Subtitle C—FDA Amendments

SEC. 321. RARE PEDIATRIC DISEASE PRIORITY REVIEW VOUCHER EXTENSION.

Section 529(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(b)(5)) is amended—

(1) by striking ''December 18, 2020'' each place it appears and inserting ''September 30, 2024''; and

(2) in subparagraph (B), by striking ''December 18, 2022'' and inserting ''September 30, 2026''.

SEC. 322. CONDITIONS OF USE FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 351(k)(2)(A)(iii) of the Public Health Service Act (42 U.S.C. 262(k)(2)(A)(iii)) is amended—

(1) in subclause (I), by striking ''; and'' and inserting a semicolon;

(2) in subclause (II), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(III) may include information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product.''.