

# Information for Patients 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 health care 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 medications will be affected?

A: Insulin and other biological product medications such as human growth hormone (somatropin), pancrelipase, chorionic gonadotropin, follitropin alfa, and menotropins will be regulated by the FDA as biological products.

For a list of products that will transition, please see the FDA’s [Preliminary List](#) for more information.

### Q: Will access to my insulin or transitioning medication change with the transition?

A: The transition should have no impact on access to medications that are transitioning. When biosimilar and interchangeable products are eventually approved, the FDA anticipates a variety of treatment options to be available which may make pricing more competitive.

**Q: Will the physical appearance or content of my insulin or other biological product medication change with the transition? Will anything change with how I use or administer my medication?**

A: The content of the insulin or biological product will not change upon the transition and there will not be a need to do anything different to administer or use the insulin product or other medication because of the transition. The physical appearance of the insulin or biological product should not appear different; however, there will be certain transition-related revisions to product labeling over time.

**Q: Will I need to do anything differently to obtain my insulin or biological product medication at the pharmacy after the transition?**

A: There should be no change in how you obtain your medication at the pharmacy.

**Q: Will my insurance coverage or insurance co-pay be affected by the transition?**

A: The FDA does not regulate health insurance, drug pricing, or reimbursement. When biosimilar and

interchangeable insulins or other biological products are eventually approved, a variety of new treatment options will be available, which may make pricing more competitive.

**Q: Will prices go down after the transition?**

A: The FDA does not regulate drug pricing or reimbursement. When biosimilar and interchangeable insulins or other biological products are eventually approved, a variety of new treatment options will be available, which may make pricing more competitive.

**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 biological 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](http://www.fda.gov/biosimilars)
- Patient Materials about Biosimilar and Interchangeable Products: [www.fda.gov/drugs/biosimilars/patient-materials](http://www.fda.gov/drugs/biosimilars/patient-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](http://www.fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act)