4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0530]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Medical Devices: The Pre-Submission Program and Meetings with FDA Staff

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: "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." 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 on Medical Devices: Pre-Submission Program and Meetings with FDA Staff--(OMB Control Number 0910-NEW)

This guidance describes the Pre-Submission program for medical devices reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding the information that should be submitted in a Pre-Submission Package and procedures that should be followed for meetings between CDRH and CBER staff and industry representatives or application sponsors. In addition to Pre-Submissions, the guidance addresses other feedback mechanisms including Informational Meetings, Study Risk Determinations, Formal Early Collaboration Meetings, and Submission Issue Meetings and the procedures to request feedback using these mechanisms. When approved by OMB, this guidance document will supersede "Pre-IDE Program: Issues and Answers--Blue Book Memo D99-1" dated March 25, 1999.

A Pre-Submission is defined as a formal written request from an applicant for feedback from FDA to be provided in the form of a formal written response or, if the manufacturer chooses, a meeting or teleconference in which the feedback is documented in meeting minutes. A Pre-Submission is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or application preparation. The proposed collections of

information are necessary to allow the Agency to receive Pre-Submission Packages in order to implement this voluntary submission program.

Over time, the FDA pre-investigational device exemption (pre-IDE) program evolved to include feedback on premarket approval (PMA) applications, humanitarian device exemption applications, Evaluation of Automatic Class III Designations (de novo petitions), 510(k) submissions, Clinical Laboratory Improvement Amendments categorization requests, as well as to address questions related to whether a clinical study requires submission of an IDE. During discussions with representatives of the medical device industry in the development of the Agency's recommendations for the Medical Device User Fee Amendments of 2012 (MDUFA III) (Pub. L. 112-144), both the industry and the Agency agreed that the Pre-Submission (formerly pre-IDE) process provided important additional transparency to the IDE and premarket review processes. In response, the Secretary's 2012 Commitment Letter to Congress (MDUFA III Commitment Letter) included FDA's commitment to institute a structured process for managing Pre-Submissions.

To fulfill the Secretary's commitment to the industry, this final guidance: (1) Describes the Pre-Submission program (formerly the IDE program) for medical devices reviewed in CDRH and CBER; (2) describes other feedback mechanisms including Informational Meetings, Study Risk Determinations, Formal Early Collaboration Meetings, and Submission Issue Meetings; (3) assists device manufacturers and their representatives who seek meetings with the FDA by providing guidance and recommendations regarding information that should be included in a Pre-Submission Package or other request for feedback; and (4) provides guidance as to the procedures that CDRH and CBER intend to follow when industry representatives or application sponsors request a meeting with review staff.

In the Federal Register of July 13, 2012 (77 FR 41413), FDA published a notice of availability combined with a 60-day notice requesting public comment on the proposed collection of information. FDA received no PRA-related comments.

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

Table 1.--Estimated Annual Reporting Burden [1]

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
CDRH	2,465	1	2,465	137	337,705
CBER	79	1	79	137	10,823
Total					348,528

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

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA estimates that it will receive approximately 2,544 pre-submission packages annually. The Agency reached this estimate by reviewing the number of submissions received by the Agency under the Pre-IDE program over the past 10 years. Based on FDA's experience with the Pre-IDE program, FDA expects the Pre-Submission program to continue to be utilized as a viable program in the future and expects that the number of pre-submission packages will increase over its current rate and reach a steady state of approximately 2,544 submissions per year.

FDA estimates from past experience with the Pre-IDE program that the complete process involved with the program takes approximately 137 hours. This average is based upon estimates by FDA administrative and technical staff that is familiar with the requirements for submission of a Pre-Submission and related materials, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Therefore, the total reporting burden hours is estimated to be 348,528 hours.

Table 2.--Estimated Annual Reporting Burden[1]

No. of Respondents	Total Burden Hours Annualized	Hourly Wage Rate	Total Cost Annualized
2,544	137	$150	$52,279,200

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

The average to industry per hour for this type of work is $150, resulting in a cost of $20,550 per respondent. The estimated submission cost of $20,550 multiplied by 2,544 submissions per year equals $52,279,200, which is the aggregated industry reporting cost annualized.

FDA's annual estimate of 2,544 submissions is based on experienced trends over the past several years. FDA's administrative and technical staffs, who are familiar with the requirements for current pre-submissions, estimate that an average of 137 hours is required to prepare a pre-submission. However, we recognize there is a variance in the preparation submission because of the vast and varying complexities of medical devices.

Dated: October 25, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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