4164-01-P

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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	No. of Respondents	No. 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.

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