Guidance for Industry – User Fee Waivers, Reductions, and Refunds for Drug and Biological Products

OMB Control Number 0910 - NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection approval request is for a Food and Drug Administration (FDA) draft guidance for industry entitled "User Fee Waivers, Reductions, and Refunds for Drug and Biological Products." The draft guidance provides recommendations to applicants considering whether to request a waiver or reduction in user fees assessed under Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This draft guidance describes the types of waivers and reductions permitted under the user fee provisions of the FD&C Act, and the procedures for submitting requests for waivers or reductions and requests for reconsideration and appeal. It also provides clarification on related issues such as user fee exemptions for orphan drugs.

Under Section 736(d) of the FD&C Act, FDA will grant a waiver of or reduction in one or more user fees assessed under Section 736(a) of the FD&C Act when it finds that an applicant meets the eligibility criteria under one of the following provisions:

- A waiver or reduction is necessary to protect the public health.
- The assessment of the fee would present a significant barrier to innovation because of limited resources available to the person or other circumstances.
- The applicant is a small business submitting its first human drug to the Secretary for review.

The draft guidance describes how to submit requests for waivers, reductions, and refunds of certain user fees. It also includes recommendations for submitting information for requests for reconsideration of denials of waiver or reductions requests, and for requests for appeals. The FD&C Act also provides for waiver or reduction of user fees if the fees would exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for the applicant, but fees-exceed-the-costs waivers and reductions are not addressed in this guidance document.

A. Public Health Waivers

Under the guidance an applicant may qualify for a waiver of or reductions in application, product, and/or establishment fees if the waiver or reduction is necessary to protect the public health. Under this provision, FDA may grant a public health waiver of or reduction in user fees if the Agency finds that the following two criteria are met:

- The product protects the public health; and
- The applicant shows that a waiver or reduction is necessary to continue an activity that protects the public health.

To qualify for a waiver or reduction in user fees under this provision, an applicant must meet both criteria.

B. Barrier to Innovation Waivers

Under Section 736(d)(1)(B) of the FD&C Act, an applicant may qualify for a waiver of or reduction in application, product, and/or establishment fees when the assessment of the fees would present a significant barrier to innovation because of limited resources available to the applicant or other circumstances. Under this provision, FDA may grant a waiver or reduction in user fees if:

- The product or other products or technologies under development by the applicant are innovative; and
- The fee(s) would be a significant barrier to the applicant's ability to develop, manufacture, or market innovative products or to pursue innovative technology.

To qualify for a waiver or reduction in user fees under this provision, an applicant must meet both criteria.

C. Financial Considerations for Public Health and Barrier-to-Innovation Waivers and Reductions

When evaluating requests for waivers of or reductions in user fees under the public health or barrier to innovation provisions, the Agency considers the financial resources of the applicant and its affiliates, regardless of who submits a request for a waiver or reduction of user fees. The limited financial resources of an applicant and its affiliates are an important indicator of whether user fees are a barrier to innovation or a waiver or reduction is necessary to protect the public health. FDA will consider the total annual revenue of an applicant and its affiliates in determining whether the applicant has limited financial resources. In addition to total annual revenue of the applicant and its affiliates, FDA considers other available assets, including net proceeds, cash, and total assets.

D. Small Business Waivers

Under Section 736(d)(1)(D) of the FD&C Act, an applicant is eligible for a waiver of the application fee if the applicant is a small business submitting its first human drug application to the Agency for review and does not have another product approved under a human drug application and introduced or delivered for introduction into interstate commerce. An applicant is eligible for a small business waiver when:

- The applicant employs fewer than 500 employees, including employees of affiliates;
- The applicant does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce; and
- The applicant, including its affiliates, is submitting its first human drug application.

To qualify for a small business waiver, an applicant must meet all of these criteria.

The FDA works with the Small Business Administration (SBA), which makes the determinations on whether the applicant is a small business for purposes of user fee waivers. SBA asks the applicant to submit certain information. That submission of information to SBA is already approved by OMB under OMB control number 3245-0101.

2. Purpose and Use of the Information Collection

This information is used by the private sector, pharmaceutical companies considering whether to request a waiver, reduction, or refund of fees assessed under Sections 735 and 736 or the FD&C Act.

3. Use of Improved Information Technology and Burden Reduction

The submissions noted in the guidance are generally in the form of letters, which the Agency is happy to receive electronically by e-mail or by fax.

4. Efforts to Identify Duplication and Use of Similar Information

The information requested under the guidance does not duplicate any other information 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 requested under the guidance applies to small as well as

large companies. 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

The frequency of information submission recommended by this guidance is intended to provide applicants with the opportunity to request waivers, reductions, and refunds for user fees assessed under Sections 735 and 736 of the FD&C Act. The guidance provides procedures that will encourage open and prompt communication between pharmaceutical companies requesting waivers and FDA. Although the Agency may occasionally request additional data to complete its review of a request for a waiver, reduction, or refund, generally, this collection of information is a one-time collection.

7. Special Circumstances Relating to the Guidelines of 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

8a. Publication in the FEDERAL REGISTER

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the Federal Register of March 14, 2011 (76 FR 13629). No comments were received.

8b. Outside Consultation

No comments were received in response to the Federal Register notice.

9. Explanation of Any Payment or Gift to Respondents

FDA has not provided and has no intention to provide any payment of gift to respondents under this guidance.

10. Assurance of Confidentiality Provided to Respondents

FDA plans to disclose to the public information about its actions granting or denying requests for waivers and reductions of user fees. This disclosure will be consistent with the laws and regulations governing the disclosure of confidential commercial or financial information.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

The draft guidance describes how to submit requests for waivers, reductions, and refunds of certain user fees. It also includes recommendations for submitting information for requests for reconsideration of denials of waiver or reduction requests, and for requests for appeals. We estimate that the total annual number of waiver requests submitted for all of these categories will be 90, submitted by 75 different sponsors. We estimate that the average burden hours for preparation of a submission will total 16 hours. Because FDA may request additional information from the applicant during the review period, we have also included in this estimate time to prepare any additional information.

The reconsideration and appeal requests are not addressed in the FD&C Act, but are discussed in the draft guidance. We estimate that we will receive 3 requests for reconsideration annually from 3 respondents, and that the total average burden hours for a reconsideration request will be 24 hours. We estimate that we will receive 1 request annually for an appeal of a user fee waiver determination, and that the time needed to prepare an appeal would be approximately 12 hours. Reconsideration requests are sent to the Associate Director for Policy at the Center for Drug Evaluation and Research (CDER), and requests for appeals are sent to the User Fee Appeals Officer at FDA, with a copy to the Associate Director for Policy at CDER.

We have also included in this estimate both the time needed to prepare the request for appeal and the time needed to create and send a copy of the request for an appeal to the Associate Director for Policy at CDER.

The burden for filling out and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) has not been included in the burden analysis, because that information collection is already approved by OMB under OMB control number 0910-0297. The collections of information associated with a new drug application or biologics license application have been approved under OMB control numbers 0910-0001 and 0910-0338, respectively.

We have included in the burden estimate the preparation and submission of application fee waivers for small businesses, because small businesses requesting a waiver must submit documentation to FDA on the number of their employees and must include the information that the application is the first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval. Because the Small Business Administration (SBA) makes the size determinations for FDA, small businesses must also submit information to the SBA. The submission of information to SBA is already approved by OMB under OMB control number 3245-0101.

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

Table 1. – Estimated Annual Reporting Burden

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Federal Food, Drug, and Cosmetic Act Section 736	75	1.2	90	16	1,440
Reconsideration Requests	3	1	3	24	72
Appeal Requests	1	1	1	12	12
Total					1,524

12b. Annualized Cost Burden Estimate

FDA estimates an average industry wage of $75 per hour (including overhead and benefits) for preparing and submitting the information requirements in this guidance.

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

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

14. Annualized Cost to the Federal Government

There are approximately 8 FTEs devoted to the user fee waiver program. Approximately 50% of FTE time is devoted to review of and response to requests for waivers, reductions, and refunds for drug and biological products. If each FTE equals approximately $269,000, the total

burden to the Federal Government would be approximately $1,076,000 (8 x 50% x $269,000 = $1,076,000).

15. Explanation for Program Changes or Adjustments

This is a new collection of information.

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

The Agency is not seeking to not display the expiration date for OMB approval of the information collection.

17. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

1. Agency/Subagency originating request

FDA

2. OMB control number b. [ ] None

a. 0910 - NEW

3. Type of information collection (*check one*)

a. [X] New Collection

b. [ ] Revision of a currently approved collection

c. [x] Extension of a currently approved collection

d. [ ] Reinstatement, without change, of a previously approved collection for which approval has expired

e. [ ] Reinstatement, with change, of a previously approved collection for which approval has expired

f. [ ] Existing collection in use without an OMB control number

For b-f, note Item A2 of Supporting Statement instructions

4. Type of review requested (*check one*)

a. [x] Regular submission

b. [ ] Emergency - Approval requested by at close of comment period

c. [ ] Delegated

5. Small entities

Will this information collection have a significant economic impact on a substantial number of small entities? [ ] Yes [x] No

6. Requested expiration date

a. [X] Three years from approval date b. [ ] Other Specify:____/

7. Title User Fee Waivers, Reductions, and Refunds for Drug and Biological Products

8. Agency form number(s) (*if applicable*)

9. Keywords reporting

10. Abstract The information collection deals with FDA's patent term restoration regulations on due diligence petitions for regulatory review period revision. When a patented product must receive FDA approval before marketing is permitted, the Patent and Trademark Office (PTO) may add a portion of FDA's review time to the term of a patent. Petitioners may request reductions in the regulatory review time if FDA marketing approval was not pursued with ``due diligence.''

11. Affected public (*Mark primary with "P" and all others that apply with "x"*)

a. ___ Individuals or households d. ___ Farms

b. _x_ Business or other for-profit e. ___ Federal Government

c. ___ Not-for-profit institutions f. ___ State, Local or Tribal Government

12. Obligation to respond (*check one*)

a. [X] Voluntary- (guidance document)

b. [ ] Required to obtain or retain benefits

c. [Mandatory

13. Annual recordkeeping and reporting burden

a. Number of respondents _____

b. Total annual responses _____

1. Percentage of these responses collected electronically

c. Total annual hours requested 1,524

d. Current OMB inventory ___

e. Difference _____

f. Explanation of difference

1. Program change _____

2. Adjustment New collection _____

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*

a. Total annualized capital/startup costs 0

b. Total annual costs (O&M) 0

c. Total annualized cost requested 0

d. Current OMB inventory 0

e. Difference 0

f. Explanation of difference

1. Program change _____

2. Adjustment _____

15. Purpose of information collection (*Mark primary with "P" and all others that apply with "X"*)

a. __ Application for benefits e.__ Program planning or management

b. __ Program evaluation f.__ Research

c. __ General purpose statistics g. X Regulatory or compliance

d. __ Audit

16. Frequency of recordkeeping or reporting *(check all that apply)*

a. [ ] Recordkeeping b. [ ] Third party disclosure

c. [x] Reporting

1. [x] On occasion 2. [ ] Weekly 3. [ ] Monthly

4. [ ] Quarterly 5. [ ] Semi-annually 6. [ ] Annually

7. [ ] Biennially 8. [x] Other (describe) one-time

17. Statistical methods

Does this information collection employ statistical methods

[ ] Yes [x] No

18. Agency Contact (person who can best answer questions regarding the content of this submission)

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