

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](http://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  $\leq 40$  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 ... WRIGHT CITY, OK	12/19/2002
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 .... SAN MARCOS, TX	12/19/2002

**FELONY CONTROL SUBSTANCE CONVICTION**

DELEHANTY, ALLISON JILL ... BETHALTO, IL	12/19/2002
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 .... CLARENCE CTR, NY	12/19/2002

**PATIENT ABUSE/NEGLECT CONVICTIONS**

ASHER, JONATHAN PATRICK FT COLLINS, CO	12/19/2002
BEST SARVER, REBECCA .... ENID, OK	12/19/2002
BURTON, PHILLIP TAROME .. LANCASTER, CA	12/19/2002
ELLIOTT, NICOLE LEE ANN ... SPOKANE, WA	12/19/2002
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	
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**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 ... LAKE CHARLES, LA	12/19/2002
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 ... MORENO VALLEY, CA	12/19/2002
DIAZ, FREDERICK .....	12/19/2002
BRONX, NY	
DORIAN, JEFFREY PHILIP .... DAVIE, FL	12/19/2002
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 ... PORTSMOUTH, OH	12/19/2002
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 HENRICHSEN, DAVID A .....	12/19/2002	EUREKA SPRINGS, AR RISING, ALISA ANN .....	12/19/2002	SPANISH FORT, AL SERVIALL SYSTEMS .....	12/19/2002
PHOENIX, AZ HERRING, ALMA JANETTE GRIFFIN .....	12/19/2002	OGALLALA, NE ROONEY, LORI COUTRE .....	12/19/2002	MIAMI, FL	
LAKE HAVASU CITY, AZ HILL, EDGAR H JR .....	12/19/2002	CARLISLE, PA ROSENTHAL, MICHAEL JAY ..	12/19/2002	<b>QUALITY IMPROVEMENT ORGANIZATION CASES</b>	
VIRGINIA BCH, VA HOLLAR, KIMBERLY J .....	12/19/2002	CLAREMONT, CA SALAS, ANGELA AGATHA .....	12/19/2002	EDWARDS, GREGSON .....	11/27/2002
MAIDEN, NC HORTERT, SHERYL L .....	12/19/2002	SOMERTON, AZ SALAZAR, HOPE .....	12/19/2002	Dated: December 4, 2002.	
CORAOPOLIS, PA JOERG, BRIAN S .....	12/19/2002	SANFORD, CO SCHMELTER, BRENDA L .....	12/19/2002	<b>Katherine B. Petrowski,</b> <i>Director, Exclusions Staff, Office of Inspector General.</i>	
BASEHOR, KS JOHNSON, KIMBERLY KAY ...	12/19/2002	MARICOPA, AZ SCHUETZ, LAWANDA MICHELLE .....	12/19/2002	[FR Doc. 02-32000 Filed 12-20-02; 8:45 am]	
ALEX, OK JOHNSON, ELLEN DEE .....	12/19/2002	AUBURN, NE SCOTT, LYNDA MARIE .....	12/19/2002	<b>BILLING CODE 4150-04-P</b>	
CYPRESS, CA KAUFFMAN, FRANCINE J .....	12/19/2002	PEORIA, AZ SELF, RHONDA SUE .....	12/19/2002	<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b>	
VISTA, CA KEA, WILLIAM PAUL .....	12/19/2002	SAN DIEGO, CA SKROCKI, BRIAN R .....	12/19/2002	<b>Substance Abuse and Mental Health Services Administration</b>	
PASADENA, CA KENNEDY, JANET MARIE .....	12/19/2002	PLYMOUTH MEETING, PA SMITH, JEFFRY ALAN .....	12/19/2002	<b>The President's New Freedom Commission on Mental Health; Notice of Meeting</b>	
MAYER, AZ KILLION, PATTY ANN .....	12/19/2002	RIVERSIDE, CA SMITH, YTH ZOFFMAN .....	12/19/2002	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.	
SALT LAKE CITY, UT KING, WILLIAM S .....	12/19/2002	LITTLETON, CO SMITH, MARY LEE .....	12/19/2002	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.	
SAN DIEGO, CA KUNTZ, RITA ANN .....	12/19/2002	GRAND ISLAND, NE SNYDER, MICHELLE JEAN ...	12/19/2002	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.	
SALINA, KS LEYBA, SHERRY .....	12/19/2002	WISNER, NE SPINAZZOLA, VICTORIA .....	12/19/2002	Additional information and a roster of Commission members may be obtained either by accessing the Commission Web site, <a href="http://www.mentalhealthcommission.gov">http://www.mentalhealthcommission.gov</a> , or by communicating with the contact whose name and telephone number is listed below.	
PARADISE, CA LIPNICK, ROBERT N .....	12/19/2002	PHOENIX, AZ STONE, SUSAN M .....	12/19/2002	<i>Committee Name:</i> The President's New Freedom Commission on Mental Health.	
WASHINGTON, DC LONG, JAMES M .....	12/19/2002	DAYTON, OH TURNER, HERBERT LLOYD ..	12/19/2002		
BIRMINGHAM, AL LOOMAN, LESLIE CLINTON ...	12/19/2002	CROWN POINT, IN VILLANUEVA, GRACIELA .....	12/19/2002		
EDMOND, OK MANOJLOVICH, PAMELA SUE .....	12/19/2002	REEDLEY, CA WALLINGFORD, TERESA LEANN .....	12/19/2002		
SEWICKLEY, PA MARSZALEK-PATCH, JAC- QUELINE S .....	12/19/2002	WICHITA, KS WARD, GREGORY ALAN .....	12/19/2002		
VERNON, CT MCALISTER, KIMBERLY MICHELLE .....	12/19/2002	TOPEKA, KS WEINHEIMER, EUGENE H .....	12/19/2002		
SHAWNEE, OK MCGANN, JON D .....	12/19/2002	COLUMBIA, MO WHITMORE, A JAMES III .....	12/19/2002		
ENCINITAS, CA MUIRHEAD, RICHARD JAMES JR .....	12/19/2002	NEW ORLEANS, LA WILLIAMS, JON MARK .....	12/19/2002		
SEATTLE, WA MURPHY, DONNA LYNN .....	12/19/2002	LAKE CHARLES, LA WILSON, MARC DAVID .....	12/19/2002		
MERRIAM, KS NEDD, JOSETTA .....	12/19/2002	EL PASO, TX WINANS, STEVEN RONALD ...	12/19/2002		
SHREVEPORT, LA NEHLS, DONAVAN EUGENE SR .....	12/19/2002	PHOENIX, AZ WINDSOR, MICHAEL SHAWN	12/19/2002		
CALICO ROCK, AR NELSON, J KENT .....	12/19/2002	ROWLETT, TX YU, JUN .....	12/19/2002		
BOUNTIFUL, UT OBERSTAR, TERRILEE MAR- GARET .....	12/19/2002	ROWLAND HGTS, CA ZIEGEN, GARY V .....	12/19/2002		
LANCASTER, CA PATEL, PRAVIN KUMAR .....	12/19/2002	FRESNO, CA			
SYRACUSE, NY PEDERSEN, LAURA LAREE WEAVER .....	12/19/2002	<b>FEDERAL/STATE EXCLUSION/ SUSPENSION</b>			
NAMPA, ID PERCY, PIERRE JOEL .....	12/19/2002	EDMONDS, QUEHEMIAH ZALONTE. SACRAMENTO, CA	12/19/2002		
CHANDLER, AZ RAY, DIANNA L .....	12/19/2002	<b>OWNED/CONTROLLED BY CONVICTED ENTITIES</b>			
ASHEVILLE, NC RILEY, RODNEY WAYNE .....	12/19/2002	BEST NURSING CARE, INC ... MIAMI, FL COASTAL OUTPATIENT SVCS, INC .....	12/19/2002		