4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-5997]

Biosimilar User Fee Act; Stakeholder Consultation Meetings on Biosimilar User Fee Act Reauthorization; Request for Notification of Stakeholder Intention to Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders--including patient and consumer advocacy groups--notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Biosimilar User Fee Act (BsUFA). The statutory authority for BsUFA expires in September 2027. At that time, new legislation will be required for FDA to continue collecting biosimilar biological product user fees in future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next BsUFA program. The FD&C Act also requires that FDA hold discussions at least once every month with patient and consumer advocacy groups during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by January 30, 2026. Stakeholder meetings will be held monthly. It is anticipated that they will commence in April 2026. See the SUPPLEMENTARY INFORMATION section for registration information.

ADDRESSES: Submit notification of intention to participate in monthly stakeholder meetings by email to BSUFAReauthorization@fda.hhs.gov. The meetings will be held in person at the

FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, and virtually using the Microsoft Teams platform. In-person participants must be REAL ID compliant to access federal facilities. For additional information regarding REAL ID, refer to https://www.dhs.gov/real-id/real-id-faqs. Entrance for the stakeholder meeting 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/about-fda/visitor-information.

FOR FURTHER INFORMATION CONTACT: Thamar Bailey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4103, Silver Spring, MD 20993-0002, 301-796-6645, BSUFAReauthorization@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders--including patient and consumer advocacy groups--notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of BsUFA. BsUFA authorizes FDA to collect user fees from the regulated industry to support the process for the review of biosimilar biological products. The authorization for the current program (BsUFA III) expires in September 2027. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years.

Section 744I(f)(1) of the FD&C Act (21 U.S.C. 379j-53(f)(1)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer advocacy groups, in developing recommendations for the next BsUFA program. FDA will initiate the reauthorization process by holding a public meeting on December 3, 2025, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization (90 FR 52967, November 24, 2025). Section 744I(f)(3) of the FD&C Act (21 U.S.C. 379j-53(f)(3)) further requires that FDA continue meeting with representatives from patient and consumer advocacy groups at least once every month during negotiations with the

regulated industry to continue discussions of these stakeholders' views on the reauthorization. It is anticipated that these monthly stakeholder consultation meetings will commence in April 2026.

FDA is issuing this *Federal Register* notice to request that representatives from patient and consumer advocacy groups notify FDA of their intent to participate in the periodic stakeholder consultation meetings on BsUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in these stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice will be included in all patient and consumer advocacy group stakeholder consultation discussions while FDA negotiates with the regulated industry. If a representative from a patient or consumer advocacy group decides to participate in these monthly meetings at a later time, that stakeholder may join the remaining monthly patient and consumer advocacy group stakeholder consultation meetings after notifying FDA of this intention (see ADDRESSES). These stakeholder discussions will satisfy the consultation requirement in section 744I(f)(3) of the FD&C Act.

II. Notification of Intent to Participate in Periodic Patient and Consumer Advocacy Group Stakeholder Consultation Meetings

If you intend to participate in these continued periodic stakeholder consultation meetings regarding BsUFA reauthorization, please provide notification by email to BSUFAReauthorization@fda.hhs.gov by January 30, 2026. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification. Information concerning BsUFA, including the text of the law, the BsUFA III

Commitment Letter, key *Federal Register* documents, BsUFA-related guidances, performance reports, and financial reports may be found on the FDA website at https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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