Authorized Generic Drugs Final Rule
INFORMATION COLLECTION
SUPPORTING STATEMENT

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 rulemaking requires the holder of an NDA to 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. FDA is taking this action 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. FDA plans to publish this list on the Internet and to notify relevant Federal agencies that the list has been published and will be updated.

3. Use of Improved Information Technology and Burden Reduction

In the Federal Register of December 11, 2003, FDA issued a final rule amending FDA regulations governing the format in which certain labeling is required to be submitted for review with NDAs, ANDAs, supplements, and annual reports. The final rule requires the electronic submission of the content of labeling (i.e., the content of the package insert or professional labeling, including all text, tables, and figures) in NDAs, certain BLAs, ANDAs, supplements, and annual reports electronically in a form that FDA can process, review, and archive.

The following guidances for industry are among those that have been developed to improve the use of information technology in the submission of marketing applications for human drugs and related reports:

- "Providing Regulatory Submissions in Electronic Format—General Considerations" (October 2003). This guidance includes a description of the types of electronic file formats that the agency is able to accept to process, review, and archive electronic documents. The guidance also states that documents submitted in electronic format should enable the user to: (1) Easily view a clear and legible copy of the information; (2) print each document page by page while maintaining fonts, special orientations, table formats, and page numbers; and (3) copy text and images electronically into common word processing documents.
- "Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling" (January 2001). This draft guidance discusses issues related to the electronic submission of advertising and promotional labeling materials for prescription drug and biological products.
- "Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports" (June 2003). This guidance discusses general issues related the electronic submission of postmarketing periodic adverse drug experience reports for NDAs,

ANDAs, and BLAs.

- "Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions" (June 2008). This guidance discusses issues related to the electronic submission of ANDAs, BLAs, INDs, NDAs, master files, advertising material, and promotional material.

- "Providing Regulatory Submissions in Electronic Format—General Considerations" (October 2003). This draft guidance discusses general issues common to all types of electronic regulatory submissions.

- "Providing Regulatory Submissions in Electronic Format—Content of Labeling" (April 2005). This guidance discusses issues related to the submission of the content of labeling in electronic format for marketing applications for human drug and biological products.

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 under section 1 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. However, the Analysis of Impacts section of this rulemaking contains an analysis of the impact 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 is no inconsistency with these guidelines.

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), in the Federal Register of April 13, 2011 (76 FR 20677), FDA published a notice requesting comment on this information collection. We received no comments on the information collection.

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 or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of the information received by FDA under the rulemaking 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

FDA has reviewed a small sample of annual reports it has received under § 314.81(b)(2) during the past several years 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) (during FY 2006, CDER received 2,569 annual reports under § 314.81(b)(2) from 374 sponsors), we estimate that, after the implementation of § 314.81(b)(2)(ii)*(b)*, we will receive approximately 400 annual reports containing the information required under § 314.81(b)(2)(ii)*(b)* for authorized generic drugs that entered the market after January 1, 1998.

Based on the number of sponsors that currently submit all annual reports, we estimate that approximately 60 sponsors will submit these 400 annual reports. As indicated in Table 1, we are estimating that the same number of annual reports will be submitted each subsequent 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) (see the *Federal Register* of January 4, 2008 (73 FR 868)), 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 on the market on or after January 1, 1998, 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. FDA specifically requests comments on these burden estimates.

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 Respondents	Average Burden per Response (in hours)	Total Hours
Authorized generic drug information in the first annual report submitted after the implementation of § 314.81(b)(2)(ii)*(b)*	60	6.7	400	1	400
Authorized generic drug information submitted in each subsequent annual report	60	6.7	400	5/60	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
TOTAL					520

12b. Annualized Cost Burden Estimate

FDA estimates an average pharmaceutical industry loaded wage rate of $74 per hour for preparing and submitting this information collection. Thus, the total cost burden would be $38,480.

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

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

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. In addition, FDA expects that it will take approximately 15 minutes for FDA staff to compile and review the copy of that portion of each annual report containing information on any authorized generic drug.

15. Explanation for Program Changes or Adjustments

There are no changes in burden.

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 Item 19 of OMB Form 83-I.

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

DHHS/FDA

2. OMB control number b. [ ] None

a. 0910-0646

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

a. [ ] 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: Authorized Generic Drugs Final Rule

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

9. Keywords drugs

10. Abstract: The rulemaking requires the holder of an NDA to 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. FDA is taking this action 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. FDA plans to publish this list on the Internet and to notify relevant Federal agencies that the list has been published and will be updated.

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. [ ] Voluntary- (guidance document)

b. [ ] Required to obtain or retain benefits

c. [x] Mandatory

13. Annual recordkeeping and reporting burden

a. Number of respondents 60 _____

b. Total annual responses 1200 _____

1. Percentage of these responses collected electronically

Appr. 66% of annual reports are submitted with some electronic components

c. Total annual hours requested 520

d. Current OMB inventory 520 _____ e. Difference _____

f. Explanation of difference

1. Program change N/A

2. Adjustment __

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

a. Total annualized capital/startup costs _____

b. Total annual costs (O&M) _____

c. Total annualized cost requested _____

d. Current OMB inventory _____

e. Difference _____

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. [X] Annually

7. [ ] Biennially 8. [ ] Other (describe) _____

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)

Name: Elizabeth Berbakos

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OMB 83-I