DADE BEHRING

**DADE BEHRING INC.**
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FR Doc# 04-7985
Public Comment 8500008

June 9, 2004

Division of Workplace Programs, CSAP
Attn: Walter F. Vogl, PhD
5600 Fishers Lane
Rockwall II, Suite 815
Rockville, MD 20857

Re: Docket No. 04-7985: Mandatory Guidelines for Federal Workplace Drug Testing Programs

Dear Dr. Vogl,

Dade Behring Inc, a manufacturer of in vitro diagnostic devices, respectfully submits comments to the Revised Mandatory Guidelines for Federal Workplace Drug Testing Programs. The revised Mandatory Guidelines were published in the Federal Register on April 13, 2004 (69 FR 19644).

Prior to 2004, a Notice of Proposed Revisions to the Mandatory Guidelines was published in the Federal Register on August 21, 2001 (66 FR 43876). In the 2001 Federal Register Notice, the Substance Abuse and Mental Health Services Administration (SAMHSA) proposed mandatory validity testing of urine specimens. New calibrator and cutoff levels were proposed as follows:

| | |
|---|---|
| Nitrite: | 500 mcg/mL |
| pH: | 3 and 11 |
| Creatinine: | 5 and 20 mg/dL |
| Oxidants: | at least 20 mcg/dL of chromate (chromium VI) |

Based on the 2001 Federal Register Notice, manufacturers of validity tests began the lengthy process of formulating new tests to meet the Proposed Revisions.

The 2004 Federal Register Notice (69 FR 19644) made changes to the calibrator levels that were previously announced in 2001. Specifically these changes are:

| | |
|---|---|
| Creatinine: | calibrator at 2 mg/dL rather than 5mg/dL |
| Oxidants: | calibrator of ≥50 mcg/dL of chromate (chromium VI) rather than 20 mcg/dL |

As a result, manufacturers must initiate new programs to meet the proposed revisions. As stated in the Federal Register notice, the proposed revision becomes effective 180 days after the FR publication date.

The cumulative effort to comply with revised guidelines in both Federal Register notices is overly burdensome and a 6 month implementation date is not sufficient for manufacturers to develop and commercialize new formulations **and** for laboratories to evaluate the new tests.

We propose a phased-in implementation for the revised Mandatory Guidelines as follows:

1. Original calibrator and cutoff levels proposed in 2001 – implementation 180 days from the 2004 Federal Register Notice.
2. New calibrator levels proposed in the 2004 Federal Register notice – implementation one year from the 2004 Federal Register Notice.

This would allow manufacturers and laboratories sufficient time to develop and evaluate tests which comply with the revised Mandatory Guidelines.

Dade Behring appreciates this opportunity to provide comments and hopes that you find these comments constructive. If you have questions, please do not hesitate to contact me at 302-631-7626 or by email: lewisyt@dadebehring.com

Sincerely,

Yuk-Ting Lewis
Regulatory Affairs and Compliance Manager