

III. Comments

The administrative record of this public meeting will remain open for 30 days after the public meeting. Interested persons may submit to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments by June 11, 2004. You may also send comments to the Division of Dockets Management via e-mail to FDADockets@oc.fda.gov. Submit two paper copies of comments, identified with the docket number found in brackets in the heading of this document. Individuals may submit one paper copy. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Comments may be placed on the Internet and, if so, will be available for public viewing.

IV. Meeting Notes

You may request a copy of the notes of the public 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 15 working days after the public meeting, at a cost of 10 cents per page. You may examine the notes of the public meeting after June 11, 2004, at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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 March 25, 2004, from 8 a.m. to 5 p.m.

Location: Hilton Washington, DC North/Gaithersburg, Ballroom Salons A, B, C, and D, 620 Perry Pkwy., 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 3014512519. Please call the Information Line or access the Internet address of <http://www.fda.gov/cdrh/panelmtg.html> for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an injectable device intended for use in the correction of lipoatrophy of the face in human immunodeficiency virus (HIV) positive patients. Background information for this PMA, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. The material for this meeting will be posted on March 24, 2004.

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 March 15, 2004. On March 25, 2004, oral presentations from the public will be scheduled for approximately 1 hour at the beginning of committee deliberations and for approximately 1 hour near the end of the committee deliberations. Time allotted for oral public presentations may be limited. Those desiring to make formal oral presentations should notify the contact person before March 15, 2004, 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 Shirley

Meeks, Conference Management Staff, at 301-594-1283, ext. 105, 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: March 1, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-4983 Filed 3-4-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000D-1350]

Draft Guidance for Industry on Labeling for Combined Oral Contraceptives; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Labeling for Combined Oral Contraceptives." The draft guidance contains recommended labeling for combined oral contraceptives. This is the second draft of a guidance being issued on this topic.

DATES: Submit written or electronic comments on the draft guidance by May 4, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Margaret Kober, Center for Drug Evaluation and Research (HFD-580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4260.

SUPPLEMENTARY INFORMATION: