

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Beclomethasone dipropionate.
 Betamethasone dipropionate.
 Betrixaban.
 Ciprofloxacin.
 Deferasirox.
 Dexamethasone; Neomycin sulfate; Polymyxin b sulfate.
 Epinephrine.
 Ethinyl estradiol; Norethindrone acetate.
 Finafloxacin.
 Flucinolone acetonide.
 Loteprednol etabonate.
 Mecamylamine hydrochloride.
 Methscopolamine bromide.
 Methylphenidate.
 Metyrosine.
 Moxifloxacin hydrochloride.
 Nebivolol hydrochloride; Valsartan.
 Nimodipine.
 Nitisinone.
 Omeprazole.
 Rifapentine.
 Ritonavir.
 Sodium polystyrene sulfonate.
 Triamcinolone acetonide.
 Valbenazine tosylate.

III. Drug Products for Which Revised Draft Product-Specific Guidances are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Abiraterone acetate.
 Dapagliflozin propanediol; Metformin hydrochloride.
 Diclofenac sodium.
 Donepezil hydrochloride; Memantine hydrochloride.
 Esomeprazole strontium.
 Ethosuximide.
 Glatiramer acetate.
 Hydrocodone bitartrate.
 Lansoprazole.
 Latanoprost.
 Leucovorin calcium.
 Methylphenidate hydrochloride.
 Morphine sulfate; Naltrexone hydrochloride.
 Nisoldipine.
 Oxycodone hydrochloride.
 Ticagrelor.
 Triamcinolone acetonide.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to <https://www.regulations.gov> and enter Docket No. FDA-2007-D-0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR

10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are 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.

IV. Electronic Access

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

Dated: July 18, 2018.

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 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-17-031: Role of Age-Associated Metabolic Changes in Alzheimer's Disease.

Date: July 31, 2018.

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: Samuel C. Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, edwardss@csr.nih.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.

(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: July 17, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee 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, 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; Urologic and Urogynecologic Applications.

Date: July 20, 2018.

Time: 10:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Ganesan Ramesh, Ph.D., Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301-827-5467, ganesan.ramesh@nih.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Review of Aging Applications.

Date: August 13, 2018.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

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