Published on *The National Law Review* https://natlawreview.com

# Biosimilars Action Plan Update

Article By:

Joanne S. Hawana

Muriel M. Liberto, PhD, Esq.

As an immediate follow-up to last week's release of the FDA's Biosimilars Action Plan, the Agency is announcing a public hearing for September 4, 2018 to gather stakeholder input on "FDA's approach to enhancing competition and innovation in the biological products marketplace, including by facilitating greater availability of biosimilar and interchangeable products." The hearing notice, to be published in the *Federal Register* on July 25th (see here), notes that the Agency has determined that a public hearing is the most effective way for it to hear from a diverse an broad group of stakeholders, from patients and health care providers to manufacturers and professional organizations.

The hearing notice provides a list of 9 specific questions on which FDA is soliciting feedback, and in particular on how it could use its existing statutory authority to regulate biological and biosimilar products to address those issues. In addition, the notice identifies several high-level goals under the Biosimilar Action Plan and requests any and all relevant information stakeholders are able to share with the Agency. Those goals are to:

- Facilitate the efficient development of biosimilar and interchangeable products using state-of-the-art science;
- Develop information resources, as well as scientific or regulatory tools, to streamline the development of biosimilar and interchangeable products;
- Enhance the efficiency of FDA review of marketing applications for biosimilar and interchangeable products;
- Provide additional scientific or regulatory clarity regarding FDA's regulation of biological products, including FDA's review and approval of marketing applications for biological products;
- Increase health care provider, patient, and payor understanding of biological products, including biosimilar and interchangeable products; and
- Support market competition by addressing attempts to game FDA requirements or otherwise delay market entry of competing biological products.

As we have mentioned in prior posts, registration for this type of FDA public hearing is done on a first-come, first-served basis and the conference center at FDA's campus at White Oak does fill up quickly. Anyone who wishes to attend in person or present oral remarks during the event should sign up as soon as possible. This Part 15 hearing will also be webcast live for those who cannot travel to White Oak, Maryland or who do not get one of the coveted in-person slots. Although not available quite yet, when a webpage for the hearing is created on the FDA.gov site, interested parties can look there for more information.  It will be posted here:

https://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConfer



National Law Review, Volume VIII, Number 205