DEPARTMENT OF HEALTH & HUMAN SERVICES

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

FEB 04 2015

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

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

Dear Ms. Burdick:

This letter responds to your Citizen Petition to the Food and Drug Administration received on December 4, 2013. Your petition requested that FDA approve Genzyme, Inc.'s product Lemtrada (alemtuzumab) for the treatment of multiple sclerosis (MS).

The Petition asserted that Lemtrada is safe and effective for the treatment of MS and that given the severity of the disorder, the lack of a known cure, and the inability of existing therapies to meet the needs of MS patients, it is critical for physicians to have additional treatment options. According to the Petition, patients do not want to wait for either future therapies or the completion of additional trials for Lemtrada.

As you may know, FDA approved Lemtrada for the treatment of MS on November 14, 2014. Accordingly, the relief requested by your Petition has been granted, and the additional issues raised in the Petition have been rendered moot.

FDA remains committed to increasing the availability of safe, effective treatments for multiple sclerosis. Thank you for your comments to the Agency.

Sincerely,

Janet Woodcock, MD
Director
Center for Drug Evaluation and Research