

impractical or when in-depth responses are required.

The evaluation information will be used to determine whether DHDSP activities and products are reaching the intended audiences, whether they are

deemed to be useful by those audiences, and whether DHDSP efforts improve public health practices. Finally, the generic clearance format will allow the DHDSP to identify new programmatic

opportunities and to respond to partners' concerns.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 491.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Data collection mechanism	Number of respondents	Average burden per response (in hours)
State and Local Health Departments .....	Web-based survey .....	250	30/60
	Interview .....	30	1
	Focus group .....	32	1
Private Sector Partners .....	Web-based survey .....	180	30/60
	Interview .....	90	1
	Focus group .....	48	1
Academic Institutions .....	Web-based survey .....	60	30/60
	Interview .....	30	1
	Focus group .....	16	1

Dated: May 14, 2009.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163-18-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2009-N-0043]

##### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Irradiation in the Production, Processing, and Handling of Food

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 22, 2009.

**ADDRESSES:** 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, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0186. Also

include the FDA docket number found in brackets in the heading of this document.

##### FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

##### Irradiation in the Production, Processing, and Handling of Food—(OMB Control Number 0910-0186)—Extension

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the 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 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.

In this request for extension of OMB approval, FDA proposes to include and consolidate into the subject collection of information (OMB control number 0910-0186) the collection of information and associated burden hours from OMB control number 0910-0549. This inclusion is reflected in the estimated burden reported in table 1 of this document, which has increased by the addition of one recordkeeper in the large processors line, increasing the number of estimated recordkeepers from two to three.

##### Description of Respondents:

Respondents are businesses engaged in the irradiation of food.

In the **Federal Register** of February 13, 2009 (74 FR 7236), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	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

<sup>1</sup>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 3 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: Three facilities devoting 100 percent of their business to food irradiation (3 × 300 hours = 900 hours for recordkeeping annually); four facilities devoting 10 percent of their business to food irradiation (4 × 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.

Dated: May 14, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases Diabetes Mellitus Interagency Coordinating Committee; Notice of Meeting

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), on behalf of the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Diabetes Mellitus Interagency Coordinating Committee (DMICC), is convening an ad hoc planning and evaluation meeting to provide a mid-course assessment of ongoing pre-clinical research efforts supported by the Special Statutory Funding Program for Type 1 Diabetes Research and to discuss possible future directions for these efforts.

Sessions of the meeting will be open to the public as indicated below, with attendance limited to space available. Certain sessions, during which confidential information will be discussed, will be closed to the public. Members of the public planning to attend the meeting must register online at: <http://www.scgcorp.com/Type1Diabetes09/registration.asp>. This is not a meeting to solicit public comment. Therefore, members of the public are permitted to attend the open sessions as observers only. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below at least 10 days in advance of the meeting.

**Name:** Meeting on Pre-Clinical Research Supported by the Special Statutory Funding Program for Type 1 Diabetes Research.

**Place:** National Institutes of Health, Neuroscience Building, 6001 Executive Blvd., Conference Room C, Bethesda, MD 20852.

**Date:** June 17, 2009.

**Open:** 8 a.m. to 8:45 a.m.

**Agenda:** Meeting introduction; overview of the Type 1 Diabetes—Rapid Access to Intervention Development (T1D-RAID) research program.

**Closed:** 8:45 a.m. to 9:30 a.m.

**Agenda:** Mid-course assessment of T1D-RAID.

**Open:** 9:30 a.m. to 10 a.m.

**Agenda:** Overview of the Type 1 Diabetes Preclinical Testing Program (T1D-PTP)—Prevention or Reversal of Type 1 Diabetes in Rodent Models.

**Closed:** 10 a.m. to 10:30 a.m.

**Agenda:** Mid-course assessment of the T1D-PTP—Prevention or Reversal of Type 1 Diabetes in Rodent Models.

**Open:** 10:45 a.m. to 11:15 a.m.

**Agenda:** Overview of the T1D-PTP—Prevention or Reversal of Diabetic Complications in Rodent Models.

**Closed:** 11:15 a.m. to 11:45 a.m.

**Agenda:** Mid-course assessment of the T1D-PTP—Prevention or Reversal of Diabetic Complications in Rodent Models.

**Open:** 12:30 p.m. to 1 p.m.

**Agenda:** Overview of the Animal Models of Diabetic Complications Consortium (AMDCC) research program.

**Closed:** 1 p.m. to 2 p.m.

**Agenda:** Mid-course assessment of the AMDCC.

**Open:** 2 p.m. to 2:30 p.m.

**Agenda:** Overview of the Type 1 Diabetes Resource.

**Closed:** 2:30 p.m. to 3:15 p.m.

**Agenda:** Mid-course assessment of the Type 1 Diabetes Resource.

**Open:** 3:30 p.m. to 4 p.m.

**Agenda:** Overview of Beta Cell Biology Consortium (BCBC).

**Closed:** 4 p.m. to 5 p.m.

**Agenda:** Mid-course assessment of the BCBC.

**Contact Person:** Julie Wallace, PhD, Health Science Policy Analyst, Office of Scientific Program and Policy Analysis, National Institute of Diabetes and Digestive and Kidney Diseases, 9000 Rockville Pike, Building 31, Room 9A05, Bethesda, MD 20892, (301) 496-6623, [wallaceja@niddk.nih.gov](mailto:wallaceja@niddk.nih.gov).