TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Meeting Request and Information Package	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Meeting Request					
CDER	548	1	548	10	5,480
CBER	495	1	495	10	4,950
Total					10,430
Information Packages					
CDER	527	1	527	18	9,486
CBER	415	1	415	18	7,470
Total					16,956
Subtotal					27,386
Less 2,400 hours					24,986
Total					24,986

[1] There are no capital costs or operating and maintenance costs associated with this collection of information

Dated: August 19, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–22100 Filed 8–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Workshop on Bacterial Contamination of Platelets; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Bacterial Contamination of Platelets.'' The objectives of the public workshop are to obtain current information on bacterial contamination of platelets and to encourage future research and development efforts to minimize the risk of transfusion reactions. The public workshop will include an update on the epidemiology of platelet contamination, advances in detection methodology of contamination, and current strategies on bacterial inactivation and contamination avoidance. Results from a U.S. study (the BaCon Study) and similar European studies on microbial contamination will be presented.

Date and Time: The public workshop will be held on Friday, September 24, 1999, from 8:15 a.m. to 5 p.m.

Location: The public workshop will be held at the National Institutes of Health (NIH), NIH Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (CBER) (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX 301–827–2843.

Registration and Requests for Oral Presentations: Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Joseph Wilczek (address above) by Friday, September 10, 1999. Onsite registration will be done on a space-available basis on the day of the public workshop, beginning at 7:30 a.m. There is no registration fee for the public workshop. Space is limited, therefore, interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

A poster session will be set up for the public workshop. All participants are encouraged to present their study results in poster format. A limited number of abstracts may be selected for oral presentations. Send your abstracts and requests for oral presentations to Chiang Syin, Division of Transfusion Transmitted Diseases (HFM–320), CBER, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6465, FAX 301–594–6989, or e-mail ''syin@cber.fda.gov'' by Friday, September 10, 1999.

Transcripts: Transcripts of the 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 meeting transcript will also be available on CBER's website at ''http://www.fda.gov/cber/minutes/workshop-min.htm''.

Dated: August 17, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–22098 Filed 8–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0362]

Advisory Committee for Pharmaceutical Science Site-Specific Stability Subcommittee; 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: Advisory Committee for Pharmaceutical Science Site-Specific Stability Subcommittee.

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 September 22, 1999, 8:30 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, 5630 Fishers Lane, Rockville, MD.

Contact Person: Kimberly Littleton Topper at Topperk@cder.fda.gov or Angie Whitacre at Whitacrea@cder.fda.gov, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane Rockville, MD 20857, (301) 827–7001, or FDA Advisory Committee

Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss the March site-specific stability proposal from the agency and the public comments submitted to Docket No. 98D–0362.

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 September 8, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 8, 1999, 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: August 18, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–22151 Filed 8–25–99; 8:45 am]

BILLING CODE 4160–01–F

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 October 7, 1999, from 8:30 a.m. to 5 p.m., and October 8, 1999 from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Sandra L. Titus, 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, or by e-mail at ''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 October 7, 1999, the committee will consider the safety and efficacy of new drug application (NDA) supplement 20–592/S–009, Zyprexa® (olanzapine, Lilly), proposed to treat psychosis associated with dementia. On October 8, 1999, the committee will consider the safety and efficacy of NDA supplement 19–839/S–026, Zoloft® (sertraline hydrochloride, Pfizer Pharmaceuticals) proposed to treat posttraumatic stress disorder.

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 October 1, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 1, 1999, 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: August 18, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–22099 Filed 8–25–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration

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 Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held November 3, 1999, 8 a.m. to 4:30 p.m.

Location: Hilton, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Sandra L. Titus, 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, or 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 November 3, 1999, the committee will consider the safety and efficacy of new drug application (NDA) supplement 18–936/SE1–058, Prozac® (fluoxetine hydrochloride, Lilly), proposed to treat premenstrual dysphoric disorder.

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 October 27, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 27, 1999, 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: August 18, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

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