between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (see Section 351(k)(4) of the PHSA). Interchangeable products may be substituted for the reference product without the intervention of the prescribing healthcare provider (see Section 351(i)(3) of the PHSA).

The BPCI Act also includes the following, among other provisions:

- A 12-year exclusivity period from the date of the first licensure of the reference product, during which the approval of a 351(k) application referencing that product may not be made effective (see Section 351(k)(7) of the PHSA)
- A four-year exclusivity period from the date of the first licensure of the reference product, during which a 351(k) application referencing that product may not be submitted (see Section 351(k)(7) of the PHSA)
- An exclusivity period for the first biological product determined to be interchangeable with the reference product for any condition of use, during which a second or a subsequent biological product may not be determined interchangeable with that reference product (see Section 351(k)(6) of the PHSA)
- An exclusivity period for certain biological products for which pediatric studies are conducted in accordance with a written request (see Section 351(m) of the PHSA)
- A transition provision for biological products that have been or will be approved under Section 505 of the FDCA (21 U.S.C. 355) before March 23, 2020 (see Section 7002(e) of the Affordable Care Act)
- A provision stating that a 351(k) application for a biosimilar product contains a "new active ingredient" for purposes of the Pediatric Research Equity Act (PREA) (see Section 505B(n) of the FDCA)

The BPCI Act also establishes procedures for identifying and resolving patent disputes involving applications submitted under Section 351(k) of the PHSA.

3.3 Formal meetings

There are five types of formal meetings that can occur between the sponsors or applicants and the FDA staff to discuss development of a biosimilar biological product.

3.3.1 Biosimilar initial advisory meeting

A biosimilar initial advisory meeting is an initial assessment limited to a general discussion regarding whether licensure under Section 351(k)