

organizations; clinical laboratories; healthcare providers; food manufacturers; and patient and consumer groups.³ The 60-day public comment period closed on March 4, 2024.

FDA received over 30 sets of comments on the Draft Report and Plan from interested parties, including industry and trade groups; healthcare providers and entities; patient and consumer advocacy groups; researchers, scientific, and academic experts; and private citizens. The majority of comments focused on the following topics: (1) general best practices for guidance documents; (2) suggestions for improving FDA's current "Search for FDA Guidance Documents" web page; (3) FDA's guidance agendas; and (4) FDA's proposal to publish additional guidance documents as Level 1 "for immediate implementation" and Level 2 guidance, consistent with applicable statutes and regulations. FDA also received comments encouraging FDA's continued use of guidance to streamline the process for regulatory submissions and providing support for further Agency use of novel and innovative guidance formats. A few comments proposed specific topic areas for consideration of future guidance development. FDA convened a cross-Agency workgroup to carefully review, discuss, and consider all comments received as it prepared this Report and Plan.

FDA carefully considered all relevant comments received in developing this Report and Plan and is now announcing the availability of "Food and Drug Administration Report and Plan on Best Practices for Guidance." FDA's Report and Plan addresses many of the themes seen across comments received in response to the Draft Report and Plan. FDA appreciates all the feedback and will continue to reassess its best practices for guidance and make further improvements in the future as appropriate.

II. Electronic Access

Persons with access to the internet may also obtain the report and plan at <https://www.fda.gov/about-fda/reports/reports-agency-policies-and-initiatives>.

Dated: November 25, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024-28228 Filed 12-2-24; 8:45 am]

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³ See 89 FR 380 (January 3, 2024), available at <https://www.federalregister.gov/documents/2024/01/03/2023-28872/food-and-drug-administrations-draft-report-and-plan-on-best-practices-for-guidance-availability>.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 1009 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Avenir Award Program for Genetics or Epigenetics of Substance Use Disorders.

Date: February 24–25, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, National Institute on Drug Abuse, NIH, Bethesda, MD 20892, (301) 827-4471, ramadanir@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 27, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-28355 Filed 12-2-24; 8:45 am]

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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 invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research for the benefit of the public health.

FOR FURTHER INFORMATION CONTACT:

Licensing information may be obtained by emailing the licensing contact Malabika Ghosh, J.D., Ph.D.; 301-827-5414; Malabika.Ghosh@nih.gov, at the National Heart, Lung, and Blood, Office of Technology Transfer and Development, 31 Center Drive Room 4A25, MSC2479, Bethesda, MD 20892-2479. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION:

Technology description follows.

Analogues of N-Lactoyl-Phenylalanine, Methods of Synthesis, and Methods of Use

Available for licensing and commercial development are patent rights covering N-Lactoyl-Phenylalanine (Lac-Phe) analogues having appetite suppressant activity, which may be useful as therapeutics in the treatment of obesity and related secondary diseases. The patent rights also cover methods of synthesis of the N-Lactoyl-Phenylalanine (Lac-Phe) analogues are also disclosed, as well as methods of use and treatment of obesity and related secondary diseases with the Lac-Phe analogues.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Inventors

- Alan T. Remaley, M.D., Ph.D. NHLBI
- Anna Wolska, Ph.D. NHLBI
- Amaury Lucien-Philip Dasseux

Potential Commercial Applications

- Therapeutics
- obesity
- obesity co-morbidities

Development Stage

- Preclinical (data from compound optimization and in vivo validation)

Intellectual Property

- NIH Reference No. E-160-2023-0, U.S. Provisional Patent Application 63/585,791 filed September 27, 2023, International Patent Application PCT/US2024/048617 filed September 26, 2024, entitled "N-Lactoyl-Phenylalanine (Lac-Phe) compound derivatives."

Dated: November 27, 2024.

Malabika J. Ghosh,

*Technology Transfer and Patent Specialist,
National Heart, Lung, and Blood Institute,
Office of Technology Transfer and
Development.*

[FR Doc. 2024–28329 Filed 12–2–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 1009 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 purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; OCT2024 Cycle 48 NExT SEP Committee Meeting.

Date: December 10, 2024.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To evaluate the NCI Experimental Therapeutics Program Portfolio.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Room 3A44, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Persons: Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program, National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, Maryland 20817, 301–496–4291, mroczkoskib@mail.nih.gov.

Toby Hecht, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 3W110, Rockville, Maryland 20850, 240–276–5683, toby.hecht@nih.gov.

This notice is being published less than 15 days from the meeting date due to exceptional circumstances. An unanticipated number of projects for clinical trial support of promising experimental therapeutics treating various cancer types, including pediatric cancer, were received which delayed the identification of panel members with the appropriate expertise. If the meeting is not held on December 10, 2024, there will be a profound negative impact on translational cancer research resulting in a 6–9-month delay in funding which will significantly slow down the initiation of meritorious projects/clinical trials by one year.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 27, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–28356 Filed 12–2–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 1009 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Eunice Kennedy Shriver National Institute of Child Health and Human Development Initial Review Group Function, Integration, and Rehabilitation Sciences Study Section.

Date: March 17–18, 2025.

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

Agenda: To review and evaluate grant applications.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human

Development, 6710 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Helen Huang, Ph.D., Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH 6710B Rockledge Drive, Room 2137D Bethesda, MD 20892, (301) 435–8207, Helen.Huang@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 26, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–28242 Filed 12–2–24; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2023–0009]

Community Disaster Resilience Zones and the National Risk Index

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

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) is issuing this Notice to provide an update on responses to the Community Disaster Resilience Zones and the National Risk Index request for information and share FEMA's initial designations of census tracts as Community Disaster Resilience Zones.

FOR FURTHER INFORMATION CONTACT: Samantha A. Medlock, Assistant Administrator for Resilience Strategy, Federal Emergency Management Agency, fema-actionoffice-resilience-strategy@fema.dhs.gov, 202–212–8007.

SUPPLEMENTARY INFORMATION:

I. Background

A. Community Disaster Resilience Zones Act

The Community Disaster Resilience Zones Act of 2022, Public Law 117–255, 136 Stat. 2363, amended title II of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*) (Stafford Act) to add a new section 206 (42 U.S.C. 5136) that requires the: (1) maintenance of a natural hazard assessment program and