TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Type of survey | Number of respondents | Annual frequency per response | Hours per response | Total hours |
|---|---|---|---|---|
| Mail, telephone, web-based | 55,000 | 1 | .25 (15 minutes) | 13,750 |

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

Dated: September 15, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–20246 Filed 9–21–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–D–5525]**

### Statistical Approaches To Evaluate Analytical Similarity; Draft Guidance for Industry; Availability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**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Statistical Approaches to Evaluate Analytical Similarity.'' This draft guidance, when finalized, will provide advice on the evaluation of analytical similarity to sponsors interested in developing biosimilar products. Specifically, this draft guidance describes the type of information a sponsor of a proposed biosimilar product should obtain about the structural/physicochemical and functional attributes of the reference product, how that information is used in the development of an analytical similarity assessment plan for the proposed biosimilar, and the statistical approaches recommended for evaluating analytical similarity.

**DATES:** Submit either electronic or written comments on the draft guidance by November 21, 2017 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2017–D–5525 for ''Statistical Approaches to Evaluate Analytical Similarity; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). 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, or the 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 draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Scott N. Goldie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2055, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 800–835–4709 or 240–402–8010.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Statistical Approaches to Evaluate Analytical Similarity.'' This draft guidance, when finalized, will provide advice on the evaluation of analytical similarity to sponsors interested in developing biosimilar products for licensure under section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)). This evaluation is performed to support a demonstration that the proposed biosimilar is highly similar to a reference product licensed under section 351(a) of the PHS Act.

Specifically, this draft guidance, when finalized, will describe the type of information that the sponsor of a proposed biosimilar product should obtain about the structural/physicochemical and functional attributes of the reference product, how that information is used in the development of an analytical similarity assessment plan for the proposed biosimilar, and the statistical approaches recommended for evaluating analytical similarity.

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) created an abbreviated licensure pathway under section 351(k) of the PHS Act for biological products shown to be biosimilar to or interchangeable with a U.S.-licensed biological reference product (see sections 7001 through 7003 of Pub. L. 111–148). As described in section 351(k)(2)(A)(i)(I)(aa) of the PHS Act, an application for a proposed biosimilar product must include information demonstrating biosimilarity based on data derived from, among other things, ''analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components.''

This draft guidance is one in a series of guidance documents intended to implement the BPCI Act. It serves as a companion document to the guidance for industry entitled ''Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product'' (April 30, 2015, 80 FR 24257). The Quality Considerations guidance describes the Agency's recommendations to sponsors on the scientific and technical information, including the analytical studies to support a demonstration that a proposed biosimilar is highly similar to the U.S.-licensed reference product, for the chemistry, manufacturing, and controls section of a marketing application for a proposed biosimilar product.

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 current thinking of FDA on statistical approaches to evaluating analytical similarity. 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. This guidance is not subject to Executive Order 12866.

## II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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). This includes information collections related to: (1) The submission of an investigational new drug application, which is covered under 21 CFR part 312 and approved under OMB control number 0910–0014; (2) the submission of a new drug application, which is covered under 21 CFR 314.50 and approved under OMB control number 0910–0001; (3) the submission of a biologics license application under section 351(k) of the PHS Act, which is covered under 21 CFR part 601 and approved under OMB control number 0910–0719; and (4) meetings between FDA and applicants or sponsors of a biologics license application under section 351(k) of the PHS Act, which is approved under OMB control number 0910–0802.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: September 15, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–20263 Filed 9–21–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–N–0001]**

### Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will be held on November 7, 2017, from 8:30 a.m. to 5 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. For those unable to attend in person, the meeting will also be webcast and will be available at the following link: *https://collaboration.fda.gov/cbervrbpac2017.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

**FOR FURTHER INFORMATION CONTACT:** Serina Hunter-Thomas, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6307C, Silver Spring, MD 20993–0002, 240–402–5771, *serina.hunter-thomas@fda.hhs.gov;* or Rosanna Harvey, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6336, Silver Spring, MD 20993–0002, 240–402–8072, *rosanna.harvey@fda.hhs.gov;* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute