



Prescribing Interchangeable Products

Can interchangeable products be substituted for reference products by pharmacists?

Once interchangeable biological products are available in the United States, some states may permit a pharmacist to substitute an interchangeable product for the reference product without consulting the prescriber—a practice commonly called pharmacy-level substitution.

Many states have laws that address pharmacy-level substitution, and the specific laws vary from state to state. For information about prescription and substitution laws, check with your state pharmacy board.

Should a health care prescriber be concerned if his/her patient receives an interchangeable product in place of the prescribed reference product?

Prescribers and patients can expect that the interchangeable product will have the same clinical result as the reference product. Prescribers and their patients can be assured that an FDA-approved interchangeable product has been thoroughly tested and has met FDA's high standards for approval. Meeting these standards means that health care professionals and patients can be assured of the safety and effectiveness of an interchangeable product, just as they would be for a reference product.

What approval standards do interchangeable products have to meet?

A manufacturer of a proposed interchangeable product must show that the product is biosimilar to a reference product and that it can be expected to produce the same clinical result as the reference product in any given patient. The manufacturer must also demonstrate that, for a product administered to a patient more than once, there is no additional risk or reduced efficacy if a patient

switches back and forth between an interchangeable product and a reference product, compared to using the reference product without switching.

Although there are distinct approval requirements for reference products, biosimilars, and interchangeable products, the approval standards that apply to each type of biological product assure prescribers of the safety and effectiveness of each type of product. All biological products are approved only after they meet FDA's rigorous approval standards.

Can an interchangeable product be used in patients who have previously been treated with the reference product?

Yes, interchangeable products can be used in patients who have previously been treated with the reference product (treatment-experienced), as well as in patients who have not previously received the reference product (treatment-naïve). As part of the approval process for interchangeable products given more than once, manufacturers must show that patients can be switched back and forth between the reference product and the proposed interchangeable product without an increased risk in terms of safety or diminished efficacy.

Where can you find more information about interchangeable products?

FDA's "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," known as the "Purple Book," is an online resource for health care professionals and patients to locate information about approved biological products. The Purple Book provides information about whether a biological product is a reference product, biosimilar, or interchangeable product.

Product-specific information, including a summary of FDA's review of the data that were used to support approval of a biological product, can be found at the Drugs@FDA website. You can also visit www.fda.gov/biosimilars.