typically require that a certification form accompany the application/submission, as described in our April 2008 Draft Guidance. Added to the burden were generic applications/submissions, which were originally not included in the burden calculations, but have since been determined to require a certification form accompany the application/submission.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	Investigational Applications	Marketing Applications	Hours per Response	Total Hours
CDER (new application)	1,837	----	.25	459
CBER (new application)	206	----	.25	52
CDER (amendment)	20,969	----	.25	5,242
CBER (amendment)	826	----	.25	207
CDER (annual report)	4,764		.25	1,191
CBER (annual report)	878		.25	220
CDER/CBER (new application/resubmission)	----	214	.75	161
CDRH (new application)	----	424	.75	318
CDER/CBER (amendment)	----	4,451	.75	3,338
CDRH (amendment)	----	2,267	.75	1,700
CDER/CBER (efficacy supplement/resubmission)	----	259	.75	194
CDER (annual report)	----	7,753	.75	5,815
CBER (annual report)	----	629	.75	472
CDER/CBER (labeling supplement)	----	1,273	.75	955
CDRH (supplement)	----	2,526	.75	1,895
CDRH (annual report)		433	.75	325
OGD (original)		563	.75	422
OGD (BE amendment/supplement)		477	.75	358
OGD (labeling supplement)		723	.75	542
OGD (annual report)		5,173	.75	3,880
TOTAL				27,746

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

We believe the estimate of 27,746 hours per year accurately reflects the burden. We recognize that individuals or entities less familiar with FDA forms and the clinical trials data bank (ClinicalTrials.gov) may require greater than 15 and 45 minutes (depending on the type of application/submission) per response.

Dated: August 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19625 Filed 8–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0259]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review

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 September 24, 2008.

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: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0389. 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 (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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.

Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review—(OMB Control Number 0910–0389)—Extension

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506 (21 U.S.C. 356). The section authorizes FDA to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrate a potential to address an unmet medical need. Under FDAMA section 112(b), FDA issued guidance to industry on fast track policies and procedures outlined in section 506 of the act. The guidance discusses collections of information that are specified under section 506 of the act, other sections of the Public Health Service Act (the PHS Act), or implementing regulations. The guidance describes three general areas involving collection of information: (1) Fast track designation requests, (2) premeeting packages, and (3) requests to submit portions of an application. Of these, fast track designation requests and premeeting packages, in support of receiving a fast track program benefit, provide for additional collections of information not covered elsewhere in statute or regulation. Information in support of fast track designation or fast track program benefits that has previously been submitted to the agency, may, in some cases, be incorporated into the request by referring to the information rather than resubmitting it.

Under section 506(a)(1) of the act, an applicant who seeks fast track designation is required to submit a request to the agency showing that the product: (1) Is intended for a serious or life-threatening condition; and (2) the product has the potential to address an unmet medical need. Mostly, the agency expects that information to support a designation request will have been gathered under existing provisions of the 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 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 (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 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) of the act 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 is not required under section 506(c) of the act or any other provision of the act. All forms referred to in the guidance have a current OMB approval: FDA Forms 1571 (OMB Control No. 0910–0014); 356h (OMB Control No. 0910–0338); and 3397 (OMB Control No. 0910–0297).

Respondents to this information collection are sponsors and applicants who seek fast track designation under section 506 of the 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 64, and the number of requests received is approximately 77 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 60 from 54 respondents, and for each of these granted requests a pre-meeting package was submitted to the agency. FDA estimates that the preparation hours are approximately 100 hours per pre-meeting package.

In the **Federal Register** of May 6, 2008 (73 FR 25016), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Designation Request	64	1.28	82	60	4,915
Premeeting Packages	54	1.11	60	100	6,000

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

Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total	118	2.39	142	160	10,915

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

Dated: August 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19626 Filed 8–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0087] (formerly Docket No. 2007N–0461)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mental Models Study of Communicating With Health Care Providers About the Risks and Benefits of Prescription Drug Use for Pregnant and Nursing Women With Chronic Conditions

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 September 24, 2008.

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: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title, ''Mental Models Study of Communicating with Health Care Providers about the Risks and Benefits of Prescription Drug Use for Pregnant and Nursing Women with Chronic Conditions.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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.

Mental Models Study of Communicating With Health Care Providers About the Risks and Benefits of Prescription Drug Use for Pregnant and Nursing Women With Chronic Conditions

The authority for FDA to collect the information derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

The proposed information collection will help FDA advance public health by identifying misperceptions and knowledge gaps about how health care providers use information to make decisions about the use of prescription drugs for the targeted patient groups. Knowledge of these misperceptions and gaps provides opportunities for FDA to target its communications more precisely to such gaps and areas of misperception in health care providers' mental models regarding treatment decisions.

FDA engages in various communication activities to ensure that patients and health care providers have the information they need to make informed decisions about treatment options, including the use of prescription drugs. FDA regulations (21 CFR 201.57) describe the content of required product labeling, and FDA reviewers ensure that labeling contains accurate and complete information about the known risks and benefits of each drug. This data collection and analysis is designed to identify knowledge gaps that FDA could then address, which would ultimately improve decision making and potentially improve health outcomes.

The project will use ''mental modeling,'' a qualitative research method that compares a model of the decision-making processes of a group or groups to an ''expert model'' of the same decision-making processes developed from expert knowledge and experience. In this study, the decision models of certain health care providers concerning treatment options for pregnant and nursing women will be compared to an expert model concerning such treatment options that was derived from the knowledge and experience of FDA reviewers responsible for product labeling. FDA will use telephone interviews to determine from the health care providers the factors that influence their treatment decisions for pregnant and nursing women with chronic conditions. A comparison between expert and health care provider models based on the collected information may identify consequential knowledge gaps that can be redressed through messages or information campaigns designed by FDA.

Using a protocol derived from the research that resulted in the ''expert model,'' trained interviewers will conduct one-on-one telephone discussions with 24 to 30 members of each of 2 categories of health care providers (described in the following paragraph) who provide health care services to pregnant and nursing women.

The two categories of health care providers are:

(1) Those who directly care for pregnant and nursing women, including obstetricians, OB/GYNs (obstetrician/gynecologists), nurse midwives, and primary care practitioners.

(2) Selected specialties of healthcare providers who directly care for women of reproductive age who have chronic health conditions (allergists, psychiatrists, neurologists, and cardiologists).

In the **Federal Register** of December 11, 2007 (72 FR 70328), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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