

Dated: April 7, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0049]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Presubmission Conferences, New Animal Drug Applications and Supporting Regulations, and Food and Drug Administration Form 356V

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 May 13, 2011.

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 e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0032. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-

796-7651,
Juanmanuel.vilela@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.

Presubmission Conferences, New Animal Drug Applications and Supporting Regulations, and FDA Form 356V—(OMB Control Number 0910-0032)—Extension

Under section 512(b)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(b)(3)), any person intending to file a new animal drug application (NADA) or supplemental NADA or a request for an investigational exemption under section 512(j) is entitled to one or more conferences with FDA to reach an agreement acceptable to FDA establishing a submission or investigational requirement. FDA and industry have found that these meetings have increased the efficiency of the drug development and drug review processes.

Section 514.5 (21 CFR 514.5) describes the procedures for requesting, conducting, and documenting presubmission conferences. Section 514.5(b) describes the information that must be included in a letter submitted by a potential applicant requesting a presubmission conference, including a proposed agenda and a list of expected participants. Section 514.5(d) describes the information that must be provided by the potential applicant to FDA at least 30 days prior to a presubmission conference. This information includes a detailed agenda, a copy of any materials to be presented at the conference, a list of proposed indications and, if available, a copy of the proposed labeling for the product under consideration, and a copy of any background material that provides scientific rationale to support the potential applicant's position on issues listed in the agenda for the conference. Section 514.5(f) discusses the content of the memorandum of conference that

will be prepared by FDA and gives the potential applicant an opportunity to seek correction to or clarification of the memorandum.

Under section 512(b)(1) of the FD&C Act, any person may file an NADA seeking approval to legally market a new animal drug. Section 512(b)(1) of the FD&C Act sets forth the information required to be submitted in an NADA. FDA allows applicants to submit a complete NADA or to submit information in support of an NADA for phased review followed by submission of an Administrative NADA when FDA finds all the applicable technical sections are complete.

The regulations under 21 CFR 514.1 interpret section 512(b)(1) of the FD&C Act and further describe the information that must be submitted as part of an NADA and the manner and form in which the NADA must be assembled and submitted. The application must include safety and effectiveness data, proposed labeling, product manufacturing information, and where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food-producing animals. Guidance #152 entitled "Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern" outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. FDA requests that an applicant accompany NADAs, supplemental NADAs, and requests for phased review of data to support NADAs, with the FDA Form 356V to ensure efficient and accurate processing of information to support new animal drug approval.

In the **Federal Register** of February 8, 2011 (76 FR 6798), 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

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
514.5(b), (d) and (f)	154	.6	92.4	50	4,620
514.1 and 514.6	154	.1	15.4	212	3,265
514.4 ²	154	0	0	0	0
514.8(b)	154	2.84	437.36	35	15,308
514.8(c)(1)	154	.1	15.4	71	1,093
514.8(c)(2) and (c)(3)	154	.7	107.8	20	2,156
514.11	154	.2	30.8	1	31

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹—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.

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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 from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NOVANTRONE