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