

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| Total          |                    |                               |                        |                    | 100         |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 19, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01-7243 Filed 3-22-01; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00D-1033]

#### Agency Information Collection Activities; Announcement of OMB Approval; Information Program on Clinical Trials for Serious and Life-Threatening Diseases

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Information Program on Clinical Trials for Serious and Life-Threatening Diseases" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of November 9, 2000 (65 FR 67385), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0116. The approval expires on March 31, 2004. A copy of the supporting statement for this information collection is available on

the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: March 19, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01-7244 Filed 3-22-01; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

**SUMMARY:** 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:* Pediatric Subcommittee of the Anti-Infective 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 April 23, 2001, 8 a.m. to 5:30 p.m. and on April 24, 2001, 8 a.m. to 3 p.m.

*Location:* Center for Drug Evaluation and Research Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD 20857.

*Contact:* Jayne E. Peterson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: [petersonj@cder.fda.gov](mailto:petersonj@cder.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On April 23, 2001, beginning at 8 a.m., the subcommittee will discuss issues in drug development for pediatric patients with chronic hepatitis C. Beginning at 3:30 p.m., the agency will provide an update to the subcommittee as to recent efforts to ensure adequate labeling and proper pediatric use of

therapies. On April 24, 2001, the subcommittee will discuss issues involved in designing clinical trials to study anti-muscarinics for drooling in children with cerebral palsy and other neurologic diseases, as well as the ethical issues involved in performing studies with children having special needs.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by April 13, 2001. On April 23 and 24, 2001, oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 13, 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: March 16, 2001.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 01-7186 Filed 3-22-01; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Arthritis 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). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Arthritis 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 April 19 and 20, 2001, 8 a.m. to 5 p.m.

*Location:* CDER Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD. Parking and seating is limited.

*Contact:* Kathleen R. Reedy or LaNise S. Giles, 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 or e-mail: reedyk@cdcr.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On April 19, 2001, the committee will discuss new drug application (NDA) 21-239, Aslera® (prasterone, Genelabs Technologies, Inc.) for improvement in disease activity and/or its symptoms in women with mild to moderate systemic lupus erythematosus (SLE) and reduction of corticosteroid requirements in women with mild to moderate SLE.

*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 April 13, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 13, 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.

*Closed Committee Deliberations:* On April 20, 2001, from 8 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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

Dated: March 16, 20001.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 01-7183 Filed 3-22-01; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Pediatric Oncology Subcommittee of the Oncologic 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:* Pediatric Oncology Subcommittee of the Oncologic 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 April 24, 2001, 8 a.m. to 4 p.m.

*Location:* Best Western Washington Gateway Hotel, The Ballroom, 1251 West Montgomery Ave., Rockville, MD.

*Contact:* Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: at SomersK@cdcr.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The subcommittee will discuss parameters used for extrapolation from the adult to the pediatric setting in the hematological malignancies of leukemia and lymphoma.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by April 17, 2001. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., and 1 p.m. and 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 April 17, 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: March 16, 2001.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

[FR Doc. 01-7185 Filed 3-22-01; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science; 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:* Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science.

*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 May 3, 2001, 8:30 a.m. to noon.

*Location:* Center for Drug Evaluation and Research Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD.

*Contact:* Nancy Chamberlin or Jayne E. Peterson, 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: CHAMBERLIN@cdcr.fda.gov, 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 meeting will discuss strategies to identify promising areas of nonclinical scientific research to develop biomarkers and/or other evolving molecular technologies to identify or predict: (1) Drug-induced cardiac tissue injury, and (2) drug-induced vasculitis.

*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 April 20, 2001. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m. Time allotted for