accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 25, 2024.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Christina Vert at *CBERBPAC@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: March 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05074 Filed 3–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1824]

Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment; Guidance for Industry; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on February 22, 2024. The document announced the availability of a final guidance for industry entitled ''Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment.'' The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: David Reasner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6373, Silver Spring, MD 20993, 301–837–7667; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 22, 2024 (89 FR 13351), in FR Doc. 2024–03622, the following correction is made:

On page 13351, in the first column in the header of the document and in the third column in the second line of the first paragraph, ''Docket No. FDA–2024–D–0584'' is corrected to read ''Docket No. FDA–2020–D–1824.''

Dated: March 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05081 Filed 3–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2057]

Revocation of Emergency Use of a Drug Product During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Eli Lilly and Co. (Lilly), for bamlanivimab and etesevimab administered together. FDA revoked the Authorization on December 14, 2023, under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

DATES: The Authorization is revoked as of December 14, 2023.

ADDRESSES: Submit written requests for a single copy of the revocation to the Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, 6th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Johanna McLatchy, Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, 6th Floor, Silver Spring, MD 20993–0002, 301–796–3200 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On February 9, 2021, FDA issued an Authorization (EUA 094) to Lilly for bamlanivimab and etesevimab administered together, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on May 27, 2021 (86 FR 28608), as required by section 564(h)(1) of the FD&C Act. The authorization of a drug for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Request

In a request received by FDA on October 23, 2023, Lilly requested revocation of, and on December 14, 2023, FDA revoked, the Authorization for bamlanivimab and etesevimab

administered together. Because Lilly has informed FDA that all lots of bamlanivimab and etesevimab manufactured and labeled for use under EUA 094 have expired, and that Lilly does not intend to offer this product in the United States anymore, Lilly requested FDA revoke the EUA for bamlanivimab and etesevimab administered together. FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA for bamlanivimab and etesevimab administered together. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available on the internet at: *https://www.regulations.gov.*

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

December 14, 2023

Eli Lilly and Company
Attention: Jennifer Riddle Camp
Senior Director, GRA-NA
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

Re: Revocation of EUA 094

Dear Jennifer Riddle Camp:

This letter is in response to the request from Eli Lilly and Company (Lilly), received on October 23, 2023[1], that the U.S. Food and Drug Administration (FDA or Agency) revoke the EUA for bamlanivimab and etesevimab administered together. The EUA for bamlanivimab and etesevimab administered together was issued initially on February 9, 2021. Lilly has informed FDA that all lots of bamlanivimab and etesevimab manufactured and labeled for use under EUA 094 have expired and that Lilly does not intend to offer this product in the United States anymore. FDA understands that Lilly will promptly notify healthcare facilities and providers that have received bamlanivimab and etesevimab administered together under the EUA to also stop using product that remains in distribution with instructions for product return.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization based on the reasons set forth in Lilly's request for revocation to the Agency.

Accordingly, FDA hereby revokes EUA 094 for bamlanivimab and etesevimab administered together pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, bamlanivimab and etesevimab administered together is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

[1] At the time of Lilly's request, bamlanivimab and etesevimab administered together was not authorized for use in any region of the United States due to the high frequency of circulating SARS-CoV-2 variants that are non-susceptible to bamlanivimab and etesevimab.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2023.12.14 13:47:55 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dated: March 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05085 Filed 3–8–24; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Funding Opportunity for Indians Into Psychology (InPsy)

Announcement Type: New.

Funding Announcement Number: HHS–2024–IHS–INPSY–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.970.

Key Dates

Application Deadline Date: May 14, 2024.

Earliest Anticipated Start Date: July 1, 2024.

I. Step 1: Review the Opportunity

Funding Details

Type: Cooperative Agreement.

Competition type: New.

Expected total program funding: $805,932.

Expected number of awards: 3.

Funding range per award for the first budget year: $227,500 to $267,500.

The period of performance is for 5 years.

Continuation funding depends on the availability of funds and agency budget priorities.

Eligibility—Who can apply?

Eligible Applicants

Only the following type of organizations are eligible for this opportunity:

Public and nonprofit private colleges and universities that offer a Ph.D. or Psy.D. in clinical programs accredited by the American Psychological Association will be eligible to apply for a cooperative agreement under this announcement.

We will notify any applicants we determine to be ineligible.

Eligibility Exceptions

1. Individuals including sole proprietorships and foreign organizations are not eligible.

2. We do not fund concurrent projects under this program. If you get an award under this announcement, we cannot later fund you under other InPsy programs while this award is active.

Other Eligibility Criteria

All schools and training programs must have current, unrestricted accreditation by the American Psychological Association (APA). All institutions must be fully accredited without restrictions at the time of application.

See attachments for information you will submit to prove your eligibility.

Cost Sharing or Matching

This program has no cost-sharing requirement.

If you choose to include cost-sharing funds, we will not consider it during our review. However, we will hold you accountable for any funds you add, including through reporting.

Program Description

Background

The Indian Health Service (IHS) is responsible for providing federal health services to the American Indian and Alaska Native (AI/AN) people. Our mission is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.

The Indian Healthcare Improvement Act (*https://www.ihs.gov/IHCIA/*) authorizes the IHS to administer programs designed to attract and recruit qualified Indians into health professions to ensure the availability of health professionals to serve the AI/AN population.

Purpose

Our purpose is to increase the number of Indian clinical psychologists who deliver health care services to AI/AN communities. Our primary objectives are to:

1. Recruit and train Indian people to be clinical psychologists;

2. Provide stipends to people enrolled in schools of clinical psychology to pay tuition, books, fees, and stipends for living expenses.

Required Activities

1. You must develop and maintain psychology education programs and recruit people to become clinical psychologists who will provide services to AI/AN people.

2. You must provide scholarship grants to AI/AN students enrolled in clinical psychology education programs.

3. Scholarship awards are for a one-year period.

4. You may award additional stipend support to each eligible student for up to four years.

See the project narrative and merit review sections for more detail on activities.

Cooperative Agreement Terms

Cooperative agreements use the same policies as grants. The difference is that the IHS will have substantial involvement in the project during the entire period of performance. Below is a detailed description of our level of involvement.

The IHS program official will:

- Work closely with your program director to ensure timely management and that you meet all goals and objectives of your proposed project.
- Provide American Indians into Psychology scholarship materials and policies for student program reviews.
- Initiate default proceedings within 90 days after receiving your notification that a student: