consumer segments (e.g., users of relevant regulated products or at-risk population groups) and the number of labeling options that may need to be tested.

Dated: December 16, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–32160 Filed 12–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1833]

SoloPak Laboratories, Inc.; Withdrawal of Approval of 1 New Drug Application and 38 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 21, 1999 (64 FR 33097; corrected July 19, 1999 (64 FR 38675)). The document, which announced the withdrawal of approval of 1 new drug application (NDA) and 38 abbeviated new drug applications held by SoloPak Laboratories, Inc., inadvertently withdrew approval of NDA 19–961 for Ganite (gallium nitrate). FDA has subsequently learned that SoloPak, at the time it requested withdrawal of this NDA, was not its holder. Therefore, SoloPak was not authorized to make such a request. FDA confirms that approval of NDA 19–961, currently held by Genta, Inc., is still in effect.

DATES: Effective July 19, 1999.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Dated: November 25, 2002.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 02–32161 Filed 12–20–02; 8:45 am]

BILLING CODE 4160–01–S

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 January 6, 2003, from 8:30 a.m. to 5 p.m.; and on January 7, 2003, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Jayne E. Peterson, 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, petersonj@cder.fda.gov, 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. When available, background materials for this meeting will be posted 1-business day prior to the meeting on the FDA Web site at www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2003 and scroll down to Cardiovascular and Renal Drugs Advisory Committee.)

Agenda: On January 6, 2003, beginning at 8:30 a.m., the committee will discuss supplemental new drug application (SNDA) 20–386/S–032, COZAAR (losartan potassium) Tablets, Merck and Co., for the proposed indication of reduction in the risk of cardiovascular morbidity and mortality as measured by the combined incidence of cardiovascular death, stroke, and myocardial infarction in hypertensive patients with left ventricular hypertrophy. On January 7, 2003, beginning at 8 a.m., the committee will discuss SNDA 20–297/S–009, COREG (carvedilol), GlaxoSmithKline, for the proposed indication to reduce mortality and the risk of infarction in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction ≤40 percent.

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 December 23, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on January 6 and 7, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 23, 2002, 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 Jayne E. Peterson 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: December 16, 2002.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 02–32159 Filed 12–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: November 2002

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of November 2002, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal