DATES: Comments on the collection(s) of information must be received by the OMB desk officer by September 23, 2015.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 or, Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements and Supporting Regulations; *Use:* To ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries, the collected information will serve as an integral resource for oversight, monitoring, compliance, and auditing activities. Sponsors should retain documentation and data records related to their data submissions. Data will be validated, analyzed, and utilized for trend reporting. For CY 2016 reporting, the following sections will be reported and collected at the Contract-level or Plan-level: (1) Enrollment and disenrollment, (2) retail, home infusion, and long-term care pharmacy access, (3) medication therapy management programs, (4) grievances, (5) coverage determinations and redeterminations, (6) long term care utilization, (7) employer/union sponsored sponsors, and (8) plan oversight of agents. *Form Number:* CMS–10185 (OMB control number 0938–0992); *Frequency:* Annually and semi-annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 694; *Total Annual Responses:* 6,875; *Total Annual Hours:* 10,865. (For policy questions regarding this collection contact Chanelle Jones at 410–786–8008).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Part C Medicare Advantage Reporting Requirements and Supporting Regulations; *Use:* There are a number of information users of Part C reporting data, including our central and regional office staff that use this information to monitor health plans and to hold them accountable for their performance, researchers, and other government agencies such as the Government Accounting Office. Health plans can use this information to measure and benchmark their performance. *Form Number:* CMS–10261 (OMB control number 0938–1054); *Frequency:* Annually and semi-annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 561; *Total Annual Responses:* 3,508; *Total Annual Hours:* 201,503. (For policy questions regarding this collection contact Terry Lied at 410–786–8973).

3. *Type of Information Collection Request:* New collection (Request for new OMB control number); *Title of Information Collection:* Essential Community Provider Data Collection to Support QHP Certification for PY 2017; *Use:* For plan years beginning on or after January 1, 2017, Health and Human Services (HHS) intends to collect more complete provider data for inclusion on the HHS Essential Community Provider (ECP) list to ensure a more accurate reflection of the universe of qualified available ECPs in a given service area that can be counted toward an issuer's satisfaction of the ECP standard. The HHS will collect data on qualified and available ECPs from providers. Providers will submit an ECP petition to be added to the HHS ECP list or provide required missing data fields to remain on the list. The degree of provider participation in this data collection effort through the ECP provider petition will help inform HHS's future proposals for counting issuers' ECP write-ins toward satisfaction of the ECP standard. *Form Number:* CMS–10561 (OMB control number: 0938–New); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit Institutions); *Number of Respondents:* 31,634; *Total Annual Responses:* 31,634; *Total Annual Hours:* 53,491. (For policy questions regarding this collection contact Deborah Hunter at 410–786–0625.)

Dated: August 18, 2015.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–20787 Filed 8–21–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Notice of Intent To Award a Single Source Non-Competing Continuation Cooperative Agreement for two Alzheimer's Disease Supportive Services Program (ADSSP) Projects

Program Name: Alzheimer's Disease Supportive Services Program.

Award Amount: $625,809.

Project Period: September 30, 2015 through September 29, 2016.

Award Type: Cooperative Agreement.

Statutory Authority: Public Law 78–410: 42 U.S.C. 280c–3. It was amended by Public Law 101–557 and by Public Law 105–392.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.051.

Program Description

The Administration for Community Living (ACL) is announcing its intent to award single source non-competing continuation cooperative agreements to two Alzheimer's Disease Supportive Services Program (ADSSP) projects. Resources dedicated to the ADSSP grant program are restricted to the support of grants to states designed to expand the availability of dementia-capable support services for persons with Alzheimer's disease and related dementias (ADRD), their families and caregivers.

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