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

Supporting Statement

A. JUSTIFICATION:

1. Circumstances Necessitating Information Collection

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.

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.

FDA is requesting approval of:

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

2. How, By Whom, Purpose of Information Collection

The information is submitted by a person 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.

3. Consideration Given to 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 the agency component. We accept electronic submissions of these requests, but electronic submissions are not required.

4. Identification of 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. Small Business

This information collection does not have an impact on 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. Consultations with Persons Outside FDA

In accordance with 5 CFR 1320.8(d), in the Federal Register of June 22, 2006 (71 FR 35916), the agency requested comments on the proposed collection of information. FDA received no comments.

9. Payment or Gift

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

10. Confidentiality Provisions

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. Sensitive Questions

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

12. Burden of Information Collection

Burden 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.

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

13. Annual Cost to Respondents

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

14. Annual 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 $ 42.00 per hour, required to review 43 requests per year would incur $72,240 in review costs. If the designation is appealed, then the time will double.

15. Explanation of Change

The adjustment in burden is based on the average number of requests for designation received by the agency over the past five years.

16. Statistical Reporting

The reporting requirements contained in this proposal are not statistical in nature and the records are not published for statistical use.

17. Expiration Date on Form

We are not seeking approval to exempt display of the expiration date for OMB approval of the information collection.

18. Exceptions to Certification Statement

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