STATE OF NEW YORK
DEPARTMENT OF HEALTH

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Executive Deputy Commissioner

May 29, 2001

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and
Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, Maryland 20852

Re: Document Number 1147

To Whom It May Concern:

The Wadsworth Center of the New York State Department of Health wishes to comment on the proposed "Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA Applications," for device manufacturers to submit CLIA waiver requests to FDA, released for comment on March 1, 2001.

The proposed document uses the term "accuracy" as a measure for comparing a test's performance in the hands of untrained users with its performance in the hands of laboratory professionals using the device under realistic laboratory conditions. While this measure is certainly important, we recommend that FDA reconsider the appropriateness of the term "accuracy" within this context. Perhaps another term, e.g., "congruence" or "site comparability," might better convey the intended meaning. We also suggest that the term "waiver" be replaced with a term actually reflecting a test's complexity model, e.g., low complexity or minimal complexity. Unfortunately, the term "waiver" is widely taken to mean that this category of testing would be totally waived, i.e., exempted from regulatory oversight.

Finally, we would like to comment on the need for manufacturers' package inserts and instructions to be easily understood and interpreted by individuals performing these assays without the benefits of traditional laboratory training and experience. Our experience to date, based on direct onsite assessment of several hundred waived testing sites in New York State, demonstrates that a very large percentage of testing personnel consider manufacturers' instructions cumbersome and difficult to interpret. Our assessment of these sites, which total approximately 3,000 in this State, indicates that in many cases manufacturers' instructions are not being followed; we advise that manufacturers be made to recognize their critical role in educating this testing sector.

Please direct any questions in this regard to Dr. Lorraine Clarke, director of our Division of Laboratory Quality Certification, at (518) 485-5337. Thank you for the opportunity to comment on the proposed guidance document.

Sincerely,

Lawrence S. Sturman

Lawrence S. Sturman, M.D., Ph.D.
Director, Wadsworth Center

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