QUIDEL

May 31, 2001

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Steve Gutman, MD
Director, Division of Clinical Laboratory Devices
c/o Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20857

Subject: Docket No. 01D-0044 -- Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA.

Dear Dr. Gutman:

This letter includes the comments of Quidel Corporation on the Draft Guidance for clearing in vitro diagnostic (IVD) products to waived status under CLIA. We ask that it be considered with the earlier submission of our outside counsel, Nancy Cahill, and comments provided by the Advanced Medical Technology Association (AdvaMed) on the lawfulness of the clearance process now being challenged. The Draft Guidance would be strengthened with the following changes.

CLIA was enacted by Congress in 1988 to extend existing federal regulation of laboratories beyond the traditional clinical laboratory setting, largely by adding previously exempt physician office laboratories. Congress intended and intends that laboratory *testing* be regulated by CLIA, not laboratory *tests*. Under the law and 1992 regulation, different levels of regulatory scrutiny are required depending upon the complexity of the *testing* being done in a lab. This complexity scheme ended up being defined for FDA regulated IVDs by individual product reviews. And, over the years since 1988, these individual IVD product reviews have too often led to demands by CLIA regulators that products cleared for marketing by the FDA for "intended users" in point-of-care physician office settings must be changed, in configuration and in labeling, in order to be categorized as a waived test. Without *both* FDA 510(k)/PMA clearance and a CLIA waiver designation, most point-of-care test systems simply are not accessed by clinicians. Yet those of us experienced in obtaining FDA clearance to market have too often been stymied by conflicting CLIA requirements. This situation leads to our first request in any final guidance document on substance or process: in order to ensure administrative consistency and fair treatment of all petitioners, FDA must integrate 510(k)/PMA clearance requirements into CLIA complexity reviews, including waiver categorization, with a simultaneous announcement of regulatory decisions.

Our second request addresses the substantive provisions in the Draft Guidance: CLIA criteria must be focused on process regulation not product regulation, by deletion of requirements that are already handled in 510(k) reviews and/or well beyond the Congressional intent for treatment of waiver test systems (e.g., delete Sections II and III). We concur with the AdvaMed recommendation that Section IV be retitled and that *only* "Agreement Studies" (untrained versus laboratory professional) showing comparative error rates be required for categoratization to waived status.

01D-0044

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Finally, we urge FDA leadership to continue to accept and clear waiver petitions that do not conform to either the CDC's 1995 Guidelines or any final FDA Guidance Document. No other path forward is sustainable for the agency or for industry given the time it will take to reach any final rulemaking on CLIA waiver criteria. We hope that CLIA as implemented by the FDA will focus on fairness to all of the regulated parties. We also hope that the agency will consider the interests of physicians and patients by providing more definitive and timely diagnostic information with many of these test systems. By continuing to grant CLIA waiver FDA can assure a broader base of the medical community will access new simplified technologies and thereby promote otherwise unattainable public health benefits, as with rapid influenza or other infectious disease testing.

We offer our assistance in achieving our mutual goals with CLIA implementation and refinement. These comments are being sent in duplicate to the Dockets Management Branch and directly to you by FAX to ensure receipt under the May 31, 2001 deadline for public comment.

Sincerely,

Robin Weiner

Robin Weiner
Vice President,
Clinical and Regulatory Affairs

cc: Nancy E. Cahill, Esq.

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