

January 20, 2011

Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Hamburg,

We are writing to you today regarding the exclusivity period granted to reference biologic products under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

As the FDA implements the new approval pathway, the law is quite clear and was carefully drafted to instruct biosimilar applicants. It states that an applicant:

- Must wait four years after a reference brand product is first approved under a Biologics License Application (See Section 351(k)(7)(B)) to submit an application; and
- Must wait a period of 12 years before a biosimilar or interchangeable product can be approved under Section 351(k) that references a reference brand biologic product (See Section 351(k)(7)(A)).

These provisions are purposefully intended to run contemporaneously to improve consumer access to life-saving medicines. As such, during the initial four years of the 12-year period, effectively a reference brand product has both data exclusivity for its application and market exclusivity in relation to biosimilar applicants under the Section 351(k) pathway. After the initial four years, the data exclusivity expires (meaning that a biosimilar application that benefits from a reference brand biologic showing of safety and efficacy can be filed), and the market exclusivity continues for the remaining eight years. Congress wisely recognized the confusion that the terms “data” and “market” exclusivity caused during the legislative debate and chose to define clearly the process to avoid confusion.

During the legislative debate, we strongly opposed the 12-year period in these provisions because it restricts competition, delays entry of affordable medicines, and discourages real and important innovation of new cures. If the legislation is interpreted to prevent biosimilar filings for 12 years, consumers will have to endure an unknown period of delay of FDA review and approval that could stretch far beyond the 12-year total that was set in the legislation. We concur with the FDA’s initial understanding of the provision and ask that FDA implement the law as passed.

Sincerely,

AARP

Aetna

CVS Caremark

Express Scripts

Generic Pharmaceutical Association (GPhA)

Hospira

Humana

Medco

Momenta Pharmaceuticals

Mylan Labs

Pharmaceutical Care Management Association (PCMA)

Teva Pharmaceuticals

Watson Pharmaceuticals