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

specifically address criteria that FDA may consider in assessing the following areas:

1. Industry compliance with applicable laws and regulations,
2. The consistency of our inspection and compliance activities,
3. The effects of our inspection and compliance activities on product quality, and
4. The impact of our approach on public health.

II. Registration and Requests for Oral Presentations

You must preregister by May 1, 2003, if you would like to make an oral presentation. Please send your name, title, affiliation, street address, e-mail address, and telephone and fax numbers, along with a short description of the topics you wish to address, to Melanie Whelan. Due to the time constraints of this meeting, only 15 oral presentation requests can be accepted, and each presentation will be limited to 10 minutes. Each person who submits a request will receive a response by May 6, 2003, stating whether they have been included in the program. Please submit a copy of all presentation materials to Melanie Whelan by May 15, 2003.

We encourage early registration because seating is limited to the first 100 registrants. Registration closes on Monday, May 12, 2003. Please send your name and affiliation to Melanie Whelan. You will receive confirmation of your registration. There is no registration fee.

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

III. Request for Comments

The agency has established a docket to receive any ideas regarding the Team Biologics Program. Regardless of attendance at the public meeting, interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments. Submit a single copy of electronic comments or two copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Transcripts

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

Dated: April 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–9063 Filed 4–11–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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: Vaccines and Related Biological Products 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 8, 2003, from 1:30 p.m. to 4 p.m.

Location: Food and Drug Administration, 29 Lincoln Dr., bldg. 29B, conference room A, Bethesda, MD. This meeting will be held by a telephone conference call. The public is welcome to attend the open session of the meeting at the specified location.

Contact Person: Jody G. Sachs or Denise H. Royster, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–71), 301 827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will review and discuss the intramural research programs of the Laboratory of Mycobacterial Diseases & Cellular Immunology and the Laboratory of Method Development, in the Office of Vaccines Research and Review.

Procedure: On May 8, 2003, from 1:30 p.m. to 3:30 p.m., the meeting is open to the public. 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 25, 2003. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 25, 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.

Closed Committee Deliberations: On May 8, 2003, from 3:30 p.m. to 4 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The meeting will be closed to discuss personal information concerning individuals associated with the intramural laboratory research programs.

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 Jody G. Sachs or Denise H. Royster 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. 03–9030 Filed 4–11–03; 8:45 am]

BILLING CODE 4160–01–S