

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2007D-0223]

Display Date 6-20-07  
Publication Date 6-21-07  
Certifier L. CLAWSON  
DDM

**Draft Guidance for Industry on Use of the Computer Crossmatch; Availability**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 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 The draft guidance document provides recommendations to blood establishments consistent with current good manufacturing practice (CGMP) for the use of a “computer crossmatch,”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on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug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 The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.

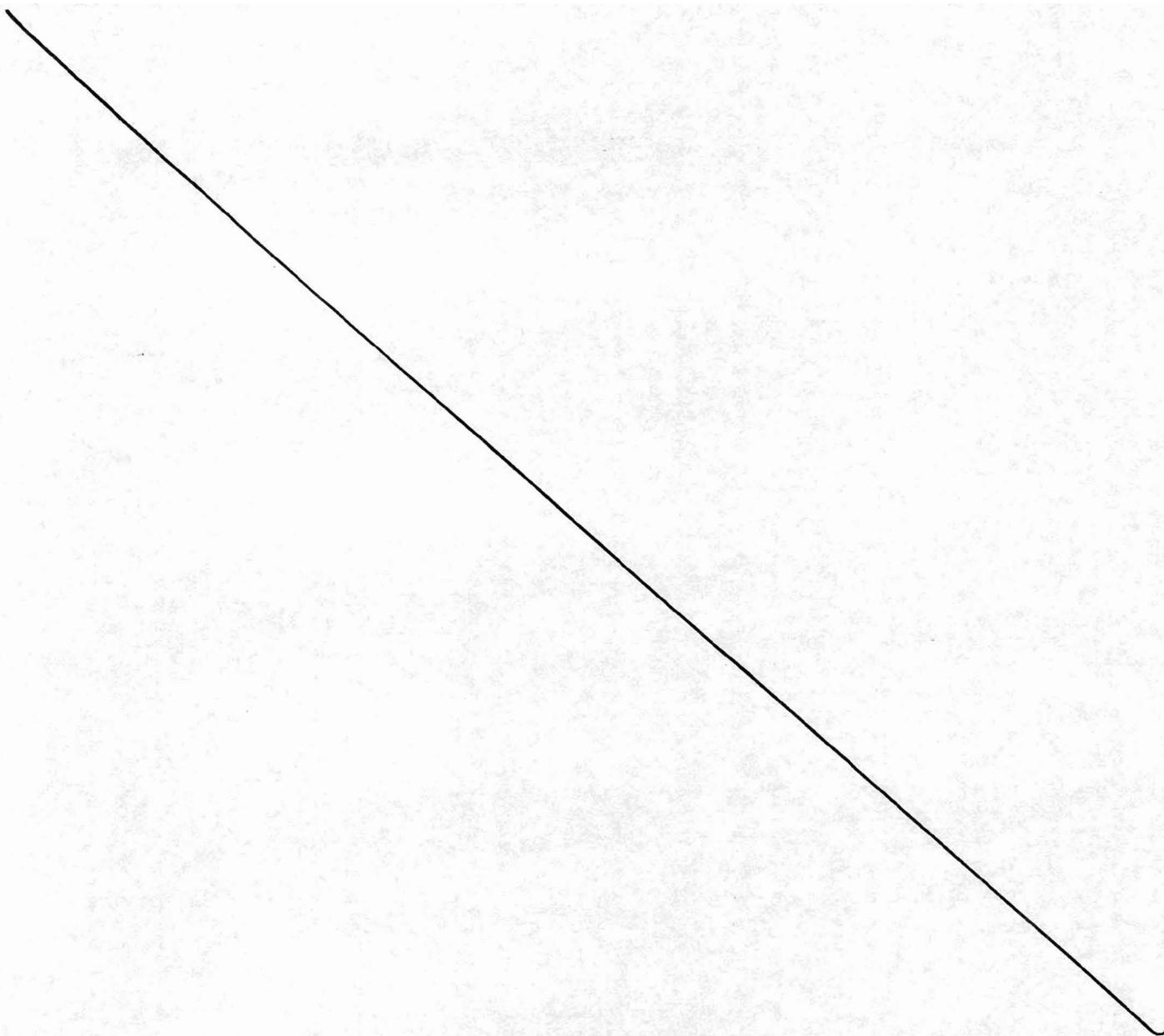
## **II. Paperwork Reduction Act of 1995**

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

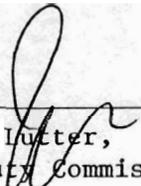
comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft 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**

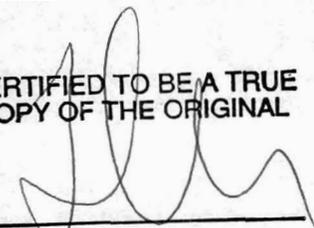
Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 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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