DATES: Submit notification of intention to participate in continued periodic stakeholder consultation meetings regarding AGDUFA reauthorization by May 16, 2016. These stakeholder meetings are expected to commence in June/July 2016 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 intention to participate.

ADDRESSES: The stakeholder meetings will be held at the Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Cassie Ravo, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6866, FAX: 240–276–9744, *Cassie.Ravo@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

In 2013 Congress passed the Animal Generic Drug User Fee Amendments of 2013 (Pub. L. 113–14; AGDUFA II). The authority for AGDUFA II expires September 30, 2018. 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, elsewhere in this issue of the **Federal Register,** we are announcing a public meeting to be held on May 16, 2016, 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, patient and consumer 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 will be important to ensure progress in these discussions. 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 discussion 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 **ADDRESSES**). 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: *cvmagdufa@fda.hhs.gov* by May 16, 2016. 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. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification.

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09152 Filed 4–19–16; 8:45 am]

BILLING CODE 4164–01–P

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 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 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, 2018. The Federal Food, Drug, and Cosmetic Act (the 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 continuity and progress in these regular discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in continued periodic stakeholder consultation meetings regarding ADUFA reauthorization by May 16, 2016. These stakeholder meetings are expected to commence in September/October 2016 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 intention to participate.

ADDRESSES: The stakeholder meetings will be held at the Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Cassie Ravo, Center for Veterinary Medicine, Food and Drug Administration,7519 Standish Pl., Rockville, MD 20855, 240–402–6866, FAX: 240–276–9744, *Cassie.Ravo@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

In 2013 Congress passed the Animal Drug User Fee Amendments of 2013 (Pub. L. 113–14; ADUFA III). The authority for ADUFA III expires September 30, 2018. Without new legislation to reauthorize the program, FDA will no longer be able to collect user fees for future fiscal years to fund the 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, elsewhere in this issue of the **Federal Register**, we are announcing a public meeting to be held on May 16, 2016, 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, patient and consumer 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 will be important to ensure progress in these discussions. 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 discussion 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 **ADDRESSES**). 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 *cvmadufa@fda.hhs.gov* by May 16, 2016. 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. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification.

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09151 Filed 4–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0230]

Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance entitled ''Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices.'' This guidance provides industry and Agency staff with recommendations regarding the technical performance assessment data for the evaluation of a digital whole slide imaging (WSI) system. The guidance provides suggestions on how to best characterize the technical aspects that are relevant to WSI performance for their intended use and determine any possible limitations that might affect their safety and effectiveness.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2015–D–0230 for ''Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices; Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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