

Control Number 0910–0572) estimated the reporting burden for a multi-year period. We are requesting that OMB extend approval for the information in this collection, as described below, which will continue to be submitted to FDA during this multi-year period.

**Annual Burden for Prescription Drug Labeling Design, Testing, and Submitting to FDA for New Drug Applications (NDAs) and Biologics License Applications (BLAs) (§§ 201.56 and 201.57) (Table 1)**

New drug product applicants must: (1) Design and create prescription drug labeling containing Highlights, Contents, and FPI; (2) test the designed labeling (e.g., to ensure that the designed labeling fits into carton-enclosed products); and (3) submit it to

FDA for approval. Based on the projected data estimated in the final rule, FDA estimates that it takes applicants approximately 3,349 hours to design, test, and submit prescription drug labeling to FDA as part of an NDA or a BLA under the revised regulations. Approximately 84 applicants submit approximately 105 new applications (NDAs and BLAs) to FDA per year, totaling 351,645 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED REPORTING BURDEN FOR NEW DRUG APPLICATIONS <sup>1</sup>

Category (21 CFR section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Burden for Labeling Requirements in §§ 201.56 and 201.57 .....	84	1.25	105	3,349	351,645

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 14, 2011.

**David Dorsey,**

*Acting Associate Commissioner for Policy and Planning.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2011–P–0578]

**Determination that Bretylium Tosylate Injection, 50 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**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Drug Administration (FDA) has determined that Bretylium Tosylate injection, 50 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness.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 Bretylium Tosylate injection, 50 mg/mL, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:**

Molly Flannery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6246, Silver Spring, MD 20993–0002, (301) 796–3543.

**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.

Bretylium Tosylate injection, 50 mg/mL, is the subject of NDA 19–030, held by Hospira, Inc., and initially approved on April 16, 1986. Bretylium Tosylate injection, 50 mg/mL, is indicated in the prophylaxis and therapy of ventricular fibrillation and in the treatment of life-threatening ventricular arrhythmias, such as ventricular tachycardia, that have failed to respond to adequate doses of a first-line antiarrhythmic agent, such as lidocaine.

In a letter dated June 17, 2010, Hospira, Inc. requested withdrawal of NDA 19–030 for Bretylium Tosylate injection, 50 mg/mL. In the **Federal Register** of June 8, 2011 (76 FR 33310), FDA announced that it was withdrawing approval of NDA 019030, effective July 8, 2011.

Academic Pharmaceuticals, Inc. submitted a citizen petition dated July 27, 2011 (Docket No. FDA–2011–P–0578), under 21 CFR 10.30, requesting that the Agency determine whether Bretylium Tosylate injection, 50 mg/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 Bretylium Tosylate injection, 50 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed the information provided by the petitioner and our files for records concerning the withdrawal of Bretylium

Tosylate injection, 50 mg/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 Bretylium Tosylate injection, 50 mg/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 Bretylium Tosylate injection, 50 mg/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: December 12, 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-D-0817]

#### **Draft Guidance for Industry and Food and Drug Administration Staff; Evaluation of Sex Differences in Medical Device Clinical Studies; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Evaluation of Sex Differences in Medical Device Clinical Studies." This document provides guidance on the study and evaluation of sex differences in medical device clinical trials, with a specific focus on addressing potential differences in study design, conduct, outcomes, and interpretation that should be considered to ensure sex-specific issues are adequately addressed in clinical trials. This draft guidance is not final nor is it in effect at this time.

**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 of 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 March 19, 2012.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Evaluation of Sex Differences in Medical Device Clinical Studies" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to (301) 847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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. Identify comments with the docket number found in brackets in the heading of this document.

#### **FOR FURTHER INFORMATION CONTACT:**

Kathryn O'Callaghan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1546, Silver Spring, MD 20993-0002, (301) 796-6349.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The purpose of this guidance is to outline the Center for Devices and Radiological Health's (CDRH's) expectations regarding sex-specific patient enrollment, data analysis, and reporting of study information. The intent is to improve the quality and consistency of available data regarding the performance of medical devices in women. This information can be of benefit to patients and their medical providers, as well as clinical researchers and others. The specific objectives of this guidance are to: (1) Better communicate the balance of risks and benefits of FDA-approved or cleared medical devices; (2) identify sex-specific questions for further study; and (3) encourage the consideration of sex and associated covariates (e.g., body size, plaque morphology, etc.) during the trial design stage.

## **II. Significance of Guidance**

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 "Evaluation of Sex Differences in Medical Device Clinical Studies." 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 requirements of the applicable statute and regulations.

## **III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Evaluation of Sex Differences in Medical Device Clinical Studies," you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to (301) 847-8149 to receive a hard copy. Please use the document number 1727 to identify the guidance you are requesting.

## **IV. Paperwork Reduction Act of 1995**

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 812.25(c) have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 807 Subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814 Subparts B and E have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 814 Subpart H have been approved under OMB control number 0910-0332; the collections of information in 21 CFR part 822 have been approved under OMB control number 0910-0449.

## **V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments.