DEPARTMENT OF HEALTH & HUMAN SERVICES

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

DEC 1 7 2013

Mr. Ronald A. Rader
President
Biotechnology Information Institute
1700 Rockville Pike, Suite 400
Rockville, MD 20852

Re: Docket No. FDA-2013-P-0776

Dear Mr. Rader:

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 June 21, 2013. Your petition requests that the Agency assign both unique and "biosimilar/ (bio)generic-type (or class) names/identifiers" for approved biological products and their active agents, and disclose associated top-level/summary product identity information in public review-related documentation, including bioprocessing and quality-related aspects.

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