Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Paul C. Brown, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 22, Rm. 6472, Silver Spring, MD 20993–0002, 301–796–0856.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a guidance for industry and review staff entitled ''Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route.'' This guidance provides recommendations regarding the nonclinical evaluation of a new formulation containing a previously approved drug substance and of a product proposed for use by an alternate route of administration for which the product was not previously approved.

Generally, nonclinical data support use of a drug product by a particular route and also reflect the planned duration of use. Much of the available nonclinical information used to support approval of the initial formulation can be used to support the safety of additional formulations assuming all legal rights to the information are met. Information used to support an initial formulation, however, may not always be sufficient to support such additional approvals because changes in the formulation could produce a new toxicity. This is particularly true if the drug product's route of administration is different or the duration of use changes markedly. Therefore, additional nonclinical studies might be recommended to ensure that the toxicity of a new formulation is fully characterized.

This guidance provides general nonclinical considerations for all reformulations or new routes of use and several route-specific considerations. The considerations in this guidance can also be applied to routes not specifically mentioned in the guidance.

This guidance finalizes the draft guidance of the same name published on March 7, 2008. Changes to the guidance include the addition of a recommendation that toxicology studies be conducted under good laboratory practices, clarification that histopathology can be limited in some cases to locally exposed tissues, the addition of a reference to the International Conference on Harmonisation guidance for industry entitled ''S10 Photosafety Evaluation of Pharmaceuticals,'' and other clarifications to the studies recommended for specific routes such as dermal, ocular, and intranasal.

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 nonclinical safety evaluation of reformulated drug products and products intended for administration by an alternate route. 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 document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: October 21, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–27418 Filed 10–27–15; 8:45 am]

**BILLING CODE 4164–01–P**

## 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; Member Conflict: Topics in Biology of Infectious Diseases Agents, Drug Resistance and Drug Discovery.

*Date:* November 16–17, 2015.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Tera Bounds, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301–435–2306, *boundst@csr.nih.gov.*

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

*Date:* November 17, 2015.

*Time:* 4:00 p.m. to 5:00 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:* Daniel F McDonald, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4110, MSC 7814, Bethesda, MD 20892, (301) 435–1215, *mcdonald@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Pathophysiological Correlates of Visual System Disorders and Mechanisms of Intervention.

*Date:* November 19, 2015.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

*Contact Person:* Alessandra C Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm 5205 MSC7846, Bethesda, MD 20892, (301) 435–1021, *rovescaa@mail.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 23, 2015.

**Carolyn Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–27427 Filed 10–27–15; 8:45 am]

**BILLING CODE 4140–01–P**