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.

(Response 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.

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 compounding pharmacist 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 a change in the status of a drug as compared to the comparable approved drug product. FDA estimates that the burden of this collection of information is as follows:

<table>
<thead>
<tr>
<th>Type of reporting</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultation between the compounding pharmacist and the prescriber and the notation on the prescription or order documenting the prescriber's determination of clinical difference.</td>
<td>10</td>
<td>25</td>
<td>250</td>
<td>0.05 (3 minutes)</td>
<td>12.5</td>
</tr>
</tbody>
</table>

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

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, PRASStaff@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,
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
requires 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>
<thead>
<tr>
<th>Reporting activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Report</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>5</td>
<td>15</td>
</tr>
</tbody>
</table>

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

Dated: July 9, 2018.

Leslie Kux,
Associate Commissioner for Policy.

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 particularly,
U.S. Forces are now deployed in
multiple locations where they serve at