

Program Name: The National Center for Benefits Outreach and Enrollment (NCBOE).

Recipient: National Council on Aging (NCOA).

Period of Performance: The award will be issued for the current project period of September 30, 2017 through September 29, 2020.

Total Award Amount: \$11,390,861 in FY 2019.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: The Medicare Improvements for Patients and Providers Act of 2008—Section 119, Public Law (Pub. L.) 110–275 as amended by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), reauthorized by the American Taxpayer Relief Act of 2012 (ATRA) and reauthorized by section 110 of the Protecting Access to Medicare Act of 2014.

Basis for Award: The National Council on Aging (NCOA) is currently funded to carry out the NCBOE Project for the period of September 30, 2017 through September 29, 2020. Much work has already been completed and further tasks are currently being accomplished. It would be unnecessarily time consuming and disruptive to the NCBOE project and the beneficiaries being served for the ACL to establish a new grantee at this time when critical services are presently being provided in an efficient manner.

The NCOA is uniquely placed to complete the work under the NCBOE grant. Since 2001, the NCOA has been the national leader in improving benefits access to vulnerable older adults. They have an unparalleled history of working with community based organizations to develop and replicate outreach and enrollment solutions, while maintaining and enhancing technology to make it easier and more efficient to find benefits. The NCOA through NCBOE accomplishes its mission by developing and sharing tools, resources, best practices, and strategies for benefits outreach and enrollment via its online clearinghouse, electronic and print publications, webinars, and training and technical assistance.

In addition, the NCOA has the BenefitsCheckUp which is, by far, the nation's most comprehensive and widely-used web-based service that screens older and disabled adults with limited incomes and resources and informs them about public and private benefits for which they are very likely to be eligible. Since the BenefitsCheckUp was launched in 2001, over 7.6 million individuals have been

assisted to identify over \$29.6 billion in potential annual benefits. In addition to a focus on Low-Income Subsidy and Medicare Savings Programs, the BenefitsCheckUp also includes more than 2,500 benefits programs from all 50 states and DC, including the addition of Medicaid expansion programs as part of Affordable Care Act; over 50,000 local offices for people to apply for benefits; nearly 2,000 application forms in every language in which they are available; and user-friendly mapping tools that allow streamlined access to program fact sheets and application forms based upon a person's locality.

NCOA is successfully meeting all programmatic goals under the current NCBOE grant.

For Further Information Contact: For further information or comments regarding this program supplement, contact Rebecca Kinney, U.S. Department of Health and Human Services, Administration for Community Living, Center for Integrated Programs, Office of Healthcare Information and Counseling; telephone (202) 795–7375; email Rebecca.Kinney@acl.hhs.gov

Dated: June 24, 2019.

Mary Lazare,

Principal Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–N–0809 and FDA–2018–N–4609]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that KANUMA (sebelipase alfa), manufactured by Alexion Pharmaceuticals Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT:

Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9856, email: althea.cuff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that KANUMA (sebelipase alfa), manufactured by Alexion Pharmaceuticals Inc., meets the criteria for a priority review voucher. KANUMA (sebelipase alfa), is indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase deficiency.

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 <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about KANUMA (sebelipase alfa), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: June 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13944 Filed 6–28–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2430]

Request for Nominations on Device Good Manufacturing Practice Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting that any industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) in the Center for Devices and Radiological Health notify