U.S. FOOD & DRUG ADMINISTRATION

Information for Health Care Providers About Regulatory Changes for Certain Biological Product Medications

There are two main statutes that provide the Food and Drug Administration (FDA) with authority to approve drug and biological product medications: the Federal Food, Drug, and Cosmetic Act (FD&C Act), which pertains to prescription drugs (both brand-name and generic), and over-the-counter drugs, and the Public Health Service Act (PHS Act), which applies to biological products, such as vaccines and therapeutic protein products.

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) created an abbreviated licensure pathway under the PHS Act for biological products that are demonstrated to be biosimilar to or interchangeable with an FDA-approved biological product. This pathway was established as a way to provide more treatment options for biological products, increase access to lifesaving medications, and potentially lower health care costs through competition.

There is a provision in the BPCI Act that requires, on March 23, 2020, that the small subset of "biological products" approved under the FD&C Act, such as insulin and human growth hormone – which for historical reasons were approved as drugs – "transition" to being regulated as biological products. Being regulated as biological products will enable transition products to serve as the reference product for biosimilar or interchangeable products approved through the abbreviated licensure pathway.

The transition is a regulatory action in which the approved drug application for a transition biological product will be "deemed" to be a biologics license application. In general, it should not change how patients' medications appear, or how healthcare providers prescribe or dispense their prescriptions.

After the transition, it will be possible for manufacturers to submit and the FDA to approve marketing applications for biosimilar and interchangeable products that reference transitioned biological products, which will help ensure that the market is competitive, and patients may have more affordable access to the medications they need.

Frequently Asked Questions

Q: Why is the FDA making this change?

A: The Biologics Price Competition and Innovation Act of 2009 required this transition, after which therapeutic biological products will be regulated under the same regulatory framework. Transitioning these drugs from the Federal Food, Drug, and Cosmetic Act (FD&C Act) to the Public Health Service Act (PHS Act) will allow for the submission and approval of marketing applications for new products that are biosimilar to, or interchangeable with, these transition biological products. This includes insulin, which has been historically regulated as a drug and not a biological product.

Q: What products will be affected?

A: Insulin and other biological products such as human growth hormone (somatropin), pancrelipase, chorionic gonadotropin, follitropin alfa, and menotropins will be regulated by the FDA as biological products. These products will be subject to the transition because each of these products falls within the definition of "biological product" (which was modified by Congress to include a "protein") based on the FDA's interpretation of the term "protein" to mean an "alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size."

For a list of products that will transition, please see the FDA's Preliminary List for more information.

Q: What should I tell patients asking about the transition of insulin and biological product medications?

A: The FDA is changing the regulatory designation of certain biological products. These biological products will not change upon the transition, so patients should continue to use them the same way. For example, patients should not see changes for instructions for use related to the transition. The transition allows for the submission of marketing applications through the abbreviated pathway for approval of biosimilar or interchangeable products to bring new competition to the market and, without compromising safety and effectiveness, potentially providing affordable treatment options. When biosimilar and interchangeable insulins or other biological products are eventually approved, the FDA anticipates a variety of new treatment options will become available, which may make pricing more competitive.

Q: I usually look up medications in the Orange Book, how can I find information about these products after the transition?

A: The biological products approved in NDAs that are deemed to be BLAs on March 23, 2020 will be removed from the Orange Book (the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations) and added to the Purple Book (the FDA's List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations). Beginning on or shortly after March 23, 2020, health care providers can find transition biological products in the Purple Book, which identifies licensed biological products by brand name and nonproprietary name. Health care providers can continue using the Orange Book to identify approved drug products that are not "biological products" and related generics approved under the FD&C Act.

Q: Will I need to do anything different to prescribe, order, or dispense insulin or other biologic products for my patients after the transition?

A: In general, prescribers should continue to prescribe and order insulin and other biological products the same way they did before the transition. In general, pharmacists should continue to dispense and counsel about insulin and other biological products the same way they did before the transition. Prescribers and pharmacists should ensure their patients understand there are no changes to the product and they should continue to use the product the same way as before the transition.

Q: When will biosimilar and interchangeable products be approved for transition products?

A: Beginning on March 23, 2020, applications for biosimilar and interchangeable products that reference transition products can be submitted to the Agency. Like with all original biosimilar and interchangeable biological product applications, the FDA is committed to reviewing and either approving or providing a complete response within 12 months.

Find Out More About the Transition and Biosimilar and Interchangeable Biological Products

- More Information about Biosimilar and Interchangeable Products: www.fda.gov/biosimilars
- Health Care Provider Materials about biosimilar and interchangeable Products: www.fda.gov/drugs/biosimilars/health-care-provider-materials
- "Deemed to be a License" Provision of the BPCI Act: www.fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act