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

	Cefixime.
	Colestipol HCl.
	Crizotinib.
D	Daunorubicin citrate.
	Diflorasone diacetate.
	Dimethyl fumarate.
	Diphenhydramine HCl.
	Doxycycline (multiple reference listed drugs).
	Doxylamine succinate; Pyridoxine HCl.
E	Esomeprazole strontium.
	Ethinyl estradiol; Levonorgestrel and Ethinyl estradiol.
	Ethinyl estradiol; Norethindrone acetate.
F	Fosfomycin tromethamine.
G	Gentamicin sulfate.
H	Hydromorphone HCl.
L	Lanreotide acetate.
	Linagliptin; Metformin HCl.
	Lomustine.
M	Menthol; Methyl salicylate.
	Metformin HCl; Sitagliptin phosphate.
O	Ospemifene.
	Oxcarbazepine.
P	Paroxetine mesylate.
	Promethazine (multiple reference listed drugs and strengths).
	Propranolol HCl.
R	Ropinirole HCl.
S	Sucralfate (multiple reference listed drugs and dosage forms).
T	Tacrolimus.
Z	Zolmitriptan.

III. Drug Products for Which Revised Draft Product-Specific BE Recommendations Are Available

FDA is announcing the availability of a revised draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

D	Dronedarone HCl.
	Duloxetine HCl.
E	Ergocalciferol
	Esomeprazole magnesium.
F	Fluorouracil.
H	Hydrochlorothiazide; Moexipril HCl.
I	Imatinib mesylate.
L	Lansoprazole.
M	Mesalamine (multiple reference listed drugs).
N	Nevirapine.
	Nilotinib HCl monohydrate.
P	Pentosan polysulfate sodium.

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, please go to *http://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft and revised draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These guidances represent the Agency's current thinking on product-specific design of BE studies to support ANDAs. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

IV. Comments

Interested persons may submit either electronic comments on any of the specific BE recommendations posted on FDA's Web site to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. The guidances, notices, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

V. 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: *July 17, 2014.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17293 Filed 7–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: HHS is announcing the availability of an interpretive rule providing HHS's interpretation of section 340B(e) of the Public Health Service Act (PHSA), entitled ''Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program.'' The interpretive rule states that section 340B(e) of the PHSA excludes drugs with an orphan designation only when those drugs are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the drug was designated under section 526 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Effective July 23, 2014.

ADDRESSES: Submit written requests for single copies of the interpretive rule to the Office of Pharmacy Affairs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 8W03A, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the interpretive rule.

FOR FURTHER INFORMATION CONTACT: CDR Krista Pedley, Director, Office of Pharmacy Affairs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 8W03A, Rockville, MD 20857, or by telephone at (301) 594–4353.

SUPPLEMENTARY INFORMATION:

I. Background

HHS is announcing the availability of an interpretive rule entitled ''Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program.'' This interpretive rule explains how HHS interprets section 340B(e) of the PHSA. 42 U.S.C. 256b(e). This interpretive rule intends to: (1) Provide clarity in the marketplace; (2) maintain the 340B Program savings for newly-eligible entities; and (3) protect the financial incentives for manufacturing orphan drugs designated for a rare disease or condition, as indicated in the Patient Protection and Affordable Care Act (''Affordable Care Act'') (Pub. L. 111–148) and intended by Congress.

Earlier this year, after notice and comment rulemaking, HHS issued a final rule on this subject, ''Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program'' (78 FR 44016, July 23, 2013) (the ''Rule''). The Rule was vacated by U.S. District Court for the District of Columbia on May 23, 2014, on the grounds that HHS does not have the authority to issue the Rule as a substantive rule. *PhRMA* v. *HHS,* No. 13–01501 (D.D.C. May 23, 2014). However, the decision did not invalidate HHS's interpretation of the orphan drug exclusion in the Rule.

Because there still is a need for HHS to clarify its interpretation of how the orphan drug exclusion in the 340B Program should be implemented to be consistent with section 340B(e) of the PHSA, HHS is making available an interpretive rule on this topic. In short, this interpretive rule clarifies that HHS interprets section 340B(e) of the PHSA as excluding drugs with an orphan designation only when those drugs are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the drug was designated under section 526 of the FD&C Act. This section of the PHSA does not exclude drugs that are transferred, prescribed, sold, or otherwise used for conditions or diseases other than for which the drug was designated under section 526 of the FD&C Act.

II. Electronic Access

Persons with access to the Internet may obtain the document at *www.hrsa.gov/opa/programrequirements/interpretiverule/.*

Dated: July 16, 2014.

Mary K. Wakefield,

Administrator, Health Resources and Services Administration.

Dated: July 18, 2014.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2014–17409 Filed 7–21–14; 11:15 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

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 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: Environmental Health Sciences Review Committee.

Date: August 14–15, 2014.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Imperial Hotel & Convention Center, 4700 Emperor Boulevard, Durham, NC 27703.

Contact Person: Linda K Bass, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat'l Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–1307.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: July 17, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–17262 Filed 7–22–14; 8:45 am]

BILLING CODE 4140–01–P

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 (5 U.S.C. App.), 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 Member Conflict: Cardiovascular and Respiratory Sciences.

Date: August 21, 2014.

Time: 8:00 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: Margaret Chandler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7814, Bethesda, MD 20892, (301) 435–1743, *margaret.chandler@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: July 17, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–17259 Filed 7–22–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Deafness and Other Communication Disorders Advisory Council.

Date: September 12, 2014

Closed: 8:30 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Room 6C6, 31 Center Drive, Bethesda, MD 20892.

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

Agenda: Staff reports on divisional, programmatic, and special activities.