



August 22, 2011

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

Docket#: FDA-2011-D-0476

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the Food and Drug Administration's (FDA's) July 12, 2011 "Draft Guidance for Industry and Food and Drug Administration Staff – Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices." AACC supports the agency's decision to downclassify devices for which safety and effectiveness is well established.

We encourage the FDA to continue its review of existing medical devices to identify others that may warrant declassification. AACC suggests that devices that meet all of the following criteria should automatically be considered for downclassification:

- 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.

We believe this change would reduce the regulatory burden on manufacturers by eliminating the need to file a petition downclassification, while ensuring faster access to newer, improved versions of these devices.

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,

A handwritten signature in black ink that reads "Ann M. Gronowski". The signature is written in a cursive, flowing style.

Ann M. Gronowski, PhD  
President, AACC