no such loss is observed, even at a higher dose. For example,

[4] Now the Government Accountability Office.

firmness of diced Roma tomatoes irradiated at 0.5 kilogray (kGy) decreased by 30 percent and firmness of cut romaine lettuce irradiated at 0.35 kGy decreased by 10 percent. However, no change in firmness was observed in shredded carrots or fresh-cut iceberg lettuce following irradiation at 1 and 2 kGy, or in celery irradiated at 1 kGy. In diced bell peppers, irradiation at 3.7 kGy reduced bell peppers' flavor and produced some off-flavors, while no effect on flavor or aroma was perceived in a control group of bell peppers that were not irradiated and in peppers irradiated at 1.32 kGy. Additionally, after storage for 9 days, off aroma was significantly higher in the control sample of bell peppers than in the two groups of irradiated peppers, coinciding with a slimy appearance attributed to microbial spoilage. Prakash and Foley also report that combining irradiation with other technologies, such as calcium treatment, warm water dips, and modified atmosphere packaging further mitigated measurable adverse effects on quality. Similarly, Kader (Ref. 1b) reported that fruits and vegetables such as papaya, strawberry, tomatoes, and dates have a high tolerance to irradiation at doses (below 1 kGy) used for insect control, while cucumber, green bean, grape, and lemon have a low tolerance at this same kilogray. Thus, whether effects occur that would change the food in a significant way will depend on the particular food that is irradiated and the dosage of irradiation used. In its decision approving the use of radiation on shell eggs, FDA cited to data in the petition showing an increased color loss in the irradiated egg yolk and a change in the egg's viscosity as the radiation dose was increased (65 FR 45280 at 45281; July 21, 2000). Such a change in the viscosity or other characteristics of the egg would affect its functionality, e.g., its cooking or binding properties. This change could be significant enough that consumers should be informed of the irradiation and its effect on the food.

In sum, irradiation of food can cause effects in food that are material in light of representations made or on consequences of use. However, whether such effects are sufficient to meet the standard of section 201(n) of the act will vary based on several factors and cannot be determined without considering the particular food and irradiation processing applied. If the change in the irradiated food is within the range of characteristics ordinarily found in such foods, then the fact that the food is irradiated and the resulting change would not be material information and would not be required to be declared on the label.

The use of irradiation is strictly voluntary and generally approved up to a maximum dose. We believe that manufacturers may adjust the dosage to get the most effective dose, while minimizing unexpected effects in the irradiated food. These food manufacturers or producers may choose to irradiate their food only if the irradiation does not alter in a significant way characteristics of the food that are material to the consumer. Thus, it is possible that many uses of irradiation will not result in a material change within the framework set out in this rule. FDA is interested in receiving information about the types of pre-market investigations, e.g., taste test panels or functional studies, done by food manufacturers to evaluate whether to irradiate and at what dose to irradiate in such a way that a material change does not result.

Food is most commonly irradiated to control food-borne pathogens. FDA is not aware of data indicating that control of food-borne pathogens as a result of food irradiation would, by itself, result in a change in the food's characteristics that would not be apparent at the point of purchase of the food and, thus, would have to be disclosed in the labeling of the food to prevent the labeling from being misleading. Consumers expect food to be safe and of a certain quality, and therefore, FDA tentatively concludes that control of food-borne pathogens alone is not an unexpected change in the food. Thus, in instances where a food has been irradiated to enhance or maintain the safety of a food by controlling food-borne pathogens that may be present, and no other changes to the food have resulted, FDA tentatively concludes that information that the food has been irradiated is not necessary to prevent the labeling from being misleading. FDA is interested in receiving any information 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 of the food, and would therefore require additional labeling to inform the consumer of such change. FDA also solicits comments on any specific changes that might be caused by irradiation that might constitute non-material changes.

On the other hand, there may be situations in which irradiation to control food-borne pathogens has had other effects on foods, such as changes to organoleptic, nutritional, or functional properties which would not be readily apparent to the consumer. In such situations, information that there are changes in the characteristics of the food as a consequence of irradiation is the material information that is required in labeling in keeping with the act, to prevent the labeling from being misleading. Further, with regard specifically to shelf life, FDA recognizes that irradiation to control the growth of food-borne pathogens may have the unintended effect of extending shelf life. We specifically request comment 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.

In the past, FDA policies on irradiation labeling have focused on the fact that the food has been processed. In the preamble to the 1986 final rule, we stated that ''* * * irradiation may not change the food visually so that in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed'' (51 FR 13376 at 13388). 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. Thus, FDA required in § 179.26(c) (21 CFR 179.26(c)) that, in addition to the radura logo, the label and labeling of irradiated foods bear the statement ''Treated with radiation'' or ''Treated by irradiation.''

In recent years, FDA policies on the labeling of foods have focused on the results of the processing of the food rather than the processing itself. As discussed earlier, although foods that have been irradiated have been processed, the irradiation does not always result in a material change in the food or in the consequences of use. Further, FDA consumer research indicates that information provided to consumers on the labels of foods is more meaningful if it describes the purpose of the irradiation (Ref. 2). FDA recognizes that labeling to inform the consumer that the product has been irradiated does not, in itself, inform the consumer if or how the product is materially changed. Thus, FDA tentatively believes that when the irradiation causes a material change in the characteristics of the food, the consumer needs to know about this change, and not just the fact that the food has been irradiated. FDA believes that this information should be provided in a disclosure statement on the label of the irradiated food. The disclosure statement would describe the material change in the properties of the food and give consumers additional information that would enable them to make better informed decisions about whether to purchase an irradiated food.

Therefore, FDA is proposing to amend § 179.26(c)(1) and (c)(2) to require that only those foods that have been treated with radiation, and in which the irradiation caused a material change in the characteristics of the food must bear the radura logo and the term ''irradiated,'' or other derivatives as discussed previously in section II.A in conjunction with explicit language describing the change in the food or its conditions of use (e.g., ''irradiated to inhibit sprouting''). In addition, as noted in the 1986 final rule (51 FR 13376 at 13391), FDA believes that the logo is still a necessary part of the label statement because it derives from the symbol that has been used internationally to convey the fact that the food has been irradiated. FDA tentatively concludes that this approach is appropriate because it would require that consumers be provided with more precise information about the material change in the characteristics of the food than what is currently required. As noted previously, such material changes may affect how products are stored and subsequently used by consumers, as well as whether or not the products are purchased in the first place. However, FDA requests comments 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.

As previously discussed in section I.D of this document, section 10809 of the FSRIA provides that anyone requesting approval of alternative labeling for a food that has been treated by irradiation, may petition FDA. As discussed in the 2002 Guidance, FDA believes that it is appropriate to use the citizen petition process provided in § 10.30. This regulation requires the petitioner to submit to the agency all relevant information regarding the petition. This relevant information includes both the information and views upon which the petitioner relies and the information known to the petitioner that is unfavorable to the petitioner's position. Thus for these purposes, relevant information would include any data known or relied upon by the petitioner (e.g., qualitative or quantitative consumer research), that show consumer understanding of the purpose and intent of the proposed alternative labeling. FDA believes that such information might include, but is not limited to, the following information: (1) Data on consumers' prior assumptions about, and perceptions of, the product characteristics in light of the proposed labeling statements and (2) data on consumer acceptance and comprehension of the proposed labeling statements in comparison to consumer acceptance and comprehension of the irradiation statement required by the current regulation (§ 179.26(c)(1)). Also, as noted in section I.D of this document, section 10808 of the FSRIA revised section 403(h) of the act to permit the use of the term ''pasteurized'' on labels of foods that have been subjected to a safe process as long as the process meets certain criteria.

Therefore, we are proposing in § 179.26(c)(1) to permit the use of alternate terms to ''irradiated'' or any of its derivatives, on the labels and labeling of irradiated foods. We are proposing in § 179.26(c)(2) that the alternate term may be used on the labels and labeling of foods that have been treated by irradiation, that is, if use of the term has been approved by FDA in response to a citizen petition submitted in accordance with § 10.30. In the case that the alternative term is ''pasteurized,'' the irradiation process must meet the criteria of section 403(h)(3) of the act. Anyone seeking to label a food as ''pasteurized'' under this provision must notify FDA and provide effectiveness data regarding the process or treatment used. The agency intends to issue guidance to interested parties who wish to notify the agency to use the term ''pasteurized'' in accordance with section 403(h)(3) of the act.

FDA and the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture, entered into a memorandum of understanding (MOU) establishing procedures to jointly respond to petitions to use food ingredients and sources of irradiation in the production of meat and poultry products (see 64 FR 72168, December 23, 1999, at *http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/88-026F.pdf*; for the MOU, see *http://www.fsis.usda.gov/Regulations_&_Policies/Labeling_FDA_MOU/index.asp*). FSIS has separately issued regulations at 9 CFR 424.22(c) regarding the irradiation of meat and poultry products (see 64 FR 72150, December 23, 1999, at *http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-076F.pdf*).

III. Analysis of Economic Impacts

A. Introduction

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: having an annual effect on the economy of $100 million or more or adversely affecting in a material way a sector of the economy, competition, jobs, the environment, public health, or safety, or State, local, or tribal governments or communities. A regulation also is considered a significant regulatory action if it raises novel legal or policy issues. We have determined that this rule is a significant regulatory action as defined by Executive Order 12866 because it raises novel policy issues.

B. Preliminary Regulatory Impact Analysis

1. The Need for the Proposed Irradiation Labeling Rule

Executive Order 12866 states, ''Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling need, such as failures of private markets to protect or improve the health and safety of the public, the environment, or the well being of the American people.''

As previously discussed in section I.D of this document, on May 13, 2002, the President signed into law the FSRIA, which contains a provision relating to irradiation labeling. Section 10809 directs FDA to publish a proposed rule and, with due consideration to public comment, a final rule to revise the current regulation governing the labeling of foods that have been treated by irradiation. This rule is proposed not to address any market failure, but to respond to section 10809 of FSRIA and because we tentatively believe that it may no longer be necessary to require that all irradiated food be labeled as such.

2. Regulatory Options

We analyzed five options for the proposed irradiation regulation:

- No new regulatory action (current state of the world, baseline).
- Remove labeling requirements for irradiated foods.
- Maintain the current labeling requirement (that is, all food that is irradiated must be labeled), but also require statements of purpose (e.g., ''Irradiated to extend shelf life'').

• Maintain the current labeling requirement, but also allow alternate terms to irradiation (e.g., ''pasteurized'').

• The proposed regulation—Only those foods treated with irradiation and for which the irradiation caused a material change in the food must bear the radura logo and the term ''irradiated'' or an alternate term such as ''pasteurized'' in conjunction with explicit language describing the change in the food or its conditions of use (e.g., ''irradiated to inhibit sprouting''). A food undergoes a material change if irradiation changes the properties of the food in a way that is not readily apparent to the consumer at the point of purchase. Therefore, in the absence of a material change, the fact that the food was irradiated is not considered a material fact and, therefore, no radura logo or label statement would be needed.

Option 1: No New Regulatory Action (baseline).

Taking no new regulatory action on irradiation labeling is option 1 in our analysis. The FSRIA requires FDA to publish a proposed rule and, with due consideration to public comment, a final rule to revise the current irradiation labeling regulation. So this is not a viable option. We include it here because the Office of Management and Budget (OMB) cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. This option will serve as the baseline against which other options will be measured for assessing costs and benefits, and we assume the baseline has zero costs and benefits.

The current regulation (§ 179.26) states that irradiated food must bear the radura logo and the phrase ''Treated with radiation'' or ''Treated by irradiation'' and does not explicitly address the inclusion of additional information that directs attention to shelf life or food safety. Currently, FDA has approved iradiation for a number of foods including spices, shell eggs, and fruits and vegetables; however, only limited amounts of irradiated foods are sold in the United States. According to a report by the General Accounting Office[5] (2000), it is estimated that 97 million pounds of food products are irradiated annually (including ''meat food products'' under the Federal Meat Inspection Act and ''poultry'' under the Poultry Products Inspection Act[6], which are regulated by the United States Department of Agriculture), which is only a small fraction of the total amount of food consumed. For example, about 1.5 million pounds of fruits and vegetables are irradiated annually. This represents only 0.005 percent of the total amount of fruits and vegetables consumed. About 95 million pounds of spices and dry or dehydrated aromatic vegetable substances are irradiated annually, which represents 9.5 percent of all spices consumed. Because spices, shell eggs, fruits and vegetables account for virtually all the food irradiation done in the United States, we use only data about those foods in our economic analysis.

Option 2: Propose to remove labeling requirements for irradiated foods

This option also may not be viable because it could violate section 403(a) of the act, which provides that the labeling of all foods, including irradiated foods, must be truthful and not misleading. In addition, section 201(n) of the act mandates that, in determining whether particular labeling is misleading, FDA consider whether the labeling fails to reveal material facts in light of representations made, or with respect to, the consequences that may result from the use of the product. Having no labeling requirements might violate these provisions. If this option were chosen, costs and benefits would be generated if many firms ceased labeling their irradiated products.

Costs: Since this option would not require labeling, search costs would increase for purchasers who do not want irradiated food. There will be an increase in search costs because these consumers would need to increase efforts to find information about irradiated foods other than on the labels or in the labeling, or obtain knowledge of producers who irradiate their food products. If firms decide to drop labeling, they would incur relabeling and label inventory costs but they would choose the least costly labeling option.

Benefits: This option could be beneficial to those firms currently labeling irradiated food by allowing them to reclaim label space on the label for private purposes, such as marketing messages or label art. Without a labeling requirement, it is possible that irradiation would become more attractive to firms because of this benefit. Any increases in the numbers of irradiated foods could, in turn, result in increased food safety or shelf life.

Option 3: Maintain the current labeling requirement (i.e., require that all irradiated food be labeled ''Treated with radiation'' or ''Treated by irradiation,'' along with the radura logo), but propose to also require statements of purpose (e.g., ''Treated with irradiation to inhibit sprouting,'' etc.).

The current regulation (§ 179.26(c)) states that irradiated food must bear the radura logo and the phrase ''Treated with radiation'' or ''Treated by irradiation.'' The current regulation does not explicitly address the inclusion of additional information that directs attention to, for example, shelf life or food safety. This option would amend the current regulation to include explicit requirements on inclusion of additional information on irradiation benefits. While it is possible that some firms that irradiate food currently include statements of purpose, this option would formally require this inclusion.

Costs: This option would generate costs because firms would be required to relabel their products in order to include statements of purpose. Tables 1 and 2 of this document outline estimated labeling costs for sectors of the food industry that may require relabeling. The food categories included in the table are currently approved for irradiation by FDA.

Table 1 outlines low, medium, and high cost estimates based on a change in the principal display panel. Table 2 outlines low, medium, and high cost estimates based on a change in the information panel or assuming that the irradiation statement is similar in cost to a nutrient content claim or health claim. It is not certain which table most likely represents costs to firms because it is not certain what conditions would make the costs in table 1 more likely or what conditions would make table 2 more likely. Both tables show estimated costs under compliance periods of 12, 24, and 36 months. In both tables 1 and 2, compliance costs decrease as the length of compliance period increases for all product categories because firms can coordinate new changes in labels with already-scheduled changes in labels. In addition, the compliance period affects whether or not firms would incur additional labor costs, such as overtime, and the volume of labeling inventory that would have to be discarded as a result of a new rule.

Cost estimates are shown in two proportions for each compliance period: If 1 percent of the industry irradiates

[5] Now the Government Accountability Office.

[6] It is our understanding that as of 2000 only a very small proportion of poultry (0.002 percent of annual consumption) and no meats were irradiated and available commercially (Ref. 10).

and if 5 percent of the industry irradiates. As can be seen in the tables, industry costs decrease as the number of firms irradiating food decreases. Data on the actual number of firms that irradiate food or will want to irradiate food in the future are not currently available. The agency requests comments on the number of firms or products that would be affected by a new irradiation labeling rule.

The cost model used in this analysis does not include costs for labeling fresh produce without packaging because fresh fruits and vegetables do not have Universal Product Codes that can be scanned. Nonetheless, it is still necessary to estimate costs associated with labeling fresh fruits and vegetables that have been irradiated.

One way of labeling fresh fruits and vegetables is by placing stickers on the produce. While it is not known how many fruit and vegetable manufacturers irradiate or will want to irradiate as a result of this rule, according to the 2002 Census of Manufacturers (Ref. 8), there are 5,836 firms that process fresh fruits and vegetables. As with costs estimates for the other food categories, it is assumed that 1 percent of these firms, or 58, may want to irradiate, or 5 percent of these firms, or 292, may want to irradiate. Our 1 percent and 5 percent assumptions are based on the generally observed very low rate of adoption of irradiation technology in food processing to date. We do not have specific data to estimate the number of firms that will irradiate if this rule is finalized, and we request comment on this assumption.

For firms, there are administrative costs involving the establishment of what the sticker will look like, as well as the costs of finding the printer to produce these stickers. Based on previous estimates of similar costs in the final rule on the Labeling of Juice Products (63 FR 24254; May 1, 1998), the agency estimates these administrative costs to be $100 per firm. In addition, printers levy one time charges for set-up in addition to the basic per unit cost of labels. The agency estimates these costs to be $250 per firm. Table 3A summarizes administrative costs associated with using stickers if 1 percent of the industry irradiates and if 5 percent of the industry irradiates.

In addition to administrative costs, there are labor costs associated with affixing stickers to the fruits and vegetables. The agency estimates the labor cost of applying the labels by multiplying the average agricultural hourly wage ($10.75) (Ref. 8a) by the approximate number of hours needed to label the irradiated fruits and vegetables. Assuming it takes one worker 1 hour to label 240 pounds of fruits or vegetables (4 pounds per minute multiplied by 60 minutes) it would take approximately 6,250 hours to label 1.5 million pounds of fruits and vegetables, the approximate amount of fruits and vegetables irradiated annually in this country. The total labor costs associated with labels would then be $67,188. Table 3B summarizes total labor costs if one worker can label 240 pounds per hour, 360 pounds per hour or 480 pounds per hour. The agency requests comments on costs associated with labeling fresh fruits and vegetables that have been irradiated.

Benefits: A statement regarding the purpose of irradiation would serve to provide more information to consumers than what is currently on the label. To the extent that the addition of the statement of purpose causes people to purchase irradiated products they may have previously avoided, and to the extent that these products have longer shelf life or lower risk of illness, then consumers will benefit. Consumers may look more favorably on irradiated food once they understand the purpose, which in turn, could result in more irradiated food in the market due to the increase in demand. Information may also be a benefit in itself even if purchases do not increase. Research indicates that providing a statement of purpose results in a more positive attitude by consumers toward the purchase of irradiated food (Ref. 3). Furthermore, research indicates that providing information about the benefits of irradiation may increase willingness of consumers to pay for irradiated food (Ref. 4).

TABLE 1.—COST ESTIMATES: IRRADIATION RELABELING, PRINCIPAL DISPLAY PANEL

Food Category	Compliance Period	Percentage of Firms Affected by Rule	Cost Estimates		
			Low	Medium	High
Spices/Seasonings	12 months	1%	$406,553	$581,000	$966,000
		5%	$2,032,033	$2,905,689	$4,831,841
	24 months	1%	$195,967	$279,944	$468,000
		5%	$981,269	$1,400,095	$2,335,798
	36 months	1%	$27,799	$39,650	$66,269
		5%	$138,995	$198,248	$331,343
Shell Eggs	12 months	1%	$236,341	$314,692	$568,084
		5%	$1,181,032	$1,570,997	$2,844,160
	24 months	1%	$144,063	$191,041	$345,471
		5%	$718,210	$955,915	$1,728,457
	36 months	1%	$61,852	$82,324	$149,000
		5%	$309,262	$411,618	$744,275
Dried Vegetables	12 months	1%	$164,604	$218,663	$394,000
		5%	$822,781	$1,094,153	$1,969,567
	24 months	1%	$92,292	$122,838	$222,307
		5%	$461,461	$614,191	$1,110,562
	36 months	1%	$32,092	$42,713	$77,233
		5%	$160,459	$213,566	$386,163
Totals	12 months	1%	$807,498	$1,114,355	$1,928,084
		5%	$4,035,846	$5,570,839	$9,645,568
	24 months	1%	$432,322	$593,823	$1,035,778
		5%	$2,160,940	$2,970,201	$5,174,817
	36 months	1%	$121,743	$164,687	$292,502

TABLE 1.—COST ESTIMATES: IRRADIATION RELABELING, PRINCIPAL DISPLAY PANEL—Continued

Food Category	Compliance Period	Percentage of Firms Affected by Rule	Cost Estimates		
			Low	Medium	High
		5%	$608,716	$823,432	$1,461,781

Note: Cost estimates include administrative, graphic design, prepress, engraving, analytical testing, market testing, and discarded inventory.
Source: RTI International, ''FDA Labeling Cost Model'' RTI Project 06673.010, March 2003.

TABLE 2.—COST ESTIMATES: IRRADIATION RELABELING, INFORMATION PANEL

Food Category	Compliance Period	Percentage of Firms Affected by Rule	Cost Estimates		
			Low	Medium	High
Spices/Seasonings	12 months	1%	$192,245	$285,335	$447,000
		5%	$959,479	$1,426,545	$2,233,436
	24 months	1%	$91,101	$134,964	$213,209
		5%	$455,504	$674,821	$1,065,921
	36 months	1%	$12,860	$19,042	$30,121
		5%	$64,298	$95,208	$150,605
Shell Eggs	12 months	1%	$107,773	$151,940	$254,488
		5%	$538,863	$759,434	$1,273,169
	24 months	1%	$65,539	$92,365	$154,472
		5%	$327,694	$461,827	$774,240
	36 months	1%	$28,221	$39,773	$66,678
		5%	$141,105	$198,863	$333,388
Dried Vegetables	12 months	1%	$76,347	$107,227	$178,332
		5%	$381,735	$536,134	$891,881
	24 months	1%	$42,110	$59,346	$99,492
		5%	$210,549	$296,732	$497,462
	36 months	1%	$14,642	$20,636	$34,595
		5%	$73,212	$103,179	$172,977
Totals	12 months	1%	$376,365	$544,502	$879,820
		5%	$1,880,077	$2,722,113	$4,398,486
	24 months	1%	$198,750	$286,675	$467,173
		5%	$993,747	$1,433,380	$2,337,623
	36 months	1%	$55,723	$79,451	$131,394
		5%	$278,615	$397,250	$656,970

Note: Cost estimates include administrative, graphic design, prepress, engraving, analytical testing, market testing, and discarded inventory.
Source: RTI International, ''FDA Labeling Cost Model'' RTI Project 06673.010, March 2003.

TABLE 3A.—COST ESTIMATES: STICKER ADMINISTRATIVE COSTS

Number of Firms	Administrative Costs	Printing Costs	Total Administrative Costs
1%, or 57	$100	$250	$19,950
5%, or 283	$100	$250	$99,050

TABLE 3B.—COST ESTIMATES: STICKER LABOR COSTS

Pounds Per Hour	Hourly Wage	Hours Needed	Total Labor Cost
240	$10.75	6,250	$67,188
360	$10.75	4,167	$44,792
480	$10.75	3,125	$33,594

Option 4: Maintain the current labeling requirement, but propose to also allow alternate terms to ''Irradiation'' (e.g., ''Pasteurized'')

The current regulation (§ 179.26(c)) states that irradiated food must bear the radura logo and the phrase ''Treated with radiation'' or ''Treated by irradiation.'' Currently, no alternate terms to irradiation are allowed. This option would maintain the requirement that irradiated food must be labeled but allow the label to contain terms other than ''irradiated,'' such as ''pasteurized.'' But the term ''pasteurized'' may be used only if the process meets the definition as provided in section 403(h)(3) of the act.

Costs: This option generates costs because some firms would opt to relabel their products, but it is uncertain how many firms would do this because this option would be voluntary. However, firms would only relabel if they thought doing so would increase profits. Tables 1 and 2 contain cost estimates for the main food categories that may be affected by this option. It is probable that firms would select a 24 to 36 month compliance period to keep costs down by coordinating the relabeling with regular labeling changes.

In the short run, there may be increased consumption of irradiated food if those consumers who do not want irradiated food do not equate the alternative term with irradiation. Also, confusion could result from the use of alternative terms with uncertain meanings, causing some consumers to increase search costs. Research indicates that many consumers regard substitute terms for irradiation to be misleading (Refs. 2 and 5). In the long run (defined here as a time period long enough for consumers to adjust to and understand the meaning of the alternate terms), consumers' distaste for the term ''irradiation'' would extend to alternate terms used in labeling, especially if there is no additional statement of purpose. Once consumers understand that the alternate terms all mean ''irradiation,'' the result would likely be

a return to the baseline number of irradiated products and labels.

Benefits: It is possible that, in the short run, consumers will not understand that the alternate terms mean the same as ''irradiation.'' However, to the extent that the substitution of terms induces consumers to buy relabeled food that they may have previously avoided and to the extent that these products benefit them in terms of safety or longer shelf life, then consumers will benefit from the substitution of terms. In the short run, the quantity of irradiated food supplied may increase in response to increased demand. As previously mentioned, the long run outcome may be the same as the baseline because, over time, consumers will come to understand that any alternate terms have the same meaning as ''irradiation.'' Once consumers understand that the alternate terms have the same meaning as ''irradiation'' they may want to discontinue consumption of the food, resulting in the number of irradiated foods returning to the same number as before the change in terms. This is a result of producers responding to the change in demand by reducing the quantity of irradiated food supplied.

Option 5: The Proposed Regulation

Only those foods treated with irradiation, and in which the irradiation caused a material change in the food such that it would change the characteristics of the food in a way that is not readily apparent to the consumer at the point of purchase must bear: (1) The radura logo and (2) the term ''irradiated'' or a derivative thereof, or an alternate term such as ''pasteurized,'' in conjunction with explicit language describing the change in the food or its conditions of use (e.g., ''irradiated to inhibit sprouting''). If a firm chooses to use an alternate term to ''irradiation'' other than ''pasteurized,'' it must submit a petition to the Secretary (FDA). If a firm wishes to use the term ''pasteurized,'' it must submit a notification including effectiveness data regarding the process or treatment to the Secretary (FDA).

This option deviates from the current regulation (§ 179.26(c)) in two major ways. First, this option would require irradiation labeling only for food items treated with irradiation if irradiation causes a material change in the food or consequences that may result from use of the food. Secondly, this option requires explicit language describing the material change and allows use of alternate terms for irradiation, as long as a petition is approved by the agency or, in the case where ''pasteurized'' is used, a notification is sent to FDA to which the agency does not object. This option allows for more labeling flexibility and it is possible that the radura logo and label statements on some irradiated food, as long as the irradiation caused no material change, could be removed. The number of products that could be marketed without irradiation labeling is uncertain because labeling requirements cannot be made in advance for all products. Rather, the need for labeling must be determined on a case-by-case basis by appropriate testing of the food irradiated under specific conditions, i.e., time and dosage, because the effect of irradiation on the properties of concern depends on the particular food. It is more likely that this option would simply allow firms more flexibility in how they label irradiated food.

Costs: This proposed rule generates costs because it requires firms to relabel some irradiated products. As with other options, Tables 1 and 2 contain cost estimates for relabeling in selected food categories. Note that cost estimates take into account all relabeling costs, including the costs of removing irradiation label statements. The requirement of a material change could reduce the number of products that would need to be labeled, so some firms would be able to remove current irradiation labeling. This rule would generate additional costs because, in order for a firm to be able to use an alternative to the term ''irradiation,'' a firm would have to submit a petition to the agency (as addressed in proposed § 179.26(c)(2)(i)). If it is the case that the desired alternate term is ''pasteurized,'' then, instead of submitting a petition, a firm must notify the agency and also submit effectiveness data on the method used in its process (as addressed in proposed § 179.26(c)(2)(ii)). Firms are not required to use an alternate term. It is assumed that a firm would choose to use an alternate term only if doing so would increase profits.

Based on previous estimates of the cost to prepare a petition or notification, FDA is assuming the average cost to prepare a petition or notification is $84 per hour (Ref. 13). The agency estimates the total cost of a petition or notification as the time needed to prepare the notification or petition multiplied by $84, the approximate cost associated with the person for preparing the notification or petition. In the case where a firm wants to use the term ''pasteurized,'' the agency does not assume this rule generates any additional cost of gathering effectiveness data; that is, presumably the firm will already have data on the effectiveness of its method, or it would not undertake the cost of irradiation. As mentioned earlier, it is not known how many firms that currently irradiate or will irradiate in the future will be required to label a product as irradiated, and will desire to use an alternative to the term ''irradiation.'' Therefore, the cost estimates are based on an estimate of the number of firms manufacturing foods that are currently approved for irradiation choosing to submit a notification or petition.

Table 4 of this document contains the initial cost estimates of preparing a notification or petition. The number of firms is based on the 2002 Census of Manufacturers (Refs. 6, 7, and 8). According to the Census of Manufacturers, there are 275 companies that manufacture spices and extracts, 311 companies that process poultry and shell eggs (the Census of Manufacturers groups poultry and shell egg processing together), and 5,836 firms that process fresh fruits and vegetables, for a total of 6,422 firms. It is possible that 1 percent of, or 64 firms in the industry will want to use an alternate term and it is possible that 5 percent of, or 321 firms in the industry will want to use an alternate term. The average of this range is 193 firms.

Table 5 of this document presents cost estimates of the annual reporting burden for additional product notifications or petitions after the initial compliance period due to, for example, new firms entering into the industry. It is assumed that one petition to use an alternate term other than ''pasteurized'' will be submitted per year. The time estimates for both tables 4 and 5 are taken from section IV of this document. We estimate that the annual notifications would be about 10 percent of the initial number, that is, 10 percent of 193 (the estimate in table 4), or 19 firms.

TABLE 4.—ESTIMATE OF TOTAL COST OF SUBMITTING NOTIFICATION OR PETITION

21 CFR Section	No. of Respondents	Total Hours	Cost Per Hour	Total Cost
179.26(c)(2)(i)	1	150	$84	$12,600

TABLE 4.—ESTIMATE OF TOTAL COST OF SUBMITTING NOTIFICATION OR PETITION—Continued

21 CFR Section	No. of Respondents	Total Hours	Cost Per Hour	Total Cost
179.26(c)(2)(ii)	193	28,950	$84	$2,431,800
Total				$2,444,400

TABLE 5.—ESTIMATED ANNUAL COST OF SUBMITTING NOTIFICATION OR PETITION

21 CFR Section	No. of Respondents	Total Hours	Cost Per Hour	Total Cost
179.26(c)(2)(i)	1	150	$84	$12,600
179.26(c)(2)(ii)	19	2,850	$84	$239,400
Total				$252,000

If irradiation causes no material change in the food, irradiation labeling would be removed under this option. Removing irradiation labeling could cause increases in search costs for consumers who desire to avoid purchasing irradiated goods and must find alternative sources to maintain knowledge of producers that irradiate their products.

Some producers may alter their products' labels to use a term other than irradiated (e.g. ''pasteurized''). However, it is uncertain how many producers would use alternate terms. Again, the use of alternative labels would generate potential costs because some consumers may wish to avoid irradiated products. As mentioned before, research indicates many consumers regard substitute terms for irradiation to be misleading (Refs. 2 and 5). These individuals would have to increase their search efforts in order to continue to be informed about approved alternate terms to irradiation. We request comment on the potential for this proposed rule if finalized to increase search costs, particularly for consumers and retailers who desire non-irradiated foods.

Benefits: This proposed rule generates benefits because it could allow consumers to make more informed decisions about the food they purchase. If the addition of a statement of purpose causes people to buy relabeled irradiated products that they may have previously avoided and if these products have, for example, longer shelf life or lower risk of illness, then consumers will benefit. If, as a result of this proposed rule, consumers look more favorably on irradiated foods, the supply of such foods may increase. If retailers are more willing to carry relabeled irradiated products, then consumers benefit from the added opportunity to buy these products.

As mentioned in the costs section of this option, if irradiation causes no material change, it is possible that some products would no longer have to bear the irradiation label statement or the radura logo, but it is uncertain how many products would fall into this category. For producers who voluntarily choose the no-label option, private benefits exceed private costs, since they no longer are required to continue with the existing labeling. That is, a firm would choose the no-label option if it believes doing so will increase profits. Reiterating the idea that the supply of irradiated food may increase as a result of this rule, it is possible that some manufacturers not currently using irradiation as a safety tool (because of the current labeling requirement) may opt to start using irradiation in order to enhance the safety of their products, if there is no material change in the product. Again, firms will only start using irradiation if they believe doing so will increase profits. As already pointed out, however, there are potential search costs for some customers.

This analysis also applies to those firms who choose alternate terms for irradiation. Private benefits will exceed private costs for firms that voluntarily choose alternate terms for irradiation, because they will no longer be required to continue using existing labeling. These firms will only choose alternate terms to irradiation if they believe doing so will increase profits. Again, this use of alternate terms can result in the previously mentioned increase in search costs for consumers who desire to avoid irradiated goods.

If the removal of explicit language indicating that a food has been irradiated causes people to buy irradiated products that they previously avoided, and if these products have lower prices or higher quality, then some consumers will benefit from the removal of information. Also, if retailers are more willing to carry unlabeled irradiated products at lower prices, then all consumers benefit from the lower prices. But it is uncertain that unlabeled irradiated products will be offered for lower prices than products that are not irradiated, because the irradiation process itself is not costless. If irradiation increases product quality but also increases the cost of production, then prices of irradiated products could be higher than the same non-irradiated products, with or without labels.

C. Summary of Options

Table 5A of this document summarizes the costs and benefits of each option analyzed. Costs are given based on the assumption that 1 percent of firms irradiate and relabel (at the medium cost level) using a 2-year compliance period if the option requires relabeling and a 3-year compliance period if relabeling is permitted voluntarily. For Option 5, it also assumes that 1 percent of firms prepare a notification to use the term ''pasteurized'' in the first year and 1 firm petitions to use another alternative term in the first year. The range of costs represents our uncertainty about the need for changes to the principal display panel or the information panel and the number of pounds of fresh fruits and vegetables that can be stickered per hour. For Option 5, the quantified costs are likely to be less than listed because some firms would be able to remove the irradiation labeling when it results in no material change when it is least costly for them to do so and will not need to submit notifications or petitions.

TABLE 5A.—SUMMARY OF COSTS AND BENEFITS OF OPTIONS

	Quantified Costs	Unquantified Costs	Unquantified Benefits
Option 1 (baseline)	0	0	0
Option 2	0	Greatest increase in search costs	Most additional labeling flexibility, potentially longer shelf-life
Option 3	$341,000 - $681,000	0	Most additional information for consumers
Option 4	$133,000 - $252,000	Increased search costs	Additional labeling flexibility
Option 5 (the proposed rule)	Less than $2,785,400 - $3,125,400	Lowest non-zero increase in search costs	Additional information for consumers, Least non-zero additional labeling flexibility

We request comments on the estimates for these options and specifically on the following three issues:

1. The number of firms or products that would be affected by a new irradiation rule.
2. The number of firms that would begin irradiating products as a result of the various options described here.
3. Whether some industry sectors should be given more time to comply than others to reduce the economic impact on them.

D. Small Entity Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. It is not known how many small firms currently irradiate food or will want to irradiate food. If small firms are using this technology, this proposed rule may have a significant economic impact on a substantial number of small entities. The agency requests comments on how this proposed rule will impact small firms.

Under contract, Eastern Research Group developed a model framework for estimating regulatory impacts on small businesses. The model is designed to accommodate a variety of potential regulatory activities, ranging from Hazard Analysis Critical Control Point (HACCP) to product labeling.

Using the 2002 Economic Census and other data, the model estimates the cash flows of representative establishments of varying class sizes of food manufacturers. Based on post-regulation cash flow and distribution of income for each model facility, the model generates the percentage of facilities in each model class that are vulnerable to closure. The model allows the agency to (1) Predict the probability and frequency of small business failure as a result of FDA regulations and (2) estimate the effects of various forms of regulatory relief on the survival of small businesses on a per-establishment basis.

Cost estimates produced by the FDA Labeling Cost Model were used to help generate estimates of the average relabeling cost for firms in two of the four food categories examined here: spices/seasonings and dried vegetables. The middle estimated costs in each food category were divided by the estimated affected stockkeeping units (SKUs) in each food category to arrive at average cost per SKU. Affected SKUs per category are then divided by total number of firms in each category to arrive at average number of affected SKUs per firm. The number of firms in each food category comes from the Ready-to-Eat Food Manufacturing Industry category in FDA's Small Business Impact Model (Ref. 9). We use these estimates to calculate cost per firm using the following formula:

Cost/Firm = (Average SKUs per firm) x (Average Middle Relabeling Cost/SKU)

This formula allows us to estimate the approximate average relabeling costs for firms in each food category. Keep in mind these are merely estimates and cost structures are treated identically across firms. That is, we assume that costs for small firms are similar to costs for large firms. The average relabeling costs for compliance periods of 12, 24, and 36 months were then entered into the Small Business Impact Model to estimate the number of firms at risk for negative cash flow, assuming all firms in each category must relabel. The results of these estimates are presented in tables 6 and 6A of this document. The table is divided into two sections, one for estimates if the information panel is affected and another for the principal display panel.

TABLE 6.—ESTIMATES OF FIRMS AFFECTED BY THE IRRADIATION RULE—CHANGES IN INFORMATION PANEL

Food Category	Compliance Period	Firms with less than 20 Employees		Firms With 20 to 499 Employees		Firms With 500+ Employees	
		Affected Firms	At-Risk Firms[1]	Affected Firms	At-Risk Firms[1]	Affected Firms	At-Risk Firms[1]
Spices/ Seasonings	12 months	139	18	133	0	2	0
	24 months	139	7	133	0	2	0
	36 months	139	1	133	0	2	0
Dried Vegetables	12 months	23	8	25	0	1	0
	24 months	23	3	25	0	1	0
	36 months	23	2	25	0	1	0

[1] Note: An ''at-risk'' firm is one that could potentially suffer from negative cash flow as a result of this proposed rule.

TABLE 6A.—ESTIMATES OF FIRMS AFFECTED BY THE IRRADIATION RULE—CHANGES IN PRINCIPAL DISPLAY PANEL

Food Category	Compliance Period	Firms with less than 20 Employees		Firms With 20 to 499 Employees		Firms With 500+ Employees	
		Affected Firms	At-Risk Firms[1]	Affected Firms	At-Risk Firms[1]	Affected Firms	At-Risk Firms[1]
Spices/ Seasonings	12 months	139	39	133	1	2	0
	24 months	139	11	133	0	2	0
	36 months	139	2	133	0	2	0
Dried Vegetables	12 months	23	8	25	0	1	0
	24 months	23	8	25	0	1	0
	36 months	23	3	25	0	1	0

[1] Note: An ''at-risk'' firm is one that could potentially suffer from negative cash flow as a result of this proposed rule.

The numbers of at-risk firms in the table are estimates generated by the model. These estimates are not based on specific data about the number of small firms affected, because there are no data available; however, they illustrate the idea that small firms, especially firms with fewer than 20 employees, could potentially be adversely affected by this proposed rule. For example, in the dried vegetable category, for a compliance period of 12 months, if as the model estimates, 23 firms would be affected, approximately 8 of these firms (or around 35 percent) would be at risk for negative cash flow as a result of this rule. However, for firms with less than 20 employees, the number of at risk firms decreases as the length of the compliance period increases. As illustrated in tables 1 and 2, when compliance periods increase, costs decrease because firms can coordinate new changes in food labels with already-scheduled changes in labels. By contrast, the model generates no at-risk firms among firms with 500+ employees, regardless of the compliance period. This result is important because the industry is characterized by a large number of small entities. The most effective regulatory relief for small firms would be extended compliance periods. As shown in tables 6 and 6A, as the compliance period increases from 12 to 36 months, the number of small firms at-risk virtually disappears.

Firms producing shell eggs are not included in the Ready-to-Eat Application of the Small Business Impact Model because eggs are not considered ready to eat. Therefore, it is not possible to estimate the number of at-risk firms. Nonetheless, small firms producing shell eggs must still be addressed in this analysis. According to the 2002 Census of Manufacturers (Ref. 6), there are 311 companies that process poultry and shell eggs. Of this number, about 25 percent, or 79 firms have 20 employees or less. Again, it is not known how many processors irradiate or will want to irradiate as a result of this rule. Therefore, we will assume this rule could affect 1 percent, or approximately 1 firm.

Firms processing fresh fruits and vegetables are also not included in the Small Business Impact Model. Again, it is not possible to estimate the number of at-risk firms. According to the 2002 Census of Manufacturers, there are 5,836 firms that process fresh fruit and vegetables. Because firm size for firms that process fresh fruits and vegetables is not yet available for the 2002 Census of Manufacturers, we use data from the 1997 Census of Manufacturers that 93 percent of these firms are single unit firms. Therefore, we estimate that there are 5,427 single unit firms that process fresh fruit and vegetables. As with the other food categories, it is not known how many of these firms irradiate or will want to irradiate as a result of this rule. Therefore, we will assume this rule could affect 1 percent, or approximately 54 firms. The agency requests comments on the number of small shell egg producers and fresh fruit and vegetable producers that could be affected by this rule.

The effects on small businesses depend also on whether the labeling change is required or voluntary. If, for example, the labeling change is to allow an alternate term, or to remove the current label, the small business would do so only if it did not impose a burden. For required labeling changes, however, the labeling costs could indeed put additional firms at risk of going out of business. The length of the compliance period for labeling requirements is the most important variable affecting the burden. The other important factor is how much of the label needs redesigning. If the labeling change is similar to a change in the information panel, and if small businesses are given at least 36 months to comply, few will be at risk.

The agency requests comments on the likely effect on small firms as a result of this proposed rule, and on the effects of longer compliance periods for these firms.

E. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the information and data needed and completing and reviewing each collection of information.

Title: Notice Concerning the Submission of Information to Use an Alternative to ''Irradiation''

Description: In this proposed rule, FDA is proposing to require the submission to the agency of data and information regarding the use of alternate terms to the word ''irradiated'' in foods that have been treated by irradiation using radioactive isotope,

electronic beam, or x-ray. FDA is proposing that an alternate term may be used in lieu of ''irradiated'' if its use is approved in response to a petition that has been submitted to FDA. If the desired alternate term is ''pasteurized,'' a notification must be sent to the Secretary (FDA) that includes effectiveness data to show that the process or treatment meets the requirements of section 403(h)(3) of the act.

Description of Respondents: Manufacturers that irradiate food and desire to use an alternate term to ''irradiation.''

FDA estimates the burden of this collection of information as follows:

TABLE 7.—ESTIMATED ONE-TIME REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Frequency of Response	Total Responses	Hours Per Response	Total Hours
179.26(c)(2)(i)	1	1	1	150	150
179.26(c)(2)(ii)	193	1	193	150	28,950
Total					29,100

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 8.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Frequency of Response	Total Responses	Hours Per Response	Total Hours
179.26(c)(2)(i)	1	1	1	150	150
179.26(c)(2)(ii)	19	1	19	150	2,850
Total					3,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Tables 7 and 8 of this document describe the reporting burden as a result of the provisions set forth in this proposed rule. Table 7 shows the estimated one time reporting burden after the regulation initially goes into effect. Table 8 shows the estimated annual reporting burden, perhaps due to firms entering into the industry and/or currently existing firms deciding to irradiate at a later date. The agency does not know how many firms will submit a notification or a petition to the agency to use an alternate to the term ''irradiation.'' It is also not known how many firms currently irradiate food they manufacture, although it is known that the amount of food irradiated each year is very small and there is only one facility that can irradiate food. However, it is assumed that most firms wishing to use an alternate term will choose to use ''pasteurized'' and submit a notification to FDA along with effectiveness data. It is also assumed that one firm per year will submit a petition to use an alternate term other than ''pasteurized'' as shown in the row corresponding to proposed § 179.26(c)(2)(i) in table 7. Proposed § 179.26(c)(2)(ii) addresses notifications. The number of firms is based on the 2002 Census of Manufacturers (Refs. 6, 7, and 8). According to the Census of Manufacturers, there are 275 companies that manufacture spices and extracts, 311 companies that process poultry and shell eggs (the Census of Manufacturers groups poultry and shell egg processing together), and 5,836 firms that process fresh fruits and vegetables, for a total of 6,422 firms. Table 7 shows the number of respondents presented as an average, based on percentages of total firms that process shell eggs, spices, and fruits and vegetables, the three categories of FDA-regulated foods that are currently approved for irradiation. It is possible that 1 percent of, or 64 firms in the industry will want to use an alternate term and it is possible that 5 percent of, or 321 firms in the industry will want to use an alternate term. The average of this range is 193 firms. Submission of the notification is voluntary because the proposed rule does not require all firms to submit notifications, only those firms that will be required to label a product as ''irradiated'' and desire use of an alternative to the term ''irradiation''. Therefore, it is assumed that there will be no annual reporting burden for this rule for products that have already submitted notifications.

Based on previous estimations of preparing notifications and preparing petitions, FDA is estimating that the time needed to prepare a notification is 150 hours. The agency already has a process for submitting citizen petitions, the burden of which is reported and approved under § 10.30. However, given some of the controversy surrounding irradiation and the use of alternative terms to irradiation, we expect more documentation and more hours spent on these petitions associated with irradiation labeling. Therefore, the agency is assuming submitting a petition will take a total of 190 hours. It is estimated that 40 of these hours are specific to the citizen petition process reported under § 10.30, with an additional 150 hours specific to the issues associated with irradiation labeling. It is this additional burden that is reported in table 7.

The annual burden following the initial round of submissions would consist of submissions for additional products, perhaps as a result of market entry. This burden is shown in table 8. Again, we also assume that, each year, one firm will petition the agency to use an alternate term other than ''pasteurized,'' in response to proposed § 179.26(c)(2)(i). We do not know how many additional firms will submit notifications in response to proposed § 179.26(c)(2)(ii) each year, so table 8 assumes the number of additional firms will be 10 percent of the firms reported in table 7. We also assume that there will not be an additional recordkeeping burden associated with this rule, as it is assumed that firms already have the effectiveness data required by the agency for inclusion in the notification.

In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to submit comments regarding

information collection to OMB (see **ADDRESSES**).

V. Analysis of Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environment assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document is published in the **Federal Register**.)

1. Conference Report on S. 830, Food and Drug Administration Modernization Act of 1997, 143 Cong. Rec. H10452, 10477, (November 9, 1997).

1a. Prakash, Anuradha and Denise Foley, ''Improving Safety and Extending Shelf Life of Fresh-Cut Fruits and Vegetables Using Irradiation in Irradiation of Food and Packaging; Recent Developments,'' ACS Symposium Series 875, V. Komolprasert and K. Morehouse editors, American Chemical Society, Washington, DC 2004.

1b. Kader, Adel A., ''Potential Applications of Ionizing Radiation in Postharvest Handling of Fresh Fruits and Vegetables,'' *Food Technology*, 117–121, June 1986.

2. ORC Macro, ''Consumers' Understanding of Food Irradiation Labeling,'' Focus Group Report, December 2001.

3. Schutz, Howard G., Christine M. Bruhn and Katherine V. Diaz-Knauf, ''Consumer Attitude Toward Irradiated Foods: Effects of Labeling and Benefits Information,'' Food Technology 43, (October 1989): 80–86.

4. Fox, John A., Dermot J. Hayes, Jason F. Shogren, ''Consumer Preferences for Food Irradiation: How Favorable and Unfavorable Descriptions Affect Preferences for Irradiated Pork in Experimental Auctions,'' *The Journal of Risk and Uncertainty*, 24:1 (2002): 75–95.

5. Cates, Sheryl C., et al., ''Consumer Research on Food Safety Labeling Features for the Development of Responsive Labeling Policy,'' RTI, March 22, 2002.

6. ''United States Census Bureau, Poultry Processing: 2002 Economic Census Manufacturing Industry Series,'' available from *http://www.census.gov/prod/ec02/ec0231i311615.pdf* (accessed October 20, 2006).

7. ''United States Census Bureau, Spice and Extract Manufacturing: 2002 Economic Census Manufacturing Industry Series,'' available from *http://www.census.gov/prod/ec02/ec0231i311942t.pdf* (accessed October 20, 2006).

8. ''United States Census Bureau, Comparative Statistics: 2002 Economic Census Manufacturing Industry Series,'' p. 9, available from *http://0-www.census.gov.mill1.sjlibrary.org/prod/ec02/ec0200ccomp.pdf* (accessed October 20, 2006).

8a. *Private Industry by State and 6-Digit NAICS Industry: Establishments, Employment, and Wages, 2004 Annual Averages*, *http://www.bls.gov/cew/ew04sector11.pdf*, December 30, 2005.

9. Eastern Research Group, Inc., ''Model for Estimating the Impacts of Regulatory Costs on The Survival of Small Businesses and its Application to Four FDA-Regulated Industries,'' Contract No. 223–01–2461, June 7, 2002.

10. General Accounting Office, ''Food Irradiation: Available Research Indicates That Benefits Outweigh Risks,'' GAO/RCED–00–217, August, 2000.

11. RTI International, ''FDA Labeling Cost Model,'' RTI Project Number 06673.010, January 2003.

12. Office of Management and Budget, ''GDP and Deflators Used in the U.S.,'' Budget of the United States Government Fiscal Year 2004, Historical Table 10.1, 2003.

13. U.S. Food and Drug Administration, Substances Generally Recognized as Safe: Notification Procedure, OMB No. 0910–0342, Supporting Statement available from *http://www.fda.gov/OHRMS/DOCKETS/98fr/05n-0457-ss00001.pdf*.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 179 be amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

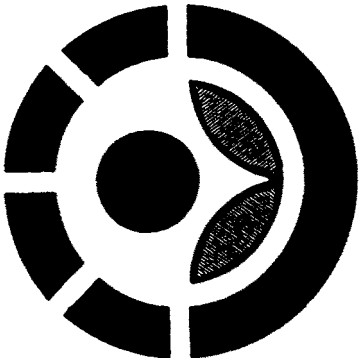
Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

2. Section 179.26 is amended by revising paragraph (c)(1); by redesignating paragraphs (c)(2) and (c)(3) as paragraphs (c)(3) and (c)(4), respectively; by revising newly redesignated paragraph (c)(3); and by adding new paragraph (c)(2) to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(c) *Labeling.* (1) The label and labeling of a retail package of a food irradiated in conformance with paragraph (b) of this section that has, as a result of the irradiation, undergone a material change in the characteristics of the food or in its consequences of use shall bear the following logo along with



the statement ''irradiated,'' or any derivatives of the term ''irradiated'' (e.g., ''irradiation,'' ''irradiate,'' ''radiation,'' etc.) or an alternate term as provided in paragraph (c)(2) of this section, in conjunction with language describing the material change in the characteristics of the food or its use. The logo shall be placed prominently and conspicuously in conjunction with the required statement. The radiation disclosure statement is not required to be more prominent than the declaration of ingredients required under § 101.4 of this chapter. As used in this provision, the term ''radiation disclosure statement'' means a written statement that discloses that a food has been intentionally subjected to irradiation and identifies the material change in the characteristics of the food or the consequences that may result from its use as a result of the irradiation.

(2) An alternate term may be used in lieu of ''irradiated,'' or any of its derivatives, if it meets the following provisions.

(i) A term that is not false or misleading in any material respect may be used in lieu of ''irradiated,'' or any of its derivatives, if its use is approved in response to a petition that has been submitted to FDA using the procedures under § 10.30 of this chapter for approval of the alternate term, or, if use of the term ''pasteurized'' is permissible

under the requirements in paragraph (c)(2)(ii) of this section. 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.

(ii) The term ''pasteurized'' may be used in lieu of ''irradiated'' or any of its derivatives if the irradiation process is:

(A) Reasonably certain to achieve destruction or elimination in the food of the most resistant microorganism of public health significance that is likely to occur in the food;

(B) At least as protective of the public health as a process or treatment that is defined as pasteurization in this chapter;

(C) Effective for a period that is least as long as the shelf life of the food when stored under normal and moderate abuse conditions; and

(D) The subject of a notification to the Secretary of Health and Human Services (the Secretary) that includes effectiveness data regarding the process or treatment and the Secretary has not made a determination in 120 days after the receipt of the notification that the process or treatment involved has not been shown to meet the requirements provided in paragraph (c)(2)(ii)(A), (B), and (C) of this section.

(3) For an irradiated food not in packaged form that has, as a result of the irradiation, undergone a material change in its characteristics or conditions of use, the required logo and the following disclosure statements, ''irradiated,'' or any of its derivatives, or an alternate term as provided in paragraph (c)(2) of this section in conjunction with language describing the material change in the characteristics of the food or conditions of use as a result of the irradiation, shall be displayed to the purchaser with either of the following:

(i) The labeling of the bulk container plainly in view or

(ii) A counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. As an alternative, each item of food may be individually labeled. In either case, the information must be prominently and conspicuously displayed to purchasers. The labeling requirement applies only to a food that has been irradiated, not to a food that merely contains an irradiated ingredient but that has not itself been irradiated.

* * * * *

Dated: March 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–1636 Filed 4–3–07; 8:45 am]

BILLING CODE 4160–01–S

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 202

[Docket No. RM 2007–3]

Registration of Claims to Copyright—Renewals

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Copyright Office is proposing to amend its regulations governing applications for registration of claims to the renewal term of copyright. This notice seeks public comment on the proposed amended regulations, which will take into account the fact that, since January 1, 2006, all applications for renewal have necessarily related to works which are subject to automatic renewal and, thus, are already in their renewal terms, making impossible any 28th– year registration of claims to the renewal term.

DATES: Comments are due May 4, 2007.

ADDRESSES: If hand delivered by a private party, an original and five copies of a comment or reply comment should be brought to Library of Congress, U.S. Copyright Office, 2221 S. Clark Street, 11th Floor, Arlington, VA. 22202, between 8:30 a.m. and 5 p.m. The envelope should be addressed as follows: Office of the General Counsel, U.S. Copyright Office. If delivered by a commercial courier, an original and five copies of a comment or reply comment must be delivered to the Congressional Courier Acceptance Site (''CCAS'') located at 2nd and D Streets, NE, Washington, DC between 8:30 a.m. and 4 p.m. The envelope should be addressed as follows: Office of the General Counsel, U.S. Copyright Office, LM–401, James Madison Building, 101 Independence Avenue, SE, Washington, DC. Please note that CCAS will not accept delivery by means of overnight delivery services such as Federal Express, United Parcel Service or DHL. If sent by mail (including overnight delivery using U.S. Postal Service Express Mail), an original and five copies of a comment or reply comment should be addressed to U.S. Copyright Office, Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Nanette Petruzzelli, Special Legal Advisor for Reengineering, P.O. Box 70400, Washington, DC 20024–0400. Telephone: 202–707–8350. Telefax: 202–707–8366.

SUPPLEMENTARY INFORMATION:

I. Background

The 1976 Copyright Act, 17 U.S.C. 101, et. seq., carried over provisions for the continued protection of certain works first published or registered for copyright under the 1909 Copyright Act. Reenacting and preserving the provisions of section 24 of the 1909 law for all works which were then in their first term of copyright protection, Section 304(a) of Title 17 as originally enacted in 1976 provided that renewal registration had to be made during the 28th year of the original term of copyright in order to secure the additional (then 47) years of renewal–term protection. 17 U.S.C. 304(a) (1976).

In 1992, Congress enacted a revision of section 304(a) of Title 17 which made renewal copyright automatic for works first published or registered from January 1, 1964, through December 31, 1977. This amendment allowed the renewal right to vest without registration of: [a] the claim to copyright during the original, 28–year term; or, [b] the claim to renewal copyright during the year immediately prior to the beginning of the renewal term (*i.e.*, during the 28th year); or, [c] the claim to renewal copyright during the renewal term. Pub. L. No. 102–307, 106 Stat. 264, enacted June 26, 1992. In order to encourage renewal registration and provide a public record of renewal rights, however, Congress also amended section 304(a) to provide certain benefits to a party who undertook the renewal registration within the 28th year of the original term of copyright. These benefits for works with timely renewal registrations include:

1. A certificate of registration constitutes prima facie evidence as to the validity of the copyright during its renewal term and of the facts stated in the certificate. 17 U.S.C. 304(a)(4)(B).

2. A derivative work prepared under the authority of a grant of a transfer or license of copyright in a work made before the expiration of the original term of copyright may not continue to be used under the terms of the grant during the renewal term without the authority of the owner of the renewal copyright. 17 U.S.C. 304(a)(4)(A).

3. A renewal copyright vests upon the beginning of the renewal term in the