



May 12, 1999

Docket Number 99N-0386
Dockets Management Branch (HFA-305)
US Department of Health and Human Resources
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Talking With Stakeholders about FDA Modernization

Dear Dr. Henney:

ACIL, the national trade association representing independent scientific, engineering and testing firms, gladly accepts the invitation to comment on the Food and Drug Administration's specific initiatives related to the FDA Modernization Act. With more than 300 member companies, operating approximately 1400 facilities nationally and internationally, ACIL promotes the value of independent testing to key audiences and supports accreditation, training, and other programs that advance industry ethics and quality.

ACIL commends the FDA for continuing an open dialogue with its industry stakeholders, and would like to comment on question 4 posed to stakeholders by the FDA, on the March 22nd public meeting notice.

Question #4: The agency stated in the "FDA Plan for Statutory Compliance," that inflation has eroded real assets that can be applied to meet its public health mission while Congress has increased its responsibilities. Because the agency must allocate its limited resources to achieve the greatest impact, what actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?

Proposed Action: Outsource increased testing of food imports to private laboratories.

Trends in Food Imports

The quantity of food imports entering into the United States is rapidly increasing. The U.S. Department of Commerce in a 1998 Trade Report indicated that food imports into the United States increased 4.1 percent between 1997 and 1998, and that food imports have increased by a total of 49.7 percent since 1992. It is evident that FDA recognizes that this increase could have negative implications on public health if the food is not monitored. As a result, FDA has determined that food import safety is its top priority, first on CFSAN's list of 1999 program priorities.

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Additionally, US Congress has proposed legislation this year that calls for more inspection and testing of food imports. If any of these bills are passed into law, additional inspection requirements may be mandated to FDA, and the agency may or may not have the additional funding to fulfill its responsibilities.

With these facts in mind, and in the spirit of public-private partnership fostered through the implementation of the FDAMA, how can private laboratories assist the FDA in completing the additional testing and surveillance that will ensue with increasing amounts of imports to the United States?

ACIL Proposal

Specifically, private laboratories can aid FDA in accomplishing one of its goals under food safety, which is to increase surveillance of imported food products at the borders. Currently, FDA only allows the use of private labs only for food imports that have been placed on automatic detention status. If FDA utilized private labs for routine surveillance of imports, it would save FDA labs the investment of time and human resources.

Of course it is essential that FDA have confidence in the private laboratories on which it relies. The means for objective demonstration of competence is laboratory accreditation. AOAC International has recently developed a criterion for accreditation of food labs, based on the globally recognized international standard, ISO 25. There are also public and private-sector-accrediting organizations qualified to accredit labs to this standard. FDA can have the assurance it needs, by accepting test data only from laboratories that have been accredited to the international standard. FDA can effectively maintain oversight by relying on a program of accreditation and proficiency testing, without increasing its workload.

If FDA chooses to rely on private labs to test more food imports, it can focus resources in other program goals for food safety such as education and inspection initiatives.

ACIL appreciates the opportunity to comment on these matters.

Respectfully Submitted,



Joseph O'Neil
Executive Director