DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

December 16, 2013

Melissa Burdick
(b) (6)
[redacted]

Dear Ms. Burdick:

Your petition to the Food and Drug Administration requesting the Agency to issue an approval for alemtuzumab because it is a safe and effective treatment for MS, including RRMS, was received by this office on 12/4/2013. It was assigned docket number FDA-2013-P-1637/CP1, and it was filed on 12/16/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)