

5509(e)(7)(A)(ii) of the ACA with respect to eligible hospitals located in rural or medically underserved areas.

In general terms, the demonstration provides a source of Medicare funding for the reasonable costs for clinical training attributable to the incremental increase in the number of APRN students enrolled in participating SONs during the demonstration relative to an established baseline. Section 5509 of the ACA sets forth limitations on the reasonable costs reimbursable under the demonstration. We will make interim payments to selected hospitals with a cost settlement process using Medicare reasonable cost principles. Participating eligible hospitals must establish written agreements with one or more applicable SONs and two or more applicable non-hospital CCSs that define the obligations of each partner with respect to the provision of qualified training and the corresponding eligible hospital's obligation to reimburse eligible partners applicable (in a timely manner) for the costs of such qualified training attributable to the partner and the mechanism for partner reimbursement. As outlined in the GNE Solicitation, applicant hospitals may partner with other hospitals in the demonstration and we will support an expanded configuration of hospital relationships under certain circumstances.

The GNE Demonstration will run for 4 years. Applicants must identify how they propose to significantly increase the APRN student enrollment and graduation rates for clinical nurse specialist, nurse practitioner, certified registered nurse anesthetist, and certified nurse midwife specialty programs. The proposal must present evidence that the applicant hospital and partner organizations are not only capable of successfully recruiting students but also providing relevant clinical training programs responsive to our changing health care system due to the growing number of insured by 2014. Applicants will be required to provide a detailed budget and narrative describing the rationale for the proposed GNE payment rate and why this would be an efficient investment for CMS.

A competitive process will be used to select eligible organizations. We will accept proposal applications in the standard format outlined in the GNE solicitation in order to be considered for review by an internal technical panel. Applications that are not received in this format will not be considered for review.

For more specific details regarding the GNE demonstration, please refer to the informational materials on our Web site

at <http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/>.

## II. Information Collection Requirements

In accordance with section 5509(a)(4) of the ACA, this information collection requirement is not subject to the Paperwork Reduction Act of 1995. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

**Authority:** Section 5509 of the ACA (Pub. L. 111–148, as amended by Pub. L. 111–152) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 19, 2012.

**Marilyn Tavenner,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2012–6940 Filed 3–21–12; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2007–D–0369]

#### Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on these draft and revised draft guidances before it

begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by May 21, 2012.

**ADDRESSES:** Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, 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 draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Doan T. Nguyen, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, (240) 276–8608.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific BE recommendations available to the public on FDA’s Web site at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA’s Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final recommendations, or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** of January 25,

2012 (77 FR 3777). This notice announces draft product-specific recommendations, either new or revised, that are being posted on FDA's Web site concurrently with publication of this notice.

## II. Drug Products for Which New Draft Product-Specific

### BE Recommendations Are Available

FDA is announcing new draft product-specific BE recommendations for drug products containing the following active ingredients:

A  
Acyclovir (multiple reference listed drugs (RLDs)),  
Amiloride,  
B  
Butenafine HCl (multiple RLDs), Chlorpromazine HCl,  
C  
Clindamycin Phosphate (multiple RLDs),  
D  
Dalfampridine,  
Dexmethylphenidate HCl,  
Dextromethorphan HBr; Quinidine Sulfate,  
Diclofenac Epolamine,  
Drospirenone Ethinyl Estradiol;  
Levomefolate,  
E  
Ethinyl Estradiol; Norethindrone,  
F  
Fenofibrate,  
Fludarabine,  
Fulvestrant,  
G  
Glyburide (multiple RLDs),  
Gransetron,  
I  
Ivermectin,  
K  
Ketoconazole (multiple RLDs),  
M  
Memantine HCl,  
Metformin Hydrochloride; Saxagliptin,  
N  
Naftifine HCl (multiple RLDs),  
Nitrofurantoin; Nitrofurantoin Macrocrystalline,  
O  
Ondansetron,  
Oxiconazole Nitrate (multiple RLDs),  
P  
Pimecrolimus,  
Procarbazine,  
Propylthiouracil,  
S  
Sumatriptan,  
T  
Tacrolimus (multiple strengths),  
Tolvaptan,  
Tretinoin (multiple RLDs),  
V  
Vardenafil HCl,

## III. Drug Products for Which Revised Draft Product-Specific BE

### Recommendations Are Available

FDA is announcing revised draft product-specific BE recommendations for drug products containing the following active ingredients:

B  
Benzoyl Peroxide; Clindamycin Phosphate (multiple RLDs),  
Bosentan,  
C  
Cholestyramine,  
Colesevelam,  
D  
Dexamethasone; Tobramycin (multiple RLDs),  
H  
Hydrochlorothiazide; Irbesartan,  
L  
Loteprednol,  
Loteprednol; Tobramycin,  
P  
Paliperidone

For a complete history of previously published **Federal Register** notices relating to product-specific BE recommendations, please go to <http://www.regulations.gov> and enter docket number 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). The 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 to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments on any of the specific BE recommendations posted on FDA's Web site. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. The guidance, notices, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## 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: March 16, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; 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:* National Heart, Lung, and Blood Institute Special Emphasis Panel; Novel Clinical Trial Methods.

*Date:* April 13, 2012.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Tony L. Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892-7924, 301-435-0725, [creazzotl@mail.nih.gov](mailto:creazzotl@mail.nih.gov).

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; Research Dissemination and Implementation.

*Date:* April 16, 2012.

*Time:* 11:30 a.m. to 2:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, VA 22202.

*Contact Person:* Keith A. Mintzer, Ph.D., Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7186, Bethesda, MD 20892-7924, 301-435-0280, [mintzerk@nhlbi.nih.gov](mailto:mintzerk@nhlbi.nih.gov).

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Clinical Trials.

*Date:* April 16, 2012.

*Time:* 1 p.m. to 5 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:* Charles Joyce, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892-7924, 301-435-0288, [cjoyce@nhlbi.nih.gov](mailto:cjoyce@nhlbi.nih.gov).