

appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 21, 2020. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

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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 November 23, 2020.

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, PRASStaff@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	Number 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.

[FR Doc. 2020-23357 Filed 10-21-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5925]

21st Century Cures Act: Annual Compilation of Notices of Updates From the Susceptibility Test Interpretive Criteria Web Page; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of the Agency’s annual compilation of notices of updates to the Agency’s Susceptibility Test Interpretive Criteria web page. The Agency established the Susceptibility Test Interpretive Criteria web page on December 13, 2017, and since establishment has provided updates to both the format of the web pages and to the susceptibility test interpretive criteria identified and recognized by FDA on the web pages. FDA is publishing this notice in

accordance with procedures established by the 21st Century Cures Act (Cures Act).

DATES: This notice is published in the **Federal Register** on October 22, 2020.

ADDRESSES: You may submit either electronic or written comments and information as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2017-N-5925 for “Susceptibility Test Interpretive Criteria Recognized and Listed on the Susceptibility Test Interpretive web page; Request for Comments.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The