

has been in effect since 2012 and will expire in 2017, FDA has met or exceeded nearly all submission performance goals while implementing program enhancements designed to ensure more timely access to safe and effective medical devices.

- **Premarket Notifications (510(k)s):** Comparison of outcomes for receipt cohorts at the same levels of completion (or “closure”) show a 16 percent decrease in total review time between FY 2010 and FY 2013 when the cohort is 99.8 percent closed, and 10 percent decrease in total review time between FY 2010 and FY 2014 when the cohort is 75.8 percent closed.

- **Premarket Approvals (PMAs):** Comparison of outcomes for receipt cohorts at the same closure levels show a 32 percent decrease in total review times between FY 2009 and FY 2012 when the cohort is 98 percent closed, and a 26 percent decrease in total review times between FY 2009 and FY 2014 when the cohort is 41 percent closed.

FDA has met or exceeded all MDUFA III performance goals for FDA time to decisions in FY 2013 and FY 2014. More information about FDA’s performance is available in the yearly MDUFA performance reports, which are available online at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/UCM2007450.htm>.

User fees and related performance goals have played an important role in providing resources and supporting the process for the review of device applications.

### III. What information should you know about the meeting?

Through this notice, we are announcing a public meeting to hear stakeholder views on the reauthorization of MDUFA for fiscal years 2018 through 2022, including specific suggestions for any changes to the program that we should consider. We will conduct the meeting on July 13, 2015. In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder interest groups (such as patient advocates, consumer protection groups, industry, health care professionals, and academic researchers). FDA will also provide an opportunity for individuals to make presentations during the meeting and for organizations and individuals to submit written comments to the docket after the meeting. The presentations should focus on program improvements and funding issues, including specific

suggestions for changes to performance goals, and not focus on other general policy issues.

Dated: June 11, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–14885 Filed 6–16–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2012–N–0473]

#### 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 July 17, 2015.

**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: 202–395–7285, or emailed to [aira\\_submission@omb.eop.gov](mailto:aira_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:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Road; COLE–14526, Silver Spring, MD 20993–0002 [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**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—21 CFR Part 179 (OMB Control Number 0910–0186)—Extension

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 the emitted radiation. 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 records required by § 179.25(e) are 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. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

In the **Federal Register** of March 31, 2015 (80 FR 17055), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but did not respond to any of the four information collection topics solicited and is therefore not addressed by the Agency.

*Description of respondents:* Respondents are businesses engaged in the irradiation of food.

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

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

21 CFR section	Number of recordkeepers	Number 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.

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 four facilities devoting 100 percent of their business to food irradiation (4 × 300 hours = 1200 hours for recordkeeping annually), and 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), 179.21(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.

Dated: June 10, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-N-0115]

**Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; Guidance for Industry and Food and Drug Administration Staff—Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Principle**

**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 July 17, 2015.

**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: 202-395-7285, or emailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0594. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, *PRAStaff@fda.hhs.gov*.

**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.

**Guidance for Industry and FDA Staff—Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle (OMB Control Number 0910-0594)—Extension**

Under the Safe Medical Devices Act of 1990 (Pub. L. 101-629), FDA may establish special controls, including performance standards, postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of the safety and effectiveness of the device. The special control guidance serves to support the reclassification from class III to class II of the automated blood cell separator device operating on a centrifugal separation principle intended for the routine collection of blood and blood components as well as the special control for the automated blood cell separator device operating on a filtration separation principle intended for the routine collection of blood and blood components reclassified as class II (§ 864.9245 (21 CFR 864.9245)).

For currently marketed products not approved under the premarket approval process, the manufacturer should file with FDA, for 3 consecutive years, an annual report on the anniversary date of the device reclassification from class III to class II or on the anniversary date of the 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360) clearance. Any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the FD&C Act should be included in the annual report. Also, a manufacturer of a device determined to be substantially equivalent to the centrifugal or filtration-based automated cell separator device intended for the routine collection of blood and blood components should comply with the same general and special controls.

The annual report should include, at a minimum, a summary of anticipated and unanticipated adverse events that have occurred and that are not required to be reported by manufacturers under