



August 23, 2011

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

Docket No. FDA-2011-D-0305

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the June 1, 2011 "Draft Guidance for Industry and Food and Drug Administration Staff/Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions." We would like to bring to your attention an additional concern to those mentioned in our August 3, 2011 submission.

As we stated previously, AACC is very concerned about the potential impact of the new RUO/IUO guidance on laboratory access to these reagents, the development of new assays, and the ability of testing facilities to perform many critical tests. Another issue that alarms us is the potential impact this document could have on the ability of clinical laboratories to purchase RUO/IUO designated instruments. The FDA states under the marketing section that it would:

"consider promotion of IVD components, instruments, or reagents labeled RUO or IUO for use in an LDT that the manufacturer knows is used to provide clinical results outside an investigation to be evidence of an intended use that conflicts with RUO and IUO labeling, which may render the device misbranded."

As a result of this guidance, manufacturers may stop selling RUO/IUO instruments to clinical laboratories, such as spectrophotometers, balances, and tandem mass spectrometers, if they believe these products are being used to generate test results for clinical use. AACC is worried that restricting laboratory access to these instruments may adversely affect clinical decision-making and, therefore patient care. We urge you to work with the broader clinical laboratory community to revise this document and ensure access to quality care is preserved.

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