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Draft Guidance for Industry on Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment.''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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 8, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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]

BILLING CODE 4160–01–S

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