consider comments in making its determination on electronic filing and in drafting a guidance document for submitting drug registration and listing information electronically. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 5 p.m., Monday through Friday.

Dated: December 29, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–534 Filed 1–8–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Adenoviral Vector Safety; Public Meeting and Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Adenoviral Vector Safety'' and a workshop of the ''Adenoviral Standards Working Group.'' The purpose of the public meeting and workshop is to discuss the scientific and technological issues related to developing voluntary industry reference standards for adenoviral vectors used to deliver human gene therapies. The voluntary industry reference standards will be used to help ensure the safety of adenoviral vectors intendedfor use in humans.

Date and Time: The public meeting and workshop will be held on February 1, 2001. The Adenoviral Vector Safety meeting will be held from 9:30 a.m. to 12 noon.

The Adenoviral Standards Working Group workshop will be held from 1 p.m. to 5 p.m.

Location: The Adenoviral Vector Safety meeting will be held at the Wilson Auditorium, National Institutes of Health, Bldg. 1, 8600 Rockville Pike, Bethesda, MD 20894.

The Adenoviral Standards Working Group workshop will be held at the National Institutes of Health, Bldg. 29B, Conference Rooms A, B, and C, 8600 Rockville Pike, Bethesda, MD 20894.

Contact: Steven R. Bauer, Center for Biologics Evaluation and Research (HFM–521), Food and Drug Administration, Bldg. 29B, rm. 2NN11, Bethesda, MD 20894, 301–827–0684, FAX 301–827–0449, or e-mail: bauer@cber.fda.gov.

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, fax number, and e-mail address) to Steven R. Bauer (address above) by Friday, January 19, 2001. There is no registration fee for the meeting or workshop. Seating is limited, therefore, interested parties are encouraged to register early. Registration at the site will be done on a space available basis on the day of the meeting and workshop, beginning at 8:30 a.m. If you need special accommodations due to a disability, please contact Steven R. Bauer at least 7 days in advance.

Agenda: The Adenoviral Vector Safety meeting will provide a forum for all members of the public to express their concerns about adenoviral vector safety and explore alternatives for enhancing the safety of adenoviral vectors.

The Adenoviral Standards Working Group workshop is cosponsored by FDA's Center for Biologics and Research (CBER) and the Williamsburg BioProcessing Foundation. The workshop will be of primary interest to public health professionals developing new human gene therapy products and manufacturers contemplating the production of such products. The objectives of the workshop are to: (1) Select adenoviruses to use as voluntary reference standards for adenoviral vectors used for human gene therapy products; (2) describe the conditions and facilities to be used when producing bulk quantities of a voluntary reference standard; (3) establish characterization protocols for voluntary reference standards; and (4) address other issues related to voluntary reference standards for adenoviral vectors.

Transcripts: Transcripts of the Adenoviral Vector Safety meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript will also be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: December 29, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–531 Filed 1–8–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic 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: Psychopharmacologic 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 February 14 and 15, 2001, 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Sandra I. Titus or Lauren W. Parcover, 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, e-mail: Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) code 12544. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 14, 2001, the committee will consider the safety and efficacy of new drug application (NDA) 21–253, Zyprexa® (olanzapine intramuscular, Eli Lilly, Inc.), proposed for the rapid control of agitation. On February 15, 2001, the committee will consider the safety and efficacy of NDA 20–919, Zeldox™ (ziprasidone mesylate intramuscular, Pfizer, Inc.), proposed for the acute control and short-term management of the agitated psychotic patient.

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 by February 7, 2001. Oral presentations from the public will be scheduled each day between approximately 1 p.m. to 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 2, 2001,