Product Jurisdiction: Preliminary Assessment of Agency Component for Review of Premarket Applications

0910-NEW

SUPPORTING STATEMENT

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

The collection of information is intended to assist sponsors in obtaining a preliminary assessment from the U.S. Food and Drug Administration (FDA or Agency) through the Pre-Request for Designation (Pre-RFD) process. The Pre-RFD process is available to provide informal, non-binding feedback regarding the regulatory identity or classification of a human medical product as a drug, device, biological product, or combination product. In addition, this informal process provides information about a non-combination or combination product's assignment to the appropriate Agency Center (Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), or Center for Biologics Evaluation and Research (CBER)) for premarket review and regulation.

Since its establishment on December 24, 2002, OCP has served as a resource for sponsors at various stages of development of their product. Sponsors often seek OCP feedback on whether their medical product will be regulated as a drug, a device, a biologic, or a combination product, and which FDA medical product Agency Center (CDER, CBER, or CDRH) will regulate it, if it is a non-combination product, or will have the primary jurisdiction for the premarket review and regulation of the product, if it is a combination product.

There are two ways that a sponsor can receive such a feedback from OCP. One option is to submit an RFD to receive a formal, binding determination for the sponsor's product with respect to classification and/or center assignment that may be changed under conditions specified in Section 563 of the FD&C Act and 21 CFR 3.9 in the regulations. The RFD process is codified in 21 CFR Part 3,[1] and OCP has issued a guidance about this process (see "How to Write a Request for Designation" at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm). A second more flexible option is for a sponsor to submit an inquiry to OCP to receive a preliminary jurisdictional assessment, which is not binding.

[1] The collection of information required by 21 CFR Part 3 is approved under OMB 0910-0523.

Many sponsors seek to utilize the flexibility of more approachable ways to interact with OCP and the medical product Agency Centers to obtain feedback from the Agency before submitting a marketing application to the Agency. Over time, these informal methods of obtaining feedback have become increasingly customary with sponsors, and for some, even preferable to the formal RFD process. Accordingly, FDA is enhancing the transparency and consistency of this process, which will now be called the "Pre-Request for Designation (Pre-RFD) Program."

The information submitted would be used by FDA as the basis for making the preliminary assignment or designation assessment. Most information is already required for premarket applications affecting drugs, devices, biological products and combination products. The respondents will be businesses or other for-profit organizations.

The clearance of the paperwork authorizes FDA to receive the information contained in the Pre-RFD. This information is necessary for FDA to make the preliminary assessments, which are not legally binding, that sponsors request. This information collection is not related to ARRA.

2. Purpose and Use of the Information Collection

The information is submitted by a business/sponsor who submits a Pre-RFD to the agency. The information is used by the agency to preliminarily assess a new product as a drug, device, biological product, or combination product, and to provide a preliminary assignment regarding responsibility for regulation of the product within FDA. FDA makes a preliminary classification and assignment assessment based on the information submitted. For example, a sponsor submits a Pre-RFD containing information about a drug/device combination product. The sponsor is uncertain whether the product should be assigned to the Center for Drug Evaluation (CDER) or the Center for Devices and Radiological Health for primary review and regulation. OCP reviews the information contained in the RFD, consults with experts from CDER, CDRH, and the Office of Chief Counsel, and then makes a preliminary assessment regarding assignment of the combination product to the most appropriate Center based on the information contained in the Pre-RFD.

3. Use of Improved Information Technology and Burden Reduction

The reporters are free to use whatever method they wish, including automated, electronic, mechanical, other technological collection techniques, or other forms of information technology. The use of improved technology to reduce burden is not applicable to the submission of a Pre-RFD for classification of drugs, devices, biological products, and combination products and assignment of agency component. We note that approximately 100% of Pre-RFDs for Fiscal Year 2016 were received as electronic copies submitted by the sponsor.

4. Efforts to Identify Duplication and Use of Similar Information

   No duplication of effort by Federal agencies has been identified. There is no similar information that can be used or modified for use. The information required by submitting a Pre-RFD for classification and assignment is not available from any other source except the person making the request.

5. Impact on Small Businesses or Other Small Entities

   This information collection does not have an impact on small businesses or other small entities. We have no information regarding the percentage of small business that submit requests for designation of a product, but we estimate that approximately 15% are small businesses.

6. Consequences of Collecting the Information Less Frequently

   If these procedural requirements were not provided, applicants would be unable to determine how to submit a Pre-RFD to FDA for the classification and assignment of drugs, devices, biological products, and combination products. There is no minimum or maximum number of times that an applicant can submit a request; therefore, there are no consequences to Federal program or policy activities if the collection is conducted less frequently.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances that require the information to be collected in a manner inconsistent with the guidelines in 5 CFR 1320.6.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), in the Federal Register of January 13, 2017 (82 FR 4351), the agency requested comments on the proposed collection of information. FDA received comments from two organizations, but they did not pertain to PRA requirements.

9. Explanation of Any Payment or Gift to Respondents

   No payment or gift is provided under the terms of this information collection.

10. Assurance of Confidentiality Provided to Respondents

    There are no questions of a sensitive nature, and no assurance of confidentiality has been provided except as provided in 21 CFR 20.61 and generally considered in reviewing data and information submitted to FDA.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature involved in this information collection.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pre-RFD Submissions	136	1	136	12 hours	1,632
Pre-RFD Meetings	136	1	136	1 hour	136
Total					1,768

12b. Annualized Cost Burden Estimate

Assuming a mean hourly wage rate of $33.77,[2] the average annually recurring cost for these requirements would be $59,705.36 (13 hours x $33.77/hr x 136 responses).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital costs or operating and maintenance costs associated with this collection.

[2] Wage is based on the 2016 Bureau of Labor Statistic's survey, National Industry Specific Occupational Employment and Wage Estimate, for standard occupational code 13-1041, compliance officer in pharmaceutical and medicine manufacturing. http://www.bls.gov/oes/current/oes131041.htm

14. Annualized Cost to the Federal Government

The cost to the Federal Government is that required to review the Pre-RFD for classification and assignment of drugs, devices, biological products, and combination products. It takes an average of 40 hours per request (ranging from 8 to 60 hours). FDA estimates that the cost of a fully supported professional employee GS 14/5, earning $60.83 per hour,[3] required to review 136 requests per year would incur $330,915.02 in review costs.

15. Explanation for Program Changes or Adjustments

This is a new request for data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

We have no plans to tabulate or publish this collection of information.

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

We believe that display of the OMB expiration date is appropriate for this collection of information.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

[3] Wage is based on the 2017 Office of Personnel Management pay scale for employees in the Washington D.C. area.