DEPARTMENT OF HEALTH & HUMAN SERVICES

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

DEC 1 2015

Perry C. Siatis, Vice President, Biotherapeutics and Legal
Neal Parker, Section Head, Legal Regulatory
AbbVie, Inc.
1 Waukegan Road
North Chicago, IL 60064

Re: Docket No. FDA-2015-P-2000

Dear Mr. Siatis and Mr. Parker:

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 June 2, 2015, and submitted on behalf of AbbVie, Inc. Your petition requests that FDA require the labeling of biosimilar biological products licensed under section 351(k) of the Public Health Service Act to include certain statements and information, including, among other things, a statement that the product is a biosimilar and, if applicable, that FDA has not found the product to be interchangeable with 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 requests.

Sincerely,

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