Application No.	Drug	Applicant
ANDA 70–656	Dopamine Hydrochloride Injection USP, 40 mg/mL.	Abbott Laboratories.
ANDA 70–657	Dopamine Hydrochloride Injection USP, 80 mg/mL.	Do.
ANDA 73–611	Diphenhydramine Hydrochloride Cough Syrup, 12.5 mg/5 mL.	Cumberland-Swan, Inc., 1 Swan Dr., Smyrna, TN 37167.
ANDA 80–195	Potassium Chloride Injection.	Miles, Inc.
ANDA 80–211	Prednisolone Tablets, 5 mg.	Private Formulations, Inc., 460 Plainfield Ave., Edison, NJ 08818.
ANDA 80–830	Vitamin A Capsules USP, 15 mg.	Del Ray Labs, Inc., 22–20th Ave., NW., Birmingham, AL 35215.
ANDA 83–021	Sulfacetamide Sodium Ophthalmic Solution USP, 10%, 15%, and 30%.	AKORN, Inc., 1222 West Grand, Decatur, IL 62526.
ANDA 83–256	Alcohol in Dextrose Injection USP, 5%/5%.	Baxter Healthcare Corp., Rte. 120 and Wilson Rd., Round Lake, IL 60073–0490.
ANDA 84–652	Chlorotrianisene Capsules USP, 12 mg.	Banner Pharmacaps, 200730 Dearborn St., P.O. Box 2157, Chatsworth, CA 91313–2157.
ANDA 84–708	Triamcinolone Tablets, 2 mg.	Roxane Laboratories, Inc., P.O. Box 16532, Columbus, OH 43216–6532.
ANDA 84–775	Triamcinolone Tablets, 4 mg.	Teva Pharmaceuticals, USA.
ANDA 85–697	Phendimetrazine Tartrate Tablets, 35 mg (pink).	Private Formulations, Inc.
ANDA 85–914	Phendimetrazine Tartrate Tablets, 35mg.	Manufacturing Chemist, Inc., c/o Integrity Pharmaceutical Corp., 5767 Thunderbird Rd., Indianapolis, IN 46236.
ANDA 86–192	Hydrochlorothiazide Tablets, 25 mg and 50 mg.	M. M. Mast & Co., 4152 Ruple Rd., Cleveland, OH 44121.
ANDA 86–217	Chlordiazepoxide Capsules, 10 mg.	Do.
ANDA 86–259	Trichlormethiazide, 4 mg.	Do.
ANDA 86–521	Dextroamphetamine Sulfate Tablets, 5 mg.	Do.
ANDA 86–523	Phenazine Capsules, 35 mg.	Do.
ANDA 86–524	Phenazine Capsules, 35 mg.	Do.
ANDA 86–525	Phenazine Capsules, 35 mg.	Do.
ANDA 86–787	Sustac (nitroglcerin) Extended-release Oral Tablets, 10 mg.	Forest Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731.
ANDA 87–255	Quinidine Sulfate Tablets, 200 mg.	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
ANDA 87–229	Nitrobon (nitroglycerin extended-release capsules) Capsules.	Inwood Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731.
ANDA 87–305	Phendimetrazine Tartrate Tablets, 35 mg.	M. M. Mast & Co.
ANDA 87–544	Nitrobon (nitroglycerin extended-release capsules) Capsules.	Inwood Laboratories, Inc.
ANDA 87–917	Theophylline Syrup, 80 mg/15 mL.	Ferndale Laboratories, Inc., 780 West Eight Mile Rd., Ferndale, MI 48220.
ANDA 89–577	Hydrocortisone Sodium Succinate for Injection USP, 100 mg/mL.	Abbott Laboratories.
ANDA 89–578	A-Hydrocort (Hydrocortisone Sodium Succinate for Injection USP), 250 mg/vial.	Do.
ANDA 89–579	A-Hydrocort (Hydrocortisone Sodium Succinate for Injection USP), 500 mg/vial.	Do.
ANDA 89–580	A-Hydrocort (Hydrocortisone Sodium Succinate for Injection USP), 1 gram/vial.	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 22, 1999.

Dated: September 8, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–24595 Filed 9–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal 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: Cardiovascular and Renal 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 October 14, 1999, 9 a.m. to 5:30 p.m.

Location: National Institutes of Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Parking in the Clinical Center is reserved for Clinical Center patients and their visitors. If you must drive, please use an outlying lot such as Lot 41B. Free shuttle bus service is provided from Lot 41B to the Clincal Center every 8 eight minutes during rush hour and every 15 minutes at other times.

Contact Person: Joan C. Standaert, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5630 Fishers Lane,

Rockville, MD 20857, 419–259–2511, or John M. Treacy, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting. Current information may also be accessed on the Internet at the FDA Website ''www.fda.gov''.

Agenda: On October 14, 1999, the committee will discuss acute coronary syndromes.

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 October 7, 1999. Oral presentations from the public will be scheduled on October 14, 1999, between approximately 9 a.m. and 10 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 7, 1999, 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: September 13, 1999

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–24593 Filed 9–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Obstetrics and Gynecology 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). At least one portion of the meeting will be closed to the public.

Name of the Committee: Obstetrics and Gynecology 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 4, 1999, 8 a.m. to 5 p.m.

Location: Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Contact Person: Elisa D. Harvey, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180 or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12524. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 4, 1999, in the morning session, the committee will discuss issues for new barrier contraceptive devices such as premarket study design, prescription versus over-the-counter availability, and premarket versus postmarket studies. The following current guidance documents are available as references: (1) ''Testing Guidance for Male Condoms Made from New Material,'' (2) ''Guidance for Industry: Uniform Contraceptive Labeling,'' and (3) ''Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases.'' Single copies of these guidance documents are available to the public by contacting the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 1–800–638–2041 or by faxing your request to 301–443–8818 and requesting the document by shelf numbers 455, 1251, and 384, respectively. They are also available on the Internet using the World Wide Web at http://www.fda.gov/cdrh/ode/oderp455.html, http://www.fda.gov/cdrh/ode/contrlab.html, and http://www.fda.gov/cdrh/ode/384.pdf.

In the afternoon session, the committee will discuss clinical study requirements for new nonextirpative methods of treating uterine fibroids.

Procedure: On October 4, 1999, from 9 a.m. to 5 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 September 27, 1999. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. and between approximately 1:30 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before September 27, 1999, 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 October 4, 1999, from 8 a.m. to 9 a.m., the meeting will be closed to permit the committee to hear and review trade secret and/or confidential commercial information regarding pending and future device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

FDA regrets that it was unable to publish this notice 15 days prior to the October 4, 1999, Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 17, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–24711 Filed 9–17–99; 3:37 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Psychopharmacologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of August 26, 1999 (64 FR 46687). The