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ALERT

Streamlining Biosimilar Approval: FDA's Public Hearing and Request for Comments

August 1, 2018

The U.S. Food and Drug Administration (FDA) seeks public input to streamline its review and approval of biosimilars. *See* Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments, 83 Fed. Reg. 35154 (July 25, 2018), (Hearing and Comments). The public hearing is calendared for September 4, 2018; presenters and attendees must register by August 14. Stakeholders may comment after the hearing through September 21.

The FDA recently studied the biosimilar market and concluded that Americans could have saved over $4.5 billion in 2017 if the U.S. had a robust biosimilar market. Samantha DiGrande, FDA Releases Biosimilar Action Plan (July 18, 2018). Through July 1, 2018, however, the FDA had approved just 11 biosimilars, and only three are marketed. *Id.* To spark biosimilar competition, the FDA released its Biosimilar Action Plan to highlight how it can support biosimilar applicants. *See generally* Food and Drug Admin., Biosimilar Action Plan: Balancing Innovation and Competition (July 2018).

The Biosimilar Action Plan calls for:

1. optimizing biosimilar and interchangeable product development and approval;
2. clarifying regulatory and scientific requirements;
3. educating patients, clinicians, and payors on biosimilars, and
4. reducing anticompetitive delays for follow-on products.

Practice Areas

Intellectual Property

Biosimilar Action Plan at 5-9; *see also* Hearing and Comments at 35155.

To achieve those ends, the FDA signals that it would clarify both regulatory requirements for biosimilar applicants and exclusivity periods for reference biologics by:

- creating resources to optimize biosimilar development and the FDA's review;
- enhancing the Purple Book (FDA's list of approved biological products);
- exploring data sharing agreements with foreign regulators;
- establishing new offices to accelerate responses to stakeholders and to educate the relevant public;
- publishing guidance documents for product labeling and demonstrating interchangeability, and
- working with manufacturers to reduce the burden when assessing product quality and manufacturing processes.

Biosimilar Action Plan at 2-3. The FDA further asks how it can:

- help biosimilars reach patients quickly after launch;
- make the Purple Book more helpful;
- facilitate a multisource biologic marketplace;
- reduce costs to development without compromising scientific standards;
- facilitate use of non-U.S.-licensed comparator products to support approval;
- incentivize product improvement without impeding biosimilar competition;
- support biosimilar applicants seeking approval for carved out uses, and
- recognize umbrella exclusivity (an exclusivity period for a reference product that also protects another product that is otherwise ineligible for a new exclusivity period).

Hearing and Comments at 35156.

Relatedly, the Federal Trade Commission (FTC) had explained how the FDA can roll back barriers to biosimilar approval and market penetration to the Department of Health and Human Services (HHS) in HHS's separate Request for Comments. Fed. Trade Comm'n, Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (July 16, 2018), (FTC Comment); *see generally* HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 Fed. Reg. 22692 (May 16, 2018).

Perhaps prompting several of the FDA's questions, the FTC Comment recommends that the FDA create an expedited approval pathway for interchangeable biosimilars, reconsider naming conventions for biosimilars, and improve the Purple Book. FTC Comment at 9. In the FTC's view, automatic substitution and naming convention are crucial to market penetration for follow-on products for two reasons. First, interchangeable biosimilars are most likely to be eligible for automatic substitution, like for generic small molecules. *Id.* at 13. Second, biosimilars named differently from the reference biologic may falsely suggest a clinically meaningful

difference between the biologic products, preventing automatic substitution. *Id.* at 15. The FTC thus also recommends making the Purple Book akin to the Orange Book. *Id.* at 18. The Orange Book is an interactive tool, listing for example exclusivities, interchangeability, and applicant holders; even simple sorting allows users to find meaningful information, like whether follow-on products are approved. By contrast, the Purple Book is two PDF spreadsheets – it provides less information and no sorting capabilities. *Cf.* Food and Drug Admin., Orange Book, *with* Food and Drug Admin., Purple Book.

The FDA now seeks further input for bringing interchangeable biosimilars to market. Interested parties may present concerns and recommendations at the FDA's White Oak campus on September 4, 2018, or submit comments after the hearing through September 21.