Irradiation in the Production, Processing and Handling of Food

0910-0186

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the FD&C Act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum (or minimum and maximum) energy of radiation emitted by X-ray tube sources. Section 179.21(b)(2) requires that the label or accompanying labeling bear adequate directions for installation and use and a statement supplied by FDA that indicates maximum dose of radiation allowed. Section 179.26(c) requires that the label or accompanying labeling bear a logo and a radiation disclosure statement. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.).

The Food and Drug Administration requests continued OMB approval for the information collection requirements contained in the following citations:

21 CFR 179.21(a)(5), 179.21(b)(1), 179.21(b)(2), and 179.26(c) – Third Party Disclosure
Requires labeling of a radiation source to ensure safe use.

21 CFR 179.25(e) - Recordkeeping
Requires maintenance of records in irradiation treatment of foods.

2. Purpose and Use of the Information Collection

The records required by § 179.25(e) are used by FDA inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. The agency cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation. The labeling of a radiation source required by §§ 179.21(b)(1), 179.21(b)(2), and 179.26(c) assists the agency in ensuring safe use.
Description of Respondents: The respondents are businesses engaged in the irradiation of food. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Food processors are free to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials.
The agency estimates that close to one-hundred percent (100%) of the records will be maintained electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication at the federal level because no other federal agency requires food processors to retain these records or label radiation sources.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that ten percent (10%) of respondents are small businesses. A limited number of firms process food using irradiation. The recordkeeping and labeling requirements are no more burdensome for small businesses than for large businesses, and such records would ordinarily be kept by these food processors for their own use as a matter of good management procedures. Consumer Safety Officers in the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, at FDA are available by telephone to answer any questions about recordkeeping requirements. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. If the recordkeeping requirements were not met by the food processor, FDA would, in most cases, be unable to verify that the food has been processed in accordance with applicable regulations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

None of the requirements are inconsistent with 5 CFR 1320.5(d)(2). This collection of information does not involve more than quarterly submission of information to the agency, written responses to the agency in less than 30 days, submission of more than an original and 2 copies, retention of records for more than three years, the use of statistical methods, pledges of confidentiality by FDA not supported by authority established in statute or regulation, or require the disclosure of trade secrets or other confidential information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of May 17, 2012 (77 FR 29352). The agency did not receive any responsive

comments within the scope of the four collection of information topics during the 60-day response period.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20). To the extent 21 CFR 20.64 applies, FDA will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

This information collection does not involve any questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: The respondents are businesses engaged in the irradiation of food. Respondents are from the private sector (for-profit businesses).

12a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Record-keepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
179.25(e), large processors	3	300	900	1	900
179.25(e), small processors	4	30	120	1	120
Total					1,020

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

FDA bases its estimate of burden for the recordkeeping provisions of § 179.25(e) on the agency's experience regulating the safe use of radiation as a direct food additive. The number of firms who process food using irradiation is extremely limited. FDA estimates that there are three irradiation plants whose business is devoted primarily (i.e., approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. FDA

estimates that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on: (1) three facilities devoting 100 percent of their business to food irradiation (3 x 300 hours = 900 hours for recordkeeping annually); and (2) four facilities devoting 10 percent of their business to food irradiation (4 x 30 hours = 120 hours for recordkeeping annually).

No burden has been estimated for the labeling requirements in §§ 179.21(b)(1) and (b)(2) and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

12b. Annualized Cost Burden Estimate

The cost of the recordkeeping requirement to irradiation facilities is minimized because the recordkeeping requirement reflects customary business practice. FDA estimates that the cost for the retention and disclosure of records for food products under this regulation would equal approximately $28,294.80. Factoring in that this is customary business practice, FDA estimates that the average hourly wage for an employee to retain the records and make them available to regulatory officials would be equivalent to a GS-3/Step 3 level in the locality pay area of Washington-Baltimore in 2012, which is $13.87 per hour. Total annual burden hours (1,020) multiplied by $13.87 per hour equals $14,147.40. To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondents $28,294.80.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to Federal Government

FDA's review of the retained records would generally occur as part of its routine establishment inspection activities. FDA would devote approximately 5 hours per inspection to the inspection of records. FDA estimates the annualized cost to the Federal Government for the review of records retained by a firm to be $416.50 per review. In this calculation of cost, FDA estimates the hourly cost for review and evaluation at a base GS-13, step 1 salary of $42.66 per hour. Five hours multiplied by $42.66 per hour equals $213.30. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal Government $426.60 per review.

15. Explanation for Program Changes or Adjustments

The hour burden is unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish data from this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.