DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 26 2013

American Clinical Laboratory Association
Attn: Alan Mertz, President
1100 New York Ave., N.W., Suite 725 West
Washington, DC 20005

Re: Citizen Petition – Docket Number FDA-2013-P-0667

Dear Mr. Mertz:

This is an interim response to the petition dated June 4, 2013, filed by the Food and Drug Administration (FDA) on the same date. In the petition, you requested FDA to refrain from issuing guidance or rules purporting to regulate laboratory developed tests (LDTs) and to determine that LDTs are not devices regulated under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq., as amended.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact John Maiers of our Regulations Staff at (301) 796-0343.

Sincerely yours,

Nancy K. Stade, JD
Deputy Director for Policy
Center for Devices and
Radiological Health