AMCP | Academy of Managed Care Pharmacy®

October 6, 2014

The Honorable Margaret Hamburg
Administrator
Food and Drug Administration
Division of Dockets Management (HFA-305)
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comments on Docket No. FDA–2013–D–1165: *Draft Guidance for Industry on Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the Public Health Service Act*

Dear Administrator Hamburg:

The Academy of Managed Care Pharmacy (AMCP) appreciates the Food and Drug Administration's (FDA) release of its *Draft Guidance for Industry on Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the Public Health Service Act* and the opportunity to provide comments on the issues presented. AMCP supports the development of a robust pathway using scientific and clinical data to ensure that Americans receive access to cost effective and affordable biologics, including biosimilars and interchangeable biosimilars, which demonstrate safety, purity, and potency in comparison to the innovator product. To achieve this goal, FDA must apply consistent regulatory standards in the approval of biosimilar agents.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's nearly 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

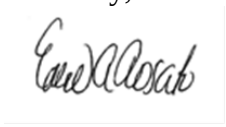
AMCP encourages FDA, consistent with our message to Congress, to consider an exclusivity period of 7 years or less on all reference biologic products to ensure that consumers receive access to more cost effective biosimilars in an expedient manner. AMCP understand that this would require a change to the *Federal Food Drug and Cosmetic Act*, but continues to believe that a shorter exclusivity period would promote greater market competition to the benefit of consumers who require biologics and also lower costs to public and private payers.

100 North Pitt Street | Suite 400
Alexandria, VA 22314
800 827 2627 | 703 683 8416
Fax 703 683 8417
www.amcp.org

In regard to the specific requirements for determining the exclusivity period and date of first licensure, AMCP recommends that FDA carefully review clinical and scientific comments from sponsors of biologics and potential biosimilar manufacturers, as well as comments on the legal issues presented in the guidance, to determine whether the proposal strikes the right balance of ensuring consumer access to biosimilars with appropriate marketing protections for sponsors of biologics. FDA should also ensure public transparency in its decisions regarding determinations of biologic exclusivity dates and date of original licensure. FDA should post analyses and relevant background information on its public website. We believe that these recommendations support the legislative intent to encourage access to biosimilar products.

Thank you again for the opportunity for the public to submit comments in response to this draft guidance and other documents related to creation of the pathway necessary for biosimilar adoption. AMCP looks forward to working with FDA and other stakeholders in ensuring that Americans have access to safe and effective biosimilar products. If you have questions or require additional information from AMCP please contact Lauren Fuller, Vice President of Government Affairs at 703-684-2625 or lfuller@amcp.org.

Sincerely,



Edith A. Rosato, RPh, IOM
Chief Executive Officer