

qualified tropical disease may be eligible for a voucher that can be used to obtain a priority review for any application submitted under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (the PHS Act). The guidance explains to internal and external stakeholders how FDA intends to implement the provisions of section 524, and provides information on using the priority review vouchers and on transferring priority review vouchers to other sponsors.

Under the guidance, sponsors of certain tropical disease drug product applications submitted under section 505(b)(1) of the FD&C Act and section 351 of the PHS Act may request a priority review voucher. Based on inquiries and discussions with industry

about section 524, we estimate that we will receive annually approximately five requests from five sponsors, and that each request will take approximately 8 hours to prepare and submit to FDA.

The guidance also states that sponsors should notify FDA of their intent to use a priority review voucher, including the date on which the sponsor intends to submit the application, at least 90 days before use. We estimate that we will receive annually approximately five notifications of intent to use a voucher from five sponsors, and that each notification will take approximately 8 hours to prepare and submit to FDA.

The guidance also permits the transfer of a priority review voucher from one sponsor to another, and states that each transfer should be documented with a letter of transfer. We estimate that we will receive approximately two letters

indicating the transfer of a voucher from two application holders, and two letters from two new voucher owners acknowledging the transfer, and that it will take approximately 8 hours to prepare and submit each letter to FDA.

In the **Federal Register** of October 20, 2008 (73 FR 62298), FDA published a 60-day notice requesting public comment on the proposed collection of information. The comments we received did not pertain to the information collection that would result from the guidance (that is, the four types of submissions estimated in table 1).

FDA estimates the burden of this collection of information as follows:

Description of Respondents: Sponsors submitting applications under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Guidance for Industry on Tropical Disease Priority Review Vouchers	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority Review Voucher Request	5	1	5	8	40
Notifications of Intent To Use a Voucher	5	1	5	8	40
Letters Indicating the Transfer of a Voucher Letter	2	1	2	8	16
Acknowledging the Receipt of a Transferred Voucher	2	1	2	8	16
Total					112

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0286]

Formal Meetings Between the Food and Drug Administration and Biosimilar Biological Product Sponsors or Applicants; Guidance for Industry; 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 for industry entitled “Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.” This guidance provides recommendations to industry on formal meetings between FDA and sponsors or

applicants relating to the development and review of biosimilar biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The guidance assists sponsors and applicants in generating and submitting meeting requests and the associated meeting packages to FDA for biosimilar biological products. This guidance finalizes the draft guidance issued on April 1, 2013.

DATES: Submit either electronic or written comments on Agency guidances 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–2013–D–0286] for Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants; Guidance for Industry; Availability. 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 this 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 or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Neel Patel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6483, Silver Spring, MD 20993–0002, 301–796–0970; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.” This guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological products regulated by CDER and CBER. For the purposes of this guidance, “formal meeting” includes any meeting that is requested by a sponsor or applicant following the request procedures provided in this guidance and includes meetings conducted in any format (*i.e.*, face to face, teleconference, or videoconference).

The Biologics Price Competition and Innovation Act of 2009 amended the Public Health Service Act (PHS Act) and other statutes to create an abbreviated licensure pathway in section 351(k) of the PHS Act (42 U.S.C. 262(k)) for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological product (see sections 7001 through 7003 of the Patient Protection and Affordable Care Act (Pub. L. 111–148)). The Biosimilar User Fee Act of 2012 (BsUFA), enacted as part of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize a new user fee program for biosimilar biological products. FDA has committed to meeting certain performance goals in

connection with the new user fee program. The performance goals, which are set forth in a letter from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives,¹ include meeting management goals for formal meetings that occur between FDA and sponsors or applicants during the development phase of a biosimilar biological product. This guidance describes the Agency’s current thinking on how it intends to interpret and apply certain provisions of BsUFA, and also provides information on specific performance goals for the management of meetings associated with the development and review of biosimilar biological products.

This guidance reflects a unified approach to all formal meetings between sponsors or applicants and FDA for biosimilar biological product development (BPD) programs. It is intended to assist sponsors and applicants in generating and submitting a meeting request and the associated meeting package to FDA for biosimilar biological products. This guidance does not apply to new drug or abbreviated new drug applications under section 505 of the FD&C Act or to biologics license applications under section 351(a) of the PHS Act.

FDA expects that review staff will participate in many meetings with biosimilar biological product sponsors or applicants who seek guidance relating to the development and review of biosimilar biological products. Because these meetings often will represent critical points in the regulatory process, it is important that there are efficient, consistent procedures for the timely and effective conduct of such meetings. The good meeting management practices in this guidance are intended to provide consistent procedures that will promote well-managed meetings and to ensure that such meetings are scheduled within a reasonable time, conducted efficiently, and documented appropriately. The following five meeting types that occur between sponsors or applicants and FDA staff during the biosimilar BPD phase are described in the guidance: (1) Biosimilar Initial Advisory meeting; (2) BPD Type 1 meeting; (3) BPD Type 2 meeting; (4) BPD Type 3 meeting; and (5) BPD Type 4 meeting.

¹ See <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf>.

On April 1, 2013 (78 FR 19492), FDA announced the availability of a draft version of this guidance. All comments received during the comment period for the draft guidance have been reviewed and, where appropriate, incorporated into this guidance. As a result of the public comments, information has been added to provide clarity on the process for requesting meetings, including identifying the appropriate meeting type, and the data expectations to support the appropriate meeting type.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on formal meetings between FDA and biosimilar biological product sponsors or applicants. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 in this guidance was approved under OMB control number 0910–0802.

III. Electronic Access

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

Dated: November 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29455 Filed 11–17–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0921]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Reporting; Electronic Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the use of the FDA Electronic Submission Gateway (ESG) and the Safety Reporting Portal (SRP) to collect adverse event reports and other safety information for FDA-regulated products.

DATES: Submit either electronic or written comments on the collection of information by January 19, 2016.

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–2012–N–0921 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal.” 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