

medical need. Mostly, the Agency expects that information to support a designation request will have been gathered under existing provisions of the FD&C Act, the PHS Act, or the implementing regulations. If such information has already been submitted to the Agency, the information may be summarized in the fast track designation request. The guidance recommends that a designation request include, where applicable, additional information not specified elsewhere by statute or regulation. For example, additional information may be needed to show that a product has the potential to address an unmet medical need where an approved therapy exists for the serious or life-threatening condition to be treated. Such information may include clinical data, published reports, summaries of data and reports, and a list of references. The amount of information and discussion in a designation request need not be voluminous, but it should be sufficient to permit a reviewer to assess whether the criteria for fast track designation have been met.

After the Agency makes a fast track designation, a sponsor or applicant may submit a premeeting package which may include additional information supporting a request to participate in certain fast track programs. The premeeting package serves as background information for the meeting

and should support the intended objectives of the meeting. As with the request for fast track designation, the Agency expects that most sponsors or applicants will have gathered such information to meet existing requirements under the FD&C Act, the PHS Act, or implementing regulations. These may include descriptions of clinical safety and efficacy trials not conducted under an investigational new drug application (IND) (*i.e.*, foreign studies), and information to support a request for accelerated approval. If such information has already been submitted to FDA, the information may be summarized in the premeeting package. Consequently, FDA anticipates that the additional collection of information attributed solely to the guidance will be minimal.

Under section 506(c) of the FD&C Act, a sponsor must submit sufficient clinical data for the Agency to determine, after preliminary evaluation, that a fast track product may be effective. Section 506(c) also requires that an applicant provide a schedule for the submission of information necessary to make the application complete before FDA can commence its review. The guidance does not provide for any new collection of information regarding the submission of portions of an application that are not required under section 506(c) of the FD&C Act or any other

provision of the FD&C Act. All forms referred to in the guidance have a current OMB approval: FDA Forms 1571 (OMB control number 0910-0014); 356h (OMB control number 0910-0338); and 3397 (OMB control number 0910-0297).

Respondents to this information collection are sponsors and applicants who seek fast track designation under section 506 of the FD&C Act. The Agency estimates the total annual number of respondents submitting requests for fast track designation to the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research is approximately 97, and the number of requests received is approximately 118 annually. FDA estimates that the number of hours needed to prepare a request for fast track designation is approximately 60 hours per request.

Not all requests for fast track designation may meet the statutory standard. Of the requests for fast track designation made per year, the Agency granted 77 from 64 respondents, and for each of these granted requests a premeeting package was submitted to the Agency. FDA estimates that the preparation hours are approximately 100 hours per premeeting package.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Reporting activity	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Designation Request	97	1.22	118	60	7,080
Premeeting Packages	64	1.20	77	100	7,700
Total					14,780

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

Dated: April 4, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
 [FR Doc. 2011-8818 Filed 4-12-11; 8:45 am]
BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0627]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of

information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 13, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0001. Also include the FDA docket number found

in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20852, 301-796-3792, Elizabeth.Berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

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 FD&C 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 FD&C Act is effective with respect to such drug. Under the FD&C 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; statistical; and pediatric use sections.

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(l) 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 FD&C 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 follow-up 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).

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 § 10.20 (21 CFR 10.20) and § 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; 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(b)(3) states that, after receipt of an FDA complete response 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(b)(3) are included under parts 10 through 16 (21 CFR parts 10 and 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(c) states that, after receipt of a complete response 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 314.153(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 are 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 are 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 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(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.

In the **Federal Register** of December 17, 2010 (75 FR 79001), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Section; [Form Number]	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
314.50(a), (b), (c), (d), (e), (f), and (k)	92	1.36	126	1,917	241,542
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	349	21.67	7,564	80	605,120
314.65	10	1.20	12	2	24
314.70 and 314.71	620	4.91	3,050	150	457,500
314.72	104	2.98	310	2	620
314.81(b)(1) [3331]	147	2.57	378	8	3,024
314.81(b)(2) [2252]	656	13.84	9,084	40	363,360
314.81(b)(3)(i) [2253]	490	61.48	30,130	2	60,260
314.94(a)(1)–(11) and (d)	110	7.83	862	480	413,760
314.96	292	35.82	10,461	80	836,880
314.97	197	26.23	5,169	80	413,520
314.99(a)	53	2.30	122	2	244
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(c)	11	1.36	15	.50	7.5
314.420	524	1.98	1,038	61	63,318
Total					3,466,037

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

Dated: April 7, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
 [FR Doc. 2011-8907 Filed 4-12-11; 8:45 am]
BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0049]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Presubmission Conferences, New Animal Drug Applications and Supporting Regulations, and Food and Drug Administration Form 356V

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 13, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0032. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-

796-7651,
Juanmanuel.vilela@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Presubmission Conferences, New Animal Drug Applications and Supporting Regulations, and FDA Form 356V—(OMB Control Number 0910-0032)—Extension

Under section 512(b)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(b)(3)), any person intending to file a new animal drug application (NADA) or supplemental NADA or a request for an investigational exemption under section 512(j) is entitled to one or more conferences with FDA to reach an agreement acceptable to FDA establishing a submission or investigational requirement. FDA and industry have found that these meetings have increased the efficiency of the drug development and drug review processes.

Section 514.5 (21 CFR 514.5) describes the procedures for requesting, conducting, and documenting presubmission conferences. Section 514.5(b) describes the information that must be included in a letter submitted by a potential applicant requesting a presubmission conference, including a proposed agenda and a list of expected participants. Section 514.5(d) describes the information that must be provided by the potential applicant to FDA at least 30 days prior to a presubmission conference. This information includes a detailed agenda, a copy of any materials to be presented at the conference, a list of proposed indications and, if available, a copy of the proposed labeling for the product under consideration, and a copy of any background material that provides scientific rationale to support the potential applicant's position on issues listed in the agenda for the conference. Section 514.5(f) discusses the content of the memorandum of conference that

will be prepared by FDA and gives the potential applicant an opportunity to seek correction to or clarification of the memorandum.

Under section 512(b)(1) of the FD&C Act, any person may file an NADA seeking approval to legally market a new animal drug. Section 512(b)(1) of the FD&C Act sets forth the information required to be submitted in an NADA. FDA allows applicants to submit a complete NADA or to submit information in support of an NADA for phased review followed by submission of an Administrative NADA when FDA finds all the applicable technical sections are complete.

The regulations under 21 CFR 514.1 interpret section 512(b)(1) of the FD&C Act and further describe the information that must be submitted as part of an NADA and the manner and form in which the NADA must be assembled and submitted. The application must include safety and effectiveness data, proposed labeling, product manufacturing information, and where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food-producing animals. Guidance #152 entitled "Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern" outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. FDA requests that an applicant accompany NADAs, supplemental NADAs, and requests for phased review of data to support NADAs, with the FDA Form 356V to ensure efficient and accurate processing of information to support new animal drug approval.

In the **Federal Register** of February 8, 2011 (76 FR 6798), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Section/FDA Form No.	Number of respondents ⁴	Number of responses per respondent	Total annual responses	Average burden per response (in Hours)	Total hours
514.5(b), (d) and (f)	154	.6	92.4	50	4,620
514.1 and 514.6	154	.1	15.4	212	3,265
514.4 ²	154	0	0	0	0
514.8(b)	154	2.84	437.36	35	15,308
514.8(c)(1)	154	.1	15.4	71	1,093
514.8(c)(2) and (c)(3)	154	.7	107.8	20	2,156
514.11	154	.2	30.8	1	31