

S. 2305 Biosimilar Red Tape Elimination Act

Section 1. Short Title

This Act may be cited as the “Biosimilar Red Tape Elimination Act”

Section 2. Biosimilar Biological Products

This section amends Section 351(k) of the Public Health Service Act to automatically deem all biological products licensed under this subsection as biosimilars to be interchangeable with the applicable reference products. The section also includes conforming amendments to section 351 of the Public Health Service Act, section 744G of the Federal Food, Drug, and Cosmetic Act, and section 505B of the Federal Food, Drug, and Cosmetic Act.