encouraging voluntary patient engagement in clinical studies, including guidance. FDA believes medical device clinical studies designed with patient input may help to address common challenges faced in medical device clinical studies.

While FDA acknowledges that patient engagement may be beneficial across the total product lifecycle, this guidance focuses on the applications of patient engagement in the design and conduct of medical device clinical studies. The guidance will: (1) Help sponsors understand how they can voluntarily use patient engagement to elicit experience, perspectives, and other relevant information from patient advisors (see definition in section IV) to improve the design and conduct of medical device clinical studies; (2) highlight the benefits of engaging with patient advisors early in the medical device development process; (3) illustrate which patient engagement activities are generally not considered by FDA to constitute research or an activity subject to FDA's regulations, including regulations regarding institutional review boards (IRBs); and (4) address common questions and misconceptions about collecting and submitting to FDA patient engagement information regarding the design and conduct of a medical device clinical study.

A notice of availability of the draft guidance appeared in the **Federal Register** of September 24, 2019 (84 FR 50047). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarifying terminology, adding additional background on patient engagement efforts at FDA, and clarifying how sponsors can obtain specific feedback from FDA on patient engagement plans and patient-centered study designs.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on patient engagement in the design and conduct of medical device clinical studies. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''Patient Engagement in the Design and Conduct of Medical Device Clinical Studies'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 18040 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
814, subparts A through E	Premarket Approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''	De Novo Classification Process	0910–0844
''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act''.	513(g) Request for Information	0910–0705
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
56	Institutional Review Boards	0910–0130

Dated: January 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–01374 Filed 1–25–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479; Michael Shmilovich; *shmilovm@nih.gov;* telephone: 301–435–5019. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Sulfur and Selenium Containing Cannabinoid Receptor Modulating Compounds

Available for licensing and commercial development are sulfur- and selenium-containing pyrazole molecules for potentially treating metabolic disorders, psychiatric disorders, neurological disorders, pain disorders,

gastrointestinal disorders, cancers, inflammation-related disorders, substance abuse associated pathologies, and other conditions using the same. The filed provisional patent application includes extensive descriptions of the exemplary molecules and their various constituents. Therapeutic targets of said molecules include but are not limited to the cannabinoids 1 receptor, the cannabinoid 2 receptor, GPR55, GPR18, or GPR119. The rights pursued claim compounds, pharmaceutical compositions, and methods of use.

Potential Commercial Applications:

- Pharmaceuticals
- Cancer therapy
- Inflammatory and autoimmune disease

Development Stage:

- Early stage

Inventors: Malliga R. Iyer, Ph.D. (NIAAA).

Intellectual Property: HHS Reference No. E–190–2021–0; U.S. Provisional Patent Application No. 63/265,225 filed December 10, 2021.

Licensing Contact: Michael Shmilovich; 301–435–5019; *michael.shmilovich@nih.gov*.

Dated: January 20, 2022.

Michael A. Shmilovich,

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

[FR Doc. 2022–01517 Filed 1–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2008–0010]

Board of Visitors for the National Fire Academy

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Committee management; notice of open Federal Advisory Committee meeting.

SUMMARY: The Board of Visitors for the National Fire Academy (Board) will meet virtually on Tuesday, March 15, 2022. The meeting will be open to the public.

DATES: The meeting will take place on Tuesday, March 15, 2022, 1 p.m. to 3 p.m. ET. Please note that the meeting may close early if the Board has completed its business.

ADDRESSES: Members of the public who wish to participate in the virtual conference should contact Deborah Gartrell-Kemp as listed in the **FOR FURTHER INFORMATION CONTACT** section by 5 p.m. ET on March 2, 2022, to obtain the call-in number and access code for the March 15, 2022, virtual meeting. For more information on services for individuals with disabilities or to request special assistance, contact Deborah Gartrell-Kemp as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Board as listed in the **SUPPLEMENTARY INFORMATION** section. Participants seeking to have their comments considered during the meeting should submit them in advance or during the public comment segment. Comments submitted up to 30 days after the meeting will be included in the public record and may be considered at the next meeting. Comments submitted in advance must be identified by Docket ID FEMA–2008–0010 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Electronic Delivery:* Email Deborah Gartrell-Kemp at *Deborah.GartrellKemp@fema.dhs.gov* no later than March 2, 2022, for consideration at the March 15, 2022 meeting.

Instructions: All submissions received must include the words ''Federal Emergency Management Agency'' and the Docket ID for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket and to read background documents or comments received by the National Fire Academy Board of Visitors, go to *http://www.regulations.gov,* click on ''Advanced Search,'' then enter ''FEMA–2008–0010'' in the ''By Docket ID'' box, then select ''FEMA'' under ''By Agency,'' and then click ''Search.''

FOR FURTHER INFORMATION CONTACT:

Alternate Designated Federal Officer: Stephen Dean, telephone (301) 447–1271, email *Stephen.Dean@fema.dhs.gov.*

Logistical Information: Deborah Gartrell-Kemp, telephone (301) 447–7230, email *Deborah.GartrellKemp@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Board will meet virtually on Tuesday, March 15, 2022. The meeting will be open to the public. Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix.

Purpose of the Board

The purpose of the Board is to review annually the programs of the National Fire Academy (Academy) and advise the Administrator of the Federal Emergency Management Agency (FEMA), through the United States Fire Administrator, on the operation of the Academy and any improvements therein that the Board deems appropriate. In carrying out its responsibilities, the Board examines Academy programs to determine whether these programs further the basic missions that are approved by the Administrator of FEMA, examines the physical plant of the Academy to determine the adequacy of the Academy's facilities, and examines the funding levels for Academy programs. The Board submits a written annual report through the United States Fire Administrator to the Administrator of FEMA. The report provides detailed comments and recommendations regarding the operation of the Academy.

Agenda

On Tuesday, March 15, 2022, there will be four sessions, with deliberations and voting at the end of each session as necessary:

1. The Board will discuss United States Fire Administration Data, Research, Prevention and Response.

2. The Board will discuss deferred maintenance and capital improvements on the National Emergency Training Center campus and Fiscal Year 2022 and beyond Budget Request/Budget Planning.

3. The Board will deliberate and vote on recommendations on Academy program activities to include developments, deliveries, staffing, admissions and strategic plan.

4. There will also be an update on the Board of Visitors Subcommittee Groups for the Professional Development Initiative Update and the National Fire Incident Report System.

There will be a 10-minute comment period after each agenda item and each speaker will be given no more than 2 minutes to speak. Please note that the public comment period may end before the time indicated following the last call for comments. Contact Deborah Gartrell-Kemp to register as a speaker. Meeting materials will be posted by March 10,