

Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

**G. Evaluation Criteria**

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC:

1. Background and Need (5 percent) The extent to which the applicant describes experience in related projects, and describes the context and needs related to the purpose of this program announcement.
2. Scope, Goals, and Objectives (15 percent) The extent to which the applicant provides relevant long-term goals and short-term objectives which are specific, measurable, time-phased, and achievable.
3. Operational Plan (40 percent) The extent to which the applicant provides an operational plan which addresses achievement of each of the objectives proposed. Does the applicant provide a description of each component or major activity, how it relates to objectives, and how it will be accomplished? Does the plan include a detailed time-line for completion of each component or major activity?
4. Administration and Management (20 percent) The extent to which the organizational structure is described and to which adequate management control systems are in place. Is proposed staffing adequate for completion of activities under this program announcement?
5. Evaluation Plan (20 percent) The extent to which the evaluation plan provides an adequate basis for monitoring and evaluating proposed activities.
6. Budget (not scored) The extent to which the budget is reasonable, clearly justified, and consistent with stated objectives and proposed activities.

**H. Other Requirements**

Technical Reporting Requirements Provide CDC with original plus two copies of:

1. progress report annually;

2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial status report and performance report, no more than 90 days after the end of the project period.

Send all reports to: Sharron P. Orum, Grants Management Specialist Grants Management Branch, Procurement and Grants Office Centers for Disease Control and Prevention (CDC) 2920 Brandywine Road, Mailstop E-13 Atlanta, Georgia 30341-4146.

The following additional requirements are applicable to this program. For a complete description of each see Addendum 1 in the application kit.

- AR98-10—Smoke-Free Workplace Requirement
- AR98-11—Healthy People 2000
- AR98-12—Lobbying Restrictions
- AR98-13—Prohibition on Use of CDC funds for Certain Gun Control Activities
- AR98-15—Proof of Non-Profit Status
- AR98-20—Conference Activities within Grants/Cooperative Agreements

**I. Authority and Catalog of Federal Domestic Assistance Number**

This program is authorized under Sections 301, 391, 392, 393, and 394 of the Public Health Service Act, [42 U.S.C. 241, 280b, 280b-1, 280b-1a, and 280b-2] as amended. Program regulations are set forth in 42 CFR Part 52. The catalog of Federal Domestic Assistance number is 93.136.

**J. Where To Obtain Additional Information**

Please refer to Program Announcement 99015 when you request information. To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888-471-6874). You will be asked to leave your name and address and you will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sharron P. Orum, Grants Management

Specialist, Grants Management Branch, Procurement and Grants Office Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, M/S E-13, Atlanta, GA 30341-4146, Telephone: (770) 488-2716, E-mail address: [spo2@cdc.gov](mailto:spo2@cdc.gov)

For program technical assistance, contact: Tom Voglesonger, Office of Research Grants National Center for Injury Prevention and Control Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop K-58, Atlanta, GA 30341-3724, Telephone: (770) 488-4265, E-mail address: [tdv1@cdc.gov](mailto:tdv1@cdc.gov)

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is <http://www.cdc.gov>.

Dated: February 10, 1999.

**John L. Williams,**

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

Proposed Project:

Title: ACF-IV-E-1 Foster Care and Adoption Assistance Financial Reporting Form.

OMB No.: New.

Description: The form provides specific data regarding claims and provides a mechanism for States to request grant awards and certify the availability of State matching funds. Failure to collect this data would seriously compromise ACF's ability to monitor expenditures. This information is also used to estimate outlays and may be used to prepare ACF budget submissions to Congress.

Respondents: State, Local or Tribal Government.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondents	Average burden hours per response	Total burden hours
ACF-IV-E-1 .....	51	4	8	1,632

Estimated Total Annual Burden Hours: 1,632.

In compliance with the requirements of Section 3506(c)(2)(A) the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways of minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: February 10, 1999.

**Bob Sargis,**

*Acting Reports Clearance Officer.*

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BILLING CODE 4184-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Current Issues in Human Subject Protection; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

The Food and Drug Administration (FDA) is announcing a national conference regarding issues in human research subject protection. Current regulatory issues, historical perspectives and future directions will be presented. Participants will have the opportunity to interact with senior Federal personnel and learn about developments in policy and regulations which affect the Institutional Review Board (IRB) system and the conduct of research involving human subjects.

**Date and Time:** The meeting will be held on March 5, 1999, 8:30 a.m. to 4:45 p.m.

**Location:** The meeting will be held at Natcher Auditorium, National Institutes of Health Campus, Bldg. 45, 9000 Rockville Pike, Bethesda, MD.

**Contact:** Paul W. Goebel, Office of Health Affairs (HFY-20), Food and Drug Administration, rm. 15-22, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1685, FAX 301-443-0232, or e-mail "pgoebel@oc.fda.gov".

**Registration:** Pre-registration is not required; however, for conference planning purposes, those who plan to attend are requested to fax or e-mail their registration information (including name, firm name, address, phone, fax number, and e-mail) to Glen Drew, FAX 301-443-0232, e-mail "gdrew@oc.fda.gov" or call Paul Goebel, Paula Waterman, or Glen Drew at 301-827-1685. There is no fee for attending the conference, and it is open to all. The agenda and background material are available on FDA's internet site at "http://www.fda.gov/oc/oha/irbagenda.htm".

If you need special accommodations due to a disability, please contact Paul Goebel at least 7 days in advance.

Dated: February 10, 1999.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98D-0007]

#### "Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products;" Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products." The guidance

document is intended to assist applicants in the preparation of the content and format of the chemistry, manufacturing, and controls (CMC) section and the establishment description section of a biologics license application (BLA), revised Form FDA 356h, which is currently being implemented for human plasma-derived biological products, animal plasma or serum-derived products. This action is part of FDA's continuing effort to achieve the objectives of the President's "Reinventing Government" initiatives and the Food and Drug Administration Modernization Act of 1997, and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

**DATES:** Written comments may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products" 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, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written comments on the guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance document entitled "Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological