

FDA NOTE TO CORRESPONDENTS

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For Immediate Release: May 9, 2011

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FDA requests input on development of user fee program for biosimilar and interchangeable biological products

The U.S. Food and Drug Administration is requesting input from stakeholders and the public relating to the development of a user fee program for biosimilar and interchangeable biological product (351(k)) applications.

Biological products are produced in a living system such as a microorganism, plant, or animal cell, while small molecule drugs are typically made through chemical synthesis.

The Biologics Price Competition and Innovation Act of 2009, a provision of the Affordable Care Act, creates an abbreviated approval pathway for biological products that are demonstrated to be highly similar (biosimilar) to, or interchangeable with an FDA-licensed biological product. It directs the FDA to develop recommendations for a 351(k) user fee program for fiscal years 2013 through 2017. The recommendations must be presented to Congress by January 15, 2012.

In addition to accepting written comments, the agency will consult with a range of groups, including scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and regulated industry. The FDA will take this input into account in developing proposed recommendations that will be published in the Federal Register for public comment, presented to Congressional committee staff, and presented at a public meeting.

A Federal Register notice, displayed today, describes the principles the FDA proposes to develop a user fee program, a proposed structure for the program, and proposed performance goals. The FDA is requesting public comment on each of these proposals, and is also posing several questions for public input. The notice also includes instructions for submitting comments and information for public and industry stakeholders who are interested in participating in meetings related to the development of recommendations for the 351(k) user fee program. The notice is available at <http://www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm>

For more information:

[Biologics Price Competition and Innovation Act of 2009](#)

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/UCM215031>

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