agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2016–09055 Filed 4–19–16; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–D–0973]**

### Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information.'' This document is a revised version of a draft guidance that published in February 2003 entitled ''Comparability Protocols: Chemistry, Manufacturing, and Controls Information.'' A related draft guidance entitled ''Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information,'' that published in September 2003, was withdrawn on May 6, 2015.

The revised draft guidance provides recommendations to human drug and biologics manufacturers on implementing a chemistry, manufacturing, and controls (CMC) postapproval change(s) through the use of a comparability protocol (CP). By using a CP, manufacturers who 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 change. This draft guidance is intended to establish a framework to promote manufacturing of quality drug products.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 20, 2016.

**ADDRESSES:** You may submit comments as follows:

*Electronic Comments*

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–2016–D–0973 for ''Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information.'' 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 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Stephen Moore, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 21, Rm. 2012, 10903 New Hampshire Ave.,

Silver Spring, MD 20993–0002, 301–796–7579 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7268, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–7911.

**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/QuestionsandAnswersonCurrentGoodManufacturingPracticescGMPforDrugs/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.*

[FR Doc. 2016–09137 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–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.