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#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information." This draft guidance is a revised version of a draft guidance that published in February 2003 entitled "Comparability Protocols: Chemistry, Manufacturing, and Controls Information." A related draft guidance entitled "Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information," which published in September 2003, was withdrawn on May 6, 2015 (80 FR 26059).

The revised draft guidance provides recommendations to holders of applications for human drugs and biologics on implementing a chemistry, manufacturing, controls (CMC) postapproval change(s) through the use of a comparability protocol (CP). The revised draft guidance applies to new drug applications (NDAs), abbreviated new drug applications (ANDAs), or biologics license applications (BLAs) regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) or supplements following 21 CFR 314.70 or 21 CFR 601.12.

On February 25, 2003 (68 FR 8772), FDA announced the availability of the first draft version of this guidance. The public comment period closed on June 25, 2003. A number of comments were received, which the Agency considered carefully as it prepared this revised draft guidance.

We revised the guidance for the following reasons:

- To provide more flexibility regarding filing procedures for a notification of change in a condition established in an approved application.
- To include current pharmaceutical quality concepts.
- To add an appendix to address commonly asked questions.

This revised draft guidance provides recommendations to human drug manufacturers on implementing CMC postapproval change(s) through the use of a CP. By using an approved CP, manufacturers whom fall within the

scope of this guidance will not have to submit commercial-scale CMC information on postchange products to FDA before making the proposed changes. The draft guidance is intended to establish a framework to promote manufacturing of quality drug products by employing the following:

- Effective use of knowledge and understanding of the product and manufacturing process.
- A robust control strategy.
- Risk management activities over a product's life cycle.
- An effective pharmaceutical quality system.

This draft guidance incorporates the modern regulatory concepts stated in the guidance for industry entitled "PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance," (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070305.pdf>) the Pharmaceutical Current Good Manufacturing Practices for the 21st Century Initiative (<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/QuestionsandAnswers/CurrentGoodManufacturingPracticescGMPforDrugs/UCM071836>), the Critical Path Initiative (<http://www.fda.gov/scienceresearch/specialtopics/criticalpathinitiative/default.htm>), and the quality by design principles described in the guidance for industry entitled "Q8(R2) Pharmaceutical Development" (<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm073507.pdf>). In publishing this draft guidance, FDA is communicating its expectations and support for the described approach.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on comparability protocols for applications regulated in CDER and CBER as described previously. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information requested in the draft guidance is covered under FDA

regulations 21 CFR 314.50, 314.70, and 314.81(b)(2) for human drugs and 21 CFR 601.2 and 601.12 for biologics. The collection of information is approved under the following OMB Control Numbers: 0910-0001 for human drugs and 0910-0338 for biologics.

##### III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.regulations.gov>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: April 14, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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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 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 Generic Drug User Fee Act (AGDUFA). The statutory authority for AGDUFA 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 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 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 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.*

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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 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