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.

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 are related to the burden for the submission of investigational new drug applications that are covered under 21 CFR part 314

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 Chinetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–408–9436, fungai.chinetsa@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.

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