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35949 Nicolet Ct., Fremont, California 94536 Phone/FAX 510-792-1529 gail@highbergassociates.com

Docket No. 01D-0044 4 June, 2001
Dockets Management Branch
Division of Management Systems and Policy 7666 '01 JUN -7 A9:59
Office of Human Resources and Management Services
Food & Drug Administration
5630 Fishers Lane
Room 1061, (HFZ-305)
Rockville, MA 20852

Re: Comments on Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA

As requested by Clara Sliva, I am sending a copy of the May 30, 2001 letter that I sent Clara Sliva regarding my comments on the recent CLIA Draft guidance document.

Thank you for the opportunity to provide my comments,
Please do not hesitate to contact me if you have any questions regarding my comments (phone/fax- 510-792-1527; email gail@highbergassociates.com).

Best Regards Gail Rodrick-Highberg

Gail Rodrick-Highberg
Clinical and Regulatory Consultant
Highberg Associates

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Clara Sliva MT (ASCP)
Acting CLIA Coordinator
FDA- DCLD

30 May 2001

SENT VIA EMAIL: clia@cdrh.fda.gov

Re: Comments on Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA

Dear Clara,

I had marked on my calendar that today was the last day to submit comments on the Draft Guidance Document and hoped I could get my comments in before you ended the comment period.

I think that overall the Guidance Document provides a much-needed outline of the expectations for obtaining a CLIA Waiver. The only area that I think is a little unreasonable is the switch from the requirement of 60 untrained users to 300 for the **"Untrained/Professional Agreement Study for Qualitative Tests".** This has essentially changed the process for an assessment of the directions for use into an "over-the-counter" type of field study.

I think this change represents an unreasonable burden for manufacturers and signals that the CLIA waiver process is reserved for OTC tests. I work with a lot of small manufacturers that are continually coming up with innovative tests that are simple, visual qualitative Class I and Class II devices that have the potential to greatly help the medical community. They work closely with the FDA to obtain clearance for these tests only to be faced with the reality that they will be unable to sell the devices to their target market (small labs including physician office laboratories) unless they can obtain a CLIA waiver for these devices.

I think that the original CDC requirements for 60 untrained users along with the other guidelines established in the recent guidance document should be adequate to determine if the device is eligible for a CLIA waiver.

Thank you for the opportunity to provide my comments,
Please do not hesitate to contact me if you have any questions regarding my comments (phone/fax- 510-792-1527; email gail@highbergassociates.com).

Best Regards Gail Rodrick-Highberg

Gail Rodrick-Highberg
Clinical and Regulatory Consultant
Highberg Associates

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