V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document at any time. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 3, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–10749 Filed 5–11–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0198]

Draft ''Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human 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 draft document 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. The draft guidance document, when finalized, will recognize as acceptable for use by both licensed and unlicensed manufacturers that collect human blood and blood components, the full-length donor history questionnaire and accompanying materials (Version No. 1, dated April 2004) prepared by the Interorganizational Uniform Donor History Questionnaire Task Force. The full-length donor history questionnaire and accompanying materials (DHQ documents) provide a specific process for administering questions to donors of blood and blood components intended for transfusion and further manufacture to determine their eligibility to donate consistent with FDA requirements and recommendations.

DATES: Submit written or electronic comments on the draft guidance by August 10, 2004, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration,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 draft guidance may also be obtained by mail by calling the Center for Biologics and Research Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft 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: Joseph L. Okrasinski, Jr., 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 draft document 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. The draft guidance document, when finalized, will recognize as acceptable for use by licensed and unlicensed manufacturers that collect blood and blood components the full-length donor history questionnaire and accompanying materials (Version No. 1, dated April 2004) prepared by the Interorganizational Uniform Donor History Questionnaire Task Force. The DHQ documents provide a specific process for administering questions to donors of blood and blood components to determine their eligibility to donate consistent with FDA requirements and recommendations. FDA believes the DHQ documents will assist manufacturers in complying with the regulations under part 640 (21 CFR part 640). The guidance also advises licensed manufacturers of blood and blood components how to report the change to implement the DHQ documents described in the guidance to FDA under § 601.12 (21 CFR 601.12).

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency'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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 collection(s) of information in §§ 601.12, 606.160, 640.3, and 640.63 cited in the guidance have been approved by OMB under OMB control numbers 0910–0338 and 0910–0116.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: May 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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