

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 809 and 864

[Docket No. 97N-0135]

DUMB

Display Date	3-29-01
Publication Date	3-30-01
Certifier	J. M. Windsor

**Hematology and Pathology Devices; Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing; Delay of Effective Date**

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

**ACTION:** Final rule; delay of effective date.

---

**SUMMARY:** In accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled "Regulatory Review Plan," published in the **Federal Register** on January 24, 2001 (66 FR 7702), this action temporarily delays for 60 days the effective date of the rule entitled "Hematology and Pathology Devices; Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing," published in the **Federal Register** on April 7, 2000 (65 FR 18230).

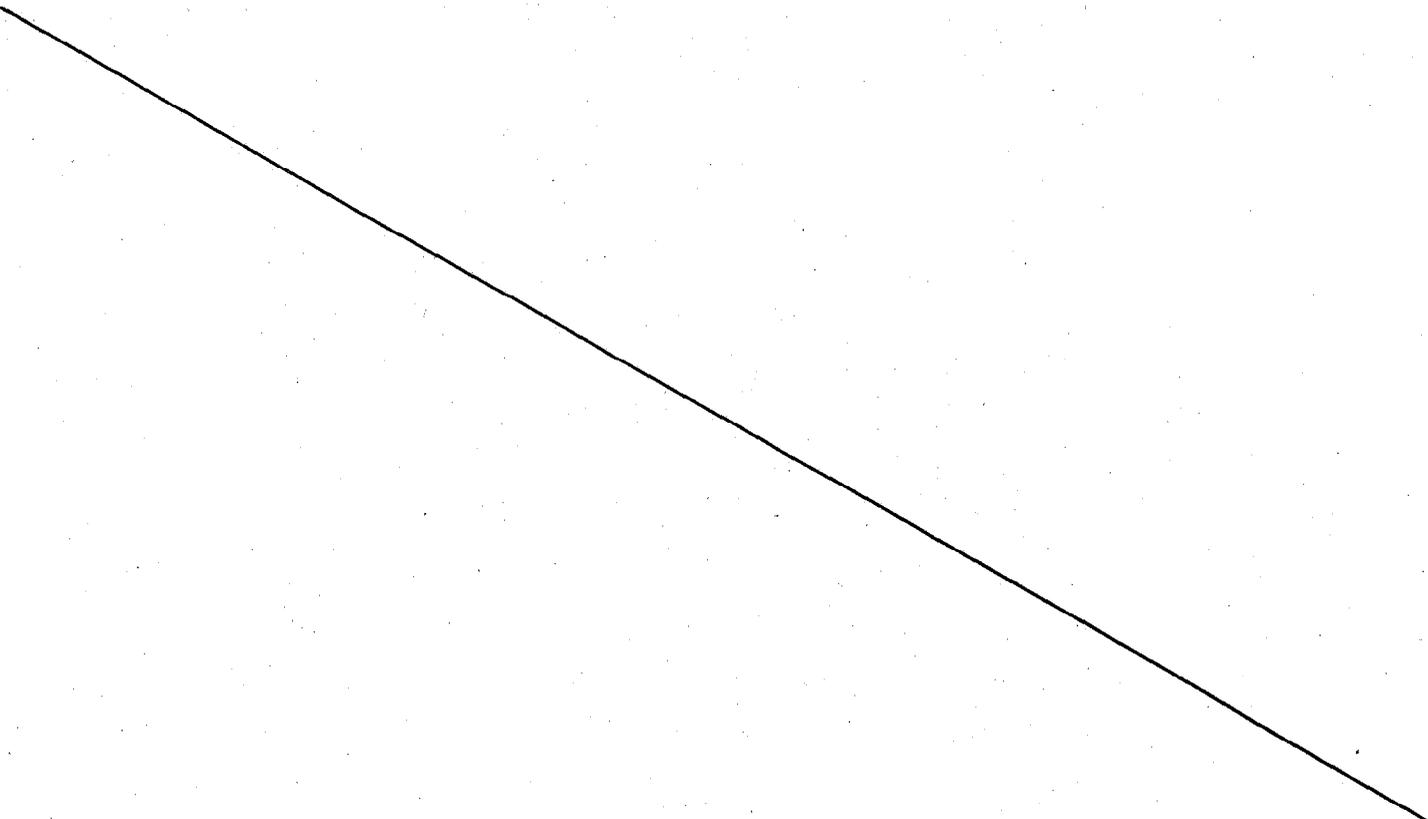
**DATES:** The effective date of the "Hematology and Pathology Devices; Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing," amending 21 CFR parts 809 and 864 published in the **Federal Register** on April 7, 2000 (65 FR 18230), is delayed for 60 days, from April 9, 2001, to a new effective date of June 8, 2001.

**FOR FURTHER INFORMATION CONTACT:** Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-2974.

**SUPPLEMENTARY INFORMATION:** The rule: (1) Reclassifies over-the-counter (OTC) test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) and exempts them from premarket notification (510(k)) and current good manufacturing

practice requirements; (2) designates OTC test sample collection systems for drugs of abuse testing as restricted devices under the Federal Food, Drug, and Cosmetic Act; and (3) establishes restrictions intended to assure consumers that: The underlying laboratory test(s) are accurate and reliable, the laboratory performing the test(s) has adequate expertise and competency, and the product has adequate labeling and methods of communicating test results to consumers.

The agency's implementation of this delay of effective date without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The temporary 60-day delay in the effective date is necessary to give the Department of Health and Human Services officials the opportunity for further review and consideration of new regulations, consistent with the Assistant to the President's memorandum of January 20, 2001, sent to all executive departments and agencies. Given the imminence of the effective date, seeking prior public comment on this temporary delay would have been impractical, as well as contrary to the public interest in the orderly issuance and implementation of regulations. The imminence of the effective date is also good cause for making this action effective immediately upon publication.



Dated: March 23 2001  
March 23, 2001.

Ann M. Witt

Ann M. Witt,  
Acting Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

**BILLING CODE 4160-01-S**

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

Jan Windser