James C. Greenwood
President & CEO

May 30, 3012

The Honorable John Boehner
Speaker of the House
H-232, The Capitol
U.S. House of Representatives
Washington, DC 20515

The Honorable Nancy Pelosi
Minority Leader
H-204, The Capitol
U.S. House of Representative
Washington, DC 20515

Dear Speaker Boehner and Minority Leader Pelosi:

On behalf of the Biotechnology Industry Organization (BIO), I am writing to express our support for H.R. 5651, the Food and Drug Administration Reform Act of 2012, which includes a reauthorization of the Prescription Drug User Fee Act (PDUFA V). This bipartisan bill will incentivize the development of lifesaving therapies for patients and strengthen America's global leadership in biomedical innovation. We commit to working with you in a collaborative fashion on remaining areas of interest in this legislation.

The bill will enhance the drug development and review process through increased transparency and scientific dialogue, advance regulatory science, and strengthen post-market surveillance. It also provides transparent, predictable performance goals and a dedicated, independent funding stream to ensure that FDA can facilitate the development and evaluation of biosimilars products. BIO appreciates the inclusion of the enhanced accelerated approval pathway provision which will help expedite the development of modern, targeted, and personalized therapies for patients suffering from serious and life-threatening diseases, while preserving robust standards for safety and effectiveness. In addition, BIO strongly supports the permanent reauthorization of the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA).

Under the PDUFA V agreement, the biotechnology industry has reinforced its commitment to a well-funded drug and biologics program that supports sound, science-based regulation consistent with FDA's public health mission. However, user fees are intended to support limited FDA activities around the drug review process and were never intended to supplant a sound base of appropriations. User fees currently account for nearly two-thirds of the cost of human drug review. We urge Congress to support FDA's mission and fund the Agency at the Administration's FY12 requested levels.

BIO represents over 1,100 members involved in the research and development of innovative healthcare, agricultural, industrial, and environmental technologies. We look forward to working with you on timely passage of this important legislation. Thank you.

Sincerely,

James C. Greenwood
President & CEO