DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 19, 2013

FILE COPY

Mark McCamish, MD, PhD
Head Global Biopharmaceutical Development
Sandoz International GmbH
Industriestr. 25
D-83607 Holzkirchen
Germany

Dear Mr. McCamish:

Your petition to the Food and Drug Administration requesting the Agency to require that a biosimilar be identified by the same international nonproprietary name as the reference product, was received by this office on 10/28/2013. It was assigned docket number FDA-2013-P-1398/CP1, and it was filed on 11/19/2013. 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)