Congress of the United States
Washington, DC 20515

July 18, 2007

The Honorable John D. Dingell, Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Joe Barton, Ranking Member
House Committee on Energy & Commerce
322A Rayburn House Office Building
Washington, D.C. 20515

The Honorable Edward M. Kennedy, Chairman
Senate Committee on Health, Education,
Labor, and Pensions
428 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Michael B. Enzi, Ranking Member
Senate Committee on Health, Education,
Labor, and Pensions
428 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairmen Dingell and Kennedy, Ranking Members Barton and Enzi,

Now that the House and Senate have completed consideration of several bills to reauthorize programs and functions of the Food and Drug Administration (FDA) and are moving toward conferencing this legislation, we strongly urge you to exclude extraneous measures that have not been fully considered by both houses. In particular, we are extremely concerned that complex legislation to create an expedited pathway of approval for so-called "follow-on" biologics or "biosimilars" might be included in a conference report on FDA legislation.

Over the past few months the Senate Committee on Health, Education, Labor, and Pensions has had lengthy deliberations, negotiations, and Committee markup on this critical matter. However, biosimilars legislation has not passed the full Senate and the House Energy & Commerce Committee has not had the opportunity to deliberate and consider the complicated scientific, legal, and economic issues involved in creating a new pathway for follow-on biologics/biosimilars. We believe the establishment of a pathway for biosimilars is appropriate for Congress to consider, but only after consideration of the views of all stakeholders and full deliberation, hearings, and markup by the appropriate committees. Until such time, we oppose inclusion of biosimilar legislation in the context of unrelated FDA reauthorizations.

We are also deeply concerned that efforts to resolve differences over biosimilars will endanger prompt enactment of legislation which provides necessary funding for vital FDA functions such as drug and medical device approval and safety monitoring. We understand that the FDA has indicated it will begin to issue notices of reductions in force to FDA employees within weeks if Congress does not act quickly to reauthorize user fee programs that fund these critical programs. Clearly, we should not endanger the jobs of vital, talented public servants as we work to resolve the complicated issues related to biosimilars.

Thank you for your leadership on these important issues. We look forward to working with you to ensure the health and safety of the American people.

Sincerely,