

What Exclusivity Periods Are Associated with Biosimilars?

An applicant may not submit an aBLA until four years after the reference product is licensed by the FDA. (See BPCIA § 351(k).) Further, any biosimilar licenses “may not be made effective” until 12 years after the reference product was licensed. (See BPCIA § 351(l).)

Thus, upon FDA approval, reference products benefit from 12 years of exclusivity, which is more than double the five years of exclusivity typically granted for small molecule pharmaceuticals.

WHAT IS CONSUMER FRAUD?