ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–3	15	15	.417	94
ORR–4	15	60	.250	225

Estimated total annual burden hours: 319.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503. Attn: Desk Officer for ACF. E-mail address: *Karen_Y._Matsuoka@omb.eop.gov.*

Dated: October 26, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–8958 Filed 10–27–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission of OMB Review; Comment Request

Title: Compassion Capital Fund Evaluation—Intermediary Survey.

OMB No.: New Collection.

Description: This proposed information collection activity is for a survey to be completed by Compassion Capital Fund intermediary grantees as a part of the outcome and impact study components of the Compassion Capital Fund Evaluation.

The Compassion Capital F und Evaluation is a multi-component study designed to examine the effectiveness of the Compassion Capital Fund (CCF) in meeting its objective of improving the organizational capacity of faith-based and community organizations. The CCF program works through intermediary organizations to provide capacity building assistance to interested faith-based and community organizations. The purpose of this data collection activity is to obtain more detailed information about the management processes and service delivery and monitoring approaches used by CCF intermediaries in providing technical and financial assistance to increase the organizational capacity of faith-based and community organizations.

Respondents: CCF intermediary grantees.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Intermediary survey	54	1	.5	27

Estimated Total Annual Burden Hours: 27.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L/Enfant Promenade, SW., Washington, DC 20447, ATtn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sen directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *Karen_Y._Matsuoka@omb.eop.gov.*

Dated: October 5, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–8959 Filed 10–27–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0420]

Agency Information Collection Activities; Proposed Collection; Comment Request; Orphan Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the procedures by which sponsors of orphan drugs may request eligibility for the incentives by implementing a program as outlined in the Orphan Drug Act.

DATES: Submit written or electronic comments on the collection of information by December 29, 2006.

ADDRESSES: Submit electronic comments on the collection of

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

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Orphan Drugs—21 CFR 316 (OMB Control Number 0910–0167)—Extension

Sections 525 through 526 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa through 360 dd) give FDA statutory authority to do the following: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the act and sets forth procedures FDA will use in administering the act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the non-clinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Section 316.20 specifies the content and format of an orphan drug application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.26 allows an applicant to amend the applications under certain circumstances. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

The information requested from respondents represents, for the most part, an accounting of information already in the possession of the applicant. It is estimated, based on frequency of requests over the past 5 years, that 171 persons or organizations per year will request orphan-drug designation and none will request formal recommendations on design of preclinical or clinical studies.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Responses	Total Hours
316.10, 316.12, & 316.14	5	1	5	130	650
316.20, 316.21, & 316.26	171	2.0	342	130	44,460
316.22	30	1	30	2	60
316.27	25	1	25	4	100
316.30	500	1	500	2	1,000
316.36	.2	3	.6	15	9
Total					46,279

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

Dated: October 23, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18067 Filed 10–27–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0198]

Guidance for Industry on Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components,'' dated October 2006. The guidance document provides blood establishments that collect blood and blood components intended for transfusion or for further manufacture with advice on reporting to FDA a manufacturing change consisting of the implementation of a standardized full-length donor history questionnaire and accompanying materials (DHQ documents). The guidance document addresses which DHQ documents are acceptable, and establishes the process for FDA to recognize other DHQ documents in the future. The guidance announced in this notice finalizes the draft guidance entitled ''Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components'' dated April 2004.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the 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*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components,'' dated October 2006. The guidance document provides blood establishments that collect blood and blood components intended for transfusion or for further manufacture with advice on reporting to FDA a manufacturing change consisting of the implementation of DHQ documents. Acceptable DHQ documents (DHQ documents that provide licensed and unlicensed manufacturers with one means of complying with the FDA requirements for collecting donor history information) will provide manufacturers with a specific process for administering questions to donors of blood and blood components to determine their eligibility to donate. The guidance document advises licensed manufacturers who choose to implement acceptable DHQ documents on how to report the manufacturing change to FDA, and recognizes the Donor History Questionnaire Version No. 1.1 dated June 2005 (v.DHQ–1.1), prepared by the AABB (formerly known as the American Association of Blood Banks) Donor History Task Force, as acceptable DHQ documents.

In the future, FDA may recognize other DHQ documents as acceptable, and intends to make all of the acceptable DHQ documents available on FDA's Web site. FDA believes that acceptable DHQ documents will assist manufacturers in complying with the regulations under 21 CFR 640.3 and 640.63. The guidance also advises licensed manufacturers of blood and blood components who choose to implement acceptable DHQ documents on how to report the manufacturing change to FDA under 21 CFR 601.12.

In the **Federal Register** of May 12, 2004 (69 FR 26399), FDA announced the availability of the draft guidance entitled ''Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components'' dated April 2004. This draft guidance contained the full-length donor history questionnaire and accompanying materials (Version No. 1, dated April 2004) (v.DHQ–1). FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes to the guidance includes the following: (1) Added a statement to direct inquiries regarding the v.DHQ–1.1 or other AABB DHQ documents to the task force; (2) clarified how to implement acceptable DHQ documents, including v.DHQ–1.1, and the self-administration of these documents; and (3) added a separate Web site link to access all DHQ documents that FDA has recognized as acceptable. In addition, FDA received many comments on the v.DHQ–1, and forwarded these comments to the task force. In response, the task force submitted updated DHQ documents (v.DHQ–1.1), for FDA's review. The guidance announced in this notice finalizes the draft guidance dated April 2004, and refers to the v.DHQ–1.1.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR 606.160 have been approved under OMB control numbers 0910–0116; those in 21 CFR 601.12 have been approved under 0910–0338.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the