

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-196T	51	4	2	408
ACF-196	51	4	8	1,632

Estimated Total Annual Burden Hours: 2,040.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,
Reports Clearance Officer.
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BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-P-0170]

Determination That REQUIP XL (Ropinerole Hydrochloride) Extended-Release Tablets, 3 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA) has determined that REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ropinerole hydrochloride extended-release tablets, 3 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Jay Sitlani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6370, 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 (§ 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.

REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, are the subject of NDA 22-008, held by GlaxoSmithKline, and initially approved on June 13, 2008. REQUIP XL is indicated for the treatment of treatment of signs and symptoms of idiopathic Parkinson's disease.

REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, are currently listed in the "Discontinued Drug Product List" section of the Orange Book. GlaxoSmithKline has never marketed REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg. In previous instances (see, e.g., 72 FR 9763, 61 FR 25497), 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 April 1, 2009 (Docket No. FDA-2009-P-0170), under 21 CFR 10.30, requesting that the Agency determine whether REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, were 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 REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, 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 REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, 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 REQUIP XL (ropinerole hydrochloride) extended-release tablets, 3 mg, 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: February 14, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-3954 Filed 2-17-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0097]

Draft Guidance for Industry on Providing Submissions in Electronic Format—Standardized Study Data; 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 “Providing Submissions in Electronic Format—Standardized Study Data.” This draft guidance establishes FDA’s recommendation that sponsors and applicants submit nonclinical and clinical study data in a standardized electronic format. The draft guidance recognizes that standardized study data promotes the efficient review of this information. The purpose of this draft guidance is to promote the use of data standards for study data, and increase the number of standardized study data submissions to the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health.

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 either electronic or written comments on the draft guidance by April 23, 2012.

ADDRESSES: Submit written requests for single copies of the draft 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, suite 200N, 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kieu Pham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4677, Silver Spring, MD 20993-0002, 301-796-1616, or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210, or

Terrie Reed, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3324, Silver Spring, MD 20993-0002, 301-796-6130.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Providing Submissions in Electronic Format—Standardized Study Data.” FDA routinely receives submissions of the results of scientific studies, including clinical trials and animal studies. For many years, FDA has requested that clinical study data be submitted electronically because paper case report tabulations (CRTs) are universally recognized as being highly inefficient to support analysis and review. The data in paper CRTs are not machine-readable and therefore cannot be easily analyzed using modern analytic software. Although submission of clinical study data in electronic format has become relatively routine, these data are often submitted using nonstandard formats.

FDA has long recognized the advantage of standardizing study data, as have many sponsors and applicants. Data submitted in a standard electronic format are easier to understand, analyze, and review.

This draft guidance establishes FDA’s recommendation that sponsors and applicants submit clinical and nonclinical study data in a standard electronic format. As sponsors and applicants move toward standardized electronic study data submissions, there is a need to understand FDA’s expectations for such data submissions. This draft guidance provides FDA’s current thinking on the submission of study data in a standard electronic format.

The draft guidance refers submitters to FDA’s Study Data Standards Resource Web page at <http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>, where there is useful information describing which data standards to use and how to use them.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on submitting standardized study data in electronic format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the