

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 abbreviated 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 exclusion 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

Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject, city, state	Effective date
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PROGRAM-RELATED CONVICTIONS

ADEM, SUNDAY JOSEPH	12/19/2002
INGLEWOOD, CA	
DE AQUINO, ANTHONY	12/19/2002
HO-HO-KUS, NJ	
DRAKE, MELISSA ANN	12/19/2002
MAYSEL, WV	
ELSAIED, SAYAD MOSTAFA KAMAL	12/19/2002
LOS ANGELES, CA	
FONTENOT, MONA	12/19/2002
JARREAU, LA	
FORTIN, KAREN M	12/19/2002
CASCO, ME	
JACKSON, DONALD EDWARD FAYETTEVILLE, TN	12/19/2002
JONES, LORETTA ANN	12/19/2002
SIGNAL HILL, CA	
JONES, LINDA GAIL	12/19/2002
FLORENCE, SC	
MAGLIO, GLYNIS BROWN	12/19/2002
POTTSBORO, TX	
MEN, YEN	12/19/2002
KENT, WA	
MILES, ALICE BURNS	12/19/2002
TALLAHASSEE, FL	
NADOLNI, DIANE MARIE	12/19/2002
LAKELAND, TN	
NURSERY ROAD VILLA, INC CLEARWATER, FL	12/19/2002
O'NEAL, JACQUELINE	12/19/2002
MIRAMAR, FL	
OSORIA, KARLA	12/19/2002
RESEDA, CA	
OTIS, STEPHEN MASON	12/19/2002
MILTON, FL	
PEREZ, LEONARDO ANDREZ PEMBROKE PINES, FL	06/04/2001
QUARANTA, NICHOLAS	12/19/2002
MIAMI, FL	
RICHARDS, PATRICIA ANN	12/19/2002
WRIGHT CITY, OK	
RODRIGUEZ, FRANCISCO	12/19/2002
MIAMI, FL	
VIEITES, MERCEDES	01/10/2002
PEMBROKE PINES, FL	
YANCY, KAUWYANA RASHAE LITTLE ROCK, AR	12/19/2002

FELONY CONVICTION FOR HEALTH CARE FRAUD

BOYD, JONATHAN YATES	12/19/2002
HOUSTON, TX	
DESCANT, STEVEN PATRICK	12/19/2002

Subject, city, state	Effective date
SAN ANTONIO, TX	
REAUME, DAVID GEORGE	12/19/2002
SAN MARCOS, TX	

FELONY CONTROL SUBSTANCE CONVICTION

DELEHANTY, ALLISON JILL ...	12/19/2002
BETHALTO, IL	
HAYS, JON RILEY	12/19/2002
MARION, IL	
STILLWILL, GEORGE A	12/19/2002
FORT DIX, NJ	
WOLF, LESLIE RAE	12/19/2002
WAYNESVILLES, OH	
WOLMERING, CAROLYN A	12/19/2002
CLARENCE CTR, NY	

PATIENT ABUSE/NEGLECT CONVICTIONS

ASHER, JONATHAN PATRICK FT COLLINS, CO	12/19/2002
BEST SARVER, REBECCA	12/19/2002
ENID, OK	
BURTON, PHILLIP TAROME ..	12/19/2002
LANCASTER, CA	
ELLIOTT, NICOLE LEE ANN ...	12/19/2002
SPOKANE, WA	
HOBSON, JAMES T	12/19/2002
HOULKA, MS	
LEE, WINFRED	12/19/2002
WASHINGTON, DC	
MARTIN, SCOTT W	12/19/2002
JOHNSON CITY, TN	
MOORE, CONSTANCE	12/19/2002
ROCHESTER, NY	
RANSON, CLIFFORD	12/19/2002
COLUMBIA, SC	
SMITH, KAREN KELLY	12/19/2002
FAIRFAX, OK	
SPEIGHT, KIEA	12/19/2002
ENID, OK	
WEBB, CURTIS O'NEAL	12/19/2002
BANGOR, PA	

CONTROLLED SUBSTANCE CONVICTIONS

HODJATI, HASSAN H.	
SILVER SPRING, MD	

LICENSE REVOCATION/SUSPENSION/ SURRENDERED

ANDERSON, SUSAN COLLEEN	12/19/2002
LUSBY, MD	
ANDERSON, JOY	12/19/2002
FARGO, ND	
ANDERSON, JORDAN BAXTER	12/19/2002
OMAHA, NE	
ANTHONY, DAWN M	12/19/2002
GREENSBORO, NC	
ASPLIN, MICHAEL S	12/19/2002
SEMI VALLEY, CA	
ATKINSON, ORAN W	12/19/2002
BRONX, NY	
BAIER, FIN TRAVIS	12/19/2002
PRESCOTT, AZ	
BAKER, KEVIN WAYNE	12/19/2002
NORFOLK, NE	
BECKER, STACY LYNN SHIRLEY	12/19/2002

Subject, city, state	Effective date
RANCHO PALOS VERDES, CA	
BELLAIRE, EMILY	12/19/2002
ANTELOPE, CA	
BIRD, VICTORIA HAINES	12/19/2002
CHANDLER, AZ	
BOHANNON, RHONDA C	
BRISCOE	12/19/2002
PLEASUREVILLE, KY	
BUSH, FRANK J	12/19/2002
DENVER, CO	
CANTILADO, STEVEN PHIL-LIP	12/19/2002
SAN PEDRO, CA	
CARLONI, SUSAN M	12/19/2002
PROVIDENCE, RI	
CELAYA, LINDA GAIL	12/19/2002
LOS ANGELES, CA	
CHRISTOPHERSON, ANNETTE L	12/19/2002
SCHERTZ, TX	
COLLINS, BEVERLY R	12/19/2002
PORTLAND, ME	
CONNER, DENITA DEANNE ...	12/19/2002
LAKE CHARLES, LA	
COOPER, DEBRA A	12/19/2002
ROANOKE, VA	
CREEF, BRENDA S	12/19/2002
MIDLOTHIAN, VA	
CRUZ, SHANNON L	12/19/2002
PUEBLO WEST, CO	
DAMON, DONNA LYNN	12/19/2002
TUCSON, AZ	
DANSIE, VAE ENNISS	12/19/2002
RIVERTON, UT	
DE GASTON, ALEXIS NEAL ...	12/19/2002
MORENO VALLEY, CA	
DIAZ, FREDERICK	12/19/2002
BRONX, NY	
DORIAN, JEFFREY PHILIP	12/19/2002
DAVIE, FL	
DREW, ARVIETTE D	12/19/2002
PORTSMOUTH, VA	
DYESS, DANIEL KEITH	12/19/2002
MOBILE, AL	
EDINGTON, STEVEN NOLAN PARAGOULD, AR	12/19/2002
EDWARDS, CARMEN WILLIAMS	12/19/2002
ANTIOCH, CA	
ESPINO, GRISELDA	12/19/2002
SANTA ANA, CA	
FELDMAN, NORMA J	12/19/2002
HARTSDALE, NY	
FOREMAN, JULIE ANN	12/19/2002
HASTINGS, NE	
FRAULINI, MICHAEL MARK	12/19/2002
PORTSMOUTH, OH	
GOODWIN, BARBARA G	12/19/2002
DICKSON, TN	
GORE, OWEN C	12/19/2002
CHANDLER, AZ	
GRAY, HARRY L	12/19/2002
BRADFORD, VT	
GREEN, MARY ELISE	12/19/2002
TUCSON, AZ	
GREGOR, CHARLENE M	12/19/2002
PARK CITY, UT	
GROUT, RANDALL L	12/19/2002
LENOIR, NC	
HAMPTON, MARY CAROL	12/19/2002
GAINSVILLE, TX	
HANLON, DONNA C	12/19/2002

Subject, city, state	Effective date	Subject, city, state	Effective date	Subject, city, state	Effective date
OAKFORD, PA		EUREKA SPRINGS, AR		SPANISH FORT, AL	
HENRICHSSEN, DAVID A	12/19/2002	RISING, ALISA ANN	12/19/2002	SERVIAL SYSTEMS	12/19/2002
PHOENIX, AZ		OGALLALA, NE		MIAMI, FL	
HERRING, ALMA JANETTE		ROONEY, LORI COUTRE	12/19/2002		
GRIFFIN	12/19/2002	CARLISLE, PA		QUALITY IMPROVEMENT ORGANIZATION	
LAKE HAVASU CITY, AZ		ROSENTHAL, MICHAEL JAY ..	12/19/2002	CASES	
HILL, EDGAR H JR	12/19/2002	CLAREMONT, CA		EDWARDS, GREGSON	11/27/2002
VIRGINIA BCH, VA		SALAS, ANGELA AGATHA	12/19/2002	BROWNSVILLE, TX	
HOLLAR, KIMBERLY J	12/19/2002	SOMERTON, AZ			
MAIDEN, NC		SALAZAR, HOPE	12/19/2002		
HORTERT, SHERYL L	12/19/2002	SANFORD, CO			
CORAOPOLIS, PA		SCHMELTER, BRENDA L	12/19/2002		
JOERG, BRIAN S	12/19/2002	MARICOPA, AZ			
BASEHOR, KS		SCHUETZ, LAWANDA			
JOHNSON, KIMBERLY KAY ...	12/19/2002	MICHELLE	12/19/2002		
ALEX, OK		AUBURN, NE			
JOHNSON, ELLEN DEE	12/19/2002	SCOTT, LYNDA MARIE	12/19/2002		
CYPRESS, CA		PEORIA, AZ			
KAUFFMAN, FRANCINE J	12/19/2002	SELF, RHONDA SUE	12/19/2002		
VISTA, CA		SAN DIEGO, CA			
KEA, WILLIAM PAUL	12/19/2002	SKROCKI, BRIAN R	12/19/2002		
PASADENA, CA		PLYMOUTH MEETING, PA			
KENNEDY, JANET MARIE	12/19/2002	SMITH, JEFFRY ALAN	12/19/2002		
MAYER, AZ		RIVERSIDE, CA			
KILLION, PATTY ANN	12/19/2002	SMITH, YTH ZOFFMAN	12/19/2002		
SALT LAKE CITY, UT		LITTLETON, CO			
KING, WILLIAM S	12/19/2002	SMITH, MARY LEE	12/19/2002		
SAN DIEGO, CA		GRAND ISLAND, NE			
KUNTZ, RITA ANN	12/19/2002	SNYDER, MICHELLE JEAN ...	12/19/2002		
SALINA, KS		WISNER, NE			
LEYBA, SHERRY	12/19/2002	SPINAZZOLA, VICTORIA	12/19/2002		
PARADISE, CA		PHOENIX, AZ			
LIPNICK, ROBERT N	12/19/2002	STONE, SUSAN M	12/19/2002		
WASHINGTON, DC		DAYTON, OH			
LONG, JAMES M	12/19/2002	TURNER, HERBERT LLOYD ..	12/19/2002		
BIRMINGHAM, AL		CROWN POINT, IN			
LOOMAN, LESLIE CLINTON ...	12/19/2002	VILLANUEVA, GRACIELA	12/19/2002		
EDMOND, OK		REEDLEY, CA			
MANOJLOVICH, PAMELA		WALLINGFORD, TERESA			
SUE	12/19/2002	LEANN	12/19/2002		
SEWICKLEY, PA		WICHITA, KS			
MARSZALEK-PATCH, JAC-		WARD, GREGORY ALAN	12/19/2002		
QUELINE S	12/19/2002	TOPEKA, KS			
VERNON, CT		WEINHEIMER, EUGENE H	12/19/2002		
MCALISTER, KIMBERLY		COLUMBIA, MO			
MICHELLE	12/19/2002	WHITMORE, A JAMES III	12/19/2002		
SHAWNEE, OK		NEW ORLEANS, LA			
MCGANN, JON D	12/19/2002	WILLIAMS, JON MARK	12/19/2002		
ENCINITAS, CA		LAKE CHARLES, LA			
MUIRHEAD, RICHARD JAMES		WILSON, MARC DAVID	12/19/2002		
JR	12/19/2002	EL PASO, TX			
SEATTLE, WA		WINANS, STEVEN RONALD ...	12/19/2002		
MURPHY, DONNA LYNN	12/19/2002	PHOENIX, AZ			
MERRIAM, KS		WINDSOR, MICHAEL SHAWN	12/19/2002		
NEDD, JOSETTA	12/19/2002	ROWLETT, TX			
SHREVEPORT, LA		YU, JUN	12/19/2002		
NEHLS, DONAVAN EUGENE		ROWLAND HGTS, CA			
SR	12/19/2002	ZIEGEN, GARY V	12/19/2002		
CALICO ROCK, AR		FRESNO, CA			
NELSON, J KENT	12/19/2002				
BOUNTIFUL, UT					
OBERSTAR, TERRILEE MAR-					
GARET	12/19/2002				
LANCASTER, CA					
PATEL, PRAVIN KUMAR	12/19/2002				
SYRACUSE, NY					
PEDERSEN, LAURA LAREE					
WEAVER	12/19/2002				
NAMPA, ID					
PERCY, PIERRE JOEL	12/19/2002				
CHANDLER, AZ					
RAY, DIANNA L	12/19/2002				
ASHEVILLE, NC					
RILEY, RODNEY WAYNE	12/19/2002				

**FEDERAL/STATE EXCLUSION/
SUSPENSION**

EDMONDS, QUEHEMIAH
ZALONTE.
SACRAMENTO, CA

12/19/2002

**OWNED/CONTROLLED BY CONVICTED
ENTITIES**

BEST NURSING CARE, INC ...
MIAMI, FL
COASTAL OUTPATIENT
SVCS, INC

12/19/2002

12/19/2002

Dated: December 4, 2002.

Katherine B. Petrowski,
*Director, Exclusions Staff, Office of Inspector
General.*

[FR Doc. 02-32000 Filed 12-20-02; 8:45 am]

BILLING CODE 4150-04-P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Substance Abuse and Mental Health
Services Administration**

**The President's New Freedom
Commission on Mental Health; Notice
of Meeting**

Pursuant to Executive Order 13263, notice is hereby given of a meeting of the President's New Freedom Commission on Mental Health in January 2003.

The meeting will be open and will consider how to accomplish the Commission's mandate to conduct a comprehensive study of the United States mental health service delivery system and to make recommendations on improving the delivery of public and private mental health services for adults and children. The Commission meeting will receive reports from several of its subcommittees, including Older Adults, Rural Issues, Rights and Engagement and Mental Health Interface with General Medicine. There will also be panel presentations on several related topics.

Attendance by the public will be limited to space available. Public comments are welcome. Please communicate with the individual listed as contact below to make arrangements to comment or to request special accommodations for persons with disabilities.

Additional information and a roster of Commission members may be obtained either by accessing the Commission Web site, <http://www.mentalhealthcommission.gov>, or by communicating with the contact whose name and telephone number is listed below.

Committee Name: The President's New Freedom Commission on Mental Health.