4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0493]

Agency Information Collection Activities; Proposed Collection; Comment Request; Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded

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 collection of information associated with the criteria and procedures for classifying over-the-counter (OTC) drugs as generally recognized as safe and effective and not misbranded, in accordance with regulations and discussed in the Guidance for Industry "Time and Extent Applications for Nonprescription Drug Products."

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@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.

Additional Criteria and Procedures for Classifying OTC Drugs as Generally Recognized as Safe and Effective and Not Misbranded--21 CFR 330.14 (OMB Control Number 0910-0688)--Extension

In the Federal Register of January 23, 2002 (67 FR 3060), we established regulations in § 330.14 (21 CFR 330.14) providing additional criteria and procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded (2002 time and extent application (TEA) final rule). These regulations state that OTC drug products introduced into the U.S. market after the OTC drug review began and OTC drug products without any marketing experience in the United States can be evaluated under the monograph process if the conditions (e.g., active ingredients) meet certain "time and extent" criteria outlined in § 330.14(b). The regulations allow a TEA to be submitted to us by any party for our consideration to include new conditions in the OTC drug monograph system. TEAs must provide evidence described in § 330.14(c) demonstrating that the condition is eligible for inclusion in the monograph system. (Section 330.14(d) specifies the number of copies and address for submission of a TEA.) If a condition is found eligible, any interested parties can submit safety and effectiveness information as explained in § 330.14(f). Safety and effectiveness data includes the data and information listed in 21 CFR 330.10(a)(2), a listing of all serious adverse drug experiences that may have occurred, and an official or proposed compendial monograph. We published the Guidance for Industry "Time and Extent Applications for Nonprescription Drug Products" in September 2011.

In the Federal Register of February 8, 2011 (76 FR 6801), we published a 60-day notice requesting public comment on the proposed collection of information. In that notice, we stated

that, based on the number of submissions we had received in the 8 years following publication of the TEA final rule, we expected to receive an average of two TEAs and two submissions of safety and effectiveness data each year. In the same document, we stated our estimate that approximately 1,525 hours are required to prepare a TEA and approximately 2,350 hours to prepare a safety and effectiveness submission. This estimate is based on a comment from a manufacturer that filed two TEAs that was submitted to the Agency in response to the 60-day notice requesting public comment on this proposed collection of information in the Federal Register of October 8, 2010, (75 FR 62404). The commenter included, as part of the estimated burden of safety and effectiveness data submission, an estimate to submit environmental data to conduct an environmental assessment, as required by the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 et seq.) (see 21 CFR 25.1), or the application of any categorical exclusion that may be warranted (21 CFR 25.20(f)). Because the information provided in the submission is based on actual experience by a TEA applicant and included an estimated burden to comply with NEPA, we agreed with the submission and adjusted our estimates accordingly. Based on our experience since the February 8, 2011, Federal Register notice, we continue to estimate that we will receive two TEAs and two safety and effectiveness submissions each year, and that it will take approximately 1,525 hours to prepare a TEA and 2,350 hours to prepare a comprehensive safety and effectiveness submission, to include environmental data.

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
330.14(c)--Time & Extent Application and (d)[2]--submission of information; confidentiality	2	1	2	1,525	3,050
330.14(f)--Request for data and views and (i)[3]--compendial monograph	2	1	2	2,350	4,700
Total					7,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] TEA.
[3] Safety and effectiveness submission, including environmental data in accordance with 21 CFR 25.1.

Dated: March 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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