

organizations; clinical laboratories; healthcare providers; food manufacturers; and patient and consumer groups.<sup>3</sup> 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.*

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<sup>3</sup> 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](mailto: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.*

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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](mailto: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."