

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](mailto: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](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.

#### 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

Medical Device Reporting (MDR) (part 803 (21 CFR part 803)). The reporting of adverse device events summarized in an annual report will alert FDA to trends or clusters of events that might be a safety issue otherwise unreported under the MDR regulation.

Reclassification of this device from class III to class II for the intended use of routine collection of blood and blood components relieves manufacturers of the burden of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by reducing the burden. Although the special control guidance recommends that manufacturers of these devices file with FDA an annual report for 3 consecutive years, this would be less burdensome than the current postapproval requirements under part

814, subpart E (21 CFR part 814, subpart E), including the submission of periodic reports under § 814.84.

Collecting or transfusing facilities and manufacturers have certain responsibilities under Federal regulations. For example, collecting or transfusing facilities are required to maintain records of any reports of complaints of adverse reactions (21 CFR 606.170), while the manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event (§ 803.50(b)). In addition, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§ 803.50).

In the special control guidance document, FDA recommends that manufacturers include in their three

annual reports a summary of adverse reactions maintained by the collecting or transfusing facility, or similar reports of adverse events collected, in addition to those required under the MDR regulation. The MedWatch medical device reporting code instructions (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm106737.htm>) contains a comprehensive list of adverse events associated with device use, including most of those events that we recommend summarizing in the annual report.

In the **Federal Register** of January 29, 2015 (80 FR 4927), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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

Reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Report .....	4	1	4	5	20

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

Based on FDA records, there are approximately four manufacturers of automated blood cell separator devices. The estimated average burden per response is based on the time that the manufacturers will spend preparing and submitting the annual report.

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910–0120 (premarket notification submission 501(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR, part 803).

Dated: June 10, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

[Document Identifier: HHS–OS–0990–new–30D]

### Agency Information Collection Activities; Proposed Collection; Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before July 17, 2015.

**ADDRESSES:** Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the document identifier HHS–OS–0990–new–30D for reference. Information Collection Request Title: Title X Sustainability Assessment Tool for Grantees and Service Sites.

**Abstract:** The Office of Population Affairs within the Office of the Assistant Secretary for Health seeks to collect data

from the Title X centers on efforts related to (1) assisting individuals in obtaining health insurance; (2) partnerships with primary care providers; (3) availability and use of electronic health records; (4) monitoring patient care quality; (5) factors affecting revenue sources; and (6) the way that sites conduct analyses to consider the cost of providing services.

**Need and Proposed Use of the Information:** The Title X Family Planning Program (“Title X program” or “program”) is the only Federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services (e.g., screening for breast and cervical cancer, sexually transmitted diseases (STDs), and human immunodeficiency virus [HIV]). By law, priority is given to persons from low-income families (Section 1006[c] of Title X of the Public Health Service Act, 42 U.S.C. 300). The Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health administers the Title X program.

The American health care system is experiencing unprecedented levels of change as a result of the Patient Protection and Affordable Care Act (ACA). The exact impact of these health system changes to Title X centers needs to be assessed in order to ensure the