TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

<table>
<thead>
<tr>
<th>21 CFR Section</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>610.2 (a)</td>
<td>73</td>
<td>92.9</td>
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<td>77</td>
<td>6,827</td>
</tr>
<tr>
<td>660.6(b)</td>
<td>2</td>
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<td>660.38(a) (2)</td>
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<tr>
<td>864.92(b)</td>
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<td>1</td>
<td>1</td>
<td>5</td>
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<tr>
<td>Total</td>
<td>77</td>
<td></td>
<td>6,827</td>
<td></td>
<td>20,572</td>
</tr>
</tbody>
</table>

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

Dated: July 6, 2012.

Leslie Kux,  
Assistant Commissioner for Policy.  
[FR Doc. 2012–17079 Filed 7–12–12; 8:45 am]

BILLING CODE 4160–01–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 Food and Drug Administration 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) 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 13, 2012.

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: Ila S. Mizrahi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, Ila.Mizrahi@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 Food and Drug Administration 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 device, 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.

Colleting or transfusing facilities, and 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 manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event (§ 803.30(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.

Based on FDA records, there are approximately four manufacturers of automated blood cell separator devices. We estimate that the manufacturers will spend approximately 5 hours 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, 21 CFR part 803).

Dated: July 6, 2012.

Leslie Kux,
Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration**

[Docket No. FDA–2012–P–0271]

**Determination That TOPOTECAN INJECTION (Topotecan Hydrochloride) 1 Milligram (Base)/1 Milliliter, 3 Milligram (Base)/3 Milliliters, 4 Milligram (Base)/4 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that TOPOTECAN INJECTION (topotecan hydrochloride) 1 milligram (mg) (base)/1 milliliter (mL), 3 mg (base)/3 mL, 4 mg (base)/4 mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for topotecan hydrochloride intravenous solution 1 mg (base)/1 mL, 3 mg (base)/3 mL, 4 mg (base)/4 mL, if all other legal and regulatory requirements are met.

In the **Federal Register** of February 15, 2012 (77 FR 8879), 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>
<thead>
<tr>
<th>Reporting activity</th>
<th>Number of respondents</th>
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<td>5</td>
<td>20</td>
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1 There are no capital costs or operating and maintenance costs associated with this collection of information.