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 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

The following industry guidances relevant to submitting annual reports and other information 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-—Annual reports for NDAs and ANDAs". This guidance discusses issues related to the electronic submission of annual reports for NDAs and ANDAs.
- "Providing Regulatory Submissions in Electronic Format--NDAs". This guidance provides information on how to submit a complete archival copy of an NDA in electronic format and applies to the submission of original NDAs as well as to the submission of supplements and amendments to NDAs.
- "Providing Regulatory Submissions in Electronic Format--General Considerations". 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-—General Considerations". This draft guidance discusses general issues common to all types of electronic regulatory submissions.

These guidance documents 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
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
As required by section 3506(c)(2)(B) of the PRA, FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the Federal Register of September 29, 2008 (73 FR 56529). All of the comments are summarized and responded to in the preamble of the final rule. The following comment pertained to the information collection:

One comment opposed the provision requiring separate submission of the required information by mail in either hard copy or electronic format. The comment stated that this provision is contrary to FDA's long-standing record of encouraging and facilitating electronic regulatory submissions and to its goal to use information technology to facilitate the application and review processes. The commenter believes that for annual reports currently submitted in electronic format, FDA should not require separate submission of the authorized generic information to the Office of Pharmaceutical Science.

(Response) The purpose of this rule is to facilitate FDA's obligation to accurately report a complete list of all authorized generic drugs included in annual reports and to update the list in a timely fashion. To fulfill our obligation, we need ready access to the required information. Therefore, in this final rule, we are requiring that the section 505(t) (authorized generics) information be separately sent to us, as proposed. However, in response to the comments, we have modified the language in § 314.81(b)(2)(ii)(b) to provide that the authorized generics information may also be submitted to FDA using email, in lieu of sending the information by regular mail or courier. FDA believes this will provide an alternative method of submission that may be more convenient for some sponsors. We encourage sponsors that currently elect to submit their annual reports in electronic format to continue to do so. At such time that electronic submission of annual reports is mandated by FDA and FDA develops the capability to readily retrieve information it

needs to comply with section 505(t) of the act, separate submission of the authorized generic information will no longer be necessary, and the language in § 314.81(b)(2)(ii)(b) of the codified has been clarified to reflect this. Until electronic submission of annual reports is required and FDA can readily retrieve the authorized generics information from the annual reports database, sponsors must submit the authorized generics information separately by regular mail or email (regardless of what format the sponsor currently uses to submit its annual report).

9. Explanation of Any Payment or Gift to Respondents
No payment or gift was provided 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
Questions of a sensitive nature are not applicable to this information collection.

12. Estimates of Annualized Hour Burden and Total Costs to Respondents/Recordkeepers
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)*	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	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 hour	400
Authorized generic drug information submitted in each subsequent annual report	60	6.7	400	15 minutes	100
The submission of a copy of that portion of each annual report containing authorized generic drug information	60	6.7	400	3 minutes	20
TOTAL					520

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

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 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

This is a new collection for a final rule. To comply with FDAAA 2007, 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.

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.