sponsors and other external parties and identifies our current best practices for the efficient development, issuance, and use of such communications. As a part of this draft report and plan, FDA is also considering opportunities to advance the use of innovative forms of communication, to streamline the processes for regulatory submissions, and to implement innovative communication development processes and to transition or update communication practices used during the COVID–19 PHE. Pursuant to section 2505(c) of the Consolidated Appropriations Act, in this **Federal Register** notice announcing the availability of this document, FDA is seeking public comment on this ''Best Practices for FDA Communication with Interested Parties: Draft Report for Public Comment.''

II. Request for Comments

FDA is soliciting comments on its ''Best Practices for FDA Communication with Interested Parties: Draft Report for Public Comment'' from interested parties. Specifically, we request feedback on the following areas of communication:

Communications Questions

1. Are there communication practices that other Federal agencies use to communicate with interested parties, such as regulated industry, that would be consistent with FDA's statutory and regulatory requirements and helpful for FDA to consider implementing?

2. Recognizing that FDA used many innovative communications processes and practices during the COVID–19 public health emergency, what types of communications were most beneficial/useful during the COVID–19 pandemic and why?

III. Electronic Access

Persons with access to the internet may obtain the draft report and plan at *https://www.fda.gov/about-fda/reports/reports-agency-policies-and-initiatives* or *https://www.regulations.gov.*

Dated: November 25, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28229 Filed 12–2–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5653]

Food and Drug Administration Report and Plan on Best Practices for Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled ''Food and Drug Administration Report and Plan on Best Practices for Guidance'' (Report and Plan). FDA is publishing this Report and Plan in response to the Consolidated Appropriations Act, 2023, which directs FDA to issue a report identifying best practices for the efficient prioritization, development, issuance, and use of guidance documents and a plan for implementation of such best practices.

DATES: The announcement of the report and plan is published in the **Federal Register** on December 3, 2024.

ADDRESSES: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Report and Plan.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993–0002, 301–827–4830.

SUPPLEMENTARY INFORMATION:

I. Background

Clear, concise, and timely communication through guidance documents is essential to the public health mission of FDA. FDA guidance documents are prepared for FDA staff, industry, and the public to describe the Agency's interpretation of, or policy on, a regulatory issue. (21 CFR 10.115(b)). Specifically, FDA uses guidance documents to assist regulated industry, FDA staff, and the public in understanding the Agency's current thinking on policy, scientific, medical, and regulatory issues, such as: the design, manufacturing, and testing of regulated products; content and evaluation of applications for product approvals; and inspection and enforcement policies. Timely publication of guidance documents significantly benefits public health by providing transparency and valuable insight into approaches that may assist industry and other interested parties in complying with applicable statutes and regulations, ensuring consumer and patient safety, and developing new and innovative products to improve public health.

As part of FDA's Transparency Initiative, in 2011, FDA publicly released a comprehensive report entitled ''Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency'' (2011 GGP Report).[1] The 2011 GGP Report identified ''best practices'' and made recommendations to streamline the development of guidance documents, reduce the time between issuing draft and final guidance documents, and improve access to guidance documents on FDA's website. Since 2011, FDA has made significant strides to implement the recommendations in the 2011 GGP Report and to modernize and enhance our best practices for the efficient initiation, prioritization, development, review, clearance, and issuance of our guidance documents. As a result of these and other Agency improvement efforts, and as explained in the Report and Plan, FDA has significantly increased the number of guidance documents it publishes annually.

As part of FDA's reassessment of its best practices for guidance and in accordance with section 2505(a) of the Consolidated Appropriations Act, 2023, FDA published a ''Draft Report and Plan on Best Practices for Guidance'' (Draft Report and Plan) on our website on December 28, 2023.[2] Pursuant to section 2505(c) of the Consolidated Appropriations Act, 2023 in a **Federal Register** notice announcing the availability of the Draft Report and Plan, FDA solicited public comment from a broad range of interested parties, including researchers; academic organizations; pharmaceutical, biotechnology, and medical device developers; clinical research

[1] FDA, ''Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency,'' available at *https://www.fda.gov/media/82644/download.*

[2] See *https://www.fda.gov/about-fda/reports/fda-reports-good-guidance-practices.* As explained in the Draft Report and Plan, FDA will issue a separate Report and Plan in accordance with Section 2505(b) of the Consolidated Appropriations Act, 2023.

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]

BILLING CODE 4164–01–P

[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]

BILLING CODE 4140–01–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 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.''