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

Re: Docket No. 01D-0286

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) is responding to the Food and Drug Administration's (FDA's) request for comments on its draft guidance document, "Premarket Notifications [510(k)s] for In Vitro HIV Drug Resistance Genotype Assays," which outlines the agency's current views on special controls for HIV drug resistance assay premarket notifications. Our comments on the draft are very specific to the agency's description of Analyte Specific Reagents (ASRs).

In the October 2001 draft guidance document, the FDA states that *"ASRs are Class III devices when they are intended as a component in a test for use in the diagnosis of a contagious condition, such as HIV. We consider commercially distributed ASRs used in genotyping systems to detect HIV mutations to be class III devices requiring premarket approval."* This definition is a significant departure from existing FDA policy.

Until recently, the FDA considered ASRs used in HIV genotyping assays as class I medical devices. Now, in this draft guidance, the agency is proposing to reclassify them as class III devices, thus subjecting them to more stringent agency standards. AACC is concerned that this change, if adopted, may limit hospitals' and commercial facilities' access to these reagents, thus hindering their ability to develop new and even better, in-house tests for their patients.

We are perplexed as to the rationale for this policy change. The November 27, 1999 final ASR rule states that only a few ASRs would be categorized as class III devices and that these would be tests "intended to diagnose those contagious diseases that are highly likely to be fatal and where accurate diagnosis offers an opportunity to mitigate the public health impact of the condition." Similar language is mentioned in the draft guidance document. Yet this definition, as we interpret it, should exclude ASRs used in HIV genotyping from the class III categorization.

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