TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section/FDA Form No.	Number of respondents [4]	Number of responses per respondent	Total annual responses	Average burden per response (in Hours)	Total hours
558.5(i)	154	.01	1.54	5	8
514.1(b)(8) and 514.8(c)(1) [3]	154	.21	32.34	90	2,911
FDA Form 356V	154	5.1	785.4	5	3,927
Total					33,319

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Substantial Evidence—Because 21 CFR 514.4 only defines substantial evidence, it should not be viewed as creating additional collection burden.
[3] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall preapproval safety evaluation.
[4] Based on the number of sponsors subject to animal drug user fees, FDA estimates that there was an average of 154 annual respondents during the 5 fiscal years, from October 1, 2005, through September 30, 2010, on which these estimates were made. We use this estimate consistently throughout the table and calculate the "annual frequency per respondent" by dividing the total annual responses by the number of respondents.

Dated: April 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8906 Filed 4–12–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0485]

Determination That NOVANTRONE (Mitoxantrone Hydrochloride) Injection, Equivalent to 25 Milligrams Base/12.5 Milliliter and Equivalent to 30 Milligrams Base/15 Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 NOVANTRONE (mitoxantrone hydrochloride) Injection, equivalent to (EQ) 25 milligrams (mg) base/12.5 milliliters (mL) and EQ 30 mg base/15 mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Rachel Bressler, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6302, Silver Spring, MD 20993–0002, 301–796–4288.

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.

NOVANTRONE (mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 mL, is the subject of NDA 19–297, held by EMD Serono, and initially approved on December 23, 1987. NOVANTRONE is indicated for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (*i.e.,* patients whose neurologic status is significantly abnormal between relapses). NOVANTRONE (mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 mL, is currently listed in the "Discontinued Drug Product List" section of the Orange Book. There are approved ANDAs for NOVANTRONE (mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 mL; these ANDAs are listed in the Orange Book.

Apotex, Inc., submitted a citizen petition dated September 3, 2008 (Docket No. FDA–2008–P–0485), under 21 CFR 10.30, requesting that the Agency determine whether NOVANTRONE (mitoxantrone hydrochloride) Injection, 25 mg/12.5 mL and 30 mg/15 mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that NOVANTRONE (mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NOVANTRONE

(mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NOVANTRONE (mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 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 NOVANTRONE (mitoxantrone hydrochloride) Injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to NOVANTRONE Injection. Additional ANDAs for mitoxantrone hydrochloride injection, EQ 25 mg base/12.5 mL and EQ 30 mg base/15 mL, may also 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: April 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8819 Filed 4–12–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0164]

Draft Guidance for Industry on Safety Labeling Changes; Implementation of the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act." The Food and Drug Administration Amendments Act of 2007 (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) authorizing FDA to require certain drug and biological product application holders to make safety related labeling changes based upon new safety information that becomes available after the drug or biological product is approved under the FD&C Act or the Public Health Service Act (the PHS Act). This draft guidance provides information on the implementation of the new provisions, including a description of the types of safety labeling changes that ordinarily might be required under the new legislation, how FDA plans to determine what constitutes new safety information, the procedures involved in requiring safety labeling changes, and enforcement of the requirements for safety labeling changes.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 12, 2011.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kristen Everett, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–796–5400, or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act." In the past, FDA has requested that holders of applications for approved products make labeling changes related to safety after approval to address serious risks. FDA learned of the potential for such serious risks from a variety of sources. In most cases, application holders responded to these requests by negotiating appropriate language with FDA staff to address the concerns, and then submitting a supplement or amended supplement to obtain approval of the change. Negotiations were often protracted, and FDA had few tools available at its disposal to end negotiations and require the changes. Congress recognized the limitations of FDA's authority in this area and, in FDAAA, gave FDA new authority to require safety labeling changes in certain circumstances.

Title IX, section 901 of FDAAA (Pub. L. 110–85) amended the FD&C Act by adding new section 505(o)(4) (21 U.S.C. 355(o)(4)). Section 505(o)(4) authorizes FDA to require, and if necessary, order labeling changes if FDA becomes aware of new safety information that FDA believes should be included in the labeling of certain prescription drug and biological products approved under section 505 of the FD&C Act or section 351 of the PHS Act (42 U.S.C. 262). Specifically, section 505(o)(4) of the FD&C Act applies to prescription drug products with an approved new drug application (NDA) under section 505(b) of the FD&C Act, biological products with an approved biologics license application (BLA) under section 351 of the PHS Act, or prescription drug products with an approved abbreviated new drug application (ANDA) under section 505(j) of the FD&C Act if the reference listed drug (RLD) with an approved NDA is not currently marketed. FDAAA imposes timeframes for application holders to submit and FDA staff to review such changes, and gives FDA new enforcement tools to bring about timely and appropriate labeling changes. This draft guidance provides information on the implementation of the new provisions, including a description of the types of safety labeling changes that ordinarily