DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3586]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups About Drug Products as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 April 14, 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 0910–0677. 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, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Focus Groups About Drug Products as Used by the Food and Drug Administration OMB Control Number 0910–0677—Extension

Focus groups provide an important role in gathering information because they allow for a more in-depth understanding of individuals' attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative research tool have three major purposes:

- To obtain information that is useful for developing variables and measures for quantitative studies;
- to better understand people's attitudes and emotions in response to topics and concepts;
- and to further explore findings obtained from quantitative studies.

FDA will use focus group findings to test and refine its ideas and to help develop messages and other communications, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

FDA's Center for Drug Evaluation and Research, Office of the Commissioner, and any other Centers or Offices conducting focus groups about regulated drug products may need to conduct focus groups on a variety of subjects related to consumer, patient, or healthcare professional perceptions and use of drug products and related materials, including but not limited to, direct-to-consumer prescription drug promotion, physician labeling of prescription drugs, Medication Guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sales of medical products, and consumer and professional education.

Annually, FDA projects about 20 focus group studies using 160 focus groups with an average of 9 persons per group, and lasting an average of 1.75 hours each. FDA is requesting this burden for unplanned focus groups so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

In the **Federal Register** of November 7, 2016 (81 FR 78161), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received in response to the notice.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus Groups About Drug Products	1,440	1	1,440	1.75	2,520

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

Dated: March 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–05099 Filed 3–14–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0575]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 April 14, 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 0910–0765. 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, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Guidance for Industry (GFI) on Expedited Programs for Serious Conditions—Drugs and Biologics

OMB Control Number 0910–0765—Extension

The FDA has established four programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions: (1) Fast track designation including rolling review, (2) Breakthrough therapy designation, (3) Accelerated approval, and (4) Priority review designation. In support of these, the Agency has developed the guidance document, ''GFI: Expedited Programs for Serious Conditions—Drugs and Biologics.'' The guidance outlines the programs' policies and procedures and describes applicable threshold criteria, including when to submit information to FDA. Respondents to the information collection are sponsors of drug and biological products appropriate for these expedited programs.

Priority Review Designation Request. The guidance describes that a sponsor may expressly request priority review of an application. Based on information from FDA's databases and information available to FDA, we estimate that approximately 48 sponsors will prepare and submit approximately 1.7 priority review designation submissions that receive a priority review in accordance with the guidance and that the added burden for each submission will be approximately 30 hours to develop and submit to FDA as part of the application (totaling 2,400 hours).

Breakthrough Therapy Designation Request. The guidance describes the process for sponsors to request breakthrough therapy designation in an application. Based on information from FDA's databases and information available to FDA, we estimate that approximately 87 sponsors will prepare approximately 1.29 breakthrough therapy designation submissions in accordance with the guidance and that the added burden for each submission will be approximately 70 hours to prepare and submit (totaling 7,910 hours).

In the **Federal Register** of November 29, 2016 (81 FR 85973), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received in response to the notice.

FDA estimates the burden of this collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance on expedited programs	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority Review Designation Request	48	1.7	80	30	2,400
Breakthrough Therapy Designation Request	87	1.29	113	70	7,910
Total					10,310

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

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR parts 202.1, 314, and 601; sections 505(a), 506(a)(1), 735, and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a), 356(a)(1), 379(g), and 379(h)) have been approved under OMB control numbers 0910–0686, 0910–0001, 0910–0338, 0910–0014, and 0910–0297.

Dated: March 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–05104 Filed 3–14–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0041]

Agency Information Collection Activities; Proposed Collection; Comment Request; Safety Assurance Case

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 associated with safety assurance cases.

DATES: Submit either electronic or written comments on the collection of information by May 15, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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