will be posted to our Web site after the meeting.

IX. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: May 2, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–10688 Filed 5–8–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0086]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Potential Tobacco Product Violations Reporting Form

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 June 9, 2014.

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 0910–0716. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Potential Tobacco Product Violations Reporting Form—(OMB Control Number 0910–0716)—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended section 201 *et seq.* of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321 *et seq.*) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. FDA is requesting an extension of OMB approval for the collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act.

FDA created a Tobacco Call Center (with a toll-free number: 1–877–CTP–1373). Callers are able to report potential violations of the Tobacco Control Act, and FDA will conduct targeted followup investigations based on information received. When callers report a violation, the caller will be asked to provide as much certain information as they can recall, including: The date the potential violation occurred; product type (e.g., cigarette, smokeless, roll-your-own); tobacco brand; potential violation type; type of potentially violative promotional materials; who potentially violated; and the name, address, phone number, and email address of the potential violator. The caller will also be asked to list the potential violator's Web site (if available), describe the potential violation, and provide any additional files or information pertinent to the potential violation.

FDA currently provides a form that may be used to solicit this information from the caller (Form FDA 3779, Potential Tobacco Product Violations Report), and seeks renewal of Form FDA 3779. This form is posted on FDA's Web site. The public and interested stakeholders are also able to report information regarding possible violations of the Tobacco Control Act through the following methods: Calling the Tobacco Call Center using the Center for Tobacco Products' (CTP) toll-free number; using a fillable Form FDA 3779 found on FDA's Web site; downloading a PDF version of the form to send via email or mail to FDA; requesting a copy of Form FDA 3779 by contacting CTP and sending by mail to FDA; and sending a letter to FDA's CTP. The public and interested stakeholders will also be able to report information regarding possible violations of the Tobacco Control Act in the future using FDA's tobacco violation reporting smartphone application.

In the **Federal Register** of February 18, 2014 (79 FR 9216), 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 and Form FDA 3779	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting violations of the FD&C Act, as amended by the Tobacco Control Act, by telephone, Internet form, mail, smartphone application, or email	400	2	800	[2] 0.25	200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 15 minutes.

FDA estimates that submitting the information (by telephone, Internet, mail, smartphone application, or email) will take 0.25 hours (i.e., 15 minutes) per response. FDA estimates the number of annual respondents to this collection of information will be 400, who will each submit 2 reports by telephone, Internet, mail, smartphone application, or email. This estimate is based on the rate of reporting through Form FDA 3779, reports received from FDA's toll-

free telephone number and email address, and FDA experience. Each report is expected to take 0.25 hours to complete and submit; therefore, total burden hours for this collection of information is estimated to be 200 hours (800 responses × 0.25 hours per response). The total burden hours for this collection have decreased by 50 hours (from 250 to 200) because the number of estimated respondents decreased from 1,000 to 400, and the annual responses are expected to drop from 1,000 to 800. Based on past submissions to FDA, the number of estimated annual respondents is expected to decrease from 1,000 to 400 and each respondent's number of submissions is expected to increase from 1 to 2 annually. Therefore, the number of responses is expected to decrease from 1,000 to 800 annually (400 respondents × 2 responses).

Dated: May 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–10657 Filed 5–8–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1478]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Providing Waiver-Related Materials in Accordance With Draft Guidance for Industry on Providing Postmarket Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format

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 (the PRA).

DATES: Fax written comments on the collection of information by June 9, 2014.

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 title. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reporting in Accordance With International Conference on Harmonisation—Periodic Benefit Risk Evaluation Report (E2C(R2)) Guidance—(OMB Control Number 0910–NEW)

I. Background

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. In January 2012, the ICH Steering Committee agreed that the ''E2C(R2) Periodic Benefit-Risk Evaluation Report'' draft guidance (the draft PBRER guidance) should be made available for public comment. The PBRER is intended to provide a common standard for periodic reporting on approved drugs or biologics among the ICH regions. The harmonized PBRER is intended to promote a consistent approach to periodic postmarket safety reporting among the ICH regions and to enhance efficiency by reducing the number of reports generated for submission to the regulatory authorities.

The draft PBRER guidance revises an earlier version of this guidance issued in 1997 with an addendum issued in 2004. In the **Federal Register** of April 11, 2012 (77 FR 21782), FDA announced the availability of the draft PBRER guidance for public comment. FDA presented the comments received as part of the considerations by the E2C(R2) Expert Working Group for revisions of the guidance. A final version of the guidance was subsequently endorsed by the ICH on November 15, 2012, and published as the ICH harmonized tripartite guideline ''Periodic Benefit-Risk Evaluation Report (PBRER) E2C(R2)'' (the PBRER guidance), available at *http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html.* FDA anticipates issuing final guidance on this topic that is consistent with the final ICH document, published November 2012, and thus is seeking PRA approval for information collections consistent with that document.

II. Voluntary Preparation of Periodic Safety Reports in Conformance With the ICH E2C(R2) PBRER Guidance, in Lieu of PADERs/PAERs Required Under 21 CFR 314.80(c)(2) and 600.80(c)(2)

FDA currently has OMB approval for the required submission of periodic adverse drug experience reports (PADER) for drugs subject to a new drug application (NDA) or an abbreviated new drug application (ANDA) (§ 314.80(c)(2) (21 CFR 314.80(c)(2)); OMB control number 0910–0230), and for the required submission of periodic adverse experience reports (PAER) for drugs subject to a biologics license application (BLA) (§ 600.80(c)(2) (21 CFR 600.80(c)(2)); OMB control number 0910–0308). Such reports include, for the reporting interval, reports of serious, expected adverse experiences and all non-serious adverse experiences and an index of these reports, a narrative summary and analysis of adverse experiences, an analysis of the 15-day Alert reports submitted during the reporting interval, and a history of actions taken because of adverse experiences. Applicants must submit each PADER/PAER to FDA quarterly for the first 3 years after the product is approved by FDA and annually thereafter. As described in the supporting documentation under OMB control numbers 0910–0230 and 0910–0308, FDA currently has OMB approval for approximately 60 hours for the preparation and submission of each PADER under § 314.80(c)(2) and 28 hours for the preparation and submission of each PAER under § 600.80(c)(2).

There is considerable overlap in the information required under §§ 314.80(c)(2) and 600.80(c)(2) and the information requested in a periodic safety report using the ICH E2C(R2) PBRER format. As a result, and as discussed further in this document, FDA, in the **Federal Register** of April 8, 2013 (78 FR 20926), announced the availability of a draft guidance to indicate its willingness to accept postmarket periodic safety reports using the ICH PBRER format in lieu of the