

between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: July 1, 2011.

Steven Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2011-16974 Filed 7-7-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0237]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 8, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of

Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0646. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs—(OMB Control Number 0910-0646)—Extension

In the **Federal Register** of July 28, 2009 (74 FR 37163), FDA published a final rule that required the holder of a new drug application (NDA) to notify the Agency if an authorized generic drug is marketed by clearly including this information in annual reports in an easily accessible place and by sending a copy of the relevant portion of the annual reports to a central contact point. We took this action as part of our implementation of the Food and Drug Administration Amendments Act, which requires that FDA publish a list of all authorized generic drugs included in an annual report after January 1, 1999, and that the Agency update the list quarterly. We initially published this list on June 27, 2008, on the Internet and notified relevant Federal Agencies that the list was published, and we will continue to update it.

During the past several years, FDA has been reviewing annual reports it has received under § 314.81(b)(2) (21 CFR 314.81(b)(2)) to discern whether an authorized generic drug is being

marketed by the NDA holder. Based on information learned from this review and based on the number of annual reports the Agency currently receives under § 314.81(b)(2), we estimate that we will receive approximately 400 annual reports containing the information required under § 314.81(b)(2)(ii)(b), for authorized generic drugs that were marketed during the time period covered by an annual report submitted after January 1, 1999. Based on the number of sponsors that currently submit annual reports, we estimate that approximately 60 sponsors will submit these 400 annual reports with authorized generics. As indicated in table 1 of this document, we are estimating that the same number of annual reports will be submitted each year from the same number of sponsors containing the information required under § 314.81(b)(2)(ii)(b), and that the same number of copies of that portion of each annual report containing the authorized generic drug information will be submitted from the same number of sponsors. Concerning the hours per response, based on our estimate of 40 hours to prepare each annual report currently submitted under § 314.81(b)(2), we estimate that sponsors will need approximately 1 hour to prepare the information required under § 314.81(b)(2)(ii)(b) for each authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999; approximately 15 minutes to prepare the information required under § 314.81(b)(2)(ii)(b) for each subsequent annual report; and approximately 3 minutes to submit to FDA a copy of that portion of each annual report containing the authorized generic drug information.

In the **Federal Register** of April 13, 2011 (76 FR 20677), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR 314.81(b)(2)(ii)(b)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) ²	Total hours
Authorized generic drug information on first marketed generics in an annual report	60	6.7	400	1	400
Authorized generic drug information submitted in each subsequent annual report	60	6.7	400	15/60	100
The submission of a copy of that portion of each annual report containing authorized generic drug information	60	6.7	400	3/60	20

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

21 CFR 314.81(b)(2)(ii)(b)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) ²	Total hours
Total	520

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

² Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format “[number of minutes per response]/60.”

Dated: July 1, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
 [FR Doc. 2011-17141 Filed 7-7-11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 [Docket No. FDA-2011-D-0108]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Revised Draft Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by August 8, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202-395-7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-New and title “Revised Draft Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and

Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792,
Elizabeth.Berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Revised Draft Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability—(OMB Control Number 0910—New)

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled “User Fee Waivers, Reductions, and Refunds for Drug and Biological Products.” This revised draft guidance provides recommendations for applicants planning to request waivers or reductions in user fees assessed under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379g and 379h). This revised 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. The revised draft guidance also provides clarification on related issues such as user fee exemptions for orphan drugs. After comments are received and considered, FDA intends to promptly issue a final guidance.

This revised draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on user fee waivers and reductions for drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain

approval from OMB for each collection of information that they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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.