''Guidance for Industry: Computerized Systems Used in Clinical Trials.'' The guidance document provides guidance for computerized systems used to create, modify, maintain, archive, retrieve, or transmit clinical data intended for submission to FDA. Whether collected or reported electronically or in paper form, clinical data must meet certain quality standards, and this guidance is intended to provide information on how computerized systems can meet these standards.

DATES: Written comments on the guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials'' to the Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs (ORA), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. 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: James F. McCormack, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0425.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials.'' This guidance pertains to long-standing regulations covering clinical trial records under 21 CFR parts 300, 500, and 800. On March 20, 1997 (62 FR 13430), FDA published a regulation providing uniform, enforceable, baseline standards for electronic records and electronic signatures, codified in 21 CFR part 11. To formulate supplemental guidance on the use of computerized systems in clinical trials, an agency working group representing the Bioresearch Monitoring Program Managers from each center within FDA and the Office of Regulatory Affairs prepared a draft of this present guidance. In the **Federal Register** of June 18, 1997 (63 FR 33094), FDA published the draft guidance which allowed 60 days for public comment. Upon petition, FDA extended the comment period for an additional 60 days. FDA received more than 500 comments from 24 respondents. Over the following 12 months, the agency working group reviewed all public comments and made appropriate changes to the guidance.

This guidance document represents the agency's current thinking on computerized systems used in clinical trials. 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. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information contained in the guidance document may be applicable to all situations. The document is intended to provide useful 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 that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance 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 using the World Wide Web (WWW). For WWW access, connect to the Office of Regulatory Affairs at ''http://www.fda.gov/ora/compliance__ref/bimo/default.html''.

Dated: May 3, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–11582 Filed 5–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0512]

''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and for the Completion of the Form FDA 356h, 'Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use;''' 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: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h, 'Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use.''' This 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, for human blood and blood components intended for transfusion or for further manufacture. In addition, this guidance document provides assistance for the completion of the BLA. 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 (Modernization Act), 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 entitled ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h,

'Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use'' 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 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: Astrid L. Szeto, 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 document entitled ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h, 'Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use.''' This guidance document is intended to provide instructions on the completion of the revised Form FDA 356h, including CMC and establishment description sections for human blood and blood components intended for transfusion or for further manufacture. The guidance announced in this notice has been revised based on comments received on the draft guidance entitled ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h, 'Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use''' announced in the **Federal Register** of July 10, 1998 (63 FR 37401) and finalizes that draft document.

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of a new harmonized Form FDA 356h entitled ''Application to Market a New Drug, Biologic, or an Antibiotic for Human Use.'' The new harmonized form is intended to be used by applicants for all drug and biological products, to include blood and blood components. Manufacturers may voluntarily begin using the form for human blood and blood components. FDA will announce in the future when manufacturers are required to use this form for all products. Use of the new harmonized form will allow biological product manufacturers to submit a single application, the BLA, instead of two separate license application submissions, a product license application (PLA) and an establishment license application (ELA).

This guidance document represents the agency's current thinking on content and format of the CMC and establishment description information sections of a license application for human blood and blood components intended for transfusion or for further manufacture. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons, may at any time, submit written comments to the Dockets Management Branch (address above) 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 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 document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: April 30, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–11735 Filed 5–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Research, Purification, and Further Development of Immunosuppressive Factor(s) Released From Human Glioblastoma Cells in Culture

The National Cancer Institute's Experimental Immunology Branch has identified and characterized the activity of a soluble factor(s) produced by human glioblastoma tumor cells that suppresses T cell responses in health donor blood samples.

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks a Cooperative Research and Development Agreement (CRADA) Collaborator to aid NCI in the further characterization and commercial development of the immune-suppressive factor(s) generated from glioblastoma tumor cells. The glioblastoma-generated factor(s) appear to act by causing antigen-presenting cells (APCs), such as monocytes, to undergo a change in cytokine production which induces apotosis or antigen-specific unresponsiveness (''anergy'') in T cells. NCI has partially purified and characterized the immunosuppressive factor(s). Several applications for this technology have been identified. They include (1) therapy for graft-host rejection in transplantation surgeries; (2) treatment of autoimmune diseases; and (3) suppression of severe allergic responses. NCI is looking for a CRADA Collaborator with a demonstrated record of success in protein purification and immunosuppressive therapeutics for the eventual use of this factor(s) in the clinical treatment of patients. The proposed term of the CRADA can be up to five (5) years.

DATES: Interested parties should notify this office in writing of their interest in filing a formal proposal no later than July 9, 1999. Potential CRADA Collaborators will then have an additional thirty (30) days to submit a formal proposal.