Stephen Ripley, 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:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway.'' Labeling must conform to the content and format requirements delineated in §§ 201.57(d) and 201.57 (21 CFR 201.56(d) and 201.57). Labeling for drugs approved under the accelerated approval process is fundamentally the same as for drugs approved under the traditional pathway; however, for drugs approved under accelerated approval there are additional labeling requirements as described in § 201.57(c)(2)(i)(B) and recommended elements for consideration. This guidance discusses FDA's recommendations for developing the indication and usage statements in the prescribing information for drugs approved under accelerated approval as defined in 21 CFR part 314, subpart H (for new drug applications) and 21 CFR part 601, subpart E (for biologics license applications), specifically 21 CFR 314.510 and 21 CFR 601.41. The guidance also discusses labeling considerations for indications approved under accelerated approval when clinical benefit has been verified and FDA terminates the conditions of accelerated approval under 21 CFR 314.560 or 21 CFR 601.46, or when FDA withdraws accelerated approval of an indication while other indications for the drug remain approved.

This guidance finalizes the draft guidance of the same name issued March 25, 2014 (79 FR 16344). Changes from the draft guidance include the recommendations regarding how to fulfill the regulatory requirement that the labeling for drugs approved under accelerated approval include a succinct description of the limitations of usefulness of the drug and any uncertainty about clinical benefits. The draft guidance proposed recommending inclusion of a statement in the indication describing the specific clinical benefit that remains to be established; the final guidance states that simply reporting the endpoint used, without this additional statement, may be sufficient, except in certain circumstances when additional context about the approval should be included.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on labeling for human prescription drug and biological products approved under accelerated approval. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: January 16, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–00894 Filed 2–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Clinical Care Commission

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Clinical Care Commission (the Commission) will conduct a virtual meeting on February 20, 2019. The Commission is charged to evaluate and make recommendations to the U.S. Department of Health and Human Services (HHS) Secretary and Congress regarding improvements to the coordination and leveraging of federal programs related to awareness and clinical care for complex metabolic or autoimmune diseases that result from issues related to insulin that represent a significant disease burden in the United States, which may include complications due to such diseases.

DATES: The meeting will take place on February 20, 2019, from 1:00 p.m. to approximately 5:00 p.m. Eastern Time (ET).

ADDRESSES: The meeting will be held online via webinar. To register to attend the meeting, please visit the registration website at *https://events.kauffmaninc.com/events/nccc2/register/?t=24.*

FOR FURTHER INFORMATION CONTACT: Clydette Powell, Designated Federal Officer, National Clinical Care Commission, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Suite LL–100, Rockville, MD 20852. Email: *OHQ@hhs.gov.* Phone: 240–453–8239. Additional information may be obtained at *https://health.gov/hcq/national-clinical-care-commission.asp.*

SUPPLEMENTARY INFORMATION: The National Clinical Care Commission Act (Pub. L. 115–80) requires the HHS Secretary to establish the National Clinical Care Commission. The Commission consists of representatives of specific federal agencies and non-federal individuals and entities who represent diverse disciplines and views. The Commission will evaluate and make recommendations to the HHS Secretary and Congress regarding improvements to the coordination and leveraging of federal programs related to awareness and clinical care for complex metabolic or autoimmune diseases that result from issues related to insulin that represent a significant disease burden in the United States, which may include complications due to such diseases.

The inaugural meeting of the Commission was held on October 31, 2018, during which non-federal Commission members were sworn-in, and various federal interagency efforts surrounding diabetes program were presented. This virtual meeting will consist of presentations by the remaining federal agencies on the Commission which were not covered in the inaugural meeting. The final meeting agenda will be available prior to the meeting at *https://health.gov/hcq/national-clinical-care-commission.asp.*

Public Participation at Meeting: The Commission invites public comment on issues related to the Commission's charge. There will be no opportunity for oral comments at this virtual meeting. Written comments are welcome

throughout the process of the Commission and may be emailed to *OHQ@hhs.gov, or by mail to the following address: Public Commentary, National Clinical Care Commission,* 1101 Wootton Parkway, Suite LL–100, Rockville, MD 20852. Written comments should not exceed three pages in length.

To virtually attend the Commission meeting, individuals must pre-register at the registration website at *https://events.kauffmaninc.com/events/nccc2/register/?t=24.* Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate the special accommodation when registering online or by notifying Jennifer Gillissen at *jennifer.gillissen@kauffmaninc.com* by February 11.

Authority: The National Clinical Care Commission is required under the National Clinical Care Commission Act (Pub. L. 115–80). The Commission is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C., App.) which sets forth standards for the formation and use of federal advisory committees.

Dated: January 24, 2019.

Donald Wright,

Deputy Assistant Secretary for Health.

[FR Doc. 2019–00360 Filed 2–1–19; 8:45 am]

BILLING CODE 4150–32–P

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 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 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 of Child Health and Human Development Initial Review Group; Obstetrics and Maternal-Fetal Biology Subcommittee.

Date: February 22, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Peter Zelazowski, Ph.D., Scientific Review Officer, National Institutes of Health, NICHD, SRB, 6710B Rockledge Drive, Bethesda, MD 20892, 301–435–6902, *PETER.ZELAZOWSKI@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: January 30, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00892 Filed 2–1–19; 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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: Microbiology, Infectious Diseases and AIDS Initial Review Group, Microbiology and Infectious Diseases Research Committee, Microbiology and Infectious Diseases Research Committee (MID).

Date: June 11–12, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Amir E. Zeituni, Ph.D., Scientific Review Program, Division of Extramural Activities, SRP, RM 3G51, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20852–9823, 301–496–2550, *amir.zeituni@nih.gov.*

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group, Microbiology and Infectious Diseases Research Committee, Microbiology and Infectious Diseases Research Committee (MID).

Date: October 17–18, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Amir E. Zeituni, Ph.D., Scientific Review Program, Division of Extramural Activities, SRP, RM 3G51, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20852–9823, 301–496–2550, *amir.zeituni@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: January 29, 2019.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00832 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 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: Center for Scientific Review Special Emphasis Panel; PAR Panel: Molecular and Cellular Causal Aspects of Alzheimer's Disease.

Date: February 28, 2019.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn & Suites Alexandria—Old Town, 625 First Street, Alexandria, VA 22314.

Contact Person: Carole L. Jelsema, Ph.D., Chief and Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7850, Bethesda, MD 20892, (301) 435–1248, *jelsemac@csr.nih.gov.*