Nutter McClennen & Fish LLP
Attorneys at Law
www.nutter.com

FDA Issues Draft Guidance on Regulatory Exclusivity for Biologics

August 13, 2014
Advisory

On August 4, 2014, the US Food and Drug Administration (FDA) released Draft Guidance on determining eligibility of a biological drug for regulatory exclusivity.

Under the Public Health Service Act (PHS Act), as amended in 2010, an abbreviated biosimilar application can be accepted by the FDA, but not until 4 years after the first licensure of the original reference product and, once accepted, such an application cannot be fully approved by the FDA for a period of 12 years from the reference's first licensure. This reference product exclusivity is granted independently of any patent exclusivity, and therefore, by itself, provides a significant incentive to the sponsor of a Biologic License Application (BLA) who obtains the first licensure status. The date of first licensure is also critical to the timing of a follow-on biosimilar entry to the market.

Sponsors of the original BLAs generally have superior information about their products, and therefore, could gain an unfair advantage from evergreening BLAs based upon minor product improvements, each with 12 years of additional exclusivity. However, not every BLA triggers an exclusivity period. Specifically, under section 351(k)(7)(C) of the PHS Act, a new period of exclusivity is not available to the same sponsor or an affiliated party if the same product is licensed for a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength. Additionally, a structurally modified product is not eligible for a new period of exclusivity if such structural modification does not result in improved safety, purity, or potency.

The Draft Guidance provides the agency's interpretation of the following key provisions in Section 351(k)(7)(C):

- who is considered an affiliated entity (as in "licensor, predecessor in interest, or other related entity");
- what is meant by "modification to the structure"; and
- how BLA applicants can demonstrate to the FDA that a structural change indeed results in "a change in safety, purity, or potency."

The Draft Guidance will be of particular interest to BLA sponsors who are aiming at extending market exclusivity by developing second generation, improved biologics, also known as "biobetters." Additionally, the Draft Guidance may impact BLA sponsors who have multiple related products in development, for example, multiple antibodies against the same target. In many situations, the availability of regulatory exclusivity, or lack thereof, will have an impact on patent strategy and, ultimately, on the valuation of a drug or drug candidate.

All comments on the Draft Guidance should be submitted to the FDA within 60 days from publication in the Federal Register, i.e., by October 6, 2014. Please contact your Nutter attorney if you are interested in learning more about the topic or submitting comments.

This advisory was prepared by Konstantin M. Linnik and Isaac A. Hubner, members of the Life Sciences practice group at Nutter McClennen & Fish LLP. For more information, please contact Konstantin, Isaac or your Nutter attorney at 617.439.2000.

Practice Areas

Intellectual Property

Industries

Life Sciences: Biotechnology, Pharmaceuticals & Medical Devices

Health Care

Related Professionals

Michelle L. Basil
Ronald E. Cahill
James E. Dawson
Jeremy Halpern
James M. Jacobson
Konstantin M. Linnik, Ph.D.
Erin M. Anderman
Erica M. Carroll
Isaac A. Hubner, Ph.D.