

Dated: October 11, 2007.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E7-20512 Filed 10-17-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Peripheral and Central Nervous System 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:* Peripheral and Central Nervous System 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 6, 2007, from 8 a.m. to 5 p.m.

*Location:* Sheraton College Park Hotel, The Ballroom, 4095 Powder Mill Rd., Beltsville, MD. The hotel telephone number is 301-937-4422.

*Contact Person:* Darrell Lyons, 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:

*darrell.lyons@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512543. 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 new drug application (NDA) 21-894, tetrabenazine, Prestwick Pharmaceuticals, Inc., for the proposed indication to treat chorea associated with Huntington's disease.

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 is 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 21, 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 7, 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 8, 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 Darrell Lyons 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 11, 2007.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E7-20511 Filed 10-17-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Science Board to the Food and Drug Administration; Amendment of Notice

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

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Science Board to the Food and Drug Administration (Science Board). This meeting was originally announced in the **Federal Register** of October 2, 2007 (72 FR 56078). The amendment is being made to reflect a change in the *Date and Time* and *Procedure* portions of the document. There are no other changes.

#### FOR FURTHER INFORMATION CONTACT:

Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF-33), 5600 Fishers Lane, Rockville, MD, 20857, 301-827-6687, [carlos.Peña@fda.hhs.gov](mailto:carlos.Peña@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512603.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 2, 2007, FDA announced that a meeting of the Science Board would be held on October 30, 2007. On page 56078, beginning in the second column, the *Date and Time* and *Procedure* portions of the document are amended to read as follows:

*Date and Time:* The meeting will be held on December 3, 2007, from 8 a.m. to 5:30 p.m.

*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 26, 2007. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 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 16, 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 19, 2007.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: October 12, 2007.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E7-20550 Filed 10-17-07; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2007-0007]

#### Collection of Information Under Review by Office of Management and Budget: OMB Control Number: 1625-0106

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB) requesting an extension of their approval for the following collection of information: 1625-0106, Unauthorized Entry into Cuban Territorial Waters. Before submitting this ICR to OMB, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before December 17, 2007.

**ADDRESSES:** To make sure your comments and related material do not enter the docket [USCG-2007-0007] more than once, please submit them by only one of the following means:

(1) *Online:* <http://www.regulations.gov>.

(2) *Mail or Hand Deliver to:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001. Hand deliver between the hours of 9 a.m. and 5 p.m., Monday through Friday, except

Federal holidays. The telephone number is 202-366-9329.

(3) *Fax to:* Docket Management Facility: 202-493-2251.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room W12-140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://www.regulations.gov>.

A copy of the complete ICR is available through this docket on the Internet at <http://www.regulations.gov>. Additionally, copies are available from Commandant (CG-611), U.S. Coast Guard Headquarters, (Attn: Mr. Arthur Requina), 2100 2nd Street, SW., Washington, DC 20593-0001. The telephone number is 202-475-3523.

**FOR FURTHER INFORMATION CONTACT:** Mr. Arthur Requina, Office of Information Management, telephone 202-475-3523, or fax 202-475-3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, 202-366-9826, for questions on the docket.

#### SUPPLEMENTARY INFORMATION:

##### Public Participation and Request for Comments

We encourage you to respond to this request by submitting comments and related materials. We will post all comments received, without change, to <http://www.regulations.gov>. They will include any personal information you provide. We have an agreement with DOT to use their Docket Management Facility. Please see the paragraph on DOT's "Privacy Act Policy" below.

**Submitting comments:** If you submit a comment, please include the docket number for this request [USCG-2007-0007], indicate the specific section of the document to which each comment applies, providing a reason for each comment. We recommend you include your name, mailing address, and an e-mail address or other contact information in the body of your document to ensure that you can be identified as the submitter. This also allows us to contact you in the event further information is needed or if there are questions. For example, if we cannot read your submission due to technical difficulties and you cannot be contacted, your submission may not be

considered. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit them by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change the documents supporting this collection of information or even the underlying requirements in view of them.

**Viewing comments and documents:** Go to <http://www.regulations.gov> to view documents mentioned in this notice as being available in the docket. Click on "Search for Dockets," and enter the docket number for this notice (USCG-2007-0007) in the Docket ID box, and click enter. You may also visit the Docket Management Facility in room W12-140 on the West Building Ground Floor, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**Privacy Act:** Anyone can search the electronic form of all comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Privacy Act Statement of DOT in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://DocketsInfo.dot.gov>.

#### Information Collection Request

1. *Title:* Unauthorized Entry into Cuban Territorial Waters.

*OMB Control Number:* 1625-0106.

*Summary:* This information collection is needed to enforce, comply with and facilitate application for permits under the unauthorized entry into Cuban territorial seas regulations (33 CFR part 107) promulgated under 50 U.S.C. 191 and 194, and Presidential Proclamation 6867, 61 FR 8843, 3 CFR, 1996 Comp., p. 8; Presidential Proclamation 7757 (69 FR 9515, March 1, 2004).

*Need:* Title 33 CFR part 107 prescribes regulations governing the unauthorized entry by U.S. vessels into Cuban territorial waters and their applications for permits to enter. The collection of information from applicants is required to comply with the regulations and to facilitate the application process for persons seeking