the FTC and the Department of Justice, as discussed in Antitrust Considerations below. As required by the FDC Act,* the FDA has established an Internet database of all authorized generic drugs known to FDA.† To provide information for that database, NDA sponsors are required to include information about authorized generics in their annual reports.‡

If a Paragraph IV ANDA sponsor entitled to 180-day exclusivity launches an authorized generic, that launch starts the 180-day exclusivity period.§

BIOSIMILARS

As enacted in 1984, the abbreviated approval and nonpatent exclusivity provisions of the Hatch–Waxman Amendments do not apply to biological products licensed by the FDA under the Public Health Service Act. (However, biological products are within the scope of the patent term restoration provisions of Title II of the Hatch–Waxman Amendments.) In 2010, following years of debate, the BPCIA amended the Public Health Service Act to establish a regulatory pathway for the approval of abbreviated applications for biosimilar biological products. The new regulatory pathway includes both substantial similarities to, and differences from, the ANDA and 505(b)(2) NDA approval pathways established by the Hatch–Waxman Amendments.

To be eligible for approval, an abbreviated application has to establish that the proposed product is "biosimilar" to an approved reference product. That showing must be based on data derived from analytical studies, animal studies, and one or more clinical studies. Minor differences in clinically inactive components of the proposed and reference products are permitted. If the mechanism or mechanisms of action are known for the reference product, the proposed biosimilar product has to utilize the same mechanism or mechanisms of action. The proposed biosimilar product has to have the same indications for use, route of administration, dosage form, and strength as the licensed reference product.¶ A proposed biosimilar product could be licensed as "interchangeable" based on an additional showing that it can be expected to produce the same clinical result as the reference product.**

The regulatory pathway includes provisions that provide for the exchange of information relating to patents on the licensed reference product, including an opportunity for patent infringement litigation if the matter cannot be resolved. Unlike the ANDA and 505(b)(2) provisions of the FDC Act, the biosimilars provisions do not provide for any delay in FDA licensure; rather, it is up to the patent owner to seek an injunction to prevent the commercial marketing of a biosimilar product.††

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* 21 USC § 355(t) (as added by FDAAA).

† Available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm126391.htm. Accessed June 13, 2013.

‡ 21 CFR § 314.3(b) and § 314.81(b)(2)(ii)(b) (73 Fed. Reg. 56,487; September 29, 2008).

§ 21 USC § 355(j)(5)(B)(iv)(I) (as amended by MMA) (for ANDAs subject to 180-day forfeiture requirements added by MMA); *Mylan Pharmaceuticals, Inc. v. Thompson*, 207 F. Supp.2d 476, 488 (N.D. W.Va. 2001) (for pre-MMA ANDAs).

¶ 42 USC § 351(k)(2)(A).

** 42 USC § 351(k)(2)(B).

†† See 42 USC § 262(l).