

## 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?**