



August 20, 2007

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

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the July 26, 2007 draft guidance, "In Vitro Diagnostic Multivariate Index Assays," which outlines how the Food and Drug Administration (FDA) plans to regulate IVDMIA. These assays, according to the Agency, are more complex than traditional laboratory-developed tests (LDTs) and, therefore, are in need of greater FDA oversight.

AACC believes this revised guidance is an improvement over the September 7, 2006 draft. The definition of an IVDMIA is now more succinct, understandable and reflective of the FDA's intent than the earlier version. We are particularly pleased by the inclusion of examples, which clearly delineate the types of tests subject to the guidance and those that are not. Also, we agree with the Agency's decision to continue to rely on CLIA '88 to oversee those LDTs that are not IVDMIA.

AACC is also pleased that the revised document more clearly spells out the post-market expectations for IVDMIA, such as the registration and listing requirements, as well as a description of the potential use of the de novo process for down classifying low-risk devices. The guidance also states that the FDA will not require that laboratories making minor improvements to already cleared devices submit new 510(k)s "as long as device performance is not significantly changed." We support this decision.

One shortcoming with the document, however, is that it does not specify how the FDA is going to ensure compliance, since IVDMIA laboratories are not 'typical' manufacturers and are subject to multiple regulations. AACC recommends that the Agency delineate within the document those areas that are subject to the FDA's medical device regulations and those subject to CLIA oversight and specify what sanctions may be employed for different types of violations (e.g., suspension of their CLIA certificate, fines, etc...).

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Another concern is that the timeline allowed for FDA review of currently regulated IVDMIA's may be too narrow. Currently, the guidance states that it will "exercise enforcement discretion" in regards to the regulatory requirements for IVDMIA's for 12 months from the publication of the final document and for an additional six months if a facility submits a 510(k) or PMA. We recommend that the agency increase the additional timeframe from six to 12 months to ensure that the FDA has sufficient time to review the device and make a decision.

Also, AACC recommends that the FDA revisit this policy within a year of implementation to evaluate what, if any, impact the new policy has on patient access to new technologies or the ability or willingness of laboratories to develop new testing methodologies.

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 (504) 568-4281, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in black ink that reads "Larry Broussard". The signature is written in a cursive, flowing style.

Larry Broussard, PhD
President-Elect, AACC