

| NIH ref No. | Patent No. or application No. | Issue date | Filing date | Title |
|---------------------------|-------------------------------|--------------------------|-------------------------|---|
| E-282-2012-0-US-01 | 61/725,949 | | November 13, 2012 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-PCT-02 | PCT/US2013/069686 | | November 12, 2013 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-US-03 | 9,765,031 | September 19, 2017 | November 12, 2013 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-CA-04 | 2889697 | | April 27, 2015 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-EP-05 | 2919779 | January 6, 2021 | June 01, 2015 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-CH-12 | 2919779 | January 6, 2021 | November 12, 2013 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-DE-13 | 2919779 | January 6, 2021 | November 12, 2013 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-FR-14 | 2919779 | January 6, 2021 | November 12, 2013 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-GB-15 | 2919779 | January 6, 2021 | November 12, 2013 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-IE-16 | 2919779 | January 6, 2021 | November 12, 2013 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-IN-06 | 354301 | December 23, 2020 | May 1, 2015 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-JP-07 | 6272626 | January 12, 2018 | May 11, 2015 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-CN-08 | ZL201380069389.9 | August 20, 2019 | July 3, 2015 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-US-09 | 10,683,270 | June 16, 2020 | August 10, 2017 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-US-10 | 10,787,419 | September 29, 2020 | August 10, 2017 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-0-US-11 | 16/870,093 | | May 8, 2020 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-1-US-01 | 62/171,179 | | June 4, 2015 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-1-PCT-02 | PCT/US2016/035291 | | June 1, 2016 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-1-US-08 | 15/579,123 | | December 1, 2017 | Cannabinoid Receptor Mediating Compounds. |
| E-282-2012-1-US-09 | 16/438,850 | | June 12, 2019 | Cannabinoid Receptor Mediating Compounds. |
| E-140-2014-0-US-01 | 61/991,333 | | May 9, 2014 | Cannabinoid Receptor Mediating Compounds. |
| E-140-2014-0-PCT-02 | PCT/US2015/029946 | | May 8, 2015 | Cannabinoid Receptor Mediating Compounds. |
| E-140-2014-0-AU-03 | 2015255765 | | November 7, 2016 | Cannabinoid Receptor Mediating Compounds. |
| E-140-2014-0-CA-04 | 2948349 | | May 8, 2015 | Cannabinoid Receptor Mediating Compounds. |
| E-140-2014-0-CN-05 | 201580028788.X | February 7, 2020 | May 8, 2015 | Cannabinoid Receptor Mediating Compounds. |
| E-140-2014-0-EP-06 | 15728668.3 | | May 8, 2015 | Cannabinoid Receptor Mediating Compounds. |
| E-140-2014-0-IN-07 | 201637038171 | | November 8, 2016 | Cannabinoid Receptor Mediating Compounds. |
| E-140-2014-0-JP-08 | 6762930 | September 11, 2020 | May 8, 2015 | Cannabinoid Receptor Mediating Compounds. |
| E-140-2014-0-US-09 | 10,329,259 | June 25, 2019 | November 8, 2016 | Cannabinoid Receptor Mediating Compounds. |
| E-140-2014-0-HK-10 | 17105705.6 | | June 9, 2017 | Cannabinoid Receptor Mediating Compounds. |

The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective exclusive patent license territory may be worldwide and in a field of use limited to human therapeutics for fibrotic disease.

The invention covered by the patents and patent applications pertaining to NIH Ref. No. E-282-2012-0 and -1 pertain to cannabinoid receptor 1 (CB₁R) inverse agonists. CB₁R activation plays a key role in appetitive behavior and metabolism. Of importance as a therapeutic target here is that the receptor is expressed in both peripheral tissue as well as the CNS. The invention is a class of pyrazole compounds that act as CB₁ receptor inverse agonists and have been shown effective at reducing obesity and its associated metabolic consequences, and for fibrotic disease, while having no experimentally discernable neuropsychotropic side effects that are considered adverse such as the earlier antagonists rimonabant. These CB₁R receptor compounds were developed with the goals of limiting their brain penetrance without losing their metabolic efficacy due to CB₁ inverse agonism, and having a primary metabolite directly targeting enzymes involved in inflammatory and fibrotic processes associated with metabolic disorders. The patents are both compositions of matter and methods of use.

The inventions covered by HHS Ref. E-140-2014-0 also pertain to pyrazole CB₁R receptor inverse agonists. In

addition, some of these compounds also have a direct inhibitory effect on inducible nitric oxide synthase (iNOS), whereas another group of the compounds directly activates AMP kinase. There is evidence that the metabolic effects of endocannabinoids are mediated by CB₁ receptors in peripheral tissues. These dual-target compounds may be useful for treating metabolic disease and related conditions such as obesity and diabetes and their complications, and includes various fibrotic disorders, without the dangerous the side effects.

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: January 3, 2022.

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

[FR Doc. 2022-00022 Filed 1-5-22; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, 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; NIAID Research Topic No. 051 Inhaled Delivery of Clofazimine (CFZ)—An Important Anti-Tuberculosis Drug Phase

II Proposal Title: Optimized Dry Powder Formulation and Delivery for Inhaled Clofazimine (N01).

Date: January 27, 2022.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Cynthia L. De La Fuente, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20852, 240-669-2740, delafuentecl@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 30, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-00008 Filed 1-5-22; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, 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; HHS-NIH-CDC-SBIR PHS 2022-1: Development of Diagnostics to Differentiate HIV Infection from Vaccine Induced Seropositivity (Topic 103).

Date: February 2, 2022.

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

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kristina S. Wickham, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22B, Rockville, MD 20852, 301-761-5390, kristina.wickham@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 30, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-00009 Filed 1-5-22; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2020-0016]

Meetings To Implement Pandemic Response Voluntary Agreement Under Section 708 of the Defense Production Act

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

ACTION: Announcement of meetings.

SUMMARY: The Federal Emergency Management Agency (FEMA) is holding a series of meetings, under the Plan of Action to Establish a National Strategy for the Coordination of National Multimodal Healthcare Supply Chains to Respond to COVID-19, to implement the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic.

DATES:

- Wednesday, January 5, 2022, from 1 p.m. to 3 p.m. Eastern Time (ET).
- Wednesday, January 12, 2022, from 1 p.m. to 3 p.m. ET.
- Wednesday, January 19, 2022, from 1 p.m. to 3 p.m. ET.
- Wednesday, January 26, 2022, from 1 p.m. to 3 p.m. ET.

FOR FURTHER INFORMATION CONTACT:

Robert Glenn, Office of Business, Industry, Infrastructure Integration, via email at OB3I@fema.dhs.gov or via phone at (202) 212-1666.

SUPPLEMENTARY INFORMATION: Notice of these meetings is provided as required by section 708(h)(8) of the Defense Production Act (DPA), 50 U.S.C. 4558(h)(8), and consistent with 44 CFR part 332.

The DPA authorizes the making of “voluntary agreements and plans of action” with representatives of industry, business, and other interests to help provide for the national defense.¹ The President’s authority to facilitate voluntary agreements with respect to responding to the spread of COVID-19 within the United States was delegated to the Secretary of Homeland Security in Executive Order 13911.² The Secretary of Homeland Security further delegated this authority to the FEMA Administrator.³

On August 17, 2020, after the appropriate consultations with the Attorney General and the Chairman of the Federal Trade Commission, FEMA completed and published in the **Federal Register** a “Voluntary Agreement, Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic” (Voluntary Agreement).⁴ Unless terminated earlier, the Voluntary Agreement is effective until August 17, 2025, and may be extended subject to additional approval by the Attorney General after consultation with the Chairman of the Federal Trade Commission. The Agreement may be used to prepare for or respond to any pandemic, including COVID-19, during that time.

On December 7, 2020, the first plan of action under the Voluntary Agreement—the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19 (PPE Plan of Action)—was finalized.⁵ The PPE Plan of Action established several sub-committees under the Voluntary Agreement, focusing on different aspects of the PPE Plan of Action.

On May 24, 2021, four additional plans of action under the Voluntary Agreement—the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Diagnostic Test Kits and other Testing Components to respond to COVID-19, the Plan of Action to

¹ 50 U.S.C. 4558(c)(1).

² 85 FR 18403 (Apr. 1, 2020).

³ DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020); DHS Delegation Number 09052 Rev. 00 (Jan. 3, 2017).

⁴ 85 FR 50035 (Aug. 17, 2020). The Attorney General, in consultation with the Chairman of the Federal Trade Commission, made the required finding that the purpose of the voluntary agreement may not reasonably be achieved through an agreement having less anticompetitive effects or without any voluntary agreement and published the finding in the **Federal Register** on the same day. 85 FR 50049 (Aug. 17, 2020).

⁵ See 85 FR 78869 (Dec. 7, 2020). See also 85 FR 79020 (Dec. 8, 2020).