Congress of the United States
House of Representatives
Washington, D.C. 20515

Anna G. Eshoo
Eighteenth District
California

April 24, 2014

Dr. Margaret Hamburg, Commissioner
Food and Drug Administration
15B-31 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857-0001

Dear Commissioner Hamburg,

I'm writing in regard to the Biologics Price Competition and Innovation Act, legislation I authored in the House and the late Senator Edward Kennedy authored in the Senate, and was signed into law in 2010. As you know, this legislation was designed to create a new pathway at the FDA for the approval of biosimilars.

The Biologics Price Competition and Innovation Act was bipartisan, bicameral legislation which will for the first time in our country's history allow biosimilars to compete with innovative biologics to increase competition and lower prices for patients. As a consumer and patient advocate and a champion for the advancement of medical research, I very much want the law to succeed.

In order for the new biosimilars pathway to be successful, it's critical that the FDA release clear guidance on how the Act will be implemented. The FDA released three draft guidance documents on February 15, 2012, entitled "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product," "Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product," and "Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009." These documents provided a broad outline of thinking on a variety of different topics, however, they did not provide specifics on naming and interchangeability.

I believe clear and timely guidance on naming and interchangeability will allow both innovators and manufacturers of biosimilars a predictable, science-based pathway to what will be a robust and competitive market for biologics.

We recently observed the four-year anniversary of the Biologics Price Competition and Innovation Act being signed into law and I ask that you:

1. Share with me the FDA's timeline for the release of the draft guidances on naming and interchangeability;

2. Share the FDA's timeline for *finalizing* the three 2012 draft guidances.

I appreciate your attention to this issue and I thank you in advance for your cooperation and timely response.

Most gratefully,

Anna G. Eshoo
Member of Congress