June 6, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

Subject: Docket No. FDA-2011-N-0259

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to provide input to the Food and Drug Administration (FDA) on streamlining agency regulations and policies. We support the President's Executive Order 13563, "Improving Regulation and Regulatory Review, which urges agencies to review and, where possible, update and improve their rules and guidance. AACC would like to bring to your attention a number of regulatory policies that merit the agency's consideration.

Reconsideration of Device Classification
When a new medical device is reviewed by the FDA, the instrument is assigned to one of three categories: Class I; Class II; or Class III. Class I devices have the least oversight, Class III the most. A manufacturer may petition the agency to downclassify a device once it has demonstrated safety and effectiveness. AACC suggests that the FDA automatically review devices for downclassification if it meets the following criteria:

- is a moderate or high complexity device;
- has been on the market a long period of time (e.g. 15 years);
- has its performance regularly monitored by inter-laboratory surveys;
- is widely available for purchase; and
- has an exemplary safety record.

The decision to downclassify remains with the FDA. If the agency decides to downclassify a device, it would still have authority to take regulatory action, if needed. Also, the instrument would still be subject to the CLIA'88 standards regardless of the FDA designation. We believe this change would reduce the regulatory burden on manufacturers by eliminating the need to file a petition. In addition, if the agency did downclassify a device, it would reduce or eliminate the submission requirements for manufacturers of like products.

Utilization of De Novo Process
AACC also urges the FDA to expand its utilization of the de novo process. This mechanism permits the agency to reclassify low risk devices that would automatically be designated as Class III devices rather than Class I or II, solely because there is no predicate device. This means that manufacturers, in certain instances, would be able to seek clearance through the less burdensome 510(k) process, rather than the more costly and onerous pre-market approval (PMA). AACC supports this approach and is pleased that agency seems to be moving in this direction.

The use of the de novo process is particularly important for devices, such as tests for Therapeutic Drug Monitoring (TDM), where consumer demand is often limited, but the potential for improved patient care is significant. Shifting the review of a low volume, low risk test from a PMA to a 510(k) review may make development of a previously unprofitable test, now cost-effective. This change benefits the manufacturer, which now has an incentive to develop and market the test, as well as the patient, who now has access to a valuable test for managing their drug therapy.

Regulation of Laboratory Developed Tests

AACC is also concerned about a policy currently under development involving the regulation of laboratory developed tests (LDTs). In the past, the agency deferred to the Centers for Medicare and Medicaid Services (CMS) to oversee these tests, which are inspected and monitored under the CLIA'88 standards. Now the agency indicates that it wants to alter this regulatory relationship.

AACC has supported FDA initiatives to regulate areas of concern involving LDTs, such as high risk genetic tests where clinical validity has not been sufficiently verified (e.g., IVD Multivariate Index Assays) and direct-to-consumer laboratories that use aggressive marketing tactics to sell their proprietary tests. We object, however, to the FDA's plans to regulate all LDTs as medical devices. We are concerned that:

- additional regulation will make it cost prohibitive for clinical laboratories to develop and offer new tests for rare diseases; and
- the FDA would have to divert resources to set up a new regulatory structure for which there would be limited health care gains.

It's important to note that the vast majority of these tests are adequately regulated by CLIA'88. AACC recommends that the FDA target its limited resources to those areas of testing in need of additional oversight, rather than adopting a blanket regulatory policy that may do more harm than good.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (314) 362-0194, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Ann M. Gronowski, PhD
President, AACC