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,

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.

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

Dated: December 28, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–532 Filed 1–8–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Community Health Center and National Health Service Corps User/Visit Survey (OMB No. 0915–0185)

The purpose of this study is to conduct a sample survey which has the following components: (1) a personal interview survey of Community Health Center (CHC) and National Health Service Corps (NHSC) site users; and (2) a record-based study of visits to CHCs and NHSC sites. CHCs and NHSC sites serve predominantly poor minority medically underserved populations. The proposed user and visit survey will collect in-depth information about CHC and NHSC site users, their health status, the reasons they seek care, their diagnoses, and the services utilized in a medical encounter.

The proposed User/Visit Survey builds on a 1995 User/Visit Survey which was conducted to learn about the process and outcomes of care in CHC users. The 1995 User/Visit Survey included a personal interview of approximately 2000 users of 48 selected CHCs as well as medical record abstractions for about 3000 visits to these same health centers. The interview questionnaire was derived from the National Health Interview Survey (NHIS) conducted by the National Center for Health Statistics (NCHS) and the visit survey was an adaptation of the NCHS National Hospital Ambulatory Medical Care Survey (NHAMCS). Conformance with the NHIS and NHAMCS allowed comparisons between these NCHS surveys and the User/Visit Survey.

The proposed User/Visit Survey was developed using similar questionnaire methodology in conjunction with a contractor and will allow longitudinal comparisons for CHCs with the 1995 version of the survey data, including monitoring of process outcomes over time. This User/Visit Survey is the first year that NHSC non-grantee, freestanding sites will be surveyed.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Total respondents	Hours per response	Total burden hours
Site induction	65 sites	1	65	1	65
Site sampling method	65 sites	1	65	1.5	97.5
User survey	40 users at 65 sites	1	2,600	2	5,200
Visit survey	65 sites	50 records	3,250	.5	1,625
Total	2,795		5,980		6,987.5

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 2, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–473 Filed 1–8–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act, (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of January 2001.

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages

Date and Time: January 11, 2001; 9 a.m.–5:30 p.m.; January 12, 2001; 8 a.m.–4 p.m.

Place: The Doubletree Hotel Park Terrace on Embassy Row, 1515 Rhode Island Avenue, NW., Washington, DC 20005.

The meeting is open to the public.

The full Committee will meet beginning January 11, 2001, and adjourn on January 12, 2001, during the hours cited above. Agenda items will include, but not be limited to: Welcome; plenary discussion of Interdisciplinary Education; presentations by speakers representing: the HRSA Bureau of Health Professions; the Association of