SUPPORTING STATEMENT
REQUESTS FOR FEEDBACK ON MEDICAL DEVICE SUBMISSIONS
OMB Control Number 0910-0756

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Over time, the FDA pre-IDE program has evolved to include pre-submission feedback on various submission types, including PMA applications, HDE applications, de novo petitions, 510(k) submissions and CLIA categorization requests; to address questions related to an applicant's planned response to an FDA request for additional information on such submissions; and to address questions related to whether a clinical study requires submission of an IDE. Development of a more structured process for certain Pre-Submissions was identified as a mechanism to provide important additional transparency to the IDE and premarket review processes during discussions with representatives of the medical device industry in the development of the Agency's recommendations for MDUFA III. The Secretary's 2012 Commitment Letter to Congress (MDUFA III Commitment Letter) includes FDA's commitment to institute such a structured process for managing Pre-Submissions. The Pre-Submissions program has also been broadened to include those devices regulated by CBER, including those that are regulated as biologics under the PHS Act. In addition to Pre-Submissions, the final 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.

2. Purpose and Use of the Information

The information collected will support a structured process with clear recommendations for sponsors who submit Pre-Submissions and other requests for pre-submission feedback and for FDA staff and managers involved in their review, as well as expected timeframes for providing written feedback and scheduling meetings. The guidance includes recommendations for the information to be submitted as part of a Pre-Submission or other feedback request, and the timeframes in which FDA intends to provide the requested feedback. The guidance also includes recommendations for sponsors regarding how to prepare for meetings with FDA staff.

The respondents to this information collection are from the private sector; business or other for profit and non-profit organizations.

3. Use of Information Technology and Burden Reduction

Section 745A(b) of the FD&C Act, as added by section 1136 of FDASIA, requires an eCopy for the following submission types:

- Premarket notification submissions (510(k)s), including third party 510(k)s;
- Evaluation of automatic class III designation petitions (de novos);
- Premarket approval applications (PMAs), including Transitional PMAs;6

• Modular PMAs;
• Product development protocols (PDPs);
• Investigational device exemptions (IDEs)

In an effort to reduce burden, in the **Federal Register** of March 20, 1997, FDA published a final rule establishing procedures for electronic records, electronic signatures, and electronic submissions. A sponsor, applicant or manufacturer may use the appropriate technology in accordance with this rule to comply with the requirements of the guidance.

For CDRH-regulated products, in accordance with section 745A(b) of the Food, Drug, and Cosmetic Act (FD&C Act), respondents must submit an eCopy.[1] For more information about the eCopy program, please see the FDA guidance "eCopy Program for Medical Device Submissions"(http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf).

For products regulated in the Center for Biologics Evaluation and Research (CBER), respondents should consult CBER SOPP 8114: Administrative Processing of Documents Received Prior to Submitting Investigational or Marketing Applications (Pre-Application) (http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm079476.htm).

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency responsible for the collection of this information, and there are no requirements for the submission of similar information. Therefore, no duplication of data exists. No data exists from any source, other than the submitter requesting FDA pre-submission feedback, which can be used to provide FDA with information regarding planned clinical studies, IDEs, or marketing submissions for devices subject to FDA regulation.

5. Impact on Small Businesses or Other Small Entities

The information collection will have a minimal impact on a substantial number of small entities and may actually be helpful to small businesses that may not be able to afford a medical device consultant. FDA also aids small business in dealing with the requirements of the regulations by providing guidance and information through the Division of International and Consumer Education (DICE), and through the scientific and administrative staff, workshops in which FDA Staff participate, and through the CDRH website at http://www.fda.gov/MedicalDevices/default.htm. These efforts help to assure that the burden on all manufacturers, including small manufacturers, is minimized.

FDA estimates that 1,038 respondents are considered small businesses.

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1 Section 745A(b) of the FD&C Act requires submission of an eCopy for multiple submission types, including pre-submissions. FDA has interpreted this provision to include requests for feedback on medical device submissions of all types, including Study Risk Determinations, Early Collaboration Meeting requests, Informational Meeting requests, Submission Issue Meeting requests, and Day 100 Meeting requests.

6. Consequences of Collecting the Information Less Frequently

These information collection requirements are voluntary and at the discretion of the respondent, and as such the information collected pursuant to this pre-submission process cannot be collected less frequently. This program is intended to allow sponsors the opportunity to obtain targeted FDA feedback related to product development, including planned nonclinical evaluations, whether a clinical study is needed, proposed clinical study protocols, or data requirements prior to making a submission to the Agency. Such requests for pre-submission feedback are not required prior to submission of an IDE or any premarket application, but are strongly encouraged. It is the applicant's decision whether or not to submit a Pre-Submission or other type of pre-submission feedback request prior to submission of an IDE, 510(k), PMA, HDE, de novo petition or CLIA categorization request. However, early interaction with FDA on planned nonclinical and clinical studies and careful consideration of FDA's feedback may improve the quality of subsequent submissions and facilitate the development process for new devices.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.6

This information collection is consistent with the guidelines prescribed in 5 CFR 1320.6.

8. Efforts to Consult Outside Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 07/28/2016 (81 FR 49678). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts in any manner or form shall be provided to respondents under this regulation.

10. Assurance of Confidentiality Provided to Respondent

Confidentiality of information submitted to FDA under a pre-submission program is governed by the provisions of 21 CFR Parts 20 is mandated. These provisions do not permit disclosure of information in a premarket notification submission that is trade secret or commercial confidential unless that information has been previously disclosed or as permitted under the Federal Freedom of Information Act. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. Information provided under this collection is handled in a manner to comply with the FDA regulations on public information in 21 CFR Part 20.

11. Justification for Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden and Costs

The pre-submission request for feedback program, as outlined in the final guidance, covers

different types of submissions available to applicants as a mechanism to obtain FDA feedback regarding potential or planned medical device IDE or premarket submissions. These submissions include the following:

- Pre-Submission – A Pre-Submission is defined as a formal written request from an applicant/sponsor 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.
- Informational Meeting – An applicant/sponsor may request a meeting in which the intent is to share information with FDA without the expectation of feedback.
- Study Risk Determination – A study risk determination may be submitted to FDA when a sponsor, clinical investigator or Institutional Review Board (IRB) would like FDA's help in determining whether a planned clinical study is significant risk, and would require an IDE, or nonsignificant risk, and would not require an IDE.
- Formal Early Collaboration Meetings – The FD&C Act provides for two types of early collaboration meetings, agreement and determination meetings, which are intended to facilitate interaction between FDA and applicants and provide clear direction for testing and development of those devices requiring clinical investigations to support marketing. The FD&C Act makes it clear that the determinations or agreements resulting from these meetings are to be binding.
    - Determination meetings – A Determination Meeting, as described in section 513(a)(3)(D) of the FD&C Act, is available to anyone anticipating submitting a PMA or product development protocol (PDP) and is intended to provide the applicant with the Agency's determination of the type of valid scientific evidence that will be necessary to demonstrate that the device is effective for its intended use. As a result of this meeting, FDA will determine whether clinical studies are needed to establish effectiveness and, in consultation with the applicant, determine the least burdensome way of evaluating device effectiveness that has a reasonable likelihood of success.
    - Agreement meetings – An Agreement Meeting, described in section 520(g)(7) of the FD&C Act, is open to any person planning to investigate the safety or effectiveness of a class III product or any implant, including submitters of 510(k)s for eligible devices. The purpose of this meeting is to reach agreement on the key parameters of the investigational plan (see 21 CFR 812.25), including the clinical protocol.
- Submissions Issue Meeting – A sponsor or applicant may request a Submission Issue Meeting to discuss deficiencies identified during premarket review of a 510(k), de novo, IDE, HDE, or PMA application.
    - Day 100 meetings - Day 100 meetings for original PMAs and Panel-track PMA Supplements are a subset of Submission Issue Meetings. A PMA applicant may request a Day 100 Meeting to discuss the review status of their PMA application.

Each of these submission types will have a different recommended level of information

commensurate with the type of feedback requested. Below is a summary of what the FDA generally recommends that all pre-submission requests for feedback include; however, the details for each submission type are provided in the final guidance document:

- a cover letter that clearly identifies the submission type in the reference line (e.g., Submission Issue Meeting request)
- a detailed device description;
- proposed intended use/indications for use of the product;
- proposed plan for clinical evaluation of the product or protocol for a planned clinical study, if applicable;
- a reference to the premarket submission number and any other related documents, if applicable;
- a brief statement describing the purpose, scope, or objectives of the meeting;
- focused questions for which the applicant/sponsor is seeking guidance from FDA, if applicable;
- if a meeting is requested, the preferred meeting format (i.e., in-person or by teleconference);
- a proposed agenda describing the topics or deficiencies for discussion and the estimated time for each agenda item;
- three (3) or more preferred dates and times when the applicant/sponsor is available to meet given the guidelines in the final guidance for scheduling;
- the planned attendees or the type of subject matter experts the applicant/sponsor plans to invite so that FDA can ensure appropriate Agency experts are in attendance; and
- a list of any audiovisual equipment needed, such as conference phone or LCD projector.

12a. Annualized Hour Burden Estimate

Based on experienced trends over the past several years, an estimated 2,544 submissions are expected each year. 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. There is a variance in the preparation submission because of the vast and varying complexities of medical devices.

The estimate of burden for this collection of information is shown in the following table:

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

12b. Annualized Cost Burden Estimate

The average to industry per hour for this type of work is $150. Therefore, FDA estimates the total reporting cost to industry for a pre-submission request for feedback at $20,550 per submission. The estimated submission cost of $20,550 multiplied by 2,544 pre-submissions per year equals $52,279,200.

FDA has based these estimates on previous submissions and conversations with industry and trade association representatives, and from internal review of previous submissions.

13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no additional costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA estimates that a total of 90 full time equivalent (FTE) positions consisting of a combination of medical officers, dental officers, scientific, and engineering professionals and support staff are required for participation in the pre-submission process. Based on a cost of $283,487 per position (which is the agency's average cost of an FTE including their benefits), the estimated annual Federal cost is $25,513,830.

*Based on the Department of Health and Human Services, Fiscal Year 2015, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 11-13).

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments to the estimated burden. Annualized cost to the Federal government has been updated using information based on the Department of

Health and Human Services, Fiscal Year 2015, Food and Drug Administration, Justification of Estimates for Appropriations Committees, which increased the cost to $25,513,830 from $12,798,000 ($25,513,830 - $12,798,000 = $12,715,830).

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish or tabulate the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exception to Certification for Paperwork Reduction Act Submissions

FDA is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions.