the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 16, 2002.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 02–32183 Filed 12–20–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0063]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Consumer Surveys on Food and Dietary Supplement Labeling Issues

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments on the collection of information by January 22, 2003.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Consumer Surveys on Food and Dietary Supplement Labeling Issues—(OMB Control Number 0910–0492)—Extension

FDA is requesting an extension of the OMB approval of consumer surveys to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting the labeling of conventional foods and dietary supplements. Determining how consumers are likely to interpret various kinds of claims, disclaimers, warnings, caution statements, and notice statements that might appear in labeling is critical to agency decisionmaking under the Federal Food, Drug, and Cosmetic Act and the first amendment. It is often necessary to test actual or proposed labeling statements in realistic situations with typical consumers to determine what these label statements are communicating to consumers.

FDA or its contractor will collect and use information gathered from telephone, mail, shopping mall intercept, or Internet surveys to evaluate how consumers understand and respond to existing label statements, label statements proposed by industry or consumers, and other label statements that are under consideration as part of FDA's policy development process. Potential respondents to the surveys will be individual consumers either randomly chosen to represent specified populations or randomly assigned to experimental treatment conditions to control for the effects of individual differences in the population on the interpretation of label statements. In all instances, FDA will strive to collect a representative sample of individuals from the overall population or from relevant population groups as appropriate. FDA's general selection method will use stratification, with random sampling within the strata, to achieve representativeness for both overall populations and sensitive subpopulations, such as at-risk individuals or user segments. In the rare cases where geography is a limiting factor, FDA will use population-based cluster sampling to limit Government expense while preserving the statistical properties of the sample.

Respondents will provide background information and respond to package labels that contain the variations of label statements to be tested. Measures will include both self-reported comprehension and acceptance, as well as direct behavioral measures of consumer use and understanding of the package labeling.

FDA will use the information from the surveys in evaluating regulatory and policy options with respect to labeling. The agency often lacks empirical data about how consumers understand and respond to statements they might see in product labeling. The information gathered from such surveys can be used to test consumer comprehension and behavioral impact of various label statements and formats, taking into account the existing distribution of behavior, knowledge, and attitudes in the population that provides the context for understanding such statements. The surveys will help FDA assess consumer reactions to existing and proposed label statements.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Mail questionnaire	1,000	1	1,000	1	1,000
Telephone survey	2,000	1	2,000	.5	1,000
Internet or mail intercept survey	4,000	1	4,000	.5	2,000
Total					4,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates assume that as many as one mail survey project, one telephone survey project, and two Internet or mail intercept survey projects may be done on an annual basis. Estimates are based on the expected number of respondents necessary to obtain a statistically significant representation of important

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