## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–N–1095]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health

**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:** Fax written comments on the collection of information by September 22, 2017.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0769. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

#### Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health—OMB Control Number 0910–0769—Extension

This information collection request collects information voluntarily submitted to Center for Devices and Radiological Health (CDRH) on actual or potential health risk concerns about a medical device or radiological product or its use. Because, prior to the establishment of the electronic submission process for voluntary allegations to CDRH, there had been no established guidelines or instructions on how to submit an allegation to CDRH, allegations often contained minimal information and were received via phone calls, emails, or conversationally. CDRH has established a consistent format and process for the submission of device allegations that enhances our timeliness in receiving, assessing, and evaluating voluntary allegations. The information provided in the allegations received by CDRH may be used to clarify the recurrence or emergence of significant device-related risks to the general public and the need to initiate educational outreach or regulatory action to minimize or mitigate identified risks.

In the **Federal Register** of May 30, 2017 (82 FR 24716) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Electronic submission of voluntary allegations to CDRH. | 700 | 1 | 700 | .25 (15 minutes) ..... | 175 |

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

Dated: August 17, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–17836 Filed 8–22–17; 8:45 am]

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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

**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:** Fax written comments on the collection of information by September 22, 2017.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 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, 10A63, 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—21 CFR 330.14, OMB Control Number 0910–0688—Revision

This information collection supports Agency regulations. Specifically, FDA regulations at § 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 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 includes the data and information listed in § 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 that it will take approximately 1,525 hours to prepare a TEA and 2,350 hours to prepare a comprehensive safety and effectiveness submission. This information is reflected in rows 1 and 2 of table 1.

Recently FDA revised its regulations at 21 CFR part 330 (81 FR 84465, November 23, 2016), thus adding 6 hours to FDA's 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 FDA's 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 FDA refuses to file the safety and effectiveness data submission. Under § 330.14(j)(3), if FDA refuses to file the submission, the Agency will notify the sponsor in writing, state the reason(s) for the refusal, and provide the sponsor with 30 days in which to submit a written request for an informal conference with the Agency about whether the Agency should file the submission. We estimate that approximately one respondent will annually submit a request for an informal conference, and that preparing and submitting each request will take approximately 1 hour. This is reflected in row 3 of table 1.

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 approximately two respondents annually will submit such signed statements, and that preparing and submitting each signed statement will take approximately 1 hour. This is reflected in row 4 of table 1.

Under § 330.14(k)(1), FDA, 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 submitted under § 330.14(f). We estimate that approximately one respondent will annually submit such a request, and that preparing and submitting the request will take approximately 1 hour. This is reflected in row 5 of table 1.

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 annually submit such a request, and that preparing and submitting the request will take approximately 2 hours. This is reflected in row 6 of table 1.

In the **Federal Register** of May 30, 2017 (82 FR 24723), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR part 330; activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 330.14(c) and (d); time and extent application and submission of information | 2 | 1 | 2 | 1,525 | 3,050 |
| 330.14(f) and (i); safety and effectiveness data | 2 | 1 | 2 | 2,350 | 4,700 |
| 330.14(j)(3); sponsor request for informal conference | 1 | 1 | 1 | 1 | 1 |
| 330.14(j)(4); sponsor signed statement that submission is complete | 2 | 1 | 2 | 1 | 2 |
| 330.14(k)(l); sponsor request for FDA withdraw of TEA consideration | 1 | 1 | 1 | 1 | 1 |
| 330.14(k)(2); sponsor request for FDA to not deem submission withdrawn | 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.

Dated: August 17, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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