or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

A Library Of Participant Questions To Be Used In Exposure Investigation Questionnaires—New—The Agency for Toxic Substances and Disease Registry (ATSDR).

ATSDR is mandated pursuant to the 1980 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and its 1986 Amendments, the Superfund Amendments and Reauthorization Act (SARA) to prevent or mitigate adverse human health effects and diminished quality of life resulting from the exposure to hazardous substances in the environment. Exposure Investigations are an approach developed by ATSDR that employs targeted biologic and environmental sampling to assist ATSDR to better characterize past, current, and possible future human exposures to hazardous substances in the environment. The purpose of Exposure Investigations is to determine in a timely manner whether community residents are being exposed to chemical contaminants at levels that might affect their health. Exposure Investigations are usually requested by officials of a state health agency, county health departments, the Environmental Protection Agency, the general public, and ATSDR staff.

During an Exposure Investigation ATSDR conducts biomarker testing or environmental testing or both. Biomarkers may be sampled in urine, blood, or hair. Environmental samples (*e.g.*, air, water, soil, or food) can be taken from the environment where people live, spend leisure time, or other places they might come into contact with contaminants under investigation. In addition to the suspected environmental exposure source being investigated, additional exposure to the contaminant may come from other sources encountered in daily activities such as jobs, hobbies, household products, lifestyle, medicines, and foods.

To assist in interpreting the sampling results, a survey questionnaire appropriate to the specific contaminant will be administered to participants. Only a limited number of questions pertinent to exposure routes of the contaminant of concern will be administered in an investigation. Questions will be asked about the presence or absence of a specific exposure and an estimate of its extent and duration. Exposure to other sources of the contaminant of concern will also be queried in the survey. The information gathered in the survey will allow ATSDR to more accurately interpret its testing results and determine a likely source of elevated biomarker tests.

Questionnaires will generally be administered face-to-face and occasionally by phone or mail. Typically, ATSDR conducts between 10–15 exposure investigations nationally each year that would require a questionnaire. The number of participants per investigation ranges from 10 to less than 50.

ATSDR is seeking approval for a set of 40–43 potential questions. Of these, approximately 12–15 questions about the pertinent environmental pathways in an Exposure Investigation will be used. This number can vary depending on the number of contaminants being investigated, the route of exposure (breathing, eating, touching), and a number of other sources (*e.g.*, products, jobs) of the chemical(s). We will also collect general information (*e.g.*, name, address,) necessary to conduct the investigation; there are approximately 28 questions that will collect demographic information. There are no costs to respondents other than their time.

Topic areas for the complete set of questions include the following:

(1) Media specific which includes: air (indoor/outdoor); water (water source and plumbing); soil, and food (gardening, fish, game, domestic animals).

(2) Other sources such as: occupation; hobbies; household uses or house construction; lifestyle (*e.g.*, smoking); medicines and/or health conditions, and foods.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response in hours)	Total burden (in hours)
Exposure Investigation Participants	750	1	30/60	375
Total				375

Dated: January 25, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–1713 Filed 1–28–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0441]

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 March 2, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (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.

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. 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 section 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 section 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 OMB 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 OMB 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). This form has been revised as a result of the requirements in the final rule ''Postmarketing Studies for Approved Human Drug and Licensed Biological Products; Status Reports,'' published in the **Federal Register** of October 30, 2000 (65 FR 64607). The rule describes the types of postmarketing studies covered by the status reports, the information to be included in the reports, and the type of information that FDA would consider appropriate for public disclosure. The rule implemented section 130(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The changes to the form include adding new spaces for the new status reports, reporting for biological products, and editorial changes.

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 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 § 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 hour 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 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 OMB 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) 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)(4) requires notice to FDA by ANDA or section 505(b)(2) 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) 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 part 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 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 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 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 OMB 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 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 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 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) is included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and is 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 OMB 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 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 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 parts 10 through 16 hearing regulations, in accordance with § 314.201, and is 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 is included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and is 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 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 0910–0194 and are not included in the hour burden estimates in table 1 of this document.)

In the **Federal Register** of October 8, 2004 (69 FR 60402), FDA announced an opportunity for public comment on these information collection estimates. No comments were submitted that pertained to the information collection estimates in the October 8, 2004, 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.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section; [FDA 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)	72	1.44	104	1,642	170,768
314.50(i) and 314.94(a)(12)	194	2.34	454	2	908
314.50(j)	70	3.71	260	2	520
314.52 and 314.95	24	2.25	54	16	864
314.54	16	1	16	300	4,800
314.60	275	19.06	5,242	80	419,320
314.65	10	1	10	2	20
314.70 and 314.71	234	10.99	2,572	150	385,800
314.72	61	4.52	276	2	552
314.81(b)(1) [3331]	115	3.88	447	8	3,576
314.81(b)(2) [2252]	612	12.47	7,632	40	305,280
314.81(b)(3)(i) [2253]	332	44.09	14,638	2	29,276
314.94(a) and (d)	100	4.59	459	480	220,320
314.96	275	23.63	6,500	80	520,000
314.97	200	16.75	3,350	80	268,000
314.99(a)	44	2.02	89	2	178
314.101(a)	2	1	2	.50	1

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

21 CFR Section; [FDA Form Number]	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours Per Response	Total Hours
314.107(c)(4), 314.107(e)(2)(iv), and 314.107(f)	3	2	6	1	6
314.110(a)(5)	41	1.26	52	.50	26
314.120(a)(5)	12	1.16	14	.50	7
314.420	403	1.72	694	61	42,334
Total					2,372,556

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

Dated: January 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–1814 Filed 1–27–05; 12:53 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0514]

Draft Guidance for Industry on Abbreviated New Drug Applications: Impurities in Drug Substances; Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''ANDAs: Impurities in Drug Substances; Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides recommendations on what chemistry, manufacturing, and controls information to include regarding the reporting, identification, and qualification of impurities in drug substances produced by chemical synthesis when submitting documentation for an abbreviated new drug application (ANDA), drug master file (DMF), or a supplement to support changes in drug substance synthesis or process.

DATES: Submit written or electronic comments on the draft guidance May 2, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Scott Furness, Center for Drug Evaluation and Research (HFD–640), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5849.

SUPPLEMENTARY INFORMATION:

I. Background

On December 3, 1999, FDA published in the **Federal Register** (64 FR 67917) the guidance for industry entitled ''ANDA's: Impurities in Drug Substances.'' The guidance provided recommendations for including information in ANDAs and supporting DMFs on the content and qualification of impurities in drug substances produced by chemical syntheses.

FDA is announcing the availability of a draft guidance for industry entitled ''ANDAs: Impurities in Drug Substances,'' which revises the December 3, 1999, guidance. The guidance is being revised to update information on listing of impurities, setting acceptance criteria, and qualifying impurities in conformance with the revision of the guidance for industry entitled ''Q3A Impurities in New Drug Substances'' (Q3A(R), published in February 2003). The guidance is also being revised to remove sections of the guidance containing recommendations that are no longer needed because they are addressed in the more recent Q3A(R).

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this draft guidance was approved under OMB Control Nos. 0910–0001 and 0910–0032.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on these topics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 24, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–1752 Filed 1–28–05; 8:45 am]

BILLING CODE 4160–01–S