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.

[FR Doc. 99–3802 Filed 2–16–99; 8:45 am]

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]

BILLING CODE 4160–01–F

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

Products, Animal Plasma or Serum-Derived Products.'' This guidance document provides general information for the preparation of CMC and establishment description sections of the BLA, revised Form FDA 356h, which is currently being implemented for human plasma-derived biological products, animal plasma or serum-derived products. This guidance document supersedes the draft guidance entitled ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products or Animal Plasma or Serum-Derived Products'' that was announced in the **Federal Register** of January 21, 1998 (63 FR 3145).

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of a revised Form FDA 356h that will be used as a single harmonized application form for all drugs and licensed biological products. Manufacturers may voluntarily begin using this form for human plasma-derived biological products, animal plasma or serum-derived products. FDA will announce in the future when manufacturers are required to use this form for all products. Use of the new harmonized Form FDA 356h will allow a biologic product manufacturer to submit one BLA instead of two separate license applications (product license application and establishment license application).

This guidance document represents the agency's current thinking on the content and format of the CMC and establishment description information section of a BLA for human plasma-derived biological products, animal plasma or serum-derived products. 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 statute, regulations, or both. As with other guidance documents, FDA does not intend this guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. The guidance document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons, may at any time, submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: February 5, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–3715 Filed 2–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0121]

Draft Guidance for Industry on Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Containing Certain Active Moieties/ Active Ingredients Based on a Biopharmaceutics Classification System; 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 ''Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Containing Certain Active Moieties/Active Ingredients Based on a Biopharmaceutics Classification System.'' When final, the guidance will provide recommendations to sponsors of investigational new drug applications (IND's) and applicants submitting new drug applications (NDA's), and abbreviated new drug applications (ANDA's) who intend to perform bioavailability and bioequivalence (BA/BE) studies for immediate release solid oral products during either the preapproval or postapproval periods.

DATES: Written comments on the draft guidance document may be submitted by April 19, 1999. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copy of the draft guidance for industry entitled ''Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Containing Certain Active Moieties/ Active Ingredients Based on a Biopharmaceutics Classification System'' to the Drug Information Branch (HFD–210), 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 Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ajaz S. Hussain, Center for Drug Evaluation and Research (HFD–940), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5927.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Containing Certain Active Moieties/ Active Ingredients Based on a Biopharmaceutics Classification System.'' When it becomes final, this guidance for industry will provide recommendations on when in vivo BA/BE studies may be waived for NDA's and ANDA's submitted to the Center for Drug Evaluation and Research during either the preapproval or postapproval period.

In 1974, the Office of Technology Assessment's Drug Bioequivalence Study Panel made eleven recommendations, one of which stated:

> It is neither feasible nor desirable that studies of bioavailability be conducted for all drugs or drug products. Certain classes of drugs for which evidence of bioequivalence is critical should be identified. Selection of these classes of drugs should be based on clinical importance, ratios of therapeutic to toxic concentrations in blood, and certain pharmaceutical characteristics.

Based on this and other recommendations of the panel, FDA proposed and finalized regulations in 1977 entitled ''Bioequivalence Requirements and In Vivo Bioavailability Procedures'' (42 FR 1624, January 7, 1977). In these regulations, now at 21 CFR 320.33, under the title ''Criteria and Evidence to