Evaluation and Research, (HFD–860), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4132, Silver Spring, MD 20993, 301–796–1697.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products—Quality Considerations.'' This guidance describes points to consider to help ensure product quality and performance for MDIs and DPIs. It describes chemistry, manufacturing, and controls information recommended for inclusion in new drug applications (NDAs) and abbreviated new drug applications (ANDAs); however, the principles are applicable to products used during clinical trials and over the product lifecycle, as well. It also provides recommendations on certain aspects of labeling for NDA and ANDA MDI and DPI products. FDA previously published a draft guidance on this topic on November 13, 1998. The present guidance is a revision of the previous draft, updated to reflect current standards and requirements to enhance understanding of development approaches for these products consistent with the quality by design paradigm.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products—Quality Considerations.'' 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. Paperwork Reduction Act of 1995

This guidance includes information collection provisions 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 referenced in this guidance that are related to the burden for the submission of investigational new drug applications are covered under 21 CFR part 312 and have been approved under OMB control number 0910–0014. The collections of information referenced in this guidance that are related to the burden for the submission of new drug applications that are covered under 21 CFR part 314 have been approved under OMB control number 0910–0001. The submission of prescription drug product labeling under 21 CFR 201.56 and 201.57 is approved under OMB control number 0910–0572.

The guidance also discusses labeling for MDI and DPI drug products, and references 21 CFR part 201. In the **Federal Register** of December 18, 2014 (79 FR 75506), FDA published its proposed rule on the electronic distribution of prescribing information for human prescription drugs, including biological products. In Section VII, ''Paperwork Reduction Act of 1995,'' FDA estimated the burden to design, test, and produce the label for a drug product's immediate container and outer container or package, as set forth in 21 CFR part 201, including §§ 201.10, 201.100(b), and other sections in subpart A and subpart B.

III. Electronic Access

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

Dated: April 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–08200 Filed 4–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Grant (R01).

Date: May 11, 2018.

Time: 11:00 a.m. to 12:30 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: J. Bruce Sundstrom, Ph.D., Scientific Review Officer Scientific Review Program, Division of Extramural Activities, Room 3G11A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, 240–669–5045, *sundstromj@niaid.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: April 13, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–08171 Filed 4–18–18; 8:45 am]

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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; Global Noncommunicable Diseases and Injury Across the Lifespan: Exploratory Research.

Date: April 25, 2018.

Time: 11:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Fungai Chanetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770 Bethesda, MD 20892, 301–408–9436, *fungai.chanetsa@nih.hhs.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.