

the party to whom FDA will send the invoice for any fees that are assessed under this section.

*C. How much will this fee be?*

The fee is based on the number of direct hours spent on such reinspections, including time spent conducting the physical surveillance and/or compliance reinspection at the facility, or whatever components of such an inspection are deemed necessary, making preparations and arrangements for the reinspection, traveling to and from the facility, preparing any reports, analyzing any samples or examining any labels if required, and performing other activities as part of the OAI reinspection until the facility is again determined to be in compliance. The direct hours spent on each such reinspection will be billed at the appropriate hourly rate shown in table 2 of this document.

**IV. Fees for Non-Compliance With a Recall Order Under Section 743(a)(1)(B)**

*A. What will cause this fee to be assessed?*

The fee will be assessed for not complying with a recall order under section 423(d) (21 U.S.C. 350l(d)) or section 412(f) of the FD&C Act (21 U.S.C. 350a(f)) to cover food recall activities associated with such order performed by the Secretary (and by delegation, FDA) (section 743(a)(1)(B) of the FD&C Act). Non-compliance may include the following: (1) Not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA.

*B. Who will be responsible for paying this fee?*

Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for a domestic facility (as defined in section 415(b) of the FD&C Act) and an importer who does not comply with a recall order under section 423 or under section 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

*C. How much will this fee be?*

The fee is based on the number of direct hours spent on taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and

from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2 of this document.

**V. How must the fees be paid?**

An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment must be made within 90 days of the invoice date in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Detailed payment information will be included with the invoice when it is issued.

**VI. What are the consequences of not paying these fees?**

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the U.S. Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Dated: July 24, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-16069 Filed 7-26-18; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Meeting of the President's Council on Sports, Fitness, and Nutrition**

**AGENCY:** President's Council on Sports, Fitness, and Nutrition, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice of meeting.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the President's Council on Sports, Fitness, and Nutrition (PCSFN) will hold its annual meeting. The meeting will be open to the public.

**DATES:** The meeting will be held on September 21, 2018, from 9:30 a.m. to 12:30 p.m.

**ADDRESSES:** Newseum, Knight Conference Center 7th Floor, 555 Pennsylvania Ave. NW, Washington, DC 20001.

**FOR FURTHER INFORMATION CONTACT:** Ms. Holli M. Richmond, Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, Tower Building, 1101 Wootton Parkway, Suite 560, Rockville, MD 20852, (240) 276-

9567. Information about PCSFN, including details about the upcoming meeting, can be obtained at [www.fitness.gov](http://www.fitness.gov).

**SUPPLEMENTARY INFORMATION:** The primary functions of the PCSFN include (1) advising the President, through the Secretary, concerning progress made in carrying out the provisions of Executive Order 13265, as amended by Executive Order 13824, and recommending to the President, through the Secretary, actions to accelerate such progress; (2) recommending to the Secretary a national strategy to expand children's participation in youth sports, encourage regular physical activity, including active play and promote good nutrition for all Americans. Recommendations may address, but are not necessarily limited to, increasing awareness of the benefits of participation in sports and regular physical activity, as well as the importance of good nutrition; promoting private and public sector strategies to increase participation in sports, encourage regular physical activity, and improve nutrition; developing metrics that gauge youth sports participation and physical activity to inform efforts that will improve participation in sports and regular physical activity among young Americans; and establishing a national and local strategy to recruit volunteers who will encourage and support youth participation in sports and regular physical activity, through coaching, mentoring, teaching, or administering athletic and nutritional programs. The Council's performance of these functions shall take into account the Department of Health and Human Services' Physical Activity Guidelines for Americans, including consideration for youth with disabilities.

The Council shall meet, at a minimum, one time per fiscal year. The meeting will be held to (1) assess ongoing Council activities; and, (2) discuss and plan future projects and programs. The agenda for the planned meeting is being developed and will be posted at [www.fitness.gov](http://www.fitness.gov) when it has been finalized.

The meeting that is scheduled to be held on September 21, 2018, is open to the public and the media. Every effort will be made to provide reasonable accommodations for persons with disabilities and/or special needs who wish to attend the meeting. Persons with disabilities and/or special needs should call (240) 276-9567 no later than close of business Monday, September 10, 2018, to request accommodations. Members of the public who wish to attend the meeting are asked to pre-register by sending an email to

*rsvp.fitness@hhs.gov* or by calling (240) 276-9567. Registration for public attendance must be completed before close of business Wednesday, September 12, 2018.

Dated: July 12, 2018.

**Holli M. Richmond,**

*Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, U.S. Department of Health and Human Services.*

[FR Doc. 2018-16056 Filed 7-26-18; 8:45 am]

**BILLING CODE 4150-35-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive Patent License: Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Molecular Targeting Technologies, Inc. (MTTI); a Delaware corporation, with its principle place of business in West Chester, Pennsylvania, to practice the inventions embodied in the patent application listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

**DATES:** Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development August 27, 2018 will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892-2479, phone number 301-435-5019, or *shmilovm@mail.nih.gov*.

**SUPPLEMENTARY INFORMATION:** The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to MTTI: HHS Ref. E-150-2016-1-PCT-01, International Patent Application PCT/US2017/054863 filed October 3, 2017, entitled "Chemical Conjugates of Evans Blue Derivatives and Their Use As Radiotherapy And Imaging Agents."

The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective patent license will be granted worldwide and in a field of use not broader than radiotherapeutics for somatostatin-receptor expressing neuroendocrine tumors.

The invention pertains to a radiotherapeutic against neuroendocrine tumors that express somatostatin receptor. Radionuclide therapies directed against tumors that express somatostatin receptors (SSTRs) have proven effective for the treatment of advanced, low- to intermediate-grade neuroendocrine tumors. The subject radiotherapeutic covered by the subject patent estate includes a somatostatin (SST) peptide derivative like octreotate (TATE), conjugated to an Evans Blue (EB) analog, and further chelated via DOTA to therapeutic radionuclide <sup>177</sup>Lu, a beta emitter. The EB analog reversibly binds to circulating serum albumin and improves the pharmacokinetics of SST peptide derivatives and reduce peptide-receptor radionuclide therapy toxicity. EB analog conjugated to octreotate (EB-DOTATATE) has been shown by the inventors to provide reversible albumin binding *in vivo* and extended half-life in circulation. When EB-TATE is slowly released into the tumor microenvironment, tumor uptake and internalization into SSTR positive tumors resulted in delivery of radioactive particles and tumor cell killing. EB-TATE displayed significantly more favorable pharmacokinetics than TATE alone by achieving higher tumor to non-tumor penetration as evidenced by positron emission tomography.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: July 20, 2018.

**Michael A. Shmilovich,**

*Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.*

[FR Doc. 2018-16065 Filed 7-26-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meetings

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

The meetings 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 grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; U01 SEP: Glycobiologists Alliance for Cancer Research.

*Date:* August 30, 2018.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W102, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Shakeel Ahmad, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Bethesda, MD 20892-9750, 240-276-6349, *ahmads@mail.nih.gov*.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI Program Project IV (P01).

*Date:* September 27-28, 2018.

*Time:* 4:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

*Contact Person:* Sanita Bharti, Ph.D., Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W122, Bethesda, MD 20892-9750, 240-276-5909, *sanitab@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention