FDA's guidance document states that the documentation condition would be met if the prescription for the compounded radiopharmaceutical makes clear that the prescriber identified the relevant change between the approved radiopharmaceutical and the compounded radiopharmaceutical and the clinical difference that the change produces for the patient.

(Comment 3) One commenter recommended that the guidance document require written documentation when a commercially manufactured radiopharmaceutical is compounded for a patient because the radiopharmaceutical is unavailable due to a drug shortage.

(Response 3) The guidance document explains that FDA does not consider a compounded radiopharmaceutical to be essentially a copy of a marketed FDA-approved radiopharmaceutical if the FDA-approved radiopharmaceutical is on FDA's drug shortage list (see section 506E of the FD&C Act (21 U.S.C. 356e)) at the time of compounding and distribution. FDA maintains a database for drug shortages. If the Agency identifies a compounded radiopharmaceutical that has the characteristics of a drug that is ''essentially a copy,'' FDA intends to review its database to determine whether there was a shortage of the approved radiopharmaceutical at the time of compounding and distribution.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of reporting	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Consultation between the compounder and prescriber and the notation on the prescription or order documenting the prescriber's determination of clinical difference.	10	25	250	0.05 (3 minutes)	12.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The total estimated third-party disclosure burden for the guidance document is shown above.

We estimate that a total of approximately 10 compounders annually (''No. of Respondents'' in table 1, line 1) will consult a prescriber to determine whether they decided that the compounded radiopharmaceutical has a change that produces a clinical difference for an identified individual patient as compared to the comparable approved radiopharmaceutical. We estimate that compounders will document this determination on approximately 250 prescriptions or orders for compounded radiopharmaceuticals (''Total Annual Disclosures'' in table 1, line 1). We estimate that the consultation between the compounder and the prescriber and noting this determination on each prescription or order that does not already document this determination will take approximately 3 minutes per prescription or order.

In the **Federal Register** of December 29, 2016 (81 FR 96011), FDA also estimated the annual recordkeeping burden for maintaining records of prescriptions or orders documenting certain information from prescribers. While acquiring additional information from the public about State pharmacy practices since we published 81 FR 96011, FDA has determined that because the time, effort, and financial resources necessary to comply with this collection of information would be incurred by compounders in the normal course of their activities, it is excluded from the definition of ''burden'' under 5 CFR 1320.3(b)(2). FDA understands that maintaining records of prescriptions for compounded drug products is part of the usual course of the practice of compounding and selling drugs and is required by States' pharmacy laws and other State laws governing record keeping by healthcare professionals and healthcare facilities.

Dated: July 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–15095 Filed 7–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0115]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and FDA Staff—Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 August 15, 2018.

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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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 as the special control for the automated blood cell separator device operating by centrifugal or filtration separation principle intended for the routine collection of blood and blood components (§ 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 (FD&C Act) (21 U.S.C. 360(k)) 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. The report should also include any subsequent change to the preamendments class III device requiring a 30-day notice in accordance with 21 CFR 814.39(f).

Reclassification of this device from class III to class II 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 21 CFR part 814, subpart E, including the submission of periodic reports under 21 CFR 814.84.

Collecting or transfusing facilities, the intended users of the device, and the device manufacturers have certain responsibilities under the 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 device 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) (21 CFR 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 the **Federal Register** of February 22, 2018, (83 FR 7745), 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 discussed here.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Report	3	1	3	5	15

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on FDA records, there are approximately three manufacturers of automated blood cell separator devices. We estimate that the manufacturers will spend approximately 5 hours preparing and submitting the annual report. The total burden hours are reduced from previous collections due to a decrease in the number of manufacturers.

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910–0120 (premarket notification submission 510(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR, part 803).

Dated: July 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–15089 Filed 7–13–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Declaration Regarding Emergency Use of Treatment for Uncontrolled Hemorrhage Due to Agents of Military Combat

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to the Federal Food, Drug, and Cosmetic (FD&C) Act. On June 7, 2018, Patrick M. Shanahan, Deputy Secretary of Defense, determined in accordance with the Federal Food, Drug and Cosmetic Act, as delegated by the Secretary of Defense, that there is a military emergency or significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces. More specifically, U.S. Forces are now deployed in multiple locations where they serve at