4160-01-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) 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-New and title "Guidance for Industry on Expedited Programs for Serious Conditions--Drugs and Biologics." 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.

Guidance for Industry on Expedited Programs for Serious Conditions--Drugs and Biologics--(OMB Control Number 0910-New)

Description of Respondents: Respondents to this collection of information are sponsors that develop drugs and biological products.

Burden Estimate: This guidance outlines FDA's policies and procedures related to the following expedited programs for serious conditions: (1) Fast track designation including rolling review, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation. In addition, this guidance describes threshold criteria generally applicable to these expedited programs.

This guidance refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR parts 202.1, 314, and 601, and sections 505(a), 506(a)(1), 735, and 736 of the Federal Food, Drug, and Cosmetic Act (FD&C 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.

This guidance proposes the following new collections of information:

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 47 sponsors will prepare and

submit approximately 1 priority review designation submission 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 1,410 hours).

Breakthrough Therapy Designation Request. The guidance describes the process for sponsors to request breakthrough therapy designation in an application. Based on information available to FDA, we estimate that approximately 24 sponsors will prepare approximately 1 breakthrough therapy designation submission in accordance with the guidance and that the added burden for each submission will be approximately 70 hours to prepare and submit (totaling 1,680 hours).

Promotional Materials for Accelerated Approval Under Part 314. The guidance describes section 506(b)(2)(B) of the FD&C Act and FDA's accelerated approval regulations (§§ 314.550 and 601.45). These provisions authorize FDA to require sponsors to submit copies of all promotional materials to the Agency for consideration prior to their dissemination. The regulations provide that copies of all promotional materials including promotional labeling as well as advertisements intended for dissemination or publication within 120 days following marketing approval must be submitted to FDA during the preapproval period. The regulations further provide that after 120 days following marketing approval, unless otherwise informed by the Agency, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement. Currently, FDA has OMB approval for the submission of copies of all promotional materials under part 601 (OMB control number 0910-0338) but does not have approval for the submission of copies of all promotional materials under part 314.

Based on information from FDA's databases and information available to FDA, we estimate that approximately 20 sponsors will submit promotional materials for accelerated approval 7 times annually in accordance with § 314.550 and that the burden for each submission will be approximately 120 hours (a total of 16,800 hours).

In the Federal Register of June 26, 2013 (78 FR 38349), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received 26 comments. However, these comments did not address the information collection.

FDA estimates the burden of this collection of information 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	47	1	47	30	1,410
Breakthrough Therapy Designation Request	24	1	24	70	1,680
Promotional Materials for Accelerated Approval Under § 314.550	20	7	140	120	16,800
Total					19,890

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

Dated: November 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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