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June 20, 2011

BY ELECTRONIC MAIL

Ms. Charlotte A. Christin
Senior Policy Advisor
Office of the Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Ms. Christin

ACIL, as part of its mission, has over the years had a number of meetings with the FDA Division of Field Science (DFS). The purpose of these meetings has been to discuss and better understand the needs of both parties so as to improve the quality of work performed by private laboratories, including work received by the FDA. To this end, Carl Sciacchitano, Director of DFS, attended our recent annual conference in San Diego where we continued discussions about ways to improve interaction between the private lab community and the agency. We agreed to continue meetings regarding the science of sampling and analysis.

Further, we agreed to pursue:

- Development of a document that provides private labs direction regarding methods of analysis;
- Identification of appropriate ways to validate methods utilizing ISO17025 section 5.4 and to assure that the method is suitable for its intended use; and
- Identification of appropriate sampling procedures.

While we were attempting to set up a continuation of these meetings, the Food Safety Modernization Act was enacted. The new law established a daunting schedule for FDA promulgation of implementing regulations, including laboratory accreditation and some other issues that pertain to the laboratories. Due to administrative procedure concerns, DFS was "uncomfortable" in continuing to meet with us.

We believe the issues that can and should be discussed between ACIL and DFS are different from issues to be decided in rulemakings to implement the Food Safety Modernization Act. Therefore, we respectfully propose a resumption of the ACIL/DFS meetings for the exclusive purpose of discussing the ongoing current daily business of exchange of data regarding detention without physical examination.

Naturally, we are eager to participate in such meetings in a manner that is fully consistent with FDA administrative procedures. We hope to hear from you soon how these constructive meetings might resume.

Respectfully submitted,

John W. Bode

JWB:mhh