DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

MAY 20 2014

Melissa Burdick
670 Vauxhall St. Ext.
Waterford, CT 06385-4351

Re: Docket No. FDA-2013-P-1637

Dear Ms. Burdick:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on December 4, 2013. Your petition requests that FDA approve Genzyme, Inc.'s product Lemtrada (alemtuzumab) for the treatment of multiple sclerosis, including relapsing-remitting multiple sclerosis.

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

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research