Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications

0910-0523
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under section 563 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301) et seq., a person may submit a request for a written statement regarding: (1) the classification of a product as a drug, device, biological product, or combination product, or (2) the agency organizational component that will be responsible for the premarket review and regulation of the product. If the product is determined to be a combination product, section 503(g) of the act (21 U.S.C. 301) mandates that FDA assign an agency center to review and regulate it based on each product's primary mode of action.

Sections 503 and 563 of the act are consistent with the provisions in existing FDA regulations relating to jurisdictional designation for new products. The existing product jurisdiction regulations (21 CFR Part 3), which were adopted in 1991 to implement certain provision of the Safe Medical Devices Act of 1990, established a procedure by which a product sponsor may obtain a designation naming the organizational component in FDA that will have primary responsibility for the premarket review and regulation of any combination product, or any product whose jurisdiction is unclear or in dispute. Part 3 states that a sponsor must submit a written request for designation to FDA. After review of the request, FDA makes a jurisdictional determination and assigns the product to the appropriate agency Center for the product's premarket review and regulation. Part 3 enhances the efficiency of agency management and operations by providing procedures for classifying and determining which agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute. Part 3 establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as the basis for making the assignment or designation decision. Most information required by the regulation 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 renewal of the paperwork clearance for Part 3 authorizes FDA to receive the information contained in the request for designation. This information is necessary for FDA to make the jurisdictional determinations that both the regulations and the act

require when jurisdiction is unclear or in dispute. This information collection is not related to ARRA.

FDA is requesting approval of:

21 CFR Part 3—Drugs, Devices, Biological Products, and Combination Products; Product Classification and Assignment of Agency Component

2. Purpose and Use of the Information Collection

The information is submitted by a business/sponsor who submits an application or submission (including a petition, notification, and any other similar form of request). The information is used by the agency to classify a new product as a drug, device, biological product, or combination product and assign responsibility for regulation of the product within FDA. FDA makes a classification and assignment decision based on the information submitted. For example, a sponsor submits a Request for Designation (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 assigns the combination product to the most appropriate Center based on the information contained in the 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 request for classification of drugs, devices, biological products, and combination products and assignment of agency component. We note that approximately 100% of RFDs for Fiscal Year 2014 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 request 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 request 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 28, 2016 (81 FR 46935), the agency requested comments on the proposed collection of information. FDA received no comments.

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

21 CFR Part	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
3	84	1	84	24 hours	2,016

12b. Annualized Cost Burden Estimate

Assuming an hourly wage plus benefit rate of $39.32,[1] the average annually recurring cost for these requirements would be $79,269 (24 hours x $39.32/hr x 84 responses).

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

[1]

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

14. Annualized Cost to the Federal Government

The cost to the Federal Government is that required to review the request 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 $59.13 per hour, required to review 84 requests per year would incur $198,676.80 in review costs. If the designation is appealed, then the time will double.

15. Explanation for Program Changes or Adjustments

FDA has adjusted the total number of responses (an increase of 25 responses) and the total annual hour burden (an increase of 600 hours). The increase is due to the number of respondents who submitted requests for designation over the past three years. There was an adjusted increase of $63,850.80 (previously $134,826) to the total annual cost to the Federal Government due to the increase of responses.

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.