heading of this document. You should annotate and organize your comments to identify the specific questions to which they refer. To ensure timely handling, the outer envelope should be clearly marked with the docket number listed in the heading of this document along with the statement ''Counterfeit Drug Meeting.'' Comments to the docket can be reviewed in the Division of Dockets Management Monday through Friday between 9 a.m. and 4 p.m.

IV. Transcripts

You may request a copy of the transcript of the meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 14 working days after the meeting at a cost of 10 cents per page or on compact disc at a cost of $14.25 each. You can also examine the transcript Monday through Friday between 9 a.m. and 4 p.m. in the Division of Dockets Management.

V. Electronic Access

Persons with access to the Internet may obtain additional information on the public meeting at *http://www.fda.gov/oc/initiatives/counterfeit/*.

Dated: September 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–22789 Filed 9–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Biotechnology Subcommittee of the Food 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: Food Biotechnology Subcommittee of the Food 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 September 24, 2003, from 8:30 a.m. to 4:30 p.m.

Location: JW Marriott Hotel, 1331 Pennsylvania Ave., Washington, DC, 202–314–4714.

Contact Person: Michael Watson, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3122, or FDA Advisory Committee Information Line, 1–800–741–8138 301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: The purpose of the meeting is to discuss the science-based approaches to the molecular characterization of bioengineered foods as part of FDA's safety assessment.

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 10, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. to 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 10, 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 Michael Watson 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: August 28, 2003.

Peter J. Pitts,

Asssociate Commissioner for External Affairs.

[FR Doc. 03–22581 Filed 9–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General and Plastic Surgery Devices Panel of the Medical Devices 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: General and Plastic Surgery Devices Panel of the Medical Devices 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 October 14, 2003, from 8 a.m. to 10 p.m., and October 15, 2003, from 7:30 a.m. to 5 p.m.

Location: Gaithersburg Marriott, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: David Krause, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 141, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12519. Please call the Information Line or access the Internet at *http://www.fda.gov/cdrh/panelmtg.html* for up-to-date information on this meeting.

Agenda: On October 14 and 15, 2003, the committee will discuss, make recommendations, and vote on a premarket approval application for Silicone Gel-Filled Breast Prostheses. Background information, including the agenda and questions for the committee, will be available to the public on October 10, 2003, on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

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 30, 2003. Oral presentations from the public will be scheduled on October 14, 2003, between approximately 8 a.m. and 12 noon, and on October 15, 2003, between approximately 7:30 a.m. and 11:30 a.m. Time allotted for each presentation is limited. Those desiring to make formal

oral presentations should notify the contact person before September 30, 2003, and submit a brief statement of the general nature of the comments they wish to present, and the names and addresses of proposed participants.

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 AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, 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: August 29, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–22580 Filed 9–4–03; 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; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science. This meeting was announced in the **Federal Register** of August 14, 2003 (68 FR 48614). The amendment is being made to reflect a change in the date and time, agenda, and procedure portions of the meeting. Due to administrative complications, all topics previously announced will be discussed on September 17, 2003. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Hilda Scharen, 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 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.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 2003, FDA announced that a meeting of the Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science would be held on September 17 and 18, 2003. On page 48614, in the second column, the agenda portion of the meeting is amended to read as follows:

Date and Time: The meeting will be held on September 17, 2003, from 8:30 a.m. to 5 p.m.

Agenda: On September 17, 2003, the subcommittee will discuss the following topics: (1) Quality by design and how it is distinct from approaches that attempt to test in quality; and (2) define principles by which risk management is integrated into decisionmaking.

Procedures: Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 29, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–22628 Filed 9–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0385]

Draft ''Guidance for Industry: Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information'' dated September 2003. The draft guidance document provides recommendations to applicants on preparing and using comparability protocols for changes in chemistry, manufacturing, and controls of products in approved marketing applications. The guidance applies to comparability protocols that applicants would submit in biologics license applications (BLAs) or supplements to these applications for therapeutic recombinant deoxyribonucleic acid (DNA) derived protein products, naturally derived protein products, plasma derivatives, vaccines, allergenics and therapeutic DNA plasmids. The guidance also applies to new drug applications (NDAs), abbreviated new drug applications (ANDAs), new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), or supplements to these applications for protein drug products, and certain peptides that are not sufficiently characterizable (i.e., complex mixture of small peptides).

DATES: Submit written or electronic comments on the draft guidance by December 4, 2003, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448; or to the Office of Training and Communications, Division of Communications Management, Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857; or to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (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: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210; or Stephen K.