INFORMATION section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Statistical Approaches to Evaluate Analytical Similarity.'' This draft guidance, when finalized, will provide advice on the evaluation of analytical similarity to sponsors interested in developing biosimilar products for licensure under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Specifically, this draft guidance, when finalized, will describe the type of information that the sponsor of a proposed biosimilar product should obtain about the structural/physicochemical and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This draft guidance is one in a series of guidance documents intended to implement the BPCI Act.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

modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On November 7, 2017, the committee will meet in an open session to discuss and make recommendations on the clinical development plan for Pfizer's investigational *Staphylococcus aureus* vaccine intended for pre-surgical prophylaxis in elective orthopedic surgical populations.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 31, 2017. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 2:15 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 23, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 24, 2017.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 15, 2017.

Anna K. Abram,

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

[FR Doc. 2017–20240 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–2011–N–0016]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping and Records Access Requirements for Food Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 23, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0560. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Recordkeeping and Records Access Requirements for Food Facilities—21 CFR 1.337, 1.345, and 1.352

OMB Control Number 0910–0560—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 414 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350c), which requires that persons who manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. Sections 1.326 through 1.363 of our regulations (21 CFR 1.326 through 1.363) set forth the requirements for recordkeeping and records access. The requirement to establish and maintain records improves our ability to respond to, and further contain, threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

Information maintained under these regulations will help us identify and locate quickly contaminated or potentially contaminated food and inform the appropriate individuals and food facilities of specific terrorist threats. Our regulations require that records for non-transporters include the name and full contact information of sources, recipients, and transporters; an adequate description of the food, including the quantity and packaging; and the receipt and shipping dates (§§ 1.337 and 1.345). Required records for transporters include the names of consignor and consignee, points of origin and destination, date of shipment, number of packages, description of freight, route of movement and name of each carrier participating in the transportation, and transfer points through which shipment moved (§ 1.352). Existing records may