Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

March 28, 2007

The Honorable Edward M. Kennedy, Chairman
The Honorable Michael B. Enzi, Ranking Member
Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Kennedy and Ranking Member Enzi:

The Biotechnology Industry Organization (BIO) understands and respects your Committee's interest in establishing a statutory pathway for the approval of follow-on biologics. BIO recently developed a set of key principles that we believe should guide the creation of such a pathway, in order to ensure patient safety and preserve incentives for innovation. I have attached these principles for your consideration. BIO strongly urges you to adopt these principles in drafting any legislation creating a pathway allowing for the approval of follow-on biologics.

We also firmly believe that any work to establish a follow-on biologics pathway should be independent of the reauthorization of the Prescription Drug User Fee Act (PDUFA). Reauthorizing PDUFA early this year would help ensure the user fee program fully supports the internal scientific capabilities of the Food and Drug Administration in advancing biomedical innovation and does not delay patient access to new therapies. Attaching the creation of a statutory pathway for follow-on biologics to PDUFA would undoubtedly delay reauthorization, as it will take some time to appropriately resolve the many difficult scientific, legal, and patent-related issues raised by a follow-on pathway.

We look forward to working with you and your staff in order to ensure that any statutory pathway for follow-on biologics meets these principles while preserving the biotechnology industry's drive to discover breakthrough therapies for life-threatening illnesses and diseases.

Sincerely,

James Greenwood

James C. Greenwood
President and CEO

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