4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded--Time and Extent Applications for Nonprescription Drug Products

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: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0688. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@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.

Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded--Time and Extent Applications for Nonprescription Drug Products (21 CFR 330.14)

OMB Control Number 0910-0688--Extension

This information collection supports Agency regulations and associated guidance. Specifically, FDA regulations in § 330.14 (21 CFR 330.14) establish additional criteria and procedures for classifying over-the-counter (OTC) drugs as generally recognized as safe and effective and not misbranded. These regulations state that OTC drug products introduced into the U.S. market after the OTC drug review began in 1972 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 the regulations. The regulations allow a time and extent application (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 include the data and information listed in 21 CFR 330.10(a)(2), a listing of all

serious adverse drug experiences that may have occurred (§ 330.14(f)(2)), and an official or proposed compendial monograph (§ 330.14(i)).

Based on our experience with submissions we have received under § 330.14, we estimate that we will receive two TEAs and two safety and effectiveness submissions each year and assume that it will take 1,525 hours to prepare a TEA and 2,350 hours to prepare a comprehensive safety and effectiveness submission.

We revised our regulations in part 330 (21 CFR part 330) (81 FR 84465, November 23, 2016), thus adding 6 hours to our estimated annual reporting burden for the information collection. Specifically, § 330.14(j) clarifies the requirements on content and format criteria for a safety and effectiveness data submission and provides procedures for our review of the submissions and determination of whether a submission is sufficiently complete to permit a substantive review.

Section 330.14(j)(3) describes the process for cases in which we refuse to file the safety and effectiveness data submission. Under § 330.14(j)(3), if we refuse to file the submission, we will notify the sponsor in writing, state the reason(s) for the refusal, and allow the sponsor 30 days to submit a written request for an informal conference with us about whether we should file the submission. We estimate one respondent will submit a request for an informal conference each year and assume that preparing and submitting each request will take 1 hour.

Under § 330.14(j)(4)(iii), the safety and effectiveness data submission must contain a signed statement that the submission represents a complete safety and effectiveness data submission and that the submission includes all the safety and effectiveness data and information available to the sponsor at the time of the submission, whether positive or negative. We estimate

that two respondents will submit such signed statements each year and assume that preparing and submitting each signed statement takes 1 hour.

Under § 330.14(k)(1), we, in response to a written request from a sponsor, may withdraw consideration of a TEA submitted under § 330.14(c) or a safety and effectiveness data submission under § 330.14(f). We estimate that one respondent will submit such a request each year and assume that preparing and submitting the request takes 1 hour.

Under § 330.14(k)(2), a sponsor may request that FDA not withdraw consideration of a TEA or safety and effectiveness data submission. We estimate one respondent will submit such a request each year and assume that preparing and submitting the request takes 2 hours.

To assist respondents with the information collection, we developed the guidance document entitled "Time and Extent Applications for Nonprescription Drug Products" (available from our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/time-and-extent-applications-nonprescription-drug-products) issued consistent with our good guidance practice regulations at 21 CFR 10.115, which provide for comment at any time. The guidance explains what information an applicant should submit to FDA to request that a drug product be included in the OTC drug monograph system and describes the process for submitting that information.

In the *Federal Register* of July 30, 2020 (85 FR 45892), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

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

21 CFR Part and Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Time and extent application and submission of information (§ 330.14(c) and (d))	2	1	2	1,525	3,050
Safety and effectiveness data (§ 330.14(f) and (i))	2	1	2	2,350	4,700
Sponsor request for an informal conference (§ 330.14(j)(3))	1	1	1	1	1
Sponsor signed statement that submission is complete (§ 330.14(j)(4))	2	1	2	1	2
Sponsor request for FDA to withdraw TEA consideration (§ 330.14(k)(1))	1	1	1	1	1
Sponsor request for FDA not to deem the submission withdrawn (§ 330.14(k)(2))	1	1	1	2	2
Total					7,756

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: October 14, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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