There are currently 15 active ADSSP grantees engaged in the development of dementia-capable systems in their state to support individuals with ADRD and their caregivers. ACL will provide additional resources to support the expansion of promising program activities under existing ADSSP projects in the states of Minnesota and Ohio. Both the Minnesota and Ohio grantees are engaged in projects that are building the dementia-capability of their state systems that merit expansion. The state of Minnesota will expand on their existing program efforts to build strong linkages between a Health Care Partner (HCP) and Community Based Organizations (CBO). The state of Ohio will expand on their existing ADSSP project goal to enrich the lives of veterans suffering from cognitive and physical challenges and their caregivers by expanding Ohio's Music & Memory℠ program living in their homes and communities.

Justification: ACL is committed to the success, continued expansion and sustainability of ADSSP projects. Each of the identified existing cooperative agreement projects has components within them from which the communities that they serve will benefit and merit uninterrupted expansion. To ensure uninterrupted continuation toward achieving and exceeding their goals and objectives and expansion of program efforts, ACL plans to issue one-year non-competing awards to both the Minnesota Board on Aging and the Ohio Department on Aging.

I. Agency Contact

For further information or comments regarding this action, contact Erin Long, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Aging, Washington, DC 20201; telephone (202) 357–3448; fax (202) 357–3549; email *Erin.Long@acl.hhs.gov.*

Dated: August 11, 2015.

Kathy Greenlee,

Assistant Secretary for Aging.

[FR Doc. 2015–20796 Filed 8–21–15; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0229]

Use of Rare Pediatric Disease Priority Review Voucher; Approval of a Drug Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the recent approval of a drug product under an application for which the sponsor redeemed a rare pediatric disease priority review voucher. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to redeem priority review vouchers submitted by sponsors of product applications that might otherwise not qualify for priority review. These vouchers entitle the holder of such a voucher to priority review of a single human drug application submitted under the FD&C Act or the Public Health Service Act. FDA has approved PRALUENT (alirocumab), manufactured by Sanofi-Aventis U.S. Inc., under a priority review.

FOR FURTHER INFORMATION CONTACT: Larry Bauer, Rare Diseases Program, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4842, FAX: 301–796–9858, email: *larry.bauer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the recent approval of a drug product under an application for which the sponsor redeemed a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), added by FDASIA, FDA will grant a priority review for a new drug or biological product application that redeems a priority review voucher, even if that product might not otherwise qualify for a priority review. FDA has recently approved PRALUENT (alirocumab), manufactured by Sanofi-Aventis U.S. Inc., under a priority review. PRALUENT (alirocumab) is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of low-density lipoprotein cholesterol.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.*

For further information about PRALUENT (alirocumab), go to the Drugs@FDA Web site at *http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.*

Dated: August 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20833 Filed 8–21–15; 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:

Janssen Biotech, Inc., et. al. v. *Celltrion Healthcare Co., Ltd., et al.,* 15–cv–10698 (D. Mass., filed March 6, 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: August 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20780 Filed 8–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Science Board to the Food and Drug Administration; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public, via Webcast.

Name of Committee: Science Board to the Food and Drug Administration (Science Board).

General Function of the Committee: The Science Board provides advice to the Commissioner of Food and Drugs and other appropriate officials on specific, complex scientific and technical issues important to the FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments including in regulatory science, input into the Agency's research agenda, and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on September 15, 2015, from 4 p.m. until 5:30 p.m.

Location: This meeting will take place via Webcast. To access the link for the Webcast check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link. Information regarding special accommodations due to a disability may be accessed at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Contact Person: Rakesh Raghuwanshi, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, Bldg. 1, Rm. 3309, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4769, *rakesh.raghuwanshi@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 *http://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.

Agenda: The Science Board will be provided with a report from the Science Looking Forward subcommittee.

FDA intends to make background material available to the public no later than 2 business days before the meeting. Background material is available at *http://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 September 8, 2015. Oral presentations from the public will be scheduled between approximately 4:30 p.m. and 5:30 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 September 1, 2015. 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 September 2, 2015.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Rakesh Raghuwanshi 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 *http://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: August 18, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–20820 Filed 8–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0564]

Agency Information Collection Activities; Proposed Collection; Comment Request; Dietary Supplement Labeling Requirements and Recommendations Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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