PBSA Feedback: FDA Biosimilars Website

In October 2017, the Food and Drug Administration (FDA) launched a new section on their main FDA.gov website dedicated to biosimilars. The homepage billboard on the FDA Biosimilars website reads: “Biosimilars are safe, effective treatment options.” The website includes information about how biosimilars are developed, reviewed, and approved, how they are prescribed, as well as educational materials, including online courses, webinars, and presentations.

Patients for Biologics Safety & Access (PBSA) would like to work in close coordination with the FDA to ensure that the website material accurately reflects the latest information about biosimilars and paints a clear picture about how biosimilars are developed, reviewed, and approved. PBSA has provided specific edits to website content in red in the following document and included additional suggestions for new content areas in purple.

PBSA comments and feedback about the existing FDA Biosimilars website assume that this information and content was developed for a prescriber audience. PBSA will have additional suggestions for a patient-focused educational effort.

Below is a summary of draft PBSA suggested changes to the website information. A detailed set of draft suggested changes to text is attached.

- **Clearly define and differentiate biosimilars and biologics.** Use the first section of the website to define, in plain language, biosimilars and biologics, and the key differences between them as it relates to patient safety, approvals, etc.
- **Define key terms like bioequivalent, approval process, and similarity** throughout the website or create a short glossary section with brief definitions of all key terms.
- **Explain laws surrounding substitution.** Two questions on the website must clearly explain current law surrounding whether a biosimilar and/or interchangeable can be substituted for the reference product at the pharmacy level.
- **Provide more information on FDA approval processes** as it relates to the review process for biosimilars and interchangeable products. Provide short explanations where referenced or link to more information on the FDA website about the approval processes.
- **Reference FDA draft guidance on interchangeable products.** Throughout the website, it’s important that FDA reference this draft guidance to ensure readers understand that no interchangeable products are currently approved.
- **Include additional questions about biosimilars and interchangeable products.** FDA should include additional questions/sections on the website that address whether a biosimilar needs to demonstrate similarity to other biosimilars and/or interchangeable products.
- **Emphasize the importance of the patient/doctor relationship.** FDA must include new language, regarding prescribing a biologic vs. a biosimilar, that emphasizes that doctors and patients should have an open dialogue about the difference in taking a reference product or a biosimilar, including possible new side effects, what symptoms it may or may not help, etc.
- **Include FDA Purple Book language** that clearly states the health care provider’s authority to prescribe biosimilars and/or interchangeable products.
- **Edit outreach materials (infographic, gifs) to better show differences between biosimilars and interchangeable products.**
FDA Biosimilars Website

Congress, through the Biologics Price Competition and Innovation Act (BPCI Act) of 2009, created an abbreviated licensure pathway 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, increase access to lifesaving medications and potentially lower health care costs through competition.

FDA requires biosimilar and interchangeable biological products meet the Agency’s rigorous approval standards. That means patients and health care professionals will be able to rely upon the safety and effectiveness of the biosimilar or interchangeable product, just as they would the reference biological product, hereinafter referred to as reference product.

Visit the pages below to learn more:

**Biosimilar and Interchangeable Products**

Biological products are the fastest-growing class of therapeutic products in the United States. When patients are prescribed a biological product, biosimilar and interchangeable products can offer additional treatment options, potentially lowering health care costs.

Learn more about biologics, biosimilars, interchangeable products, and other related terms below.

**What is a biological product (aka a biologic treatment)?**

Biological products (biologics) are regulated by the Food and Drug Administration (FDA) and are used to diagnose, prevent, treat, and cure diseases and medical conditions. Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. There are many types of biological products approved for use in the United States, including therapeutic proteins (such as filgrastim), monoclonal antibodies (such as adalimumab), and vaccines (such as those for influenza and tetanus).

The nature of biological products, including the inherent variations that can result from the manufacturing process, can present challenges in characterizing and manufacturing these products that often do not exist in the development of small molecule drugs. Slight differences between manufactured lots of the same biological product (i.e., acceptable within-product variations) are normal and expected within the manufacturing process. As part of its review, FDA assesses the manufacturing process and the manufacturer’s strategy to control within-product variations. These control strategies are put in place to help ensure that manufacturers produce biological products with consistent clinical performance.

Back to Top
What is a reference biologic product?

A reference product is the single brand name original biological product, already approved by FDA, against which a proposed biosimilar product is compared. A reference product is approved based on, among other things, a full complement of safety and effectiveness data. Generally, the data and information necessary to demonstrate the safety and effectiveness of a reference product will include clinical trials for all the disease indications being sought by the manufacturer.

A proposed biosimilar product is compared to and evaluated against a reference biologic product to ensure that the product is highly similar and has no clinically meaningful differences.

What is a biosimilar product?

A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. These two standards are described further below.

When is a biosimilar permitted to be developed?

Briefly describe when a biosimilar is permitted to be developed (i.e., when a reference product’s patent has expired)

What is the difference between biologic products and biosimilar products?

Create a brief section that clearly explains key differences between biologics and biosimilars.

What does it mean to be “highly similar”?

Minor differences between the references product and the proposed biosimilar product in clinically inactive components are acceptable.

A manufacturer developing a proposed biosimilar must demonstrates that its product is highly similar to the reference product by extensively analyzing (i.e., characterizing) the structure and function of both
the reference product and the proposed biosimilar. State-of-the-art technology is used to compare characteristics of the products, such as purity, chemical identity, and bioactivity. The manufacturer uses results from these comparative tests, along with other information, to demonstrate that the biosimilar is highly similar to the reference product.

Minor differences between the reference product and the proposed biosimilar product in clinically inactive components are acceptable. For example, these could include minor differences in the stabilizer or buffer compared to what is used in the reference product. Any differences between the proposed biosimilar product and the reference product are carefully evaluated by FDA to ensure the biosimilar meets FDA’s high approval standards.

As mentioned above, slight differences (i.e., acceptable within-product variations) are expected during the manufacturing process for biological products, regardless of whether the product is a biosimilar or a reference product. For both reference products and biosimilars, lot-to-lot differences (i.e., acceptable within-product differences) are carefully controlled and monitored.

What does it mean to have “no clinically meaningful differences”?

A manufacturer must also demonstrate that its proposed biosimilar product has no clinically meaningful differences from the reference product in terms of safety, purity, and potency (safety and effectiveness). This is generally demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, an assessment of clinical immunogenicity, and, if needed, additional clinical studies. Please provide an example of when additional clinical studies are needed.

What is an interchangeable product?

An interchangeable product is a biosimilar product that meets additional requirements outlined by the Biologics Price Competition and Innovation Act. As part of fulfilling these additional requirements, information is needed to show that an interchangeable product is “expected to produce the same clinical result as the reference product in any given patient”. Also, for products administered to a patient more than once to an individual, the risk in terms of safety and reduced efficacy of alternating or switching back and forth between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. An interchangeable product and a reference product will have been evaluated.

An interchangeable product may be substituted for the reference product without the involvement of the prescriber. FDA’s high standards for approval should assure health care providers that they can be confident in the safety and effectiveness of an interchangeable product, just as they would be for an FDA-approved reference product.

As of this writing, the FDA has issued draft guidance to industry on the requirements for the approval of interchangeable products. We are reviewing comments before issuing final guidance. No product has yet been approved by FDA as an interchangeable product.
What is the difference between a biosimilar and an interchangeable product?

As mentioned above, an interchangeable product, in addition to being biosimilar, meets additional requirements based on further evaluation and testing of the product. A manufacturer of a proposed interchangeable product will need to provide additional information to show that an interchangeable product is expected to produce the same clinical result as the reference product in any given patient. Also, for a product that is administered to a patient more than once, a manufacturer will need to provide data and information to evaluate the risk, in terms of safety and decreased efficacy, of alternating or switching between the products.

As a result, a product approved as an interchangeable product means that FDA has concluded it may be substituted for the reference product without consulting the prescriber. For example, say a patient self-administers a biological product by injection to treat their rheumatoid arthritis. To receive the biosimilar instead of the reference product, the patient may need a prescription from a health care prescriber written specifically for that biosimilar. However, once a product is approved by FDA as interchangeable, the patient may be able to take a prescription for the reference product to the pharmacy and, depending on the state, the pharmacist could substitute the interchangeable product for the reference product without consulting the prescriber. Note that pharmacy laws and practices vary from state to state.

FDA undertakes a rigorous and thorough evaluation to ensure that all products, including biosimilar and interchangeable products, meet the Agency’s high standards for approval. As of this writing, the FDA has issued draft guidance to industry on the requirements for the approval of interchangeable products. We are reviewing comments before issuing final guidance. No product has yet been approved by FDA as an interchangeable product.

Are biosimilars the same as generic drugs?

No. While biosimilars and generic drugs are versions of brand name drugs and may offer more affordable treatment options to patients, they are not the same as generic drugs. Biosimilars and generics are each approved through different abbreviated pathways that avoid duplicating costly clinical trials. But biosimilars are not generics, and there are important differences between biosimilars and generic drugs.

For example, the active ingredients of generic drugs are the same as those of brand name drugs. In addition, the manufacturer of a generic drug must demonstrate that the generic is bioequivalent to the brand name drug.

By contrast, biosimilar manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components. To be classified as “highly similar”, biosimilar manufacturers must also demonstrate that there are no clinically
meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness. (PBSA suggests the inclusion of a table comparing characteristics of generic drugs and biosimilars.)

**Biosimilar Development, Review, and Approval**

All FDA-approved biological products, including reference, biosimilar, and interchangeable products, undergo a rigorous evaluation to ensure that patients can rely on their efficacy, safety, and quality.

Learn more about the development, review, and approval processes for biologics below.

*What is the approval process for biosimilar products?*

All FDA-approved biological products, including reference products and biosimilar products, undergo a rigorous evaluation so that patients can be assured of the efficacy, safety, and quality of these products.

A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared. A reference product is approved in a “standalone” application that must contain all data and information necessary to demonstrate its safety and effectiveness. Generally, the data and information necessary to demonstrate the safety and effectiveness of a reference product will include clinical trials for all the disease indications being sought by the manufacturer.

A biosimilar is highly similar to, and has no clinically meaningful differences in safety, purity, and potency (safety and effectiveness) from, an existing FDA-approved reference product. The goal of a biosimilar development program is to demonstrate biosimilarity between the proposed biosimilar product and the reference product, not to independently establish the safety and effectiveness of the proposed product. **By demonstrating biosimilarity, FDA assumes that the biosimilar product is as safe and effective as the reference product.**

The manufacturer of a proposed biosimilar product generates an array of data comparing the proposed product to the FDA-approved reference product in order to demonstrate biosimilarity. The comparative data are generated and evaluated in a stepwise fashion that begins with a foundation of detailed analytical (structural and functional) characterization and comparison of the products, moving on to animal studies if necessary and then to comparative clinical studies.

Consequently, rather than generating the same full profile of nonclinical and clinical data as the reference product, a manufacturer that shows its proposed biosimilar product is highly similar to and has no clinically meaningful differences from the FDA-approved reference product may rely in part on FDA’s previous determination of safety and effectiveness for the reference product for approval. This generally means that biosimilar manufacturers do not need to conduct as many expensive and lengthy clinical trials, potentially leading to faster access to these products, additional therapeutic options, and reduced costs for patients.

[Back to Top](#)
**What data are required for approval of a biosimilar or interchangeable product?**

A biosimilar product application must include data demonstrating biosimilarity to the reference product. This usually includes data from:

- Analytical studies demonstrating that the biological product is highly similar to the reference product, notwithstanding minor differences in clinically inactive components;
- Animal studies, including an assessment of toxicity; and
- A clinical study or studies sufficient to demonstrate safety, purity, and potency of the proposed biosimilar product in one or more of the indications for which the reference product is licensed. This typically includes assessing immunogenicity, pharmacokinetics (PK), and, in some cases, pharmacodynamics (PD) and may also include a comparative clinical study.

In addition to the data listed above, an application for an interchangeable product must also include information or data demonstrating that:

- The proposed interchangeable product is expected to produce the same clinical result as the reference product in any given patient; and,
- For a product administered more than once to an individual, switching between the proposed interchangeable product and the reference product does not increase safety risks or decrease effectiveness compared to using the reference product without such switching between products.

[PBSA suggests including a side-by-side comparison chart showing the differences in the application/approval process for reference products vs biosimilars.]

As of this writing, the FDA has issued draft guidance to industry on the requirements for the approval of interchangeable products. We are reviewing comments before issuing final guidance. No product has yet been approved by FDA as an interchangeable product.

**Do all biosimilar applications have the same types of data?**

When considering licensure of a biosimilar product, FDA reviews the totality of the data and information, including the foundation of detailed analytical (structural and functional) characterization, animal studies if necessary, then moving on to clinical pharmacology studies and, as needed, other comparative clinical studies.
The bullets above outline the types of data and information to be included in a biosimilar product application. FDA evaluates each biosimilar product on a case-specific basis to determine what data are needed to demonstrate biosimilarity and which data elements can be waived if deemed scientifically appropriate. This determination may be informed by what is already publicly known about the reference product.

Many factors can help tailor the data requirements for each biosimilar application. Some examples include:

- The strength and robustness of the comparative analytical studies showing similar structure and function between the proposed biosimilar and the reference product. For example, analytical similarity data showing very few analytical differences may provide strong support that the proposed product is highly similar.

- How similar the PK and PD profiles are between the biosimilar and reference product. (PBSA suggests that a brief explanation of PK and PD profiles be included here.)

- Pre-existing information about the safety profile of the reference product. For example, if it is known that patients have the potential to develop immune responses with adverse outcomes to the reference product, FDA will likely require a more rigorous evaluation of immune responses with the biosimilar.

**Why do we need an abbreviated approval pathway for biological products?**

Biological products are the fastest-growing class of therapeutic products in the United States and account for a substantial and increasing portion of health care costs. Congress, through the Biologics Price Competition and Innovation Act, created an abbreviated approval pathway to provide the public with greater access to safe and effective biological products. This pathway provides more treatment options, potentially lowering health care costs through competition and increasing access to lifesaving medications.

The abbreviated licensure pathway does not mean that a lower approval standard is applied to biosimilar or interchangeable products. In fact, as described above, the data package required for approval of a biosimilar or interchangeable product is extensive. If a biosimilar manufacturer can demonstrate that its product is biosimilar to the reference product, the assumption is that it is scientifically justified to rely on certain existing scientific knowledge about the safety and effectiveness of the reference product to support approval. This allows for a potentially shorter and less costly drug development program for a biosimilar.

**Can a biosimilar be approved for an indication that is approved for the reference product even if the biosimilar is not directly studied in that indication?**

Yes, a biosimilar product may be approved for an indication without direct studies of the biosimilar in that indication. If the total evidence in the biosimilar application supports a demonstration of biosimilarity for at least one of the reference product’s indications, then it is possible for the biosimilar
manufacturer to use data and information to scientifically justify approval for other indications that were not directly studied by the biosimilar manufacturer. This concept is called “extrapolation” and is critical to the goals of an abbreviated pathway—improving access and options at a potentially lower cost.

Extrapolation is based on (1) all available data and information in the biosimilar application, (2) FDA’s previous finding of safety and efficacy for other approved indications for the reference product, and (3) knowledge and consideration of various scientific factors for each indication. Extrapolation is not an assumption that the data from one directly studied indication or population alone is sufficient to support approval in a different non-studied indication or population. The biosimilar manufacturer must provide scientific justification to support extrapolation.

These scientific justification factors include knowledge of the mechanism(s) of action, PK, PD, efficacy, safety, and immunogenicity of the reference product in each of its approved indications. FDA evaluates all of the biosimilar product data to assess whether there are differences between the biosimilar and the reference product that may affect these scientific factors in any of the indications or populations not directly studied by the biosimilar manufacturer. If no such differences are identified, approval of the biosimilar for other non-studied indications or populations is generally supported.

FDA works with biosimilar manufacturers during product development to determine what data are needed to support extrapolation. Remember that a reference product manufacturer must show its product is safe and effective for each indication for which approval is sought, most often through indication-specific clinical trials. Since the goals of a biosimilar development program are different from those of a reference product development program (see the first question above), FDA believes it is generally unnecessary from a scientific perspective to require a biosimilar manufacturer to conduct clinical trials in all the same disease indications for which the reference product was studied and approved.

PBSA suggests that answers to these additional important questions be included in the final version of the website:

- Does a biosimilar have to demonstrate that it is highly similar to other approved biosimilars/interchangeable products?
- Does an interchangeable product have to demonstrate that it is highly similar with other approved biosimilars and interchangeable products?
- Can a biosimilar be used in patients who have previously been treated with another biosimilar or interchangeable product?
- Does the label of a biosimilar product include the safety data for the biosimilar or of the reference biologic?

**Prescribing Biosimilar and Interchangeable Products**

All biosimilar and interchangeable products meet FDA’s rigorous standards for approval for the indications (medical conditions) described in product labeling. Once a biosimilar has been approved by FDA, patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.

Learn more about the prescribing of biosimilar and interchangeable products below.
**Can biosimilar and interchangeable products be substituted for reference products by pharmacists?**

No, not under current law. When the FDA carries out a scientific review of a proposed biosimilar, the evaluation does not include a determination of whether the biosimilar is interchangeable with the reference product and whether the biosimilar can be substituted for the reference product at the pharmacy level. While substitution of a biosimilar for a reference product is a matter of state pharmacy law, no state law (It is our current understanding that states need explicit legal authority for pharmacies to automatically substitute. We are seeking more input on this legal question before finalizing this language) provides for automatic substitution of biosimilars for originator biologics (reference products). For information about prescription and substitution laws, check with your state pharmacy board.

**Can interchangeable products be automatically substituted for reference products by pharmacists?**

No product has yet been approved by the FDA as an interchangeable product. As of this writing, the FDA has issued draft guidance to industry on the requirements for the approval of interchangeable products. We are reviewing comments before issuing final guidance.

Once interchangeable biological products are approved and made 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. [PBSA recommends briefly addressing the difference between non-medical switching and 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.

When FDA carries out a scientific review of a proposed biosimilar, the evaluation does not include a determination of whether the biosimilar is interchangeable with the reference product and whether the biosimilar can be substituted for the reference product at the pharmacy. Substitution of a biosimilar for a reference product is a matter of state pharmacy law and is a decision that is generally outside of FDA’s regulatory role.

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?**

While FDA has not yet issued final guidance on the approval of interchangeable products, 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. As of this writing, the FDA has issued draft guidance to industry on the requirements for the approval of interchangeable products. We are reviewing comments before issuing final guidance. No product has yet been approved by FDA as an interchangeable product.

What approval standards do interchangeable products have to meet?

While FDA has not yet issued final guidance on the approval of interchangeable products, according to the BPCIA and FDA’s draft guidance, 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. As of this writing, the FDA has issued draft guidance to industry on the requirements for the approval of interchangeable products. We are reviewing comments before issuing final guidance. No product has yet been approved by FDA as an interchangeable product.

What is the difference between receiving a reference product and a biosimilar product?

Patients and their physicians should have an open dialogue before deciding to prescribe a biosimilar product in replacement of a reference product. While patients and physicians can expect that there will be no clinically meaningful differences between taking a reference product and a biosimilar when these products are used as intended for the indications (medical conditions) for which the biosimilar is approved, it’s critical that patients fully understand the any potential side effects that may come with switching. All reference products and biosimilar products meet FDA’s rigorous standards for approval for the indications (medical conditions), described in product labeling. Once a biosimilar has been approved by FDA, patients and health care providers can be assured of the safety and effectiveness of the biosimilar, just as they would for the reference product.

Are biosimilars approved for all the same indications as the reference product?

Biosimilar products may be approved for all or a subset of the same indications as the reference product. Biosimilars may have fewer indications than the reference product if, for example, a reference
product has unexpired exclusivity for an indication that prevents other manufacturers from obtaining approval for that particular indication. Health care prescribers should review the specific product labeling (prescribing information) and approved indications to determine the most appropriate product for their patient. Patients and their physicians should have an open dialogue before deciding to prescribe a biosimilar product in replacement of a reference product. While patients and physicians can expect that there will be no clinically meaningful differences between taking a reference product and a biosimilar when these products are used as intended for the indications (medical conditions) for which the biosimilar is approved, it’s critical that patients fully understand any potential side effects that may come with switching. All reference products and biosimilar products meet FDA’s rigorous standards for approval for the indications described in product labeling. Once a biosimilar has been approved by FDA, patients and health care providers can be assured of the safety and effectiveness of the biosimilar, just as they would for the reference product.

**How does the FDA distinguish between reference products and biosimilars in official reporting?**

The FDA adds four-letter suffixes at the end of newly approved biologics' and biosimilars nonproprietary names. Nonproprietary names that include distinguishing suffixes can serve as a key element to identify specific products in spontaneous adverse event reporting and to reinforce accurate product identification in billing and claims records used for active pharmacovigilance.

**Can a biosimilar or interchangeable product be used in patients who have previously been treated with the reference product?**

Yes, biosimilars and 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).

Before approval of the biosimilar product, FDA may request additional data that looks at safety information for treatment-experienced patients who undergo a single transition (single switch) from a reference product to a biosimilar product. This is meant only to capture major safety concerns. FDA does not require data on the safety of switching a patient multiple times to and from the reference product or other approved biosimilars or interchangeable products.

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 [PBSA recommends briefly describing accepted ways manufacturers may demonstrate this efficacy requirement].

This statement from the current “Purple Book” should be included here: “Healthcare providers can prescribe biosimilar and interchangeable biological products just as they would prescribe other medications. The BPCI Act describes an interchangeable product as a product that may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product. In contrast, FDA expects that a biosimilar product will be specifically prescribed by the healthcare provider and cannot be substituted for a reference product at the pharmacy level.”
Also, for a more general audience, there should be a brief explanation of what the Purple Book is and where to find it.

Where can you find more information about biosimilar and 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.

**Biosimilar Product Information**

The Food and Drug Administration approves biosimilar products and provides the scientific and regulatory advice needed to bring safe and effective biosimilars to market. The approval of biosimilar products can improve access to care for patients by increasing the number of medication options and potentially lower costs.

**FDA-Approved Biosimilar Products**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Approval Date</th>
<th>More Information</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Product</th>
<th>Date</th>
<th>Information Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renflexis (Infliximab-abda)</td>
<td>May 2017</td>
<td><a href="#">Renflexis information</a></td>
</tr>
<tr>
<td>Cyltezo (Adalimumab-adbm)</td>
<td>August 2017</td>
<td><a href="#">Cyltezo information</a></td>
</tr>
<tr>
<td>Mvasi (Bevacizumab-awwb)</td>
<td>September 2017</td>
<td><a href="#">Mvasi information</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Press Release: <a href="#">FDA approves first biosimilar for the treatment of cancer</a></td>
</tr>
</tbody>
</table>

**Learn More**

**Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations**

The “Purple Book” lists biological products, including any biosimilar and interchangeable biological products, licensed by FDA under the Public Health Service Act.

**Patient and Prescriber Outreach Materials**

**“What is a Biosimilar” Infographic**

The following section of the infographic must be deleted or reworded to emphasize that biosimilar products are not tested to assure safety and efficacy when switched back and forth while interchangeable products are required to meet this additional safety requirement.

**A biosimilar is approved by FDA after rigorous evaluation and testing by the applicant**

Prescribers and patients should have no concerns about using these medications instead of reference products because biosimilars:

**Biosimilar Safety and Monitoring GIF**

The GIF reads “Biosimilars… Are Carefully Monitored to Ensure Quality.” It needs to explain how they are carefully monitored for quality and also mention monitoring for safety. Otherwise, we recommend the GIF be removed from the website.