

What Is the BPCIA?

BPCIA

Congress enacted the **Biologics Price Competition and Innovation Act (BPCIA)** to provide an abbreviated pathway for biosimilars to gain FDA approval through submission of an abbreviated Biologics License Application (aBLA).

At a high level, the BPCIA includes two main statutory provisions: 42 U.S.C. § 262(k) relates to the regulatory aspects of the Act, while 42 U.S.C. § 262(l) outlines a framework for the applicant and reference product sponsor to resolve patent disputes.

Related Capabilities

Life Sciences