

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.

[FR Doc. 2019–13962 Filed 6–28–19; 8:45 am]

BILLING CODE 4154-01-P

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]

BILLING CODE 4164-01-P

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

FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to fill an upcoming vacancy on DGMPAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for an upcoming vacancy effective with this notice.

DATES: Any industry organizations interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by July 31, 2019 (see sections I and III of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by July 31, 2019.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing FDA's Advisory Committee Membership Nomination Portal at <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5264, Silver Spring, MD 20993-0002, 301-796-5960, Fax: 301-847-8505, email: Margaret.Ames@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 520 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360j), as amended, provides that DGMPAC shall be composed of two representatives of interests of the device manufacturing industry. The Agency is requesting nominations for a nonvoting industry representative to fill an upcoming vacancy on DGMPAC. FDA is publishing a separate document announcing the request for notification for voting members on DGMPAC.

I. Function of DGMPAC

DGMPAC reviews proposed regulations regarding good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packaging, storage, installation, and servicing of devices, and makes recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidance developed to assist the medical device industry in meeting the good manufacturing practice requirements and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

II. Qualifications

Persons nominated for DGMPAC should possess appropriate qualifications to understand and contribute to the committee's work as described in the committee's function.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current résumé. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

IV. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory

Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the device manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-13991 Filed 6-28-19; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2016]

Epidermolysis Bullosa: Developing Drugs for Treatment of Cutaneous Manifestations; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Epidermolysis Bullosa: Developing Drugs for Treatment of Cutaneous Manifestations." The purpose of this guidance is to assist sponsors with the development of drugs for treatment or prevention of the serious cutaneous manifestations of the heterogeneous group of disorders collectively known as epidermolysis bullosa (EB). This guidance focuses on drug development