

Secretary of Health and Human Services will be released for public comment in early November. The Committee will provide an extended period of time during the November meeting for members of the public to provide their perspectives on the oversight issues and comments on the Committee's draft report and recommendations. The Committee will also be briefed about an international analysis of oversight systems for genetic testing with a focus on the U.S. system.

As always, the Committee welcomes hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. Individuals who would like to provide public comment should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301-496-9838 or e-mail at [carrs@od.nih.gov](mailto:carrs@od.nih.gov). The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892. Anyone planning to attend the meeting who is in need of special assistance, such as sign language interpretation or other reasonable accommodations, is also asked to contact the Executive Secretary.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic and genomic technologies and, as warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the Web cast, will be available at the following Web site: <http://www4.od.nih.gov/oba/sacghs.htm>

Dated: October 17, 2007.

**Jennifer Spaeth,**

*Director, NIH Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007P-0047]

#### Nonprescription Drugs Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee

of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Nonprescription Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on December 14, 2007, from 8 a.m. to 5 p.m.

*Addresses:* Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "2007P-0047—Amend the Dosage of Oral Phenylephrine Listed in the Final Monograph on Oral Decongestants," and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on December 30, 2007.

*Location:* Hilton Washington DC/ Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301-589-5200.

*Contact Person:* Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [Diem.Ngo@fda.hhs.gov](mailto:Diem.Ngo@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301) 443-0572 in the Washington, DC area, code 3014512541. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* The committee will discuss the safety and effectiveness of phenylephrine hydrochloride and phenylephrine bitartrate as over-the-counter (OTC) oral nasal decongestants. The discussion at the meeting will address a citizen petition submitted to FDA on February 1, 2007 (Docket No. 2007P-0047/CP1), which asserts that the available data do not support the adult and pediatric doses of phenylephrine hydrochloride and phenylephrine bitartrate that are generally recognized as safe and

effective in the OTC drug monograph for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (CCABADP) in 21 CFR part 341. The meeting will focus on the review of existing safety and efficacy data and the petitioner's request that the CCABADP monograph be amended to increase the adult dose of phenylephrine hydrochloride from 10 to 25 milligrams (mg) and that of phenylephrine bitartrate from 15.6 to 40 mg.

Additional information was submitted to the docket for OTC Nasal Decongestants (Docket No. 1976N-0052N; submissions EMC140, C251, C253 and Supplement 13) and is related to the petition or the petitioner's publications. These submissions were submitted to the OTC Nasal Decongestant docket and have been cross-referenced and linked to Docket No. 2007P-0047. The petition and other relevant submissions can be found at the following Web site: <http://www.fda.gov/ohrms/dockets/dockets/07p0047/07p0047.htm>.

Other information in Docket No. 1976N-0052N may be considered. For example, see comments 10 and 11 of the Tentative Final Monograph for OTC Nasal Decongestants, published in the **Federal Register** of January 15, 1985 (50 FR 2220 at 2226).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material will be available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 30, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 22, 2007. Time allotted for each presentation may be limited. If the number of registrants

requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 23, 2007.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Diem-Kieu Ngo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 18, 2007.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. 07-5249 Filed 10-23-07; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Office of Health Information Technology, Health Center Controlled Networks Progress Reports—New**

The Office of Health Information Technology (OHIT), Division of State and Community Assistance (DSCA), plans to collect network outcome measures, conduct evaluation of those measures, and create an electronic reporting system for the following new 2007 grant opportunities: Health

Information Technology Planning Grants, Electronic Health Record Implementation Health Center Controlled Networks (HCCN), Health Information Technology Innovations for Health Center Controlled Networks, and High Impact Electronic Health Records Implementation for Health Center Controlled Networks and Large Multi Site Health Centers. In order to help carry out its mission, DSCA has created a set of performance measures that grantees will use to evaluate the effectiveness of their service programs and monitor their progress through the use of performance reporting data.

OHIT has developed an electronic performance measurement reporting instrument with HRSA's Office of Information Technology. The instrument will accomplish the following goals: monitor improved access to needed services, evaluate the productivity and efficiency of the networks, and monitor patient outcome measures. Grantees will submit their Progress Reports in a mid-year report and an accumulative annual progress report each fiscal year of the grant.

The estimates of burden are as follows:

Form	Estimated number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
HCCN Progress Reports .....	46	2	92	6 hrs	552

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: October 18, 2007.

**Alexandra Huttinger,**

*Acting Director, Division of Policy Review and Coordination.*

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**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

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The following request has been submitted to the OMB for review under the Paperwork Reduction Act of 1995:

**Proposed Project: The Nursing Education Loan Repayment Program Application (OMB No. 0915-0140)—Revision**

This is a request for revision of the Nursing Education Loan Repayment Program (NELRP) application and participant monitoring forms. The NELRP was originally authorized by 42 U.S.C. 297b(h) (section 836(h) of the Public Health Service Act) as amended by Public Law 100-607, November 4, 1988. The NELRP is currently authorized by 42 U.S.C. 297n (section 846 of the Public Health Service Act) as amended by Public Law 107-205, August 1, 2002.

Under the NELRP, registered nurses are offered the opportunity to enter into a contractual agreement with the Secretary to receive loan repayment for up to 85 percent of their qualifying educational loan balance as follows: 30