



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-6050]

Food and Drug Administration/Federal Trade Commission Workshop on a Competitive Marketplace for Biosimilars; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we), in collaboration with the Federal Trade Commission (FTC), is announcing a public workshop on March 9, 2020, "FDA/FTC Workshop on a Competitive Marketplace for Biosimilars." The purpose of the public workshop is to discuss FDA and FTC's collaborative efforts to support appropriate adoption of biosimilars, discourage false or misleading communications about biosimilars, and deter anticompetitive behaviors in the biologic product marketplace.

DATES: The public workshop will be held on March 9, 2020, from 9 a.m. to 5 p.m. Persons seeking to speak at the public workshop must register by February 24, 2020. Persons seeking to attend but not speak at the public workshop must register by March 4, 2020. Section III provides attendance and registration information. Electronic or written comments will be accepted until April 9, 2020.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security

information, please refer to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 9, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end April 9, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-6050 for "FDA/FTC Workshop on a Competitive Marketplace for Biosimilars." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." FDA will review this copy, including the claimed confidential information, in its

consideration of comments and will share it with FTC. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6522, Silver Spring, MD 20993-0002, 301-796-1042, email: sandra.benton@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA, in collaboration with FTC, is announcing the following public workshop entitled "FDA/FTC Workshop on a Competitive Marketplace for Biosimilars." The purpose of the

public workshop is to discuss FDA and FTC's collaborative efforts to support appropriate adoption of biosimilars, discourage false or misleading communications about biosimilars, and deter anticompetitive behaviors in the biologic product marketplace.

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 is also responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that emit electronic radiation, and for regulating tobacco products. Congress has given FDA, as part of the Agency's mission to promote and protect the public health, responsibility for implementing laws intended to strike a balance between encouraging and rewarding innovation in drug and biological product development and facilitating robust and timely market competition for drugs and biological products.

FDA regulates biological products under the Public Health Service Act (PHS Act) (see 42 U.S.C. 262) and the Food, Drug, and Cosmetic Act (21 U.S.C. 355). This includes review and approval of biosimilar and interchangeable products pursuant to an abbreviated licensure pathway added to the PHS Act in the Biologics Price Competition and Innovation Act of 2009 (BPCI Act),¹ which allows an applicant seeking licensure of a proposed biosimilar or interchangeable product to leverage FDA's previous determination of safety and effectiveness for a reference product licensed under section 351(a) of the PHS Act provided the sponsor can demonstrate that the biosimilar or interchangeable product meets the statutory standards for approval. The BPCI Act was enacted with the intent to balance innovation and consumer

¹Sections 7001 through 7003 of the Patient Protection and Affordable Care Act (ACA) (Pub. L. 111-148). See also Biosimilars Action Plan, <https://www.fda.gov/media/114574/download>.

interests.² FDA has and will continue to play a critical role in facilitating increased access to biosimilars, by supporting robust and timely competition through, among other things, the efficient review of applications for biosimilar and interchangeable products, which in turn may help enhance patient access and reduce cost burdens on patients and our healthcare system, in addition to helping to ensure the United States remains a driving force in medical innovation. Part of that role includes helping to ensure communication of truthful, nonmisleading, and balanced information about biological products, through FDA's oversight of prescription drug labeling and advertisements by drug manufacturers, packers and distributors and those acting on their behalf, and through FDA's own communications. This workshop will help to advance these important FDA priorities.

FTC is an independent agency charged by Congress with protecting the interests of consumers by enforcing competition and consumer protection laws. (See Federal Trade Commission Act, 15 U.S.C. 41-58.) It exercises primary responsibility for civil antitrust enforcement in the pharmaceutical industry. (For a summary of FTC's antitrust actions in the pharmaceutical industry, see https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_june_2019.pdf.) FTC also protects consumers by enforcing laws and rules that promote truth in advertising and fair business practices. FTC has substantial experience evaluating the generic drug and biosimilar marketplaces.

FTC vigorously promotes competition in the healthcare industry through enforcement, study, and advocacy. Competition in healthcare markets benefits consumers by helping to: (1) control costs and prices; (2) improve quality of care; (3) promote innovative products, services, and delivery models; and (4) expand access to healthcare goods and services. One of the FTC's

²*Id.*, section 7001(b) of the ACA.

long-standing core missions is to ensure advertising is truthful and not misleading. This allows consumers to make well-informed decisions about how best to use their resources and promotes the efficient functioning of market forces by encouraging the dissemination of accurate information. As addressed below, this proposed workshop is consistent with these FTC priorities.

As the marketplace of biological products continues to expand and evolve, FDA and FTC expect an increase in promotional activities involving reference products and biosimilar and interchangeable products. FDA, in collaboration with FTC, supports and encourages competitive markets for biological products. Supporting a competitive marketplace for biological products including biosimilar and interchangeable products, is essential for patient access to medicines and reducing healthcare costs. Biological products play a critical role in the treatment of many serious illnesses, including rare genetic disorders, autoimmune diseases, and cancer. For many of these conditions, there are no treatment alternatives other than biological products.

Both FDA and FTC have serious concerns about false or misleading communications regarding reference products and biosimilar or interchangeable products, and the potential negative effects of such communications on public health and competition. False or misleading comparisons of reference products and biosimilar or interchangeable products may constitute unfair or deceptive practices that undermine confidence in biosimilar and interchangeable products. Both agencies want to ensure that healthcare professionals and patients receive truthful and nonmisleading information about biological products.

This public workshop is a component of FDA's broader effort to facilitate the growth of a competitive market for biological products. In July 2018, FDA issued its Biosimilars Action Plan (see <https://www.fda.gov/media/114574/download>), which focuses on four areas of FDA

activities: (1) improving the efficiency of the biosimilar and interchangeable product development and approval process; (2) maximizing scientific and regulatory clarity for the biosimilar product development community; (3) developing effective communications to improve understanding of biosimilars among patients, clinicians, and payors; and (4) supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition. This joint FDA and FTC workshop furthers the activities set forth in the Biosimilars Action Plan.

II. Topics for Discussion at the Public Workshop

FDA and FTC are holding this public workshop to engage with stakeholders about certain aspects of a competitive market for biological products, including biosimilars and interchangeable products, and to discuss the important impact these products have on public health. This includes:

- U.S. Biosimilar Markets and FDA Approval Process;
- Enforcement Activities by FDA and FTC;
- The Benefits of Competition; and
- Improving Stakeholder Engagement: Education and Access.

FDA and FTC also encourage comments from stakeholders and the public relating to steps FDA and FTC can take to facilitate a competitive market for biological products.

III. Participating in the Public Workshop

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. An agenda for the workshop and any other background materials will be made available 5 days before the workshop at <https://www.fda.gov/drugs/news-events-human-drugs/public-workshop->

fdafic-workshop-competitive-marketplace-biosimilars-03092020-03092020. If you need special accommodations because of a disability, please contact Sandra Benton (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the workshop.

Registration and Requests for Open Public Workshop Speaker Slots. For those interested in participating as an Open Public Workshop speaker, please register at <https://www.eventbrite.com/e/86931096249> as "In-person Open Public Workshop presenter." Open Public Workshop registrations are due by February 24, 2020; however, if time is available, you may sign up as an Open Public Workshop speaker the day of the meeting. Time and space are limited and available on a first-come, first-served basis. Open Public Workshop speakers may be assigned no more than 5 minutes for their presentation and will deliver oral testimony only (no accompanying slide deck).

We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. All requests to make oral presentations must be received by February 24, 2020. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

In-Person Attendance: For those who would like to attend in person, but who are not participating in the Open Public Workshop, please register at <https://www.eventbrite.com/e/86931096249> as "In-person attendee--no participation." You may choose not to register; however, seating is limited, and space will be available on a first-come, first-served basis.

Persons attending FDA's workshops are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the Public Workshop: For those unable to attend in person, FDA will provide a live webcast of the workshop. To join the workshop via the webcast, please go to <https://www.fda.gov/drugs/news-events-human-drugs/public-workshop-fdaftc-workshop-competitive-marketplace-biosimilars-03092020-03092020> for the webcast address. Please register at <https://www.eventbrite.com/e/86931096249> as "online (webcast only)."

Media: Please register at <https://www.eventbrite.com/e/86931096249> as "Media" by March 4, 2020.

Transcripts: Please be advised that when a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see ADDRESSES).

Dated: January 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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