Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

May 30, 2001

Docket # 01D-0044
Dockets Management Branch
Division of management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061(HFA-305)
Rockville, MD 20852

Re: Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA Applications

The following are comments and suggestions for the draft guidance document listed above.

Page number	Draft Guidance Version	Suggestions/Comments
5 of 22	Step 2 suggests that the manufacturer send a sample device to the FDA for evaluation.	This is neither practical nor efficient. This has an incredible potential to cause backlogs and impede the process of issuing waivers.
7 of 22	III. Demonstrating " Insignificant Risk of Erroneous Result" 2nd para: "QC for waived tests may be modeled on standard laboratory QC that is devised for laboratory-based methodologies..."	The default for QC should be that the laboratory should follow their facility's procedures and policies regarding QC. If the device does not allow for this, then an alternative recommended by the manufacturer may be implemented.
10 of 22	QC Materials...	The laboratory should be permitted to use the QC material of their choice (or no QC material, depending on their facility's policies based on type of device), in place of any recommendation of the manufacturer. Further, QC material testing such as stability claims and lot-to-lot reproducibility studies (last paragraph) should not be part of the waiver submission.

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12 of 22	Untrained/Professional Precision Study for Quantitative Tests	Day-to-day variability studies are not appropriate for characterizing the performance of all test systems (e.g., glucose on whole blood analyzers).
12 0f 22	For a device that is exempt from 510(k)...	The waiver process for exempt devices should be very simple. If the studies required are similar to those required for a 510(k), this defeats the purpose of the exemption. By definition, exempt tests entail less risk and the FDA should consider automatic waiver for exempt tests.
13-14 of 22	Untrained/Professional Agreement Study for Quantitative Tests	The requirement for 300 untrained users is excessive. A study with 100 untrained users and one or two professionals should give statistically valid data. This requirement far exceeds the CDC's waiver requirements.

General Comments: In the spirit of a "least burdensome" approach to CLIA waivers, it is reasonable to expect that the FDA's CLIA waiver requirements not exceed those of the CDC. The FDA should review the draft guidance referenced in that light. Any additional requirements added by the FDA should be eliminated from the final guidance document.

Please feel free to contact me at 317/870-5610 (telephone), 317/870-5608 (Fax) or at **mme@diabetes-testing.com**.

Sincerely,

Margo Enright
Manager of Clinical Affairs
Polymer Technology Systems, Inc.

7736 Zionsville Road
Indianapolis, IN 46268
Telephone: (317) 870-5610
Fax: (317) 870-5608

Polymer Technology Systems, Inc.

Fax

To: Docket Management **From:** Margo Enright

Fax: 301/827-6870 **Pages:** 3

Phone: **Date:** 5/30/01

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