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1 Milligram (Base)/1 Milliliter, 3 Milligram (Base)/3 Milliliter, 4 Milligram (Base)/4 Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(topotecan hydrochloride) 1 milligram (mg) (base)/1 milliliter (mL), 3 mg (base)/3 mL, 4 mg (base)/4 mL, was not withdrawn from sale for reasons of safety or effectiveness.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

drug product is equivalent to withdrawing the drug from sale.

Lachman Consultant Services, Inc., submitted a citizen petition dated March 14, 2012 (Docket No. FDA–2012–P–0271), under 21 CFR 10.30, requesting that the Agency determine whether TOPOTECAN INJECTION (topotecan hydrochloride) 1 mg (base)/1 mL, 3 mg (base)/3 mL, 4 mg (base)/4 mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that TOPOTECAN INJECTION (topotecan hydrochloride) 1 mg (base)/1 mL, 3 mg (base)/3 mL, 4 mg (base)/4 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TOPOTECAN INJECTION (topotecan hydrochloride) 1 mg (base)/1 mL, 3 mg (base)/3 mL, 4 mg (base)/4 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TOPOTECAN INJECTION (topotecan hydrochloride) 1 mg (base)/1 mL, 3 mg (base)/3 mL, 4 mg (base)/4 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TOPOTECAN INJECTION (topotecan hydrochloride) 1 mg (base)/1 mL, 3 mg (base)/3 mL, 4 mg (base)/4 mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to TOPOTECAN INJECTION (topotecan hydrochloride) 1 mg (base)/1 mL, 3 mg (base)/3 mL, 4 mg (base)/4 mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 10, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–17090 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–2011–P–0081]

Determination That CHLOROMYCETIN (Chloramphenicol) Capsules, 250 Milligrams, Were 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 CHLOROMYCETIN (chloramphenicol) Capsules, 250 milligrams (mg), were withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for chloramphenicol capsules, 250 mg.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6312, Silver Spring, MD 20993–0002, 301–796–3601.

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 known generally 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 (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.

CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, are the subject of ANDA 60–591, held by Parkedale Pharmaceuticals, and initially approved on December 8, 1950. CHLOROMYCETIN is an antibiotic indicated to treat only serious infections for which less potentially dangerous drugs are ineffective or contraindicated.

In a letter dated October 9, 2007, Parkedale Pharmaceuticals requested withdrawal of ANDA 60–591 for CHLOROMYCETIN (chloramphenicol) Capsules, 50 mg, 100 mg and 250 mg. In the **Federal Register** of February 11, 2009 (74 FR 6896), FDA announced that it was withdrawing approval of ANDA 60–591, effective March 13, 2009, and moved the drug to the ''Discontinued Drug Product List'' section of the Orange Book.

Armenpharm, Ltd., submitted a citizen petition dated February 7, 2011 (Docket No. FDA–2011–P–0081), under 21 CFR 10.30, requesting that the Agency determine whether CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition, and based on the information we have at this time, FDA has determined under § 314.161 that CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed Agency records concerning the withdrawal of CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. At the time of the approval of CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, there was significant unmet medical need. With the approval of additional therapies with less severe adverse drug effects, FDA has determined that the risks associated with CHLOROMYCETIN (chloramphenicol) Capsules, 250 mg, as currently labeled, outweigh the benefits. Most importantly, CHLOROMYCETIN