Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications
OMB Number 0910-0523 Extension

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 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 every RFD received by OCP last year (100%) included an electronic copy 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 Business 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. Less Frequent Information Collection

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 Information Collection Circumstances

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 August 25, 2009 (74 FR 42900), 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

12a. Information obtained from potential and actual respondents indicates that burden hours may vary from 2 hours for a simple request to 40 hours for a request requiring extensive analysis and compilation of information. It is estimated that the average request would take 24 hours to prepare. There is no requirement that respondents maintain a record of any requests submitted to FDA for classification or assignment. There is also no requirement for third-party disclosure. As a result there is no burden for recordkeeping or for third-party disclosure.

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

Table 1. Estimated Annual Reporting Burden

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Responses	Total Hours
3	43	1	43	24	1,032

12b. Assuming an hourly wage plus benefit rate of $42,[1] the average annually recurring cost for these requirements would be $43,344 (24 hours x $42/hr x 43 responses).

13. Estimates of Other Total Annual Costs to Respondents and Record Keepers

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

14. Annualized Cost to 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 13/5, earning $ 48.00 per hour, required to review 43 requests per year would incur $82,560 in review costs. If the designation is appealed, then the time will double.

15. Explanation for Program Changes and Adjustments

There are no program changes or adjustments in burden.

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

[1] Wage is based on the 2007 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 (NAICS 325400). The mean wage of $30.08 was increased by 40 percent to account for fringe benefits for a loaded wage of $42 per hour. http://www.bls.gov/oes/current/naics4_325400.htm#b23-0000

There are not exceptions to “Certification for Paperwork Reduction Act Submissions” for this information collection.