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 7709), 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.

Ann M. Witt
Acting Associate Commissioner for Policy.

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