



March 5, 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The American Association for Clinical Chemistry (AACCC) welcomes the opportunity to comment on the September 7, 2006 “Draft Guidance for Industry and FDA Staff Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions,” which further explains the November 1997 ASR rule. Although we agree that further clarification regarding the ASR rule is needed, we are concerned that this document goes beyond offering additional insights into the policy and, instead, makes significant policy changes.

One area of concern is the more detailed definition of ASRs in the draft guidance. The new guidance specifies that an ASR has four characteristics: “a single moiety; a single endpoint; no instructions or performance claims; and not promoted for use on specific instruments on in specific tests or test systems.” However, two of these limitations—“a single moiety” and “a single endpoint”—are not defined in this document.

In characterizing these limitations, the FDA needs to address the following:

- Can an ASR contain primers/probes directed towards multiple different possible mutations of the same gene – with the gene being the ‘individual ligand’ mentioned in the regulation?
- Should each separate mutation be a separate ASR product?
- Can primers and probes appear in the same vial?

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AACC recommends that FDA work with manufacturers and the clinical laboratory community to address these issues and further refine the ASR the definition.

Similarly, the agency has not stated, to date, how it will handle testing issues involving patient access to certain laboratory-developed tests if manufacturers are required to remove certain ASRs from the market (i.e, reconfigure them), especially when no comparable IVD is available. We are particularly concerned that a strict interpretation of a single moiety, such as a single primer or single probe, could significantly reduce the availability of ASRs for molecular diagnostics. Once more, AACC urges the FDA to work with interested parties, possibly convening a stakeholder workshop, to address these concerns.

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 Vincent 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