DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0883]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's requirements on content and format of labeling for human prescription drug and biological products.

DATES: Submit either electronic or written comments on the collection of information by February 17, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products (OMB Control Number 0910–0572)—Extension

FDA's final rule entitled ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products'' (the Final Rule), which published on January 24, 2006 (71 FR 3922), and was effective on June 30, 2006, amended FDA's regulations governing the format and content of labeling for human prescription drug and biological products to require that the labeling of new and recently approved products contain highlights of prescribing information, a table of contents for prescribing information, reordering of certain sections, minor content changes, and minimum graphical requirements. These revisions were intended to make it easier for health care practitioners to access, read, and use information in prescription drug labeling; to enhance the safe and effective use of prescription drug products; and to reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information.

A. Summary of Prescription Drug Labeling Content and Format Requirements That Contain Collections of Information

Section 201.56 (21 CFR 201.56) requires that prescription drug labeling contain certain information in the format specified in either § 201.57 (21 CFR 201.57) or § 201.80 (21 CFR 201.80), depending on when the drug was approved for marketing. Section 201.56(a) sets forth general labeling requirements applicable to all prescription drugs. Section 201.56(b) specifies the categories of new and more recently approved prescription drugs subject to the revised content and format requirements in §§ 201.56(d) and 201.57. Section 201.56(c) sets forth the schedule for implementing these revised content and format requirements. Section 201.56(e) specifies the sections and paragraphs, required and optional, for the labeling of older prescription drugs not subject to the revised format and content requirements.

Section 201.57(a) requires that prescription drug labeling for new and more recently approved prescription drug products include ''Highlights of Prescribing Information.'' Highlights provides a concise extract of the most important information required under § 201.57(c) (the Full Prescribing Information (FPI)), as well as certain additional information important to prescribers. Section 201.57(b) requires a table of contents to prescribing information, entitled ''Full Prescribing Information: Contents,'' consisting of a list of each heading and subheading along with its identifying number to facilitate health care practitioners' use of labeling information. Section 201.57(c) specifies the contents of the FPI. Section 201.57(d) mandates the minimum specifications for the format of prescription drug labeling and establishes minimum requirements for key graphic elements such as bold type, bullet points, type size, and spacing.

Older drugs not subject to the revised labeling content and format requirements in § 201.57 remain subject to labeling requirements at § 201.80 (in the final rule, former § 201.57 was redesignated as § 201.80). Section 201.80(f)(2) requires that within 1 year, any FDA-approved patient labeling be referenced in the ''Precautions'' section of the labeling of older products and either accompany or be reprinted immediately following the labeling.

B. Estimates of Reporting Burden

The PRA information collection analysis in the final rule (71 FR 3964–3967) (currently approved under OMB

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 [1]

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

[1] 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.

[FR Doc. 2011–32397 Filed 12–16–11; 8:45 am]

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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 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