
William H. Gimson,
Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

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BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. 2004N–0441]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for FDA Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

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

Applications for FDA Approval to Market a New Drug—21 CFR Part 314—(OMB Control Number 0910 0001)—Extension

Under Section 505(a) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or 505(j) of the act is effective with respect to such drug. Section 505(b) and 505(j) of the act requires a sponsor to submit to FDA a new drug application (NDA) containing, among other things, full reports of investigations that show whether or not the drug is safe and effective for use, a full list of articles used as components in the drug, a full description of manufacturing methods, samples of the drugs required, specimens of the labeling proposed to be used, and certain patent information as applicable. Under the act, it is the sponsor’s responsibility to provide the information needed by FDA to make a scientific and technical determination that the product is safe and effective. This information collection approval request is for all information requirements imposed on sponsors by the regulations under part 314 (21 CFR 314), who apply for approval of a new drug application in order to market or to continue to market a drug.

Section 314.50(a) requires that an application form (Form FDA 356h) be submitted that includes introductory information about the drug as well as a checklist of enclosures.

Section 314.50(b) requires that an index be submitted with the archival copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that a summary of the application be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the NDA contain the following technical sections about the new drug: Chemistry, manufacturing, and controls; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; microbiology; clinical data; and statistical section.

Section 314.50(e) requires the applicant to submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that case report forms and tabulations be submitted with the archival copy.

Section 314.50(h) requires that patent information, as described under § 314.53, be submitted with the application.

Section 314.50(i) requires that patent certification information be submitted in 505(b)(2) applications for patents claiming the drug, drug product, method of use, or method of manufacturing.

Section 314.50(j) requires that applicants that request a period of marketing exclusivity submit certain information with the application.

Section 314.50(k) requires that an archival, review, and field copy of the application be submitted.

Section 314.52 requires that notice of certification of invalidity or noninfringement of a patent to patent holders and NDA holders be sent by 505(b)(2) applicants.

Section 314.54 sets forth the content requirements for applications filed under section 505(b)(2) of the act.

Section 314.60 sets forth reporting requirements for sponsors who amend an unapproved application.

Section 314.65 states that the sponsor must notify FDA when withdrawing an unapproved application.

Sections 314.70 and 314.71 require that supplements be submitted to FDA.
for certain changes to an approved application.

Section 314.72 requires sponsors to report to FDA any transfer of ownership of an application.

Section 314.80(c)(1) and (c)(2) sets forth requirements for expedited adverse drug experience postmarketing reports and followup reports, as well as for periodic adverse drug experience postmarketing reports (Form FDA 3500A). (The burden hours for § 314.80(c)(1) and (c)(2) are already approved by OMB under 0910–0230 and 0910–0291 and are not included in the hour burden estimates in table 1 of this document).

Section 314.80(i) establishes recordkeeping requirements for reports of postmarketing adverse drug experiences. (The burden hours for § 314.80(i) are already approved by OMB under 0910–0230 and 0910–0291 and are not included in the hour burden estimates in table 1 of this document).

Section 314.81(b)(2) requires that annual reports be submitted to FDA (Form FDA 2252). This form has been revised as a result of the requirements under § 314.80 and are not included in the hour burden estimates in table 1 of this document.

Section 314.81(b)(4) requires that field alert reports be submitted to FDA (Form FDA 3331).

Section 314.81(b)(2) requires that for amendments to an unapproved ANDA, a patent holder or approved application holder who is an exclusive patent licensee must submit to FDA a waiver that waives the opportunity to file a legal action for patent infringement.

Section 314.110(a)(3) and (a)(4) states that, after receipt of an FDA approvable letter, an applicant may notify FDA that it agrees to an extension of the review period so that it can determine whether to respond further.

Section 314.110(b) states that, after receipt of an approvable letter, an ANDA applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (The burden hours for § 314.110(a)(3) and (a)(4) are included under the parts 10 through 16 (21 CFR parts 10 through 16) hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document).

Section 314.110(a)(5) states that, after receipt of an approvable letter, a patent owner or approved application holder may notify FDA in accordance with section 314.110(a)(5) states that, after receipt of an FDA approvable letter, an applicant may notify FDA that it agrees to an extension of the review period so that it can determine whether to respond further.

Section 314.110(b) states that, after receipt of an approvable letter, an ANDA applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (The burden hours for § 314.110(a)(3) and (a)(4) are included under the parts 10 through 16 (21 CFR parts 10 through 16) hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document).

Section 314.110(a)(3) and (a)(4) states that, after receipt of an FDA approvable letter, an applicant may notify FDA that it agrees to an extension of the review period so that it can determine whether to respond further.

Section 314.110(b) states that, after receipt of an approvable letter, an ANDA applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (The burden hours for § 314.110(a)(3) and (a)(4) are included under the parts 10 through 16 (21 CFR parts 10 through 16) hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document).

Section 314.120(a)(3) states that, after receipt of a not approvable letter, an ANDA applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (The burden hours for § 314.120(a)(3) are not included in the hour burden estimates in table 1 of this document).
withdrawn for safety or effectiveness determination whether the drug was voluntarily withdrawn from sale must be accompanied by a petition seeking a determination whether the drug was withdrawn for safety or effectiveness reasons. (The burden hours for § 314.122(a) are already approved by OMB under 0910–0183 and are not included in the hour burden estimates in table 1 of this document).

Section 314.122(d) sets forth requirements for relisting petitions for unlisted discontinued products. (The burden hours for § 314.122(d) are already approved by OMB under 0910–0183 and are not included in the hour burden estimates in table 1 of this document).

Section 314.126(c) sets forth requirements for a petition to waive criteria for adequate and well-controlled studies. (The burden hours for § 314.126(c) are already approved by OMB under 0910–0183 and are not included in the hour burden estimates in table 1 of this document).

Section 314.151(a) and (b) set forth requirements for the withdrawal of approval of an ANDA and the applicant’s opportunity for a hearing and submission of comments. (The burden hours for § 314.151(a) and (b) are included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document).

Section 314.151(c) sets forth the requirements for withdrawal of approval of an ANDA and the applicant’s opportunity to submit written objections and participate in a limited oral hearing. (The burden hours for § 314.151(c) are included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the hour burden estimates in table 1 of this document).

Section 314.151(f) requires that an applicant first submit a petition for stay of action before requesting an order from a court for a stay of action pending review. (The burden hours for § 314.530(f) are already approved by OMB under 0910–0194 and are not included in the hour burden estimates in table 1 of this document).

Respondents to this collection of information are all persons who submit an application or abbreviated application or an amendment or supplement to FDA under part 314 to obtain approval of a new drug, and any person who owns an approved application or abbreviated application.

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**Table 1.—Estimated Annual Reporting Burden**

<table>
<thead>
<tr>
<th>21 CFR Section; [Form Number]</th>
<th>No. of Respondents</th>
<th>No. of Responses per Respondent</th>
<th>Total Annual Responses</th>
<th>Hours Per Response</th>
<th>Total Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>314.50 (a), (b), (c), (d), (e), (f), (h), and (k)</td>
<td>72</td>
<td>1.44</td>
<td>104</td>
<td>1,642</td>
<td>170,768</td>
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<tr>
<td>314.50(i) and 314.94(a)(12)</td>
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<td>454</td>
<td>2</td>
<td>908</td>
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<tr>
<td>314.50(j)</td>
<td>70</td>
<td>3.71</td>
<td>260</td>
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<td>520</td>
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### Table 1.—Estimated Annual Reporting Burden1—Continued

<table>
<thead>
<tr>
<th>21 CFR Section; [Form Number]</th>
<th>No. of Respondents</th>
<th>No. of Responses per Respondent</th>
<th>Total Annual Responses</th>
<th>Hours Per Response</th>
<th>Total Hours</th>
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<tbody>
<tr>
<td>314.52 and 314.95</td>
<td>24</td>
<td>2.25</td>
<td>54</td>
<td>16</td>
<td>864</td>
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<tr>
<td>314.54</td>
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<td>16</td>
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<td>10.99</td>
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<td>385,800</td>
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<td>2.02</td>
<td>89</td>
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<td>2</td>
<td>.50</td>
<td>1</td>
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<td>314.107(c)(4), 314.107(e)(2)(iv), and 314.107(f)</td>
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<td>2</td>
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<td>1</td>
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<td>52</td>
<td>.50</td>
<td>26</td>
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<td>14</td>
<td>.50</td>
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<td><strong>2,372,556</strong></td>
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1 There are no capital costs or operating and maintenance costs associated with this collection of information.


Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 04–22815 Filed 10–6–04; 11:56 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, National Cancer Institute. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personal qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Cancer Institute, Subcommittee 2—Basic Sciences.

Date: November 15–16, 2004.

Time: November 15, 2004, 7 p.m. to 9 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Holiday Inn Bethesda, Versailles IV, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Time: November 16, 2004, 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, National Cancer Institute, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Florence E. Farber, PhD, Health Scientific Administrator, Office of the Director, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 2115, Bethesda, MD 20892, (301) 496–7628, ff6p@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)