

accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 240-276-8932, 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: November 2, 2007.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E7-21979 Filed 11-8-07; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007D-0419]

#### **Draft Guidance for Industry on Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment." This guidance is intended to assist the pharmaceutical industry in designing a clinical development program for new drugs for the treatment of chronic obstructive pulmonary disease (COPD). The emphasis of this guidance is on the assessment of efficacy of a new molecular entity in phase 3 clinical studies of COPD.

**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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 8, 2008.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane,

Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### **FOR FURTHER INFORMATION CONTACT:**

Badrul A. Chowdhury, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3316, Silver Spring, MD 20993-0002, 301-796-2300.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment." This guidance is intended to assist the pharmaceutical industry in designing a clinical development program for new drugs for the treatment of COPD. The emphasis of this guidance is on the assessment of efficacy of a new molecular entity in phase 3 clinical studies of COPD.

There is pressing need to develop new drugs for COPD because the global prevalence of COPD is rising, the disease is associated with significant morbidity and mortality, and current treatment options are limited. The currently available drugs for COPD are mostly for symptomatic treatment and have not been conclusively shown to alter the underlying inflammation or to alter disease progression. The principles of development applied to COPD drugs have been generally derived from those used to develop drugs for asthma, with the primary focus aimed at demonstrating improvements in airway obstruction. With improved understanding of the pathophysiology and clinical manifestations of COPD, and the awareness of the importance of inflammation in COPD and how this inflammation differs from that occurring in asthma, this is an appropriate time to define characteristics of specific drug development programs for COPD.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on developing drugs for the treatment of COPD. It does not create or confer any

rights for or on any person and does 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.

##### **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### **III. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: November 2, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-21985 Filed 11-8-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### **National Advisory Council on Nurse Education and Practice; Notice of Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

**Name:** National Advisory Council on Nurse Education and Practice (NACNEP).

**Dates and Times:** November 15, 2007, 9 a.m.-5 p.m.

November 16, 2007, 9 a.m.-4 p.m.

**Place:** Doubletree Executive Hotel and Meeting Center, 8120 Wisconsin Avenue, Bethesda, MD 20814.

**Status:** The meeting will be open to the public.

**Agenda:** Agency and Bureau administrative updates will be provided. The purpose of the meeting will be to examine the issues facing nursing education in relation to teaching and learning strategies, the needs of employers and consumers for high quality professional nursing care across the lifespan and in a variety of settings, and nursing curricula to prepare the nursing student at the basic level (associate degree, diploma, and baccalaureate degree) to

practice in a changing health care system. The objectives of the meeting are to: (1) Examine the most effective and relevant teaching and learning methods and strategies focusing on Competency Outcomes and Performance Assessment for students in the practice disciplines; (2) identify knowledge, skills, and abilities needed by the 21st century RN workforce as seen through the eyes of employers and consumers; and (3) examine nursing curricula among all three basic RN programs {associate degree, diploma and baccalaureate programs} to understand similarities and differences in the respective programs and their ability to prepare the 21st century nursing student for professional practice.

During this meeting, the NACNEP council members will deliberate as workgroups on the content presented and formulate recommendations to the Secretary of Health and Human Services and the Congress on teaching and learning strategies for future nursing students and nursing competencies required by employers and consumers. This meeting and the meeting held in April 2008 will form the basis for NACNEP's congressionally mandated Ninth Annual Report.

*For Further Information Contact:* Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information should write or contact Dr. Joan Weiss, Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 9-35, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-5688.

Due to a delay in confirming several key speakers, this notice will publish in the **Federal Register** less than 15 days before the date of the meeting.

Dated: November 5, 2007.

**Alexandra Huttinger,**

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

[FR Doc. E7-21978 Filed 11-8-07; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2007-0049]

#### National Boating Safety Activities: Funding for National Nonprofit Public Service Organizations

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of funds availability.

**SUMMARY:** The Coast Guard seeks applications for fiscal year 2008 grants and cooperative agreements from national, nongovernmental, nonprofit public service organizations. These grants and cooperative agreements would be used to fund projects on various subjects promoting recreational boating safety on a national scope. This

notice provides information about the grant and cooperative agreement application process and some of the subjects of particular interest to the Coast Guard.

**DATES:** You may obtain application packages on or after November 1, 2007. Proposals for the fiscal year 2008 grant cycle must be received before 3 p.m. Eastern time, January 22, 2008.

**ADDRESSES:** You may obtain application packages by calling the Coast Guard at 202-372-1060. Submit proposals to: Commandant (CG-54221), U.S. Coast Guard Headquarters, 2100 Second Street, SW., Room 3100, Washington, DC 20593-0001. This notice is available from the Coast Guard and on the Internet at the Web site for the Boating Safety Division at <http://www.uscgboating.org> and at <http://www.regulation.gov>.

**FOR FURTHER INFORMATION CONTACT:** Ms. Vickie Hartberger, Boating Safety Division, U.S. Coast Guard (CG-54221), 2100 Second Street, SW., Room 3100, Washington, DC 20593-0001; 202-372-1060; e-mail [Vickie.L.Hartberger@uscg.mil](mailto:Vickie.L.Hartberger@uscg.mil). The points of contact for the nine project areas are listed at the end of each project description.

**SUPPLEMENTARY INFORMATION:** Title 46, United States Code, Chapter 131, provides for the allocation of available funds from the Sport Fish Restoration and Boating Trust Fund for State recreational boating safety grants. The majority of funds are allocated to the states and up to 5 percent of these funds may be distributed by the Coast Guard for grants and cooperative agreements for national recreational boating safety activities of national nonprofit public service organizations. We anticipate we will allocate approximately \$5,400,000 among several organizations for fiscal year 2008. Thirty-seven awards totaling \$5,219,380 were made in fiscal year 2007 ranging from \$10,000 to \$650,000. Nothing in this notice should be construed as committing the Coast Guard to dividing available funds among qualified applicants or awarding any specified amount. Applicants must be national, nongovernmental, nonprofit public-service organizations and must establish that their activities are national in scope. You may obtain an application package by writing or calling the point of contact listed in **ADDRESSES** on or after November 1, 2007. The application package contains all necessary forms, an explanation of how the grant program is administered, and a checklist for submitting a grant application. You can obtain specific information on organization eligibility,

proposal requirements, award procedures, and financial administration procedures by contacting the person listed in **FOR FURTHER INFORMATION CONTACT**.

The Boating Safety Financial Assistance Program is listed in section 97.012 of the Catalog of Federal Domestic Assistance. Prospective grantees may propose up to a 5-year grant with 12-month (fiscal year) increments identified. In effect, an award would be made for the first year and thereafter renewal is optional. Each annual increment would not be guaranteed. Under a continuation (multi-year) type of award, the Coast Guard agrees to support a grant project at a specific level of effort for a specified period of time, with a statement of intention to provide additional future support, provided funds are available, the project continues to support the needs of the government, and the achieved results warrant further support. Award of continuation grants will be made on a strict case-by-case basis to assist planning in certain large scale projects and ensure continuity. Procedures also provide for awarding noncompetitive grants or cooperative agreements on a case-by-case basis. This authority is judiciously used to fund recurring annual projects or events which can only be carried out by one organization, and projects that present targets of opportunity for timely action on new or emerging program requirements or issues. The following list includes items of specific interest to the Coast Guard, however, potential applicants should not be constrained by the list. We welcome any initiative that supports the mission of the USCG Office of Boating Safety, which is: To ensure the public has a safe, secure, and enjoyable recreational boating experience by implementing programs that minimize the loss of life, personal injury, and property damage while cooperating with environmental and national security efforts. The performance goal of the National Recreational Boating Safety Program is to reduce recreational boating casualties. To achieve this goal, our objectives, for which we need additional expertise from grant recipients, include:

- Improving the reliability of boating accident reporting, which assists in identifying causal factors that could then be addressed through education and/or regulation.
- Tracking and Increasing Awareness of Safe Boating Practices.
- Increasing lifejacket wear.
- Decreasing the number of alcohol-involved accidents.