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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1076]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 information collection in the guidance on ''Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice.''

DATES: Submit either electronic or written comments on the collection of information by December 26, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 26, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of December 26, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2014–N–1076 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- *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 second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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: 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.

Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

OMB Control Number 0910–0563—Extension

This information collection supports the guidance for industry on ''Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice.'' The guidance is available at: *https://www.fda.gov/downloads/drugs/guidances/ucm070279.pdf.* The guidance informs manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes about scientific and technical issues relating to current good manufacturing practice (CGMP). Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with CGMP requirements or during FDA's assessment of corrective actions undertaken as a result of such inspections. The guidance provides procedures that encourage open and prompt discussion of disputes and lead to their resolution. The guidance describes procedures for raising such disputes to the Office of Regulatory Affairs (ORA) and center levels and for requesting review by the dispute resolution (DR) panel.

When a scientific or technical issue arises during an FDA inspection, the manufacturer should initially attempt to reach agreement on the issue informally with the investigator. Certain scientific or technical issues may be too complex or time consuming to resolve during the inspection. If resolution of a scientific or technical issue is not accomplished through informal mechanisms before the issuance of Form FDA 483, the manufacturer can formally request DR and use the two-tiered DR process described in the guidance.

Tier one of the formal DR process involves a manufacturer raising scientific or technical issues to the ORA and center levels. If a manufacturer disagrees with the tier-one decision, tier two of the formal DR process would then be available for appealing that decision to the DR panel. The written request for formal DR to the appropriate ORA unit should be made within 30 days of the completion of an inspection and should include all supporting documentation and arguments for review, as described in this document. The written request for formal DR to the DR panel should be made within 60 days of receipt of the tier-one decision and should include all supporting documentation and arguments, as described in this document.

All requests for formal DR should be submitted in writing and include adequate information to explain the nature of the dispute and to allow FDA to act quickly and efficiently. Each request should be sent to the appropriate address listed in the guidance and include the following elements:

- Cover sheet that clearly identifies the submission as either a tier-one or tier-two DR request.
- Name and address of manufacturer inspected (as listed on Form FDA 483).
- Date of inspection (as listed on Form FDA 483).
- Date Form FDA 483 was issued (as listed on Form FDA 483).
- Facility Establishment Identifier number, if available (as listed on Form FDA 483).
- Names and titles of FDA employees who conducted inspection (as listed on Form FDA 483).
- Office responsible for the inspection (*e.g.,* district office, as listed on Form FDA 483).
- Application number if the inspection was a preapproval inspection.
- Comprehensive statement of each issue to be resolved:
  - Identify the observation in dispute.
  - Clearly present the manufacturer's scientific position or rationale concerning the issue under dispute with any supporting data.
  - State the steps that have been taken to resolve the dispute, including any informal DR that may have occurred before the issuance of Form FDA 483.
  - Identify possible solutions.
  - State expected outcome.
- Name, title, telephone and fax numbers, and email address (as available) of manufacturer contact.

The guidance responds to industry's request for a formal DR process to resolve differences related to scientific and technical issues that arise between investigators and pharmaceutical manufacturers during FDA inspections of foreign and domestic manufacturers. In addition to encouraging manufacturers to use currently available DR processes, the guidance describes the formal two-tiered DR process explained previously. The guidance also covers the following topics:

- Suitability of certain issues for the formal DR process, including examples, with a discussion of their appropriateness for the DR process.
- Instructions on how to submit requests for formal DR, and a list of the supporting information that should accompany these requests.
- Public availability of decisions reached during the DR process to promote consistent application and interpretation of regulations related to drug quality.

We estimate the burden for the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Annual frequency per response	Total annual responses	Average burden per response	Total hours
Requests for tier-one DR	2	1	2	30	60
Requests for tier-two DR	1	1	1	8	8
Total					68

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

As reflected in table 1, we estimate two manufacturers will submit two requests annually for tier-one DR, and that there will be one appeal of these requests to the DR panel (tier-two DR). We estimate also that it will take manufacturers approximately 30 hours to prepare and submit each request for a tier-one DR, and approximately 8 hours to prepare and submit each request for a tier-two DR. Based on our experience with this collection we have not changed our estimate since our last request for OMB approval.

Dated: October 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23444 Filed 10–26–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3710]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Food and Drug Administration's Education at the Point of Sale Campaign

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 November 27, 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—NEW and title ''Evaluation of FDA's Education at the Point of Sale Campaign.'' 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, 10A–12M, 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.

Evaluation of FDA's Education at the Point of Sale Campaign OMB Control Number 0910—NEW

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing a tobacco education intervention at the point of sale to reduce the public health burden of tobacco use. The campaign features advertisements intended to encourage future quit attempts among current smokers in stores that sell tobacco products.

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health, FDA requests OMB approval to collect information to evaluate the effectiveness of the point of sale tobacco education campaign. Data from this outcome evaluation study will be used to examine statistical associations between exposure to the campaign and specific outcomes of interest, which include awareness of the campaign and its messaging, tobacco-related attitudes, beliefs and risk perceptions, and motivation to quit smoking.

Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions. Comprehensive evaluation of FDA's public education campaigns will be used to document whether the intended audience is aware of and understands campaign messages, and whether campaign exposure influences tobacco-related attitudes, beliefs and risk perceptions, intentions to use tobacco, and motivation to quit smoking. Participation in the outcome evaluation study will be voluntary. All of the information collected is integral to that evaluation.

Evaluation of the Point of Sale Campaign. This outcome evaluation study will consist of four longitudinal data collection periods over 24 months (approximately every 7 months), with the first survey (Wave 1) occurring approximately 3 months after campaign launch. A fourth wave of data collection has been added to the three proposed in the 60-day notice because the campaign has been extended from 18 to 24 months. The additional wave of data collection is necessary to continue to assess the impact of the campaign. To reduce the number of participants needed to detect the effects of the campaign on outcomes of interest, the design of the campaign was changed from two treatment groups and one control group to one treatment group and one control group. The respondent numbers and burden hours below have been revised to reflect the four data collection waves and the change in the number of treatment groups.

Information will be collected from adult cigarette smokers, ages 25 to 54, about awareness of and exposure to campaign advertisements, tobacco use, and knowledge, attitudes, and beliefs related to tobacco use. Information will be collected on demographic variables including age, sex, race/ethnicity, and primary language. Participants will also be offered the option to download a smartphone application that will track their exposure to the campaign, and that will ask them to respond to a brief survey about every 6 months over 18 months.

FDA's media contractor identified 37 potential counties for the campaign. From this list, FDA's evaluation contractor has selected 30 counties to be included in the evaluation. Of these, 15 counties will receive the intervention (treatment counties), and 15 counties will not receive it (control counties). The number of counties has changed since the 60-day notice because we changed the experimental design to have one treatment group instead of two, which resulted in needing fewer counties.

Data will be collected from a longitudinal cohort that will consist of an entirely new sample of adult cigarette smokers. Addresses will be randomly selected from postal carrier routes in the 30 selected U.S. counties to identify households that contain one or more adult smokers between the ages of 25 and 54. Pre-paid pre-addressed paper screening surveys will be mailed to approximately 104,541 households. We estimate that 27,651 (9,217 annualized respondents) households will return the 10-minute screener they received by mail, and 26,258 (8,753