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

SUPPORTING STATEMENT

Terms of Clearance: This collection is approved for 1 year. By the time of the next submission, FDA will have implemented a new electronic submission format that permits electronic submitters to avoid the duplicative reporting requirement discussed in the prior term of clearance (i.e., separate notification requirement regarding authorized generics). If FDA has not implemented this format by the time of the next PRA submission, OMB will disapprove this collection as duplicative.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration Amendments Act of 2007 (FDAAA) requires that FDA publish on its Internet site a complete list of all authorized generic drugs included in an annual report submitted to the Agency after January 1, 1999, consisting of: (1) the drug trade name, (2) the brand company manufacturer; and (3) the date the authorized generic drug entered the market, and update the list quarterly and notify relevant Federal agencies about the list. Currently, there is no requirement that an NDA holder specifically report that it is marketing an authorized generic drug. To comply with this statutory requirement, FDA is adding a regulatory requirement that annual reports specifically and clearly include the required information, and that the NDA holder report the date the authorized generic drug ceased being distributed. In addition, the regulation is requiring that a copy of that portion of the annual report containing information on any authorized generic drug be sent to a central office in the Agency that will compile the list and update it quarterly.

2. Purpose and Use of the Information Collection

The NDA holder must notify the Agency when 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 office. This requirement implements FDAAA,

which requires that FDA publish a list of all authorized generic drugs included in an annual report since 1999 and that the Agency update the list quarterly. FDA will publish this list on the Internet and notify relevant Federal agencies that the list has been published and will be updated.

3. Use of Improved Information Technology and Burden Reduction

Applicants may use automated, electronic, mechanical, or other technological collection techniques or other forms of information technology to comply with this requirement. FDA has issued guidance documents to assist applicants in submitting information to the agency in electronic format. These guidance documents are available at FDA's web site. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

4. Efforts to Identify Duplication and Use of Similar Information

As stated above, the regulation is requiring that a copy of that portion of the annual report containing information on any authorized generic drug be sent to a central office in the Agency that will compile the list and update it quarterly. This submission to FDA is necessary in order to implement FDAAA which requires that FDA publish a list of all authorized generic drugs included in an annual report since 1999 and that the Agency update the list quarterly.

5. Impact on Small Businesses or Other Small Entities

Most of the pharmaceutical companies submitting these annual reports are large multinational corporations. The Analysis of Impacts section of the July 28, 2009 final rule (74 FR 37163) contained an analysis of the impact of the rulemaking on small business.

6. Consequences of Collecting the Information Less Frequently

The Congressional mandate in the Food and Drug Administration Amendments Act of 2007 that FDA publish a complete list on its Internet site of all authorized generic drugs included in an annual report submitted to the Agency after January 1, 1999, will not be met if this information is not collected.

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 accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of May 10, 2013 (78 FR 27404). No comments were received.

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.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of the information received by FDA under the reglation would be consistent with the Freedom of Information Act, the Agency's regulations under 21 CFR Part 20, and 21 CFR 314.430.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Based on the number of annual reports the Agency currently receives under § 314.81(b)(2) containing authorized generic drug information, we estimate that we will receive approximately 500 annual reports containing the required information on authorized generic drugs. Based on the number of sponsors that currently submit these annual reports, we estimate that approximately 70 sponsors will submit these 500 annual reports. We estimate that each sponsor will need approximately 30 minutes to include the required information on authorized generic drugs in each annual report.

We also estimate that we will receive authorized generic drug information on first marketed generics in approximately 20 annual reports from approximately 20 sponsors, and that each sponsor will need approximately 1 hour to include the required information in each annual report.

We also estimate that we will receive a copy of that portion of each annual report containing the authorized generic drug information for approximately 500 annual reports from approximately 70 sponsors, and that each sponsor will need approximately 3 minutes to submit a copy of that portion of each annual report containing the authorized generic drug information.

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

Table 1.--Estimated Annual Reporting Burden

21 CFR 314.81(b)(2)(ii) *(b)*	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of authorized generic drug information in each annual report	70	7	490	.5	245
Submission of authorized generic drug information on first marketed generics in an annual report	20	1	20	1	20
Submission of a copy of that portion of each annual report containing authorized generic drug information	70	7	490	.5	25
TOTAL					290

12b. Annualized Cost Burden Estimate

FDA estimates an average pharmaceutical industry wage rate of $85 per hour for preparing and submitting this information collection. Thus, the total cost burden would be:

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Applicants	290	$85	$24,650

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Under the rulemaking, FDA estimates that no additional measurable burden would be required of FDA reviewers who currently review annual reports. The total burden for FDA's review of annual reports is accounted for in OMB control number 0910-0001.

15. Explanation for Program Changes or Adjustments

The reduction in burden hours from 520 to 290 is the result of more recent data on the number of submissions.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.