SUPPORTING STATEMENT

IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

OMB Control No. 0910-0186

A. Justification

1. Necessity for the Information Collection

On April 18, 1986, the Food and Drug Administration issued final regulations pursuant to Sections 201(s), 402, 403, 409, 703 and 704 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(s), 342, 343, 348, 373, 374) (Attachment A), to permit the use of food irradiation for growth and maturation inhibition of fresh food and to disinfest food of arthropod pests at doses not to exceed 1 kilogray (100 kilorad), and for microbial disinfection of spices at doses not to exceed 30 kilogray (3 megarad) (51 FR 13376). In March 1995, the regulations were amended to authorize irradiation of frozen packaged meats at doses not less than 44 kilogray (4.4 megarad) for the purposes of sterilization of meats used in NASA's space flight programs to control food-borne pathogens (60 FR 12670).

These regulations require that food processors who treat food with irradiation make, and retain for one year past the expected shelf life of the products with a maximum of three years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.). The regulations also require that these records be available for FDA inspection. The agency believes that this recordkeeping requirement does not impose an additional burden to food processors because such records would ordinarily be kept by these processors for their own use as a matter of good management procedures. The American Society for Testing and Materials (ASTM) has set forth requirements for the retention of records within their standards for the use of irradiation to treat foods (F 1356-93, Standard Guide for the Irradiation of Fresh and Frozen Red Meats and Poultry and E 1204-93, Standard Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing) which are similar to those set forth in 21 CFR 179.25(e). (Attachment B). The ASTM Standards are developed jointly with the cooperation of industry and government.

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

21 CFR 179.25(e) - Recordkeeping

Requires maintenance of records in irradiation treatment of foods.

2. Uses of the Information

The information is used by FDA inspectors, during routine establishment inspections, to assess compliance with the regulation that establishes limits within which irradiation 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 if they have been treated with ionizing radiation and are within the limitations set forth in 21 CFR part 179. Thus, records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

3. **Use of Improved Information Technology**

There is no reporting requirement. FDA regulations do not place restrictions on specific procedures for record retention. Therefore, use of improved technology appropriate to satisfy 21 CFR 179.25(e) is acceptable to the FDA.

4. **Efforts to Avoid Duplication and Unavailability of Similar Information**

There is no duplication at the federal level because no other federal agency requires this retention of records.

5. **Methods to Minimize Burden on Small Businesses**

A limited number of firms process food using irradiation. Consumer Safety Officers in the Office of Premarket Approval, Center for Food Safety and Applied Nutrition, at FDA are available by telephone to answer any questions about recordkeeping requirements.

6. **Consequences if Data Were Collected Less Frequently**

If the information required is not obtained and kept by the food processor, the FDA would, in most cases, be unable to verify that the food has been processed in accordance with applicable regulations.

7. **Special Circumstances**

None of the requirements are inconsistent with the guidelines in 5 CFR 1320.5.

8. **Outside Consultation**

On Wednesday, December 29, 1999 (64 FR 73054), a 60-day notice for public comment (Attachment C) was published in the Federal Register. No significant comments were received.

9. Payment or Gifts

No payment or gifts are offered to respondents for fulfilling their obligation to provide information.

10. Confidentiality

To the extent 21 CFR 20.64 applies, the FDA will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Sensitive Questions

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

12. Estimate of Burden

The total annual burden estimated for this collection is 360 hours.

Estimated Annual Recordkeeping Burden					
CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
179.25(e)	3	120	360	1	360

The number of firms who process food using irradiation is extremely limited. FDA estimates that there is a single irradiation plant whose business is devoted primarily (i.e., approximately 100 per cent) to irradiation of food and other agricultural products. Two other facilities also irradiate small quantities of food (mainly spices). FDA estimates that this irradiation accounts for no more than 10% of the business for each of these firms. Therefore, the average estimated burden is based on one (1) facility devoting 100% of its business (or 300 hours for recordkeeping annually) to food irradiation; and two (2) facilities devoting 10% of their business or 60 hours (2 x 30 hours) for recordkeeping annually, to food irradiation or (300 + 60)/3 = 120 x 3 firms x 1 hour = 360 hours annually.

No burden has been estimated for the labeling requirements in. §§ 179.21(b)(2)(I) and (b)(2)(ii) 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.

b. Estimated Annualized Cost for the Burden Hours.

The cost of the recordkeeping requirement to irradiation facilities is negligible because the recordkeeping requirement reflects customary business practice. Based on discussions with a representative of the industry, we estimate that the recordkeeping burden for a facility that is entirely devoted to food irradiation would be one hour per day for 300 days, for a total of 300 hours per year or 0.15 person years. A recordkeeper who earns a salary of approximately $22,000 annually at a full-time irradiation facility would thus cost such a firm $3,300. A recordkeeper who earns a salary of approximately $22,000 annually at a facility that devotes only 10% of its business to irradiation would cost a firm approximately $330.

13. Costs to the Respondent

There are no capital costs or operating and maintenance costs associated with this collection.

14. Cost to the Federal Government

FDA would inspect any firms who use irradiation to process food as part of its routine establishment inspection activities, even in the absence of the recordkeeping requirement in 21 CFR 179.25(e). FDA would devote approximately 5 hours per inspection to the inspection of records. If FDA were to inspect each of the three firms that irradiate food once each year, FDA would spend approximately 15 hours per year on this record inspection for a total cost to the government of approximately $1550. In practice, FDA has not inspected a food irradiation firm since 1992, and therefore the cost to the government has been substantially lower than this estimate.

15. **Changes or Adjustments in Burden**

There are no changes..

16. Statistical Analysis, Publication Plans, and Schedule

The information obtained from this data collection will not be published.

17. Approval Not to Display Expiration Dates

No approval requested.

18. Exception to Certification Statement

No exceptions requested.

B. Collections of Information Employing Statistical Methods

This collection of information does not employ statistical methods.