



February 25, 2010

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

Docket No. FDA-2010-N-0054

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to provide input to the Food and Drug Administration (FDA) as it 'strengthens' the 510(k) review process. AACC shares the FDA's commitment to improving patient protections, while preserving access to new, innovative technologies. One issue that fits both these criterion, and needs to be addressed, is the agency's De Novo process.

Congress authorized the De Novo process in the FDA Modernization Act of 1997, which permits the agency to reclassify low risk devices that would automatically be classified as Class III devices, solely because there is no predicate device, as Class I or II. This means that manufacturers, in certain instances, are able to seek clearance through the less burdensome 510(k) process, rather than the more costly and onerous pre-market approval (PMA).

The use of the De Novo process is particularly important for devices, such as tests for Therapeutic Drug Management (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 such a test, previously unprofitable, 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 increased effectiveness in managing their health. AACC supports the use of the De Novo process for expanding patient access to these tests.

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We are concerned, however, that the use of the FDA De Novo process for low risk, much needed TDM tests, has dropped precipitously in recent years. We are concerned that the agency's failure to act in this area is hindering the development of new tests and advancement of patient care. AACC recommends that the FDA collaborate with professional societies, medical manufacturers and patient advocacy groups to develop a working model that allows for greater use of the De Novo process. AACC offers to assist the FDA in this important endeavor.

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 (919) 966-3724, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in black ink that reads "Catherine Hammett-Stabler". The signature is written in a cursive style.

Catherine A. Hammett-Stabler, Ph.D., DABCC, FACB  
President, AACC