

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2006D-0108]

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Certifier L. CLAWSON  
DDM

**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.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs," dated June 2007. The guidance document further explains the requirements and recommendations for the informed consent of donors of Source Plasma in plasmapheresis and immunization programs. The guidance document is designed to assist blood establishments that are planning to apply for licensure or revising their existing informed consent procedures. The guidance announced in this notice finalizes the draft guidance of the same title dated April 2006. This guidance supersedes the draft guidance document entitled "Draft Reviewer's Guide: Informed Consent for Plasmapheresis/Immunization," dated October 1995.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the 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, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER 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 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 document entitled "Guidance for Industry: Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs," dated June 2007. The guidance further explains the requirements in § 640.61 (21 CFR 640.61) and makes recommendations for the informed consent of donors of Source Plasma in plasmapheresis and immunization programs. The guidance discusses informed consent issues applicable to all Source Plasma donors, including describing the hazards of the procedures, the importance of affording the donor an opportunity to ask questions, and the potential consequences for the donor if the results of tests for communicable disease agents are reactive, positive, or outside of normal limits. The guidance also discusses additional

informed consent issues for a donor who is participating in an immunization program. The information in the guidance will assist those establishments applying for licensure as well as those establishments that are revising their existing informed consent procedures.

In the **Federal Register** of Thursday, April 27, 2006 (71 FR 24857), FDA announced the availability of the draft guidance of the same title dated April 2006. FDA received several comments on the draft guidance, and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated April 2006. This guidance will supersede the draft guidance document entitled “Draft Reviewer’s Guide: Informed Consent for Plasmapheresis/ Immunization,” dated October 1995.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’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 of 1995**

This 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 collections of information in § 640.61 and 21 CFR 640.66 have been approved under OMB control number 0910–0116.

### **III. Comments**

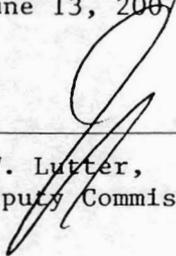
Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in 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: 6/13/07

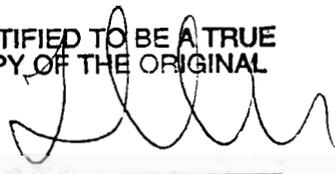
June 13, 2007.

  
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Randall W. Lutter,  
Acting Deputy Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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