DEPARTMENT OF HEALTH & HUMAN SERVICES

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

APR 24 2014

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

Re: Docket No. FDA-2013-P-1398

Dear Dr. McCamish:

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 October 28, 2013. Your petition requests that FDA require that a biosimilar biological product be identified by the same international nonproprietary name (INN) as the reference product.

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