POLSINELLI

Biosimilars

Biosimilars, or “generic biologics,” are rapidly emerging as the next frontier in the expansive pharmaceuticals industry. Polsinelli’s Biologics team is at the forefront in this field, ready to assist at every step in the complex process of obtaining approval for biosimilar drugs. The emerging Biologics License Application (BLA) pathway created by the Biologics Price Competition and Innovation Act (BPCIA) established the process for a company to seek and obtain approval for a biosimilar. As the bounds of this process have continued to take shape the past several years, our attorneys have counseled some of the world’s largest, best-known, and most influential generic, brand, and specialty pharmaceutical companies regarding the regulatory and legal issues associated with the process and BLA applications.

The BPCIA, while similar in some general respects to the Hatch-Waxman Act process for obtaining generic approval of small molecule pharmaceuticals, differs in important ways. Our team combines collective decades of experience advising clients regarding generic drugs under the Hatch-Waxman Act, with a deep bench of highly skilled and experienced professionals holding advanced degrees in the biologic fields, including molecular biology, biochemistry, chemistry, organic chemistry, microbiology, genetics, immunology, microbial pathogenesis, neuroscience, and pharmacology. Our team monitors all BLA filings and developments related to the BLA process, as well as the legal and policy developments in this rapidly-evolving area. We provide patent landscape opinions, due diligence reviews, and pre-litigation strategy in advance of the so-called BPCIA “patent dance,” and stand prepared to guide clients through litigation to obtain FDA approval of biosimilars.