TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
208.20	8	1	8	242	1,936
314.70(b)(3)(ii) and 601.12(f)	3	1	3	24	72
208.24(e)	55,000	8.3	460,000	.0014	644
208.26(a)	1	1	1	4	4
Total					2,656

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

Dated: September 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–23885 Filed 9–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0205]

Agency Information Collection Activities; Submission for OMB Review; 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 that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by October 25, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Applications for FDA Approval to Market a New Drug—Part 314 (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 under part 314 that are imposed on sponsors 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 is submitted with the archival copy of the application and that it references 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 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 section 505(b)(2) of the act 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 section 505(b)(2) of the act 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 control numbers 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 control numbers 0910–0230 and 0910–0291 and are not included in the hour 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 control number 0910–0045 and are not included in the hour 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 hour 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 10.30. (The burden hours for § 314.93 are already approved by OMB under control number 0910–0183 and are not included in the hour burden estimates in table 1 of this document).

Section 314.94(a) and (d) requires that an abbreviated new drug application (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 notice of certification of invalidity or noninfringement of a patent to patent holders and NDA holders 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 control numbers 0910–0230 and 0910–0291 and are not included in the hour 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 hour 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 hour burden estimate for ANDA waiver requests is included in table 1 of this document under estimates for §§ 314.94(a) and (d), 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)(4) requires notice to FDA by ANDA or section 505(b)(2) of the act application holders of any legal action concerning patent infringement.

Section 314.107(e)(2)(iv) 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) of the act applicants notify FDA 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. The patent owner 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 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 hour 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 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 314.120(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 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 314.120(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 control number 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 control number 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 control number 0910–0183 and are not included in the hour burden estimates in table 1 of this document).

Section 314.151(a) and (b) sets 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 314.152(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 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 314.161(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 control number 0910–0183 and are not included in the hour 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 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 314.200(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 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 314.200(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 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 314.420 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 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 314.530(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 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 314.530(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 control number 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.

In the **Federal Register** of May 29, 2001 (66 FR 29143), the agency requested comments on the proposed collections of information. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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), (h), and (k)	71	1.55	110	1,666	183,260
314.50(i) and 314.94(a)(12)	97	3.4	331	2	662
314.50(j)	92	2.7	250	2	500
314.52 and 314.95	37	2	75	16	1,200
314.54	11	1	11	300	3,300
314.60	125	19.92	2,490	80	199,200
314.65	29	1.24	36	2	72
314.70 and 314.71	204	11.54	2,354	300	706,200
314.72	70	2.90	205	2	410
314.81(b)(1) [3331]	82	3.43	281	8	2,248
314.81(b)(2) [2252]	600	12.66	7,597	40	303,880

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section; [Form Number]	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
314.81(b)(3)(i) [2253]	196	2.42	475	2	950
314.94(a) and (d)	125	2.92	365	480	175,200
314.96	225	7.25	1,631	80	130,480
314.97	175	17.44	3,052	80	244,160
314.99(a)	45	8.88	400	2	800
314.101(a)	6	1	6	.50	3
314.107(c)(4), (e)(2)(iv), and (f)	34	2	71	1	71
314.110(a)(5)	50	1.66	83	.50	41.5
314.120(a)(5)	22	1.04	23	.50	11.5
314.420	462	1.1	514	61	31,354
Total					1,984,003

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

Dated: September 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–23886 Filed 9–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1418]

International Conference on Harmonisation; Guidance on Good Manufacturing Practice for Active Pharmaceutical Ingredients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance describes current good manufacturing practice (CGMP) for manufacturing of active pharmaceutical ingredients (APIs). The guidance is intended to help ensure that all APIs meet the standards for quality and purity they purport or are represented to possess.

DATES: The guidance is effective September 25, 2001. Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Edwin Rivera, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0095, Rivera@cder.fda.gov, or John A. Eltermann, Center for Biologics Evaluation and Research (HFM–670), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3031, Eltermann@cber.fda.gov.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In accordance with the agency's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedures