DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1618]

Eli Lilly and Co.; Announcement of the Revocation of the Biologics License for LARTRUVO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the revocation of the biologics license application (BLA) for LARTRUVO (olaratumab) injection. Eli Lilly and Co. requested withdrawal (revocation) of the biologics license application and has waived its opportunity for a hearing.

DATES: The BLA is revoked as of February 25, 2020.

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: On October 19, 2016, FDA approved the BLA for LARTRUVO (olaratumab) injection held by Eli Lilly and Co. (Eli Lilly), Lilly Corporate Center, Indianapolis, IN 46285, indicated, in combination with doxorubicin, for the treatment of adult patients with soft tissue sarcoma with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery, under the Agency's accelerated approval regulations at 21 CFR part 601, subpart E. On January 18, 2019, Eli Lilly reported in a press release that the confirmatory study required as a condition of LARTRUO's accelerated approval, entitled ''Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial of Doxorubicin Plus Olaratumab Versus Doxorubicin Plus Placebo in Patients With Advanced or Metastatic Soft Tissue Sarcoma'' (ANNOUNCE trial), ''did not meet the primary endpoints of overall survival in the full study population or in the leiomyosarcoma subpopulation.'' On September 27, 2019, Eli Lilly requested withdrawal (revocation), in writing, of the BLA for LARTRUVO (olaratumab) injection (BLA 761038) under § 601.5(a) (21 CFR 601.5(a)) because the ANNOUNCE trial failed to demonstrate improvement in overall survival for olaratumab in combination with doxorubicin compared to doxorubicin alone. In that letter, Eli Lilly waived its opportunity for a hearing. On February 25, 2020, the Agency issued a letter to Eli Lilly revoking the approval to manufacture and market LARTRUVO (olaratumab) injection (BLA 761038).

Therefore, under § 601.5(a), the Agency revoked the BLA for LARTRUVO (olaratumab) injection (BLA 761038), applicable as of February 25, 2020.

Dated: July 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15516 Filed 7–16–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1647]

Science Advisory Board to the National Center for Toxicological Research Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR). The general function of the committee is to provide advice and recommendations to the Agency on research being conducted at the NCTR. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on August 18, 2020, from 8 a.m. to 5:55 p.m. (CST), and on August 19, 2020, from 8 a.m. to 11:30 a.m. (CST).

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* The meeting will be webcast both days and will be available at the following link: *https://collaboration.fda.gov/nctr1000/.*

FOR FURTHER INFORMATION CONTACT: Donna Mendrick, National Center for Toxicological Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2208, Silver Spring, MD 20993–0002, 301–796–8892, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On August 18, 2020, the SAB Chair will welcome the participants, and the NCTR Director will provide a Center-wide update on scientific initiatives and accomplishments during the past year. The SAB will be presented with an overview of the SAB Subcommittee Site Visit Report and a response to this review. The Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, Center for Tobacco Products, and Office of Regulatory Affairs will each briefly discuss their specific research strategic needs and potential areas of collaboration.

On August 19, 2020, there will be updates from the NCTR Research Divisions and a public comment session. Following an open discussion of all the information presented, the open session of the meeting will close so the SAB members can discuss personnel issues at the NCTR at the end of the day.

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 at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On August 18, 2020, from 8 a.m. to 5:55 p.m., and on August 19, 2020, from 8 a.m. to 11:30 a.m. (CST),

the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 11, 2020. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 August 3, 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 August 4, 2020.

Closed Committee Deliberations: On August 18, 2020, from 11:30 a.m. to 12 p.m. (CST), the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at the NCTR.

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 Donna Mendrick at least 14 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: July 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15524 Filed 7–16–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Commission on Childhood Vaccines

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, HHS is hereby giving notice that the Advisory Commission on Childhood Vaccines (ACCV) charter has been renewed. The effective date of the renewed charter is July 20, 2020.

FOR FURTHER INFORMATION CONTACT: Tamara Overby, Designated Federal Officer, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, 08N186A, Rockville, Maryland 20857; 301–443–3766; or *toverby@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACCV was established by section 2119 of the Public Health Service Act (the Act) (42 U.S.C. 300aa–19), as enacted by Public Law (Pub. L.) 99–660, and as subsequently amended, and advises the Secretary of Health and Human Services (the Secretary) on issues related to the implementation of the National Vaccine Injury Compensation Program (VICP). Other activities of the ACCV include: Recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 of the Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b) of the Act; advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; consulting on the development or revision of Vaccine Information Statements; and recommending to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the VICP.

The renewed charter for the ACCV was approved on July 20, 2020, which will also stand as the filing date. Renewal of the ACCV charter gives authorization for the commission to operate until July 20, 2022.

A copy of the ACCV charter is available on the ACCV's website at *https://www.hrsa.gov/advisory-committees/vaccines/index.html.* A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *http://www.facadatabase.gov/.*

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–15494 Filed 7–16–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of a virtual meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding the 68th full Council meeting utilizing virtual technology. PACHA members will be discussing novel coronavirus (COVID–19) and HIV, and Ready, Set, PrEP enrollment. The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required to provide public comment.

DATES: The meeting will be held on Thursday, August 6, from approximately 3:00 p.m. to 5:00 p.m. (ET). This meeting will be conducted utilizing virtual technology.

ADDRESSES: Instructions regarding attending this meeting virtually will be posted one week prior to the meeting at: *https://www.hiv.gov/federal-response/pacha/about-pacha.*

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW, Room L609A, Washington, DC 20024; (202) 795–7622 or *PACHA@hhs.gov.* Additional information can be obtained by accessing the Council's page on the *HIV.gov* site at *www.hiv.gov/pacha.*

SUPPLEMENTARY INFORMATION: Individuals who wish to participate in the meeting and/or provide public