guidance was a significant advance in promoting anticancer drug development. Since the S9 guidance was issued, some parties have experienced challenges implementing the nonclinical recommendations for developing anticancer pharmaceuticals outlined in that guidance. In June 2016, the ICH Assembly endorsed the current draft Q&As guidance entitled ''S9 Nonclinical Evaluation for Anticancer Pharmaceuticals—Questions and Answers'' and agreed that the draft Q&As guidance should be made available for public comment. The draft Q&As guidance is the product of the Safety Implementation Working Group (IWG) of the ICH. Comments about this draft will be considered by FDA and the Safety IWG.

The draft Q&As guidance provides guidance on implementing the S9 guidance. The Q&As were developed by the IWG to provide additional clarity for the nonclinical development of anticancer pharmaceuticals. Topics addressed in the draft Q&As guidance include the patient population covered by the S9 guidance, recovery groups in nonclinical studies, development of antibody-drug conjugates, juvenile animal studies, and the need for long-term toxicity studies when pharmaceutical development moves to patients with earlier stage diseases.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''S9 Nonclinical Evaluation for Anticancer Pharmaceuticals—Questions and Answers.'' 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. Electronic Access

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

Dated: September 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22375 Filed 9–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2489]

Receipt of Notice That a Patent Infringement Complaint Was Filed Against a Biosimilar Applicant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing notice that an applicant for a proposed biosimilar product notified FDA that a patent infringement action was filed in connection with the applicant's biologics license application (BLA). Under the Public Health Service Act (PHS Act), an applicant for a proposed biosimilar product or interchangeable product must notify FDA within 30 days after the applicant was served with a complaint in a patent infringement action described under the PHS Act. FDA is required to publish notice of the complaint in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Daniel Orr, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 240–402–0979, *daniel.orr@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148) on March 23, 2010. The BPCI Act amended the PHS Act and created an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, describes the requirements for a BLA for a proposed biosimilar product or a proposed interchangeable product (351(k) BLA). Section 351(*l*) of the PHS Act, also added by the BPCI Act, describes certain procedures for exchanging patent information and resolving patent disputes between a 351(k) BLA applicant and the holder of the BLA reference product. If a 351(k) applicant is served with a complaint for a patent infringement described in section 351(*l*)(6) of the PHS Act, the applicant is required, under section 351(*l*)(6)(C) of the PHS Act, to provide the FDA with notice and a copy of the complaint within 30 days of service. FDA is required to publish notice of a complaint received under section 351(*l*)(6)(C) of the PHS Act in the **Federal Register**.

FDA has received notice of the following complaint under section 351(*l*)(6)(C) of the PHS Act: *Amgen* v. *Sandoz,* 3:16–cv–02581 (N.D. Cal., filed May 12, 2015).

FDA has only a ministerial role in publishing notice of a complaint received under section 351(*l*)(6)(C) of the PHS Act, and does not perform a substantive review of the complaint.

Dated: September 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22376 Filed 9–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; International Center of Excellence for Malaria Research.

Date: October 13–14, 2016.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Yong Gao, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3G13B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20892–7616, (240) 669–5048, *yong.gao@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)