

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D-0262] (formerly Docket No. 01-0262)

Display Date	JUN 27 2005
Publication Date	JUN 28 2005
Certifier	L. CLAWSON
	DDM

Draft "Guidance for Food and Drug Administration Reviewers: Premarket Notification Submissions for Automated Testing Instruments Used in Blood Establishments;" Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance that was issued on August 3, 2001.

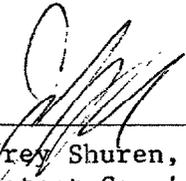
DATES: [*Insert date of publication in the Federal Register.*]

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 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 3, 2001 (66 FR 40708), FDA announced the availability of a draft document entitled "Guidance for FDA Reviewers: Premarket Notification Submissions for Automated Testing Instruments Used in Blood Establishments." This draft guidance is being withdrawn because it no longer reflects the following: (1) All of the information FDA reviewers should expect to be included in a premarket notification submitted to the Center for Biologics Evaluation and Research for such devices and (2) the recommended approach FDA reviewers should take in reviewing premarket submissions for automated

instruments testing used in blood establishments. In the future, FDA may issue for public comment draft special control guidances on instrumentation for blood borne pathogen donor screening and immunoematology testing.

Dated: 6/20/05
June 20, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S

