Guidance for Industry on Tropical Disease Priority Review Vouchers

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 1102 of the Food and Drug Administration Amendments Act (FDAAA) adds new section 524 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Section 524 is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world, and makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease products. By enacting section 524, Congress intended to stimulate new drug development for drugs to treat certain tropical diseases for which there are no or few available treatments by offering additional incentives for obtaining FDA approval for pharmaceutical treatments for these diseases. Under section 524, a sponsor of a human drug application for a qualified tropical disease may be eligible for a voucher that can be used to obtain a priority review for any application submitted under section 505(b)(1) of the FD&C Act or section 351 of the Public Health Service Act (the PHS Act). The guidance explains to internal and external stakeholders how FDA intends to implement the provisions of section 524, and also provides information on using the priority review vouchers and on transferring priority review vouchers to other sponsors.

2. Purpose and Use of the Information Collection

There has been significant outside interest in FDA's interpretation of section 1102 of the FDAAA, which adds a new section 524 to the FD&C Act. Section 524 makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease product applications that meet the criteria specified by the act. The guidance explains to internal and external stakeholders how FDA intends to implement the provisions of section 524.

3. Use of Improved Information Technology and Burden Reduction

Applicants should submit the information described in the guidance in the same manner that other application-related submissions are submitted. FDA has made available several guidances on how to submit marketing applications. These guidance documents and others are available at FDA's web site http://www.fda.gov/cder/guidance/index.htm.

4. Efforts to Identify Duplication and Use of Similar Information

This information does not duplicate any other collection.

5. Impact on Small Businesses or Other Small Entities

Although new drug development is typically an activity completed by large multinational drug firms, the information collection required under 21 CFR 314 applies to small as well as large companies submitting marketing applications. However, under the Regulatory Flexibility Act, FDA regularly analyzes regulatory options that would minimize any significant impact on small entities. FDA also assists small businesses in complying with regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

Section 524 of the FD&C Act authorizes FDA to award priority review vouchers to sponsors of certain tropical disease product applications that meet the criteria specified by section 524. This guidance enables FDA to meet that statutory requirement.

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

There are no special circumstances for this collection of information.

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

In the Federal Register of October 20, 2008 (73 FR 62298), FDA published a 60-day notice requesting public comment on the proposed collection of information. The comments we received did not pertain to the information collection that would result from the guidance (that is, the four types of submissions estimated in Table 1).

9. Explanation of Any Payment or Gift to Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents under these requirements.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted under this information collection is protected under 21 CFR 314.430 and under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under Section 310(j) of the Act.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hour and Costs

12a. Annualized Hour Burden Estimate

Under the guidance, sponsors of certain tropical disease drug product applications submitted under section 505(b)(1) of the act and section 351 of the PHS Act may request a priority review voucher. Based on inquiries and discussions with industry about section 524, we estimate that we will receive annually approximately five requests from five sponsors, and that each request will take approximately 8 hours to prepare and submit to FDA.

The guidance also states that sponsors should notify FDA of their intent to use a priority review voucher, including the date on which the sponsor intends to submit the application, at least 90 days before use. We estimate that we will receive annually approximately five notifications of intent to use a voucher from five sponsors, and that each notification will take approximately 8 hours to prepare and submit to FDA.

The guidance also permits the transfer of a priority review voucher from one sponsor to another, and states that each transfer should be documented with a letter of transfer. We estimate that we will receive approximately two letters indicating the transfer of a voucher from two application holders, and two letters from two new voucher owners acknowledging the transfer, and that it will take approximately 8 hours to prepare and submit each letter to FDA.

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

Description of Respondents: Sponsors submitting applications under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

Table 1.--Estimated Annual Reporting Burden

Guidance for Industry on Tropical Disease Priority Review Vouchers	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Priority Review Voucher Request	5	1	5	8	40
Notifications of Intent To Use a Voucher	5	1	5	8	40
Letters Indicating the Transfer of a Voucher Letter	2	1	2	8	16
Acknowledging the Receipt of a Transferred Voucher	2	1	2	8	16

TOTAL					112

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

FDA estimates an average pharmaceutical industry wage rate of approximately $85.00 per hour for preparing and submitting the information collection under the guidance. Multiplied times the total hour burden estimated above, the total cost burden to respondents is $ 9,520.

14. Annualized Cost to the Federal Government

The total cost to Federal government is $7,508 (rounded to the nearest dollar). This is calculated by multiplying the total FDA reviewer hours (128) by an average hourly wage of $58.65. The table that follows contains a breakdown of costs by each type of voucher.

Guidance for Industry on Tropical Disease Priority Review Vouchers	Total Annual Industry Submissions	FDA Hours to Review Each Submission	Total Hours	Total Cost
Priority Review Voucher Request	5	16	80	4,692
Notifications of Intent To Use a Voucher	5	8	40	2,346
Letters Indicating the Transfer of a Voucher Letter	2	2	4	235
Acknowledging the Receipt of a Transferred Voucher	2	2	4	235
TOTAL			128	7,508

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish tabulated results of these information collection requirements.

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

There are no new forms associated with this collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no certifications required.