

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.

[FR Doc. 99-3775 Filed 2-16-99; 8:45 am]

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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