

## I. Reporting

### A. Requests for Accreditation

FDA now has approximately 8 years of experience with third-party reviews under section 523 of the act. Currently there are 11 active accredited third parties. FDA does not expect to receive more than 1 application for accreditation per year for a total of 14 accredited third parties, who will be conducting third-party reviews.

### B. 510(k) Reviews Conducted by Accredited Third Parties

FDA has received 784 510(k)s with a third-party review since 2004. FDA estimates that over the next 3 years, they will accredit 1 third-party reviewer per year for a total of 14 third parties. Each third-party reviewer expects to review a total of 24 510(k) submissions per year for an annual total of 336 applications.

## II. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. At the end of 3 years, the agency expects to have 14 accredited persons for review with each third party reviewing on average 24 510(k) applications per year. The agency anticipates approximately 336 annual submissions of 510(k)s for third-party review.

Dated: June 14, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007D-0223]

#### **Draft Guidance for Industry on Use of the Computer Crossmatch; Availability**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: "Computer Crossmatch" (Electronic Based Testing for the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type)" dated June 2007. The draft guidance document provides recommendations to blood establishments consistent with current good manufacturing practice (CGMP) for the use of a "computer crossmatch," also called an "electronic crossmatch."

The computer crossmatch is an alternative to serologic crossmatch and may be used to demonstrate incompatibility between the donor's red blood cell type and the recipient's serum or plasma type.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by September 19, 2007.

**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, suite 200N, 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 CBER 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, 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: "Computer Crossmatch" (Electronic Based Testing for the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type)" dated June 2007. The draft guidance document provides recommendations consistent with CGMP for use of a "computer crossmatch" also called an "electronic crossmatch". The computer crossmatch is an alternative to serologic crossmatch and may be used to demonstrate incompatibility between the donor's red blood cell type and the recipient's serum or plasma type.

A final rule published in the **Federal Register** on August 6, 2001 (66 FR 40886) revised § 606.151(c) (21 CFR 606.151(c)) to allow either a serologic

crossmatch or a computer crossmatch. Prior to September 5, 2001, a blood establishment could only use a computer crossmatch if FDA gave its written approval for the use of a computer crossmatch as an alternate procedure under § 640.120 (21 CFR 640.120). With this revision to § 606.151(c), an application to FDA to permit use of computer crossmatch as an alternative procedure under § 640.120 is no longer necessary. Licensed establishments that change procedures to implement computer crossmatch remain subject to § 601.12 (21 CFR 601.12).

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

### II. Paperwork Reduction Act of 1995

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 collections of information in 21 CFR 606.100(b) and 606.160 have been approved under OMB control number 0910-0116. The collections of information under § 601.12 have been approved under OMB control number 0910-0338. The collections of information under 21 CFR 606.171 have been approved under OMB control number 0910-0458.

### III. Comments

The draft document 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 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 draft 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 at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: June 13, 2007.

**Randall W. Lutter,**

*Acting Deputy Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 2006D-0108]

##### 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 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: June 13, 2007.

**Randall W. Lutter,**

*Acting Deputy Commissioner for Policy.*

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