

toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product LARTRUVO (olaratumab). LARTRUVO is a platelet-derived growth factor receptor alpha blocking antibody 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. This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial. Subsequent to this approval, the USPTO received a patent term restoration application for LARTRUVO (U.S. Patent No. 8,128,929) from Imclone LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 6, 2017, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of LARTRUVO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for LARTRUVO is 3,766 days. Of this time, 3,527 days occurred during the testing phase of the regulatory review period, while 239 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* June 30, 2006. The applicant claims July 1, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 30, 2006, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42*

U.S.C. 262): February 24, 2016. The applicant claims December 10, 2015, as the date the biologics license application (BLA) for LARTRUVO (BLA 761038) was initially submitted. However, FDA records indicate that BLA 761038 was submitted on February 24, 2016.

3. *The date the application was approved:* October 19, 2016. FDA has verified the applicant's claim that BLA 761038 was approved on October 19, 2016.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,003 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including, but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: October 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-23219 Filed 10-23-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Meeting of the Advisory Committee on Interdisciplinary, Community-Based Linkages

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

ACTION: Notice.

SUMMARY: The Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL) has scheduled a public meeting. Information about the ACICBL is located on the ACICBL website at <https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/index.html>. This notice is being published less than 15 days prior to the meeting date due to unexpected administrative delays.

DATES: October 30, 2018 from 11:00 a.m.–5:00 p.m. ET.

ADDRESSES: This meeting will be held through teleconference and webinar. The conference call-in number is 1–888–455–0640; passcode: HRSA COUNCIL. The webinar link is <https://hrsa.connectsolutions.com/acicbl>.

FOR FURTHER INFORMATION CONTACT: Joan Weiss, Ph.D., RN, CRNP, FAAN, Senior Advisor and Designated Federal Official (DFO), Division of Medicine and Dentistry, HRSA, 5600 Fishers Lane, Room 15N39, Rockville, Maryland 20857; 301–443–0430; or jweiss@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACICBL provides advice and recommendations to the Secretary of HHS (Secretary) and submits an annual report to the Secretary and Congress on a broad range of issues relating to grant programs authorized by Sections 750–760, Title VII, Part D of the Public Health Service Act (PHS Act).

During the October 30 meeting, ACICBL members will discuss possible topics to work on for fiscal year 2019. Under Section 757 of the PHS Act, ACICBL submits annual reports to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives. Not later than 14 days prior to the convening of the meeting, ACICBL shall prepare and make available an agenda of the matters to be considered by ACICBL at the meeting. The agenda will be posted on the ACICBL website at <https://www.hrsa.gov/advisory-committees/>

interdisciplinary-community-linkages/index.html. Agenda items are subject to change as priorities dictate. Refer to the ACICBL website for any updated information concerning the meeting. Members of the public will have the opportunity to provide comments. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to ACICBL should be sent to Joan Weiss, DFO, using the contact information above at least 3 business days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-23185 Filed 10-23-18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2018-0963]

Area Maritime Security Advisory Committee (AMSC), Eastern Great Lakes Northwestern Pennsylvania Regional Sub-Committee Vacancy

AGENCY: Coast Guard, DHS.

ACTION: Notice of Solicitation for Membership.

SUMMARY: This notice requests individuals interested in serving on the AMSC, Eastern Great Lakes regional sub-committee Northwestern Pennsylvania Region submit their applications for membership to the Captain of the Port, Buffalo. The Committee assists the Captain of the Port as the Federal Maritime Security Coordinator (FMSC), Buffalo, in developing, reviewing, and updating the Area Maritime Security Plan (AMSP) for their area of responsibility.

DATES: Requests for membership should reach the U.S. Coast Guard Captain of the Port, Buffalo, by November 23, 2018.

ADDRESSES: Applications for membership should be submitted to the Captain of the Port at the following address: Captain of the Port, Buffalo, Attention: LCDR Marvin Kimmel, 1 Fuhrmann Boulevard, Buffalo, NY 14203-3189.

FOR FURTHER INFORMATION CONTACT: For questions about submitting an application, or about the AMSC in general, contact Mr. Joseph Fetscher, Northwestern Pennsylvania Region Sub-Committee Executive Coordinator, at 216-937-0126.

SUPPLEMENTARY INFORMATION:

Authority

Section 102 of the Maritime Transportation Security Act (MTSA) of 2002 (Pub. L. 107-295) added section 70112 to Title 46 of the U.S. Code, and authorized the Secretary of the Department in which the Coast Guard is operating to establish Area Maritime Security Advisory Committees for any port area of the United States. (See 33 U.S.C. 1226; 46 U.S.C.; 33 CFR 1.05-1, 6.01; Department of Homeland Security Delegation No. 0170.1.) The MTSA includes a provision exempting these AMSCs from the Federal Advisory Committee Act (FACA), Public Law 92-436, 86 Stat. 470 (5 U.S.C. App.2). The AMSCs shall assist the Federal Maritime Security Coordinator in the development, review, update, and exercising of the Area Maritime Security Plan for their area of responsibility. Such matters may include, but are not limited to: Identifying critical port infrastructure and operations; Identifying risks (threats, vulnerabilities, and consequences); Determining mitigation strategies and implementation methods; Developing strategies to facilitate the recovery of the Maritime Transportation System after a Transportation Security Incident; Developing and describing the process to continually evaluate overall port security by considering consequences and vulnerabilities, how they may change over time, and what additional mitigation strategies can be applied; and Providing advice to, and assisting the Federal Maritime Security Coordinator in developing and maintaining the Area Maritime Security Plan.

AMSC Membership

Members of the AMSC should have at least five years of experience related to maritime or port security operations. The Northwestern Pennsylvania Region Sub-Committee of the Eastern Great Lakes AMSC has 23 members. We are seeking to fill one (1) vacancy with this solicitation, an Executive Board member to serve as Vice-Chairperson of the Sub-Committee and concurrently as a member of the Eastern Great Lakes AMSC when so convened by the FMSC.

Applicants may be required to pass an appropriate security background check prior to appointment to the committee. Applicants must register with and remain active as a Coast Guard Homeport user if appointed. Member's term of office will be for five years; however, a member is eligible to serve additional terms of office. Members will not receive any salary or other compensation for their service on an

AMSC. In accordance with 33 CFR 103, members may be selected from Federal, Territorial, or Tribal governments; State government and political subdivisions of the State; local public safety, crisis management, and emergency response agencies; law enforcement and security organizations; maritime industry, including labor; other port stakeholders having a special competence in maritime security; and port stakeholders affected by security practices and policies.

The Department of Homeland Security does not discriminate in selection of committee members on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, gender identity, marital status, disability, and genetic information, age, membership in an employee organization, or any other non-merit factor. The Department of Homeland Security strives to achieve a widely diverse candidate pool for all of its recruitment actions.

Request for Applications

Those seeking membership are not required to submit formal applications to the local Captain of the Port, however, because we do have an obligation to ensure that a specific number of members have the prerequisite maritime security experience, we encourage the submission of resumes highlighting experience in the maritime and security industries.

Dated: October 18, 2018.

J.S. DuFresne,

Captain, U.S. Coast Guard, Captain of the Port/Federal Maritime Security Coordinator, Buffalo.

[FR Doc. 2018-23243 Filed 10-23-18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2018-0790]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625-0006

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an