

FDA NEWS RELEASE

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Media Inquiries: Sandy Walsh, 301-796-4669; sandy.walsh@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA issues draft guidance on biosimilar product development

The U.S. Food and Drug Administration today issued three draft guidance documents on biosimilar product development to assist industry in developing such products in the United States.

“ When it comes to getting new biosimilar products on the market, FDA has taken an innovative approach to supporting their development at every step of the process,” said Janet Woodcock, M.D., director of FDA’s Center for Drug Evaluation and Research.

“ These draft documents are designed to help industry develop biosimilar versions of currently approved biological products, which can enhance competition and may lead to better patient access and lower cost to consumers.”

The Patient Protection and Affordable Care Act, signed into law by President Obama on March 23, 2010, amended the Public Health Service Act to create an abbreviated approval pathway -- under section 351(k) -- for biological products that are demonstrated to be highly similar (biosimilar) to or interchangeable with an FDA-licensed biological product.

Biological products are therapies used to treat diseases and health conditions. They include a wide variety of products including vaccines, blood and blood components, gene therapies, tissues, and proteins. Unlike most prescription drugs made through chemical processes, biological products generally are made from human and/or animal materials.

A biosimilar is a biological product that is highly similar to an already approved biological product, notwithstanding minor differences in clinically inactive components, and for which

there are no clinically meaningful differences between the biosimilar and the approved biological product in terms of the safety, purity, and potency.

Through this new approval pathway, biological products are approved based on demonstrating they are biosimilar to, or interchangeable with, a biological product that is already approved by the FDA, which is called a reference product.

The following three guidance documents provide the FDA's current thinking on key scientific and regulatory factors involved in submitting applications for biosimilar products to the agency. FDA is seeking public comment on these draft guidance documents:

- *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product:*
The draft guidance is intended to assist companies in demonstrating that a proposed therapeutic protein product is biosimilar to a reference product for the purpose of submitting an application, called a "351(k)" application, to the FDA. This draft guidance describes a risk-based "totality-of-the-evidence" approach that the FDA intends to use to evaluate the data and information submitted in support of a determination of biosimilarity of the proposed product to the reference product. As outlined in the draft guidance, FDA recommends a stepwise approach in the development of biosimilar products.
- *Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product:*
The draft guidance provides an overview of analytical factors to consider when assessing biosimilarity between a proposed therapeutic protein product and a reference product for the purpose of submitting a 351(k) application. This includes the importance of extensive analytical, physico-chemical and biological characterization in demonstrating that the proposed biosimilar product is highly similar to the reference product notwithstanding minor differences in clinically inactive components.

- *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009:*

The draft guidance provides answers to common questions from people interested in developing biosimilar products. The question and answer format addresses questions that may arise in the early stages of product development, such as how to request meetings with the FDA, addressing differences in formulation from the reference product, how to request exclusivity, and other topics.

FDA will seek public comment on the guidance documents and instructions on how to submit comments will be announced in an upcoming Federal Register notice. In finalizing the guidance documents, the agency will consider the information received from the public.

For more information

[FDA: Biosimilars](#)

¹(<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm>)

- [Scientific Considerations in Demonstrating Biosimilarity to a Reference Product](#)²
- [Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product](#)³
- [Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009](#)⁴

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

