Dated: April 4, 2003.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 03–9064 Filed 4–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral 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: Antiviral 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 May 13 and 14, 2003, from 8 a.m. to 5 p.m.

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

Contact Person: Tara P. Turner, 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: *TurnerT@cder.fda.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 13, 2003, the committee will discuss new drug applications (NDA) 21–567 and 21–568, REYATAZ (atazanavir sulfate) capsules and powder for oral use, Bristol-Myers Squibb Co., proposed for the treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents. On May 14, 2003, the committee will discuss supplemental new drug application (SNDA) 20–550/S–019, VALTREX (valacyclovir hydrochloride) caplets, GlaxoSmithKline, proposed for reduction of the risk of transmission of genital herpes with the use of suppressive therapy.

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 May 6, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 13, 2003, and between approximately 11 a.m. and 12 noon on May 14, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 6, 2003, 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.

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 Tara Turner at least 7 days in advance of the meeting.

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

Dated: April 7, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–9031 Filed 4–11–03; 8:45 am]

BILLING CODE 4160–01–S

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 May 16, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD, 301–652–2000.

Contact Person: Karen M. Templeton-Somers, 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: *SomersK@cder.fda.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) code 12543. Please call the Information Line for up to date information on this meeting.

Agenda: The committee will discuss supplemental new drug application (sNDA) 20–690, supplement SE1–020, ARICEPTR (donepezil hydrochloride tablets), Eisai Medical Research Inc., indicated for the treatment of vascular dementia. The background material will become available no later than the day before the meeting and will be posted under the Peripheral and Central Nervous System Drugs Advisory Committee docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.* (Click on the year 2003 and scroll down to the Peripheral and Central Nervous System Drugs Advisory Committee meetings.)

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 May 9, 2003. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 9, 2003, 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.

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 Karen Templeton-Somers at least 7 days in advance of the meeting.

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

Dated: April 7, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–9032 Filed 4–11–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Manufacturing 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: Manufacturing 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 21 and 22, 2003, from 8:30 a.m. to 5 p.m.

Location: Marriott Washingtonian Center, Ballrooms A, B, C, and D, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Kathleen Reedy, 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: *REEDYK@cder.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: On May 21, 2003, the subcommittee will discuss: (1) The mission of the subcommittee; and (2) direction of the Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century: A Risk-Based Approach. On May 22, 2003, the subcommittee will discuss: (1) The regulatory approaches regarding aseptic manufacturing; and (2) process analytical technologies and transition from the Advisory Committee for Pharmaceutical Science—Process Analytical Technologies Subcommittee to Manufacturing Subcommittee.

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 May 13, 2003. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 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 May 13, 2003, 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.

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 Kathleen Reedy at least 7 days in advance of the meeting.

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

Dated: April 7, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–9029 Filed 4–11–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0134]

Team Biologics Program Effectiveness; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: Team Biologics Program Effectiveness. The Center for Biologics Evaluation and Research and the Office of Regulatory Affairs, FDA, are sponsoring an open public meeting to solicit views and comments in an effort to measure the effectiveness of the Team Biologics Program as it relates to the inspections of manufacturers of vaccines, allergenics, fractionated plasma products, licensed in vitro diagnostics, and therapeutic products. The goal of the public meeting is to give stakeholders the opportunity to provide input on how they think the agency should measure the effectiveness of the Team Biologics Program. We will use the information obtained to identify criteria to prospectively evaluate the Team Biologics Program.

DATES: The public meeting will be held on Wednesday, May 21, 2003, from 8 a.m. to 12 noon.

Submit requests via fax or e-mail by May 1, 2003, to make an oral presentation. Submit a copy of all presentation materials by May 15, 2003. If you are not making an oral presentation, submit registration information by May 12, 2003.

Submit written or electronic comments by June 10, 2003.

ADDRESSES: The public meeting will be held at the Parklawn Bldg., conference room D, 5600 Fishers Lane, Rockville, MD 20857.

Submit requests to make an oral presentation, registration information, and any presentation material to Melanie Whelan (*see* **FOR FURTHER INFORMATION CONTACT**). The requested registration information is listed in section II of this document.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Melanie N. Whelan, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–2000, FAX 301–827–3079, or e-mail: *Whelan@cber.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Scope of Public Meeting

FDA is seeking input on ways to evaluate the Team Biologics Program. The Team Biologics Program, established in 1997, is a partnership between FDA's Center for Biologics Evaluation and Research and the Office of Regulatory Affairs, which uses the diverse skills and knowledge of both organizations to focus resources on inspectional and compliance issues in the biologics area. Comments are sought at this public meeting about specific methods, tools, criteria, and metrics that could be used in this effort. In presentations we ask that you