SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On July 14, 2020, the committee will discuss biologic license application (BLA) 761158, for belantamab mafodotin, submitted by GlaxoSmithKline Intellectual Property Development Ltd. England. The proposed indication (use) for this product is for the treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before June 29, 2020, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 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 June 19, 2020. 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 June 22, 2020.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Yvette Waples (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://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: June 15, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13345 Filed 6–19–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0163]

Hospira, Inc., et al.; Withdrawal of Approval of 12 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 12, 2019. The document announced the withdrawal of approval of 12 abbreviated new drug applications (ANDAs) from multiple applicants. The document erroneously included ANDA 077736 for Polyethylene Glycol 3350 Powder for Oral Solution, 17 grams/scoopful, held by Breckenridge Pharmaceutical, Inc. (Breckenridge). This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 12, 2019 (84 FR 3467), in FR Doc. 2019–02032, the following correction is made:

1. On page 3467, in the table, the entry for ANDA 077736 is removed. The approval of ANDA 077736 was withdrawn effective November 2, 2018.

In the **Federal Register** of April 2, 2018 (83 FR 13994), FDA denied a hearing and issued an order withdrawing approval of multiple ANDAs for polyethylene glycol 3350, effective May 2, 2018. Breckenridge's ANDA 077736 was included in the April 2018 notice. In the **Federal Register** of July 30, 2018 (83 FR 36604), FDA subsequently published a notice granting a temporary stay of the effective date of the April 2018 notice, extending the withdrawal of approval of the ANDAs to November 2, 2018. Thus, the approval of ANDA 077736 was withdrawn effective November 2, 2018.

Dated: June 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13346 Filed 6–19–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of a Supplemental Award to Education Development Center for the Home Visiting Collaborative Improvement and Innovation Network 2.0 Cooperative Agreement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of a Supplemental Award to Education Development Center for Home Visiting Collaborative Improvement and Innovation Network 2.0 Cooperative Agreement.

SUMMARY: HRSA announces the award of a supplemental award of approximately $330,000 per year to the Education Development Center (EDC) for the Home Visiting Collaborative Improvement and Innovation Network 2.0 (HV CoIIN 2.0) for fiscal years (FY) 2020, 2021 and 2022. The supplement will allow the recipient to build a continuous quality improvement (CQI) health equity framework for the Maternal, Infant and Early Childhood Home Visiting Program (MIECHV).

FOR FURTHER INFORMATION CONTACT: Monique Fountain Hanna, Chief Medical Officer, Division Home Visiting and Early Childhood Systems, HRSA, 5600 Fishers Lane, Room 18N180,

Rockville, MD 20857, Phone: (215) 861–4385, or Email: *MFountain@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Intended Recipient of Award: Education Development Center, Inc.

Amount of Non-Competitive Award: Approximately $330,000/year for FY 2020, FY 2021, and FY 2022.

Budget Period: 09/01/2019–08/31/2020; 09/01/2020–08/31/2021; 09/01/2021–08/31/2022.

CFDA Number: 93.110.

Authority: Social Security Act, Title V, § 511 (42 U.S.C. 711).

Justification: The MIECHV Program, an evidence-based home visiting program, seeks to improve maternal and child health outcomes and address various social determinants that impact health equity such as reducing child abuse and neglect, addressing family violence, promoting child development and school readiness, and improving family economic self-sufficiency for families considered most at-risk. In support of HRSA's FY 2019–FY 2022 Strategic Goals focused on health equity, the MIECHV Program proposes to develop a home visiting specific health equity framework utilizing quality improvement as a methodology.

The HVCoIIN 2.0 is designed to facilitate the delivery and accelerate the improvement of home visiting services provided by MIECHV Program recipients, including subrecipient local implementing agencies (LIAs) utilizing continuous quality improvement methodologies. The CoIIN provides a platform and strategy for collaborative learning and quality improvement toward common measurable aims—rapid-cycle tests of change ideas.

The HVCoIIN has three main priority areas. Priority Area #2 is focused on ''testing of new change ideas.'' This priority area is designed to develop and subsequently refine discrete sets of change ideas based on evidence in the field and relevance to home visiting implementation. The grantee will carry out all the activities pertaining to the development of the health equity framework. Proposed activities will include:

- Identify a health equity framework and adapt for MIECHV;
- Develop theory of change, (how and why the desired change is expected to happen); key driver diagrams, (the relationship between the overall aim of the project, the drivers that contribute directly to the aim) change ideas, measures and proposed tests of change;
- Implement a quality improvement strategy such as: Breakthrough Series, Plan-Do-Study-Act Cycles, to test and eventually demonstrate improvements in program outcomes through a health equity collaborative; and pilot test with MIECHV awardees over 12–18 months;
- Apply the health equity framework that demonstrated improvements to twelve current HV CoIIN 2.0 scale topics (developmental screening, breastfeeding, and maternal depression) and new topic CoIINs (intimate partner violence and well child care); and
- Create a final health equity CoIIN playbook with measures, refined tests of change that can be used to spread lessons learned across home visiting programs. EDC was awarded a 5-year HV CoIIN cooperative agreement on September 1, 2017. They have successfully led the first national effort utilizing CQI methods to assist awardees in improving MIECHV Program implementation, performance measures and evidence based maternal and child health outcomes.

Grantee/organization name	Grant No.	State	FY 2020 funding	FY 2021 funding	FY 2022 funding
Education Development Center, Inc	UF4MC26525	MA	$328,797	$329,980	$324,637

Thomas J. Engels,

Administrator.

[FR Doc. 2020–13338 Filed 6–19–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Patient-Oriented Research Review Committee.

Date: July 23–24, 2020.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health (NIH), One Rockledge Center, 6705 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Stephanie Johnson Webb, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–V, Bethesda, MD 20892, (301) 827–7992, *stephanie.webb@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: June 16, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–13319 Filed 6–19–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; ''Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS–CoV–2) and Coronavirus Disease 2019 (COVID–19).''