DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 21, 2013

FILE COPY

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

Dear Mr. Rader:

Your petition to the Food and Drug Administration requesting to assign both unique and biosimilar/(bio)generic-type (or class) names/identifiers for approved biologic products and their active agents, along with disclosures of sufficient public information to enable an adequate understanding of product identity, what the products/agents are, was received by this office on 06/21/2013. It was assigned docket number FDA-2013-P-0776/CP1, and it was filed on 06/21/2013. 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,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)