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May 29, 2001

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

RE: Docket No. 01D-0044
Guidance for Clinical Laboratory Improvement Amendments of 1998 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA

Dear Dr. Hackett:

These comments are submitted by BD Diagnostic Systems (BDDS) on FDA's draft guidance entitled "Guidance for Clinical Laboratory Improvement Amendments of 1998 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA". BDDS, a part of Becton, Dickinsón and Company, develops, manufactures and markets *in vitro* diagnostic (IVD) devices.

BDDS supports the comments submitted by the Advanced Medical Technology Association (AdvaMed), a trade association representing medical device and IVD manufacturers, including BDDS. We would like to add our own comments on several issues.

Demonstrating "Accurate"

We commend FDA for providing an alternative approach to the one proposed by the Health Care Financing Administration (HCFA) and the Centers for Disease Control and Prevention (CDC) in September 1995. We concur with FDA's interpretation of "accurate" to mean that a test performs the same in the hands of both untrained users and laboratory professionals when the device is used under realistic conditions. However, we believe it is more appropriate to describe this approach as demonstrating "comparability" rather than "accuracy". It is important that FDA make this clear in the guidance to avoid confusion with the accuracy of a device established in the 510(k) or PMA processes.

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We believe that FDA's proposed study designs for demonstrating "accuracy" or comparability are too specific and may not be statistically valid in all situations for all products. The guidance should stress the use of statistically valid methodologies, but must allow flexibility in design to accommodate the diversity of devices and the ways in which a clinician uses information from an analyte. Studies must define acceptable comparability in the context of clinical utility, i.e., results from untrained users must provide the same medical information as results from laboratory professionals. For tests yielding quantitative results, such studies can be designed to assess both agreement (e.g., comparison of means) and variance between the two groups, using clinical decision points and predetermined limits around these decision points.

Demonstrating "Simple"

We recommend that the requirement that a device require no electronic or mechanical maintenance be revised as follows: "Requires no electronic or mechanical maintenance **that impacts proper function of the device if the function is not also independently verified by the device, free of operator input. For example, if an operator cleans an optical path, the device should independently verify a clean optical path before a specimen result is issued."** The revised statement allows for simple maintenance such as changing batteries, and also for more complicated maintenance, as long as the device can independently verify that maintenance was conducted properly.

We recommend that the requirement that a device produce a direct readout of result that requires no calibration, interpretation, or calculations be revised as follows: "Produces a direct readout of result that requires no calibration **beyond calibration set by the manufacturer**, interpretation, or calculation." The revised statement makes it clear that devices requiring calibration are not automatically disqualified from waiver, but that calibration should not be manually adjustable by the user (i.e., the user does not control the calibration parameters).

Redundancies with Existing FDA Requirements

Several requirements in the proposed guidance duplicate requirements imposed on manufacturers by existing FDA regulations. For example, under FDA's premarket notification regulations, manufacturers are required to conduct testing to establish the inherent performance characteristics of a device. Under FDA's Quality System Regulations, manufacturers are required to conduct hazard analyses and to address hazards identified in the analyses.

Requirements listed in "Voluntary Safeguards for Waived Tests" are particularly duplicative as manufacturers are already required under various FDA regulations to report adverse events associated with their devices, to monitor performance of their devices in the field, to take appropriate action in the field when device problems are identified, and to maintain design control validation information for inspection by FDA personnel. The level of oversight described in the guidance not only far exceeds the oversight imposed on moderate and high complexity tests, but it is inconsistent with Congressional intent regarding waived tests and the least burdensome principles.

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We thank you for the opportunity to comment on this very important draft guidance. We believe that the guidance will have a major impact on the future availability of testing devices at the point of care. If we can be of any assistance as the Agency seeks to reconcile multiple approaches to waiver criteria, please do not hesitate to contact us.

Sincerely,

Constance A. Finch

Constance A. Finch, Dr.P.H.
Director, Regulatory Affairs

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