



Ohio Revised Code

Section 3715.011 Effect of changes to federal law.

Effective: March 21, 2017

Legislation: House Bill 505 - 131st General Assembly

(A) When one of the following changes occurs under federal law with respect to a biological product or interchangeable biological product, the change is automatically effected under this chapter and Chapter 4729. of the Revised Code, subject to any rule adopted under division (B) of this section to the contrary:

(1) An article is added to or removed from the definition of biological product in subsection (i) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(i).

(2) The United States food and drug administration determines that a biological product meets the standards for interchangeability set forth in section 351 of the "Public Health Service Act," 42 U.S.C. 262(k), and the product is licensed under that subsection.

(3) The United States food and drug administration determines that a biological product no longer meets the standards for interchangeability set forth in section 351 of the "Public Health Service Act," 42 U.S.C. 262(k), and the product's license under that subsection is suspended or revoked.

(B) The state board of pharmacy may adopt rules that exclude a biological product or interchangeable biological product that, pursuant to division (A) of this section, would otherwise be included under this chapter and Chapter 4729. of the Revised Code. The board's rules shall establish criteria to be used in determining whether a product is to be excluded.

All rules adopted under this division shall be adopted in accordance with Chapter 119. of the Revised Code.
