DEPARTMENT OF HEALTH & HUMAN SERVICES

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

OCT 0 7 2016

Perry Siatis
Vice President, Biotherapeutics and Legal
AbbVie, Inc.
1 Waukegan Road
North Chicago, IL 60064

Re: Docket No. FDA-2015-P-4935

Dear Mr. Siatis:

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 17, 2015. Your petition requests that FDA, in assessing interchangeability under the Biologics Price Competition and Innovation Act, ensure that applicants seeking interchangeability determinations meet the "Safety Standards for Determining Interchangeability" set forth in Public Health Service Act section 351(k)(4) with respect to each condition of use for which the reference product is licensed.

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,

Carol J. Bennett
Deputy Director, Office of Regulatory Policy
Center for Drug Evaluation and Research