

further evaluation of the three new studies described above.

Upon review of the evidence available in peer-reviewed, published, epidemiologic studies regarding peripheral neuropathy among 9/11-exposed populations, the Science Team found that there is inadequate evidence to determine a causal association²⁸ between 9/11 exposures and peripheral neuropathy (Category V).

E. Administrator's Final Decision on Whether To Propose the Addition of Peripheral Neuropathy to the List

Pursuant to the PHS Act, sec. 3312(a)(6)(B)(iv) and 42 CFR 88.16(a)(2)(iv), and in accordance with Sec. VIII.B. of the *Policy and Procedures*, the Administrator has determined that insufficient evidence is available to take further action at this time, including proposing the addition of peripheral neuropathy to the List (pursuant to the PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.16(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the **Federal Register** (pursuant to the PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.16(a)(2)(iii)). The Administrator has also determined that requesting a recommendation from the STAC (pursuant to the PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.16(a)(2)(i)) is unwarranted.

For the reasons discussed above, the request in Petitions 032, 033, and 068 to add peripheral neuropathy to the List of WTC-Related Health Conditions is denied.

F. Approval To Submit Document to the Office of the Federal Register

The Secretary, HHS, or his designee, the Director, Centers for Disease Control and Prevention (CDC) and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), authorized the undersigned, the Administrator of the WTC Health Program, to sign and submit the document to the Office of the Federal Register for publication as an official document of the WTC Health Program. Jay Bhattacharya MD, Ph.D., Senior Official Carrying out the Delegable Duties of the CDC Director, approved

this document for publication on May 1, 2026.

John J. Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0656]

Animal Drug User Fee Act; Stakeholder Consultation Meetings on the Animal Drug User Fee Act Reauthorization; Request for Notification of Stakeholder Intent To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing this notice to request that public stakeholders notify FDA of their intent to participate in periodic consultation meetings on reauthorization of the Animal Drug User Fee Act (ADUFA). The statutory authority for ADUFA expires September 30, 2028. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders—including patient and consumer advocacy groups, veterinary professionals, and scientific and academic experts—in developing recommendations for the next ADUFA program and hold discussions with these stakeholders at least once every 4 months during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure consistent stakeholder representation at the consultation meetings.

DATES: Submit notification of intent to participate in continued periodic stakeholder consultation meetings regarding ADUFA reauthorization by June 1, 2026. These stakeholder meetings are expected to commence in June 2026 and will continue at least once every 4 months during reauthorization negotiations with the regulated industry. See the **SUPPLEMENTARY INFORMATION** section for further information regarding notification of intent to participate.

ADDRESSES: Submit notification of intent to participate in this series of

meetings by June 1, 2026 to ADUFAReauth@fda.hhs.gov. These meetings will be held in person at the FDA Harvey W. Wiley Federal Building in College Park, MD, 5001 Campus Drive, College Park, MD 20740 and virtually using the Microsoft Teams platform.

FOR FURTHER INFORMATION CONTACT: Madeline Faunce, on detail to Office of Operations, Office of Finance, Budget, and Acquisitions, Food and Drug Administration, 301-796-3464, ADUFAReauth@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

In 2023, Congress passed the Animal Drug User Fee Amendments of 2023 (Pub. L. 118-15; ADUFA V). The authority for ADUFA V expires September 30, 2028. Without new legislation to reauthorize the program, FDA will no longer be able to collect user fees for future fiscal years to fund the new animal drug review process. Section 740A(d)(1) of the FD&C Act (21 U.S.C. 379j-13(d)(1)) requires that FDA consult with a range of stakeholders in developing recommendations for consideration for the next ADUFA program, including representatives from patient and consumer advocacy groups, veterinary professionals, and scientific and academic experts. To initiate this process of consultation, we announced in the **Federal Register** of April 17, 2026 (91 FR 20695) that a public meeting is to be held on May 27, 2026, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization. The meeting and written comments submitted to the docket will provide critical input as the Agency prepares for reauthorization discussions. Section 740A(d)(3) of the FD&C Act further requires that FDA continue meeting with these stakeholders at least once every 4 months during negotiations with the regulated industry to continue discussions of their views on the reauthorization, including suggested changes to the ADUFA program.

FDA is issuing this **Federal Register** notice to request that stakeholders—including veterinary professionals, patient and consumer advocacy groups, as well as scientific and academic experts—notify FDA of their intent to participate in the periodic consultation meetings on ADUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings is essential in the reauthorization process. If you wish to participate in this part of the

²⁸ See *supra* note 5 at Sec. V.E.—Evidence is Inadequate to Determine a Causal Association.

reauthorization process, 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 future stakeholder discussions while FDA negotiates with the regulated industry. If a stakeholder decides to participate in these meetings at a later time, they may still participate in remaining meetings by notifying FDA (see **FOR FURTHER INFORMATION CONTACT**). These stakeholder discussions will satisfy the requirement in section 740A(d)(3) of the FD&C Act.

II. Notification of Intent to Participate in Periodic Stakeholder Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding ADUFA reauthorization, please submit notification by email to: ADUFAreauth@fda.hhs.gov by June 1, 2026. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, telephone number, and notice of any special accommodations required due to a disability (e.g., Closed Captioning). Stakeholders will receive confirmation and additional information about the first meeting, and subsequent meetings when scheduled, after FDA receives this notification of intent to participate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0655]

Animal Generic Drug User Fee Act; Stakeholder Consultation Meetings on the Animal Generic Drug User Fee Act Reauthorization; Request for Notification of Stakeholder Intent To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing this notice to request that public stakeholders notify FDA of their intent to participate in periodic

consultation meetings on reauthorization of the Animal Generic Drug User Fee Act (AGDUFA). The statutory authority for AGDUFA expires September 30, 2028. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders—including patient and consumer advocacy groups, veterinary professionals, and scientific and academic experts—in developing recommendations for the next AGDUFA program and hold discussions with these stakeholders at least once every 4 months during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure consistent stakeholder representation at the consultation meetings.

DATES: Submit notification of intent to participate in continued periodic stakeholder consultation meetings regarding AGDUFA reauthorization by June 1, 2026. These stakeholder meetings are expected to commence in June 2026 and will continue at least once every 4 months during reauthorization negotiations with the regulated industry. See the **SUPPLEMENTARY INFORMATION** section for further information regarding notification of intent to participate.

ADDRESSES: Submit notification of intent to participate in this series of meetings by June 1, 2026 to AGDUFAreauth@fda.hhs.gov. These meetings will be held in person at the FDA Harvey W. Wiley Federal Building in College Park, MD, 5001 Campus Drive, College Park, MD 20740 and virtually using the Microsoft Teams platform.

FOR FURTHER INFORMATION CONTACT: Madeline Faunce, on detail to Office of Operations, Office of Finance, Budget, and Acquisitions, Food and Drug Administration, 301-796-3464, AGDUFAreauth@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

In 2023, Congress passed the Animal Generic Drug User Fee Amendments of 2023 (Pub. L. 118-15; AGDUFA IV). The authority for AGDUFA IV expires September 30, 2028. Without new legislation to reauthorize the program, FDA will no longer be able to collect user fees for future fiscal years to fund the generic new animal drug review process. Section 742(d)(1) of the FD&C Act (21 U.S.C. 379j-22(d)(1)) requires that FDA consult with a range of stakeholders in developing recommendations for consideration for the next AGDUFA program, including representatives from patient and consumer advocacy groups, veterinary

professionals, and scientific and academic experts. To initiate this process of consultation, we announced in the **Federal Register** of April 17, 2026 (91 FR 20691) that a public meeting is to be held on May 27, 2026, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization. The meeting and written comments submitted to the docket will provide critical input as the Agency prepares for reauthorization discussions. Section 742(d)(3) of the FD&C Act further requires that FDA continue meeting with these stakeholders at least once every 4 months during negotiations with the regulated industry to continue discussions of their views on the reauthorization, including suggested changes to the AGDUFA program.

FDA is issuing this **Federal Register** notice to request that stakeholders—including veterinary professionals, patient and consumer advocacy groups, as well as scientific and academic experts—notify FDA of their intent to participate in the periodic consultation meetings on AGDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings is essential in the reauthorization process. If you wish to participate in this part of the reauthorization process, 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 future stakeholder discussions while FDA negotiates with the regulated industry. If a stakeholder decides to participate in these meetings at a later time, they may still participate in remaining meetings by notifying FDA (see **FOR FURTHER INFORMATION CONTACT**). These stakeholder discussions will satisfy the requirement in section 742(d)(3) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Stakeholder Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding AGDUFA reauthorization, please submit notification by email to: AGDUFAreauth@fda.hhs.gov by June 1, 2026. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, telephone number, and notice of any special accommodations required due to a disability (e.g., Closed Captioning).