

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 1993D-0394]**

**Draft Guideline for the Validation of Blood Establishment Computer Systems; Withdrawal of Guidance**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; withdrawal.

*DUMB*

Display Date	3-8-05
Publication Date	3-9-05
Control No.	J. Cooke

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance that was issued on September 28, 1993.

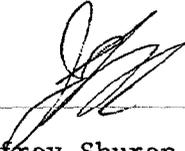
**DATES:** *[Insert date of publication in the Federal Register.]*

**FOR FURTHER INFORMATION CONTACT:** Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** In a notice containing a cumulative list of guidances available from the agency that published on January 5, 2005 (70 FR 824), FDA included the guidance document entitled, "Draft Guideline for the Validation of Blood Establishment Computer Systems." This document is being withdrawn because it no longer reflects all of FDA's current considerations on a guidance to assist manufacturers of blood and blood components,

including blood banks, plasmapheresis centers, and transfusion services in developing a computerized system validation program. FDA is revising the guidance and a draft guidance for public comment will be issued in the future.

Dated: 3/1/05  
March 1, 2005.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

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