

warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the Web cast, will be available at the following Web site: <http://www4.od.nih.gov/oba/sacghs.htm>.

Dated: December 21, 2007.

Jennifer Spaeth,

Director, NIH Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0485]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Food and Drug Administration 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 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements governing applications for FDA approval to market a new drug.

DATES: Submit written or electronic comments on the collection of information by March 4, 2008.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of the Chief Information Officer (HFA 250), Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857, 301-827-4816.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information 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** 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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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 the 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, when appropriate, and other forms of information technology.

Application for FDA Approval to Market a New Drug—(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. Under the act, it is the sponsor's responsibility to provide the information needed by FDA to make a scientific and technical determination whether the product is safe and effective for use.

This information collection approval request is for all information requirements imposed on sponsors by

the regulations under part 314 (21 CFR part 314), who apply for approval of a new drug application (NDA) or abbreviated new drug application (ANDA) 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. (The burden hours for § 314.50(h) are already approved by OMB under OMB control number 0910-0513 and are not included in the burden estimates in table 1 of this document.)

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

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 any notice of certification of invalidity or noninfringement of a patent to each patent owner and the NDA holder be sent by a section 505(b)(2) applicant that relies on a listed drug. A 505(b)(2) applicant is required to amend its application at the time notice is provided to include a statement certifying that the required notice has

been provided. A 505(b)(2) applicant also is required to amend its application to document receipt of the required notice.

Section 314.54 sets forth the content requirements for applications filed under section 505(b)(2) of the act. (The information collection burden estimate for 505(b)(2) applications is included in table 1 of this document under the estimates for § 314.50(a), (b), (c), (d), (e), (f), and (k).)

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 OMB control numbers 0910-0230 and 0910-0291 and are not included in the 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 OMB control numbers 0910-0230 and 0910-0291 and are not included in the burden estimates in table 1 of this document.)

Section 314.81(b)(1) requires that field alert reports be submitted to FDA (Form FDA 3331).

Section 314.81(b)(2) requires that annual reports be submitted to FDA (Form FDA 2252).

Section 314.81(b)(3)(i) requires that drug advertisements and promotional labeling be submitted to FDA (Form FDA 2253). Form FDA 2253 has been revised by FDA as follows: On line 8, "Please check one or both" has been revised to read "Please check only one." In the instruction for line 8, the sentence "Consumer and professional pieces should be submitted separately" has been added.

Section 314.81(b)(3)(iii) sets forth reporting requirements for sponsors who withdraw an approved drug product from sale. (The burden hours for § 314.81(b)(3)(iii) are already approved by OMB under OMB control

number 0910-0045 and are not included in the burden estimates in table 1 of this document.)

Section 314.90 sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.50 through 314.81. (The information collection burden estimate for NDA waiver requests is included in table 1 of this document under estimates for §§ 314.50, 314.60, 314.70 and 314.71.)

Section 314.93 sets forth requirements for submitting a suitability petition in accordance with 21 CFR 10.20 and 21 CFR 10.30. (The burden hours for § 314.93 are already approved by OMB under 0910-0183 and are not included in the burden estimates in table 1 of this document.)

Section 314.94(a) and (d) requires that an ANDA contain the following information: Application form; table of contents; basis for ANDA submission; conditions of use; active ingredients; route of administration, dosage form, and strength; bioequivalence; labeling; chemistry, manufacturing, and controls; samples; and patent certification.

Section 314.95 requires that any notice of certification of invalidity or noninfringement of a patent to each patent owner and the NDA holder be sent by ANDA applicants.

Section 314.96 sets forth requirements for amendments to an unapproved ANDA.

Section 314.97 sets forth requirements for submitting supplements to an approved ANDA for changes that require FDA approval.

Section 314.98(a) sets forth postmarketing adverse drug experience reporting and recordkeeping requirements for ANDAs. (The burden hours for § 314.98(a) are already approved by OMB under OMB control numbers 0910-0230 and 0910-0291 and are not included in the burden estimates in table 1 of this document.)

Section 314.98(c) requires other postmarketing reports for ANDAs: Field alert reports (Form FDA 3331), annual reports (Form FDA 2252), and advertisements and promotional labeling (Form FDA 2253). (The information collection burden estimate for field alert reports is included in table 1 of this document under § 314.81(b)(1); the estimate for annual reports is included under § 314.81(b)(2); the estimate for advertisements and promotional labeling is included under § 314.81(b)(3)(i).)

Section 314.99(a) requires that sponsors comply with certain reporting requirements for withdrawing an unapproved ANDA and for a change in ownership of an ANDA.

Section 314.99(b) sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.92 through 314.99. (The information collection burden estimate for ANDA waiver requests is included in table 1 of this document under estimates for § 314.94(a) and (d) and §§ 314.96 and 314.97.)

Section 314.101(a) states that if FDA refuses to file an application, the applicant may request an informal conference with FDA and request that the application be filed over protest.

Section 314.107(c) requires notice to FDA by the first applicant to submit a substantially complete ANDA containing a certification that a relevant patent is invalid, unenforceable, or will not be infringed of the date of first commercial marketing.

Section 314.107(e) requires that an applicant submit a copy of the entry of the order or judgment to FDA within 10 working days of a final judgment.

Section 314.107(f) requires that ANDA or section 505(b)(2) applicants notify FDA immediately of the filing of any legal action filed within 45 days of receipt of the notice of certification. A patent owner may also notify FDA of the filing of any legal action for patent infringement. If the patent owner or approved application holder who is an exclusive patent licensee waives its opportunity to file a legal action for patent infringement within the 45-day period, the patent owner or approved application holder must submit to FDA a waiver in the specified format.

Section 314.110(a)(3) and (a)(4) states that, after receipt of an FDA approvable letter, an 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 parts 10 through 16 (21 CFR parts 10 through 16) hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.110(a)(5) states that, after receipt of an 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(b) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the

burden estimates in table 1 of this document.)

Section 314.120(a)(3) states that, after receipt of a not approvable letter, an 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 included under 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)(5) states that, after receipt of a not 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 314.122(a) requires that an ANDA or a suitability petition that relies on a listed drug that has been 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 OMB control number 0910–0183 and are not included in the 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 OMB control number 0910–0183 and are not included in the 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 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 parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the 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 parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.152(b) sets forth the requirements for suspension of an ANDA when the listed drug is voluntarily withdrawn for safety and effectiveness reasons, and the applicant's opportunity to present comments and participate in a limited oral hearing. (The burden hours for § 314.152(b) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the burden estimates in table 1 of this document.)

Section 314.161(b) and (e) sets forth the requirements for submitting a petition to determine whether a listed drug was voluntarily withdrawn from sale for safety or effectiveness reasons. (The burden hours for § 314.161(b) and (e) are already approved by OMB under OMB control number 0910–0183 and are not included in the burden estimates in table 1 of this document.)

Section 314.200(c), (d), and (e) requires that applicants or others subject to a notice of opportunity for a hearing who wish to participate in a hearing file a written notice of participation and request for a hearing as well as the studies, data, and so forth, relied on. Other interested persons may also submit comments on the notice. This section also sets forth the content and format requirements for the applicants' submission in response to notice of opportunity for hearing. (The burden hours for §§ 314.200(c), (d), and (e) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.200(f) states that participants in a hearing may make a motion to the presiding officer for the inclusion of certain issues in the hearing. (The burden hours for § 314.200(f) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.200(g) states that a person who responds to a proposed order from FDA denying a request for a hearing provide sufficient data, information, and analysis to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing. (The burden hours for § 314.200(g) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the burden estimates in table 1 of this document.)

Section 314.420 states that an applicant may submit to FDA a drug master file in support of an application,

in accordance with certain content and format requirements.

Section 314.430 states that data and information in an application are disclosable under certain conditions, unless the applicant shows that extraordinary circumstances exist. (The burden hours for § 314.430 is included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the burden estimates in table 1 of this document.)

Section 314.530(c) and (e) states that, if FDA withdraws approval of a drug approved under the accelerated approval procedures, the applicant has the opportunity to request a hearing and submit data and information. (The burden hours for § 314.530(c) and (e) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.530(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 burden estimates in table 1 of this document.)

Section 314.610(b)(1) requires that applicants include a plan or approach to postmarketing study commitments in applications for approval of new drugs when human efficacy studies are not ethical or feasible, and provide status reports of postmarketing study commitments. (The information collection burden estimate for § 314.610(b)(1) is included in table 1 of this document under the estimates for §§ 314.50(a), (b), (c), (d), (e), (f), and (k) and 314.81(b)(2)).

Section 314.610(b)(3) requires that applicants propose labeling to be provided to patient recipients in applications for approval of new drugs when human efficacy studies are not ethical or feasible. (The information collection burden estimate for § 314.610(b)(3) is included in table 1 of this document under the estimates for § 314.50(e)).

Section 314.630 requires that applicants provide postmarketing safety reporting for applications for approval of new drugs when human efficacy studies are not ethical or feasible. (The burden hours for § 314.630 are already approved by OMB under OMB control numbers 0910–0230 and 0910–0291 and are not included in the burden estimates in table 1 of this document.)

Section 314.640 requires that applicants provide promotional

materials for applications for approval of new drugs when human efficacy studies are not ethical or feasible. (The information collection burden estimate for § 314.640 is included in table 1 of

this document under the estimates for § 314.81(b)(3)(i)).

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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section [Form Number]	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
314.50(a), (b), (c), (d), (e), (f), and (k)	85	1.41	120	1,917	230,040
314.50(i) and 314.94(a)(12)	96	9.61	923	2	1,846
314.50(j)	71	4.02	286	2	572
314.52 and 314.95	71	3.66	260	16	4,160
314.60	305	15.05	4,590	80	367,200
314.65	13	1.08	14	2	28
314.70 and 314.71	281	9.30	2,613	150	391,950
314.72	69	3.40	235	2	470
314.81(b)(1) [3331]	114	2.68	306	8	2,448
314.81(b)(2) [2252]	724	11.15	8,073	40	322,920
314.81(b)(3)(i) [2253]	390	61.39	23,942	2	47,884
314.94(a)(1) through (a)(11) and (d)	110	7.21	793	480	380,640
314.96	300	28	8,400	80	672,000
314.97	215	20.66	4,442	80	355,360
314.99(a)	40	2.02	81	2	162
314.101(a)	1	1	1	.50	.50
314.107(c)	56	4.1	230	.50	115
314.107(e)	25	3.92	98	.50	49
314.107(f)	56	4.1	230	.50	115
314.110(a)(5)	45	1.15	52	.50	26
314.120(a)(5)	10	1.20	12	.50	6
314.420	487	1.98	964	61	58,804
Total					2,836,795.5

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

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: December 27, 2007.
Jeffrey Shuren,
Assistant Commissioner for Policy.
 [FR Doc. E7-25593 Filed 1-3-07; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0367]

Draft Guidance for Industry on Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.