



RICK SCOTT
GOVERNOR

May 31, 2013

Secretary Kenneth W. Detzner
Secretary of State
Florida Department of State
R. A. Gray Building
500 South Bronough Street
Tallahassee, Florida 32399

Dear Secretary Detzner:

By the authority vested in me as Governor of the State of Florida, under the provisions of Article III, Section 8, of the Constitution of Florida, I do hereby approve of and transmit Committee Substitute for Committee Substitute for House Bill 365, enacted during the 115th Session of the Legislature of Florida, during the Regular Session of 2013 and entitled:

An act relating to pharmacy...

The bill allows a pharmacist to substitute an interchangeable biosimilar pharmaceutical for a prescribed biologic product under certain circumstances. This substitution may occur if the biosimilar product is deemed interchangeable by the United States Food and Drug Administration (FDA), the prescribing health care provider does not object in writing, the pharmacist informs the patient filling the prescription of the substitution, and the pharmacist maintains a written or electronic record of the substitution for two years. Additionally, the Florida Board of Pharmacy must maintain a web-based list of all FDA-approved interchangeable and biosimilar pharmaceuticals.

Congress created an abbreviated, FDA-approved licensure pathway for biosimilar pharmaceuticals as part of the new healthcare law. The FDA is currently in the process of adopting guidelines and rules for the application, approval, and interchangeability of biosimilar drugs. This bill creates Florida's first pathway to

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prescribing biosimilar products in our state. I look forward to working with the legislature to ensure that patient safety remains a primary concern as the federal regulation of biosimilar products continues to evolve and these pharmaceuticals become available in Florida. Keeping patient safety the top priority, we can design a regulatory framework that will allow Floridians access to these new pharmaceutical products while continuing to ensure we receive the highest-quality healthcare available.

For the reasons stated above, I hereby sign into law Committee Substitute for Committee Substitute for House Bill 365.

Sincerely,



Rick Scott
Governor

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TALLAHASSEE, FLORIDA

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