

UNITED STATES FOOD & DRUG ADMINISTRATION

Irradiation in the Production, Processing and Handling of Food

OMB Control No. 0910-0186

SUPPORTING STATEMENT

**Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection supports agency regulations. 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 by the Food and Drug Administration (FDA, us or we) under the food additive premarket approval provisions. 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 us 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 regulations impose recordkeeping requirements whereby records are subject to FDA inspection. We therefore request extension of OMB approval for the information collection requirements in 21 CFR 179: *Irradiation in the Production, Processing and Handling of Food*.

2. Purpose and Use of the Information Collection

The recordkeeping required under 21 CFR part 179 is used by our inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. We 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.

*Description of Respondents:* Respondents to the information collection 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. We estimate all (100%) records will be maintained electronically.

#### 4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

#### 5. Impact on Small Businesses or Other Small Entities

We estimate ten percent (10%) of respondents are small businesses. A limited number of firms process food using irradiation, however we do not believe the information collection is unduly burdensome on small entities. We also believe the recordkeeping and labeling requirements would ordinarily be kept by respondents (food processors) for their own use as a good management practice. In addition, regulatory review scientists 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 the recordkeeping requirements found in 21 CFR part 179. We aid small businesses in dealing with the requirements of the FD&C Act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide assistance via FDA's Small Business Assistance webpage on the agency's website at <https://www.fda.gov/industry/small-business-assistance>.

#### 6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. If the recordkeeping requirements are not met by the respondents to the information collection, FDA is unable to verify that food has been processed in accordance with applicable public health safety 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 us 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), we published a 60-day notice for public comment in the *Federal Register* of October 16, 2020 (85 FR 65825). Three comments were received but were unresponsive to the four collection of information topics solicited, nor did any proffer alternative estimates and therefore were not addressed.

#### 9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

#### 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 our regulations (21 CFR part 20). To the extent 21 CFR 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

## Privacy Act

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports Irradiation in the Production, Processing and Handling of Food. All records are maintained at the facility.

FDA further determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA (including vendors or service providers acting on behalf of FDA) does not use name or any other personal identifier to retrieve records from the information collected.

Under FOIA, the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade, and confidential commercial or financial information.

### 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 Cost

#### 12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
179.25(e), large processors	4	300	1,200	1	1,200
179.25(e), small processors	4	30	120	1	120
Total					1,320

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of burden for the recordkeeping provisions of § 179.25(e) on our experience regulating the safe use of radiation as a direct food additive. The number of firms who process food using irradiation is extremely limited. We estimate that there are four 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. We estimate 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) four facilities devoting 100 percent of their business to food irradiation; and (2) four facilities devoting 10 percent of their business to food

irradiation.

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 subject to review by the Office of Management and Budget under the Paperwork Reduction Act.

12b. Annualized Cost Burden Estimate

The cost of the recordkeeping requirement to irradiation facilities is minimized because the recordkeeping requirement reflects customary business practice. We estimate that the cost for the retention and disclosure of records for food products under this regulation would equal approximately \$42,636.00. Assuming this is customary business practice, we estimate 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 2021, which is \$16.15 per hour. Total annual burden hours (1,320) multiplied by \$16.15 per hour equals \$21,318. To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondents \$42,636.

Table 2.--Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate (including overhead)	Total Respondent Costs
Records Retention	1,320	\$32.30	\$42,636

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

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

14. Annualized Cost to the Federal Government

FDA review of the retained records occurs as part of its routine inspection program. We expend approximately 5 hours per inspection to the review of records. We estimate the annualized cost to the Federal government for the review of records retained by a firm to be \$496.80 per review. In this calculation of cost, we estimate the hourly cost for review and evaluation at a base GS-13, step 1 wage in the locality pay area of Washington- Baltimore in 2021 of \$49.68 per hour. Five hours multiplied by \$49.68 per hour equals \$248.40. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal government \$496.80 per review.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

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 will display the expiration date for OMB approval of the information collection as appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.