April 2009—Six senators introduce legislation in the Senate that cuts the time allowed before biosimilars could compete with the originals to five years. The present law calls for a 12-year period of exclusivity for biological drugs. The bill would give the FDA the discretion to approve biosimilars with less extensive testing.

July 2009—The Senate votes to give biologicals 12 years of market exclusivity. The White House had proposed seven years and Henry Waxman only five years.

November 2009—The proposed healthcare bill that will be brought before the House includes a provision creating a way for the FDA to approve biosimilars. The proposed bill gives brand name drug companies sales exclusivity for 12 years and allows them to extend that time frame, with minor changes to their formulas.

March 2010—President Obama signs the healthcare reform BPCI Act allowing the FDA to approve biosimilars to be marketed, with the FDA setting the rules as to what is required to gain approval.

October 2010—The FDA holds a two-day public meeting in order to obtain input on specific issues and challenges associated with the implementation of the BPCI Act.

January 2011—Debate continues over the fact that although the BPCI Act of 2010 provided for a 12-year period of exclusivity for biosimilar drugs, a controversy has arisen over the interpretation of the word *exclusivity* contained in the act.

October 2013—Biosimilar User Fee Act of 2012 (BsUFA)—The FDCA, as amended by the BsUFA, authorizes the FDA to assess and collect fees for biosimilar biological products from October 2012 through September 2017. The FDA dedicates these fees to expediting the review process for biosimilar biological products. Biosimilar biological products represent a significant public health benefit, with the potential to offer life-saving or life-altering benefits at reduced cost to the patient. BsUFA facilitates the development of safe and effective biosimilar products for the American public.

November 2014—The FDA Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations—The *Purple Book* lists biological products, including any biosimilar and interchangeable biological products licensed by the FDA under the PHSA. The lists include the date a biological product was licensed under Section 351(a) of the PHSA and whether the FDA evaluated the biological product for reference product exclusivity under Section 351(k)(7) of the PHSA. The Purple Book will also enable a user to see whether a biological product licensed under Section 351(k) of the PHSA has been determined by the FDA to be biosimilar to or interchangeable with a reference