Buchanan

FDA Biotechnology - Biologics and Biosimilars

Helping You Stay Ahead Of The Evolving Regulatory Landscape

Biologics are very different from traditional small molecule drugs. “Biologics” is a broad term that encompasses a wide variety of products, including monoclonal antibodies, vaccines, cell & gene therapy products, tissue & tissue products, and blood & blood products. Biologics must comply with the provisions of both the Public Health Service Act (PHS Act) and the Federal Food, Drug, and Cosmetic Act (FFDCA), and the licensure requirements are unique to each product type. Similarly, the licensure requirements for biosimilars are vastly different from the approval requirements for generic drugs.

Your team needs to include legal counsel who understands your technology, how to apply the legal and regulatory frameworks to that technology, and how to maximize the legal protections available for your product—all while staying ahead of the evolving product landscape. With Buchanan, you’re covered on all fronts.

How We Can Help You

The pace of biologic product innovation is rapid and increasing. In some cases, novel developments can outpace the ability of existing legal and regulatory frameworks to adapt. That means biologics and biosimilars stakeholders—including FDA itself—can face novel development, licensure, and enforcement issues. What does this mean to you? It means you need counsel who knows this landscape well.

Your Regulatory Challenge

Given the diversity of biologics, there is no one-size-fits-all regulatory pathway. Some cells and tissues, for example, are used as research tools without direct therapeutic applications. Some biologics may be marketed with minimal regulation, while others require years of clinical studies. Biologics may also be combined with other FDA-regulated drugs or devices, resulting in a combination product with its own unique jurisdictional and regulatory considerations.

The formal biosimilar licensure process was only created by statutory amendment in 2010, raising fresh questions about how to determine if two of these complex molecules are “biosimilar” and how to apply new exclusivity provisions to innovator biologics. You need regulatory counsel that can understand your technology and help you consider all of these issues in your development strategy.

Experienced Biologics and Biosimilars Counsel

Our team has deep training and experience in molecular biology, pharmacology, bioethics, and clinical trial considerations. We work closely with our IP attorneys to help them assess the strengths and weaknesses of the patent protections for your product or for a competing biologic. We help with your product development strategy and all aspects of FDA's regulations and guidance, including product jurisdiction issues, possible FDA regulatory pathways to market, legal challenges, and more.

Our clients have included large and mid-sized companies, small innovators, universities, clinical investigators, and investors. As a result, we have significant knowledge of this market sector that positions us well to review and consult on your biologics and biosimilars issues from all angles.

Key Examples of Our Work with Our Biologics and Biosimilars Clients Include:

- Helping with the FDA due diligence for a cell therapy company IPO.
- Advising on expedited approval pathways, including the regenerative medicine advanced therapy (RMAT) designation.
- Strategizing biosimilar development based on an approved reference drug that was "deemed" to be a biologic.
- Determining whether a human cell, tissue, and cellular or tissue-based product (HCT/P) requires licensure, is subject to compliance with regulations only, or is exempt from regulation, including if it is "minimally manipulated" or for "homologous use."
- Developing a business strategy for autologous stem cell products that successfully accounts for the regulatory requirements for these products.
- Providing guidance regarding the regulation of bone marrow transplants and hematopoietic stem cells.
- Assisting with licensing disputes involving cell and tissue products.
- Preparing for and attending client meetings with the FDA regarding cell and tissue product regulatory requirements.
- Providing legal and regulatory guidance for preparation of a Phase 1 investigational new drug application (IND).
- Responding to Form FDA 483 inspection observations for cell and tissue facilities.
- Identifying importation and exportation requirements for stem cells.
- Addressing cell and tissue labeling requirements.
- Addressing issues related to tissue collection for clinical research and clinical trials.
- Advising on informed consent issues.
- Conducting website reviews for cell and tissue products and services.
- Assessing IND and data ownership issues for stem cell products.
- Assisting with an investor's due diligence of a company offering an autologous HCT/P.