Common EMEA/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671)

Amendment to OMB No. 0910-0167

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

   Information collection requirements in the Orphan Drug Regulations 21 CFR Part 316 implement sections 525 through 528 of the Orphan Drug Act Amendments to the Federal Food, Drug, and Cosmetic Act (the act). These regulations specify the procedures for sponsors of orphan drugs to use in obtaining the incentives provided for in the act and set forth the procedures that the Food and Drug Administration (FDA) will use in administering the act.

   The proposed collection of information concerns the joint adoption by FDA and the European Medicines Agency (EMEA) of the Common EMEA/FDA Application Form for Orphan Medicinal Product Designation (form FDA 3671). This common application form is intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from both the European Commission and FDA by reducing the burden of preparing separate applications to meet the regulatory requirements in each jurisdiction. It highlights the regulatory cooperation between the United States (US) and the European Union (EU) mandated by the Transatlantic Economic Council (TEC). The TEC mandate involves: removal of barriers to transatlantic commerce; rationalizing, reforming, and, where appropriate, reducing regulations to empower the private sector; achieving more effective, systematic and transparent regulatory cooperation to reduce costs associated with regulation to consumers and producers.

2. Purpose and Use of the Information Collection

   FDA uses the requested information to make the determination that the drug is for a legitimately rare disease or condition and issue an orphan-drug designation. Orphan-drug designation provides financial incentives for the development of a drug for the diagnosis, prevention, or treatment of a rare disease or condition.

3. Use of Improved Information Technology and Burden Reduction

   Improved technology for filing of pre-clinical and clinical information is currently being considered by operating drug and biological review Centers in FDA. Changes made in such technologies will be adopted when appropriate within the procedures of FDA drug review and orphan products development programs.

4. Efforts to Identify Duplication and Use of Similar Information

   Since the collection of data is specifically for application for incentives under the Orphan Drug Act, there is little possibility that other agencies are collecting similar information.

5. Impact on Small Businesses or Other Small Entities

   The provisions of the Orphan Drug Act and the provisions contained in the regulation are favorable to small business interests. The orphan-drug designation provision entitles the sponsor to Federal income tax credits for clinical studies, and eligibility for grants to fund studies of orphan products. The Orphan Drug Exclusivity Provision provides protection from competition by other companies that is administered by FDA. The FDA must by law insure that a competitive product does not enter the market by withholding approval of a subsequent new drug application or biological license.

6. Consequences of Collecting the Information Less Frequently

   The frequency of the collection of the data is entirely controlled by the sponsor requesting eligibility for one of the incentives of the Orphan Drug Act.

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

   The method of collection is consistent with the guidelines of 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), a 10-day emergency notice for public comment on the information collection provisions was published in the **Federal Register** of [insert date] (72 FR #####) to which no comments were received.

9. Explanation of Any Payment or Gift to Respondents

   There are no payments or gifts provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Orphan Drug Act provides that the designation of a drug as an orphan-drug should be a public event. Accordingly, 21 CFR 316.28 provides that public notice be made of all drugs designated as orphan-drugs and will include the name and address of the sponsor, the name of the drug, the rare disease or condition for which the drug was designated, and the proposed indication for use. Similarly, public notice is made identifying sponsors' drugs and indications for use that have obtained Orphan Drug Exclusivity. 21 CFR 316.32 provides that FDA will neither publicly disclose the existence of a request for nor the substance of the request until final action is taken. Further, FDA will not publicly disclose the existence of a pending marketing application for a designated orphan-drug unless the existence of the request has been previously disclosed or acknowledged.

11. Justification for Sensitive Questions

No questions of a sensitive nature are asked.

12. Estimates of Annualized Burden Hours and Costs

Between January 2000 and May 2006, FDA and EMEA received approximately 230 comparable orphan designation requests/applications of the same drugs for the same usages, or an average of 35 per year. With the ease of a common application form, FDA anticipates the number of such requests/applications may increase in time. Therefore, assuming one request/application per respondent and, at the extreme, all respondent are US-based, FDA believes up to 40 such respondents may use the common application form each year. The respondents will be primarily pharmaceutical companies or other for-profit organizations. Since the information required for completing the common application form for the FDA submission is currently mandated by the Orphan Drug Regulations (21 CFR Part 316), there is no additional information collection burden imposed on the respondents. FDA believes the information required for the EMEA submission, for the most part, is very similar to that in the FDA submission, which is already in the respondents' possession. The respondents, however, may have to search existing data source or gather additional needed data, such as on the prevalence or the availability of alternative methods of diagnosis, prevention, and treatment of the rare disease or condition of interest in the European Community, to complete the EMEA submission. FDA estimates that it will take an additional 32 hours, 16 hours of professional time and 16 hours of support time, to compile all information required for the EMEA submission. Hence, the estimated total annual human resource hours, at most, would be 1,280 hours.

Table 1. – Estimated Annual Reporting Burden[1]					
FDA Form No.	Annual No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3671	40	1	40	32	1,280

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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

There are no other costs incurred by the respondents.

14. Annualized Cost to the Federal Government

There are no additional annual costs to the Federal Government.

15. Explanation for Program Changes or Adjustments

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16. Plans for Tabulation and Publication and Project Time Schedule

The objectives of the collection are not for publication of statistical material and do not employ statistical methods.

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

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable.