TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
610.2	73	92.9	6,782	3	20,346
660.6(b)	2	21.5	43	5	215
660.36(a) (2) and (b)	1	1	1	6	6
660.46(b)	1	1	1	5	5
Total	77		6,827		20,572

[1] 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. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@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 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 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 (§ 803.50(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 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 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 Reporting	4	1	4	5	20

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

Based on FDA records, there are approximately four manufactures 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.

[FR Doc. 2012–17080 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–P–0271]

Determination That TOPOTECAN INJECTION (Topotecan Hydrochloride) 1 Milligram (Base)/1 Milliliter, 3 Milligram (Base)/3 Milliliter, 4 Milligram (Base)/4 Milliliter, 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.

FOR FURTHER INFORMATION CONTACT: Rachel Turow, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–5094.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

TOPOTECAN INJECTION (topotecan hydrochloride) 1 mg (base)/1 mL, 3 mg (base)/3 mL, 4 mg (base)/4 mL, is the subject of NDA 200199, held by Sandoz Inc., and initially approved on February 25, 2011. TOPOTECAN INJECTION is indicated for the treatment of small cell lung cancer sensitive disease after failure of first-line chemotherapy. In clinical studies submitted to support approval, sensitive disease was defined as disease responding to chemotherapy but subsequently progressing at least 60 days (in the phase 3 study) or at least 90 days (in the phase 2 studies) after chemotherapy. TOPOTECAN INJECTION in combination with cisplatin is indicated for the treatment of stage IV–B, recurrent, or persistent carcinoma of the cervix, which is not amenable to curative treatment with surgery and/or radiation therapy.

Sandoz Inc. has never marketed TOPOTECAN INJECTION (topotecan hydrochloride) 1 mg (base)/1 mL, 3 mg (base)/3 mL, 4 mg (base)/4 mL. In previous instances (see, e.g., 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved