This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use.'' 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.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

III. 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 The collections of information discussed in this draft guidance have been approved under OMB under the following control numbers: OMB control number 0910–0001 for NDAs, ANDAs, supplements to NDAs and ANDAs, and annual reports; OMB control number 0910–0572 for prescription drug product labeling; OMB control number 0910–0338 for BLA, BLA supplements and annual reports; OMB control number 0910–0120 for premarket notifications (510(k)s); OMB control number 0910–0231 for premarket approval applications (PMAs); OMB control number 0910–0485 for medical device labeling; and OMB control number 0910–0577 for prominent and conspicuous mark of manufacturers on single-use devices. Relevant to this collection of information, FDA published its proposed rule on the electronic distribution of prescribing information for human prescription drugs, including biological products in the **Federal Register** of December 18, 2014 (79 FR 75506). 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 § 201.100(b) and other sections in subpart A and subpart B.

Dated: October 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: Center for Scientific Review Special Emphasis Panel; Program Project: Molecular structure, dynamics, and mechanism of key membrane transporters and enzymes in cellular metabolism.

Date: November 17–18, 2015.

Time: 7:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Kathryn M. Koeller, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, 301–435–2681, *koellerk@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR13–189: Imaging and Biomarkers for Early Cancer Detection.

Date: November 17, 2015.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Chiayeng Wang, Ph.D., Scientific Review Officer. Center for Scientific Review. 6701 Rockledge Drive, Room 5213, MSC 7852, Bethesda, MD 20892, 301–435–2397, *chiayeng.wang@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–14–092: Bioengineering Research Partnerships (BRP).

Date: November 17, 2015.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Mehrdad Mohseni, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7854, Bethesda, MD 20892, 301–435–0484, *mohsenim@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA grant applications: Toxicology and Digestive, Kidney and Urological Systems.

Date: November 17, 2015.

Time: 11:30 a.m. to 2:00 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: Patricia Greenwel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301–435–1169, *greenwep@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Skeletal Muscle.

Date: November 17, 2015.

Time: 1:00 p.m. to 4:00 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: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301–496–8551, *ingrahamrh@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: New Modalities for the Treatment of Pain and Drug Abuse.

Date: November 17, 2015.

Time: 1:00 p.m. to 4:00 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: Geoffrey G. Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040–A, MSC 7850, Bethesda, MD 20892, 301–435–1235, *geoffreys@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: October 16, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–26774 Filed 10–21–15; 8:45 am]

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