

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0108]

Draft “Guidance for Industry: Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs;” 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: Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs,” dated April 2006. The draft guidance document further explains the requirements on informed consent as they relate to plasmapheresis and immunization programs. The draft guidance document is designed to assist blood establishments planning to apply for licensure or those revising their existing informed consent forms in determining whether the documents include all the appropriate information. This draft guidance, when finalized, will supersede the draft guidance document entitled “Draft Reviewer’s Guide: Informed Consent for Plasmapheresis/Immunization,” dated October 1995.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the **Federal Register***] to ensure their adequate consideration in the preparation of the final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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug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 The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the 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Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Guidance for Industry: Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs,” dated April 2006. The draft guidance further explains the requirements under part 640 (21 CFR part 640) in 21 CFR 640.61 for the informed consent forms for the donors as they relate to plasmapheresis and immunization programs. The information in the draft guidance will assist those establishments applying for licensure as well as those establishments that are revising their existing informed

consent forms. The draft guidance discusses information that is recommended for the informed consent forms. This information includes, but is not limited to, the following: Clarity of the language in the informed consent form, length and frequency of the procedures, possible adverse reactions, side effects that may occur, opportunities to ask questions, and discussion concerning Acquired Immunodeficiency Syndrome (AIDS). Also discussed in the draft guidance is the use of a separate informed consent form for a donor who is participating in an immunization program including one which involves an Investigational New Drug (IND), and its recommended informational content, such as the discussion of the general risks and precautions involved, and suggestions for the health and welfare of the participants. This draft guidance when finalized will supersede the draft guidance document entitled, “Draft Reviewer’s Guide: Informed Consent for Plasmapheresis/Immunization,” dated October 1995.

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 requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 of information under §§ 640.61 and 640.66 was approved under OMB control number 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 written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) 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 guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 19, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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