

Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of the sixteenth set of final toxicological profiles of priority hazardous substances prepared by ATSDR. This set comprises two new and three updated profiles.

FOR FURTHER INFORMATION CONTACT: Ms. Carolyn Askew, Office of Communication, Agency for Toxic Substances and Disease Registry, Mailstop E-29, 1600 Clifton Road, NE., Atlanta, Georgia 30333; telephone 1-888-422-8737 or (404)498-0259.

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act (SARA) (Pub. L. 99-499) amends the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA) with regard to hazardous substances that are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these

statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the priority list of hazardous substances. This list identifies 275 hazardous substances that ATSDR and EPA have determined pose the most significant potential threat to human health. The availability of the revised list of the 275 priority substances was announced in the **Federal Register** on November 7, 2003 (68 FR 63098). For prior versions of the list of substances, see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); April 29, 1996 (61 FR 18744); November 17, 1997 (62 FR 61332); October 21, 1999 (64 FR 56792); and October 25, 2001 (66 FR 54014).

Notice of the availability of drafts of these two new and three updated toxicological profiles for public review and comment was published in the **Federal Register** on October 24, 2002, (67 FR 65357), with notice of a 90-day public comment period for each profile,

starting from the actual release date. Following the close of the comment period, chemical-specific comments were addressed, and, where appropriate, changes were incorporated into each profile. The public comments and other data submitted in response to the **Federal Register** notices bear the docket control number ATSDR-187. This material is available for public inspection at the Division of Toxicology, Agency for Toxic Substances and Disease Registry, 1825 Century Boulevard, Atlanta, Georgia, (not a mailing address) between 8 a.m. and 4:30 p.m., Monday through Friday, except legal holidays.

Availability

This notice announces the availability of two new and three updated final toxicological profiles comprising the sixteenth set prepared by ATSDR. The following toxicological profiles are now available through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161; telephone 1-800-553-6847. There is a charge for these profiles as determined by NTIS.

SIXTEENTH SET

Toxicological profile	NTIS order No.	CAS No.
1. Ammonia	PB2004-107331	007664-41-7
Ammonia Compounds		Various
2. Chlorine Dioxide*	PB2004-107332	10049-04-4
3. Copper	PB2004-107333	007440-50-8
Cupric Sulfate		007758-98-7
4. Polybrominated Biphenyls/	PB2004-107334	067774-32-7
Polybrominated Diphenyl Ethers		Various
5. Synthetic Vitreous Fibers*	PB2004-107335	Various

*Denotes new profile.

Dated: January 12, 2005.

Georgi Jones,

Director, Office of Policy, Planning, and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

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BILLING CODE 4163-70-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: December 2004

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of December 2004, 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 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
PROGRAM-RELATED CONVICTIONS	
LOCCISANO, GINA MARIA CRANSTON, RI	8/20/2003
MCGOVERN, DANA E PORT CHARLOTTE, FL	8/20/2003
MCGOVERN'S AMBULANCE SERVICE, INC PORT CHARLOTTE, FL	8/20/2003
OKOYE, PATRICK C MONTGOMERY, AL	8/20/2003
OKOYE, GODWIN S MONTGOMERY, AL	8/20/2003
CAPOBIANCO, LEO J LAS VEGAS, NV	8/20/2003
KHALATOV, LEONID WOODMERE, NY	8/20/2003
DOOLEY, MICHAEL F WOODMERE, NY	8/20/2003

Subject, city, state	Effective date	Subject, city, state	Effective date	Subject, city, state	Effective date
CARTHAGE, NY		DETROIT, MI		FLORENCE, AZ	
GRIM THIRTY-THREE, INC	8/20/2003	PARKER, KENNETH R	8/20/2003	BERKOVICH, LORA	8/20/2003
SMITHTOWN, NY		AKRON, OH		LONG BEACH, CA	
GRIMALDI, JOHN	8/20/2003	MILLER, SUSAN M	8/20/2003	YENGIBARYAN, SARKIS	8/20/2003
LAKE GEORGE, NY		ELKHART, IL		ELOY, CA	
JDS AMBULANCE CORP	8/20/2003	WELDY, DENNIS K	8/20/2003	KANIADAKIS, STEVEN J	8/20/2003
WOODMERE, NY		BRISTOL, IN		PENSACOLA, FL	
MURPHY JR, JAMES E	8/20/2003	DEVORE, MARLA A	8/20/2003	PENNIMAN, VERNANELL GIBSON	8/20/2003
NIVERVILLE, NY		SPRINGFIELD, IL		AZUZA, CA	
ABRAMS, BARRY	8/20/2003	MLODZIK, MARY BETH	8/20/2003	WHITE, VANCE KING	8/20/2003
FLUSHING, NY		PRINCETON, WI		LOS ANGELES, CA	
SABOT, THEODORE J	8/20/2003	HERMANN, RACHEL	8/20/2003	TAYLOR, GARY W	8/20/2003
PITTSFIELD, MA		TROY, OH		LOS ANGELES, CA	
HOUCHINS, EDNALEE	8/20/2003	BLACK, DOMINICA C	8/20/2003	KIOUTOUIAN, AMBARTSOUM	8/20/2003
S CHARLESTON, WV		COLUMBUS, OH		HOLLYWOOD, CA	
BELLAMY, MARY ELIZABETH		SMITH, CALVERT H JR	8/20/2003	CHEM, PHALLA	8/20/2003
ALDERSON, WV		CINCINNATI, OH		LONG BEACH, CA	
RANCOCAS VALLEY ANES-		EBERT, HEATHER R	8/20/2003	LEWANDOWSKI, REBECCA	
THESIA ASSOCIATES	11/14/2002	MOUNT GILEAD, OH		LYNN	5/2/2003
CINNAMINSON, NJ		PROPELLED THERAPEUTIC		KLAMATH FALLS, OR	
SHEARL, COWAN W	8/20/2003	SERVICES	8/20/2003	BASSEY, KRISTINE A	5/20/2003
VENICE, FL		DETROIT, MI		ANAHEIM, CA	
HORTON, ANTHONY H	8/20/2003	COMPREHENSIVE OUT-		LOPEZ, MYRNA RAMOS	8/20/2003
MAULDING, SC		PATIENT SVCS	8/20/2003	CHOWCHILLA, CA	
VIGOREAUX, ALEJANDRO	8/20/2003	CLEVELAND, OH		LOPEZ, BENJAMIN PINEDA ...	8/20/2003
MIAMI, FL		GALLO, ANGELO M	8/20/2003	SOLEDAD, CA	
RUIZ, ROBERTO	8/20/2003	WILOUGHBY, OH		LEWANDOWSKI, JENNIFER	
MIAMI, FL		GALLO, MARK A	8/20/2003	ANN	8/20/2003
SMITH, KAREN L	8/20/2003	GRAFTON, OH		LONG BEACH, CA	
MIAMI, FL		MITRIONE, ROBERT T	8/20/2003	NDEMBA, JACKSON NTONE	8/20/2003
SUBER, RAMONA	8/20/2003	YANKTON, SD		LOS ANGELES, CA	
JENKINSVILLE, SC		HENDERSON, MARTISA B	8/20/2003	JOHNSON, WILLIE LEE	8/20/2003
JONES, KESHEA T	8/20/2003	RAYVILLE, LA		RIVERSIDE, CA	
JACKSON, TN		PHILLIPS, RAYMOND RENE ..	8/20/2003	AHMED, SAEED	8/20/2003
HORTON, SAMMIE	8/20/2003	JONESBORO, LA		WASCO STATE PRISON,	
GRENADA, MS		BILLINGS, ARTHUR N	8/20/2003	CA	
GILMORE, RENEE LYNN	8/20/2003	MISSOURI, TX		AHMED, BILAL	8/20/2003
COLEMAN, FL		DANIEL, KRISTINA LEA	8/20/2003	WASCO, CA	
KWANGWARI, NGONI CHRIS-		FORT LUPTON, CO		GABRIEL, GABRIEL	8/20/2003
TOPHER	8/20/2003	DRAKE, SHERMAN HOWARD		LA PUENTE, CA	
MIAMI, FL		CASPER, WY		FARZAD, PHILIP	8/20/2003
PIPERIS, STELIOS	8/20/2003	FLUEGEL, ERIC MICHAEL	8/20/2003	ENCINO, CA	
MIAMI, FL		AURORA, CO		CHELZINGER, MICHA	8/20/2003
LIPTON, ROSS HOWARD	8/20/2003	DUPONT, ROBERT JOSEPH		TARZANA, CA	
MIAMI SHORES, FL		JR	8/20/2003	KOPILEVICH, MIKHAIL	8/20/2003
MENDEZ, EDUARDO S	8/20/2003	LEAVENWORTH, KS		WOODLAND HILLS, CA	
MIAMI, FL		GARWOOD, JAN DIERKS	8/20/2003	TSATOUROVA, INGA	8/20/2003
HERNANDEZ, JOSE R	8/20/2003	YANKTON, SD		DUBLIN, CA	
MIAMI, FL		HOUSEHOLDER, KARL OTIS			
TURNER, LISA	8/20/2003	LEAVENWORTH, KS			
ENTERPRISE, MS		LIVEOAK, KELLEY ANNE	8/20/2003		
OGUNDIYA, DEJI	8/20/2003	GREENVILLE, IL			
HERMITAGE, TN		DINKMEIER, LOU ANN	8/20/2003		
MAKINS, KATETINE C	8/20/2003	LAMAR, MO			
LAURENS, SC		BAZAZZADEGAN, JULIA			
BUCKMON, NATASHA	8/20/2003	ELAINE	8/20/2003	ORLANDER, ANDREW	8/20/2003
COLUMBIA, SC		FORTH WORTH, TX		EGLIN AFB, FL	
WILLIAMS, JULIUS III	8/20/2003	WIMBLEY, MARY E	8/20/2003	DESIMONE, ERIK DAVID	8/20/2003
STONE MOUNTAIN, GA		ST LOUIS, MO		TUCKER, GA	
ALLEN, JACK W	8/20/2003	STEPANYAN, ARTHUR	8/20/2003	MINARCIK, JOHN ROBERT	8/20/2003
ESTILL, SC		STUDIO CITY, CA		SKOKIE, FL	
REDLICH, DALE PALMER	8/20/2003	DANIELS, KAREN ANN	8/20/2003	SILVESTRO, CAROLINE L	8/20/2003
CORAL SPRINGS, FL		SACRAMENTO, CA		MENTOR, OH	
HAUGHT, BARRY D	8/20/2003	STEPANIAN, ASMIK	8/20/2003	LEON, FRANK A JR	8/20/2003
EGLIN AFB, FL		VAN NUYS, CA		LORAIN, OH	
NESPECA, THOMAS W	8/20/2003	CANCIO, MENELEO COMETA		NIELSEN, KATHERINE MARIE	8/20/2003
TAMPA, FL		LOMPOC, CA		LA JUNTA, CO	
STURSBURG, CHRISTOPHER		CANCIO, RAUL COMETA	8/20/2003	BROWN, GLENN CECIL	8/20/2003
C	8/20/2003	ELOY, AZ		ALPINE, UT	
VALRICO, FL		MIKAYELIAN, RAFIK	8/20/2003	KLINK, LORETTA LEE	8/20/2003
DAVID M MOSS, DPM, P C	8/20/2003	TERMINAL ISLAND, CA		AUBURN, CA	
GARDEN CITY, MI		URFALIAN, SARKIS	8/20/2003		
JACKSON, WAYNE D	8/20/2003	ALTADENA, CA			
		GOTTLIEB, JEFFREY	8/20/2003		

FELONY CONVICTION FOR HEALTH CARE FRAUD

ORLANDER, ANDREW	8/20/2003
DESIMONE, ERIK DAVID	8/20/2003
MINARCIK, JOHN ROBERT	8/20/2003
SILVESTRO, CAROLINE L	8/20/2003
LEON, FRANK A JR	8/20/2003
NIELSEN, KATHERINE MARIE	8/20/2003
BROWN, GLENN CECIL	8/20/2003
KLINK, LORETTA LEE	8/20/2003

FELONY CONTROL SUBSTANCE CONVICTION

GARLAND, TAMI A	8/20/2003
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Subject, city, state	Effective date	Subject, city, state	Effective date	Subject, city, state	Effective date
DANBURY, CT		DEL CITY, OK		YARDLEY, PA	
NICHOLSON, LISA F	8/20/2003	PHILLIPS, DARREN WAYNE ..	8/20/2003	KASSELL, ELEANOR A	8/20/2003
PENSACOLA, FL		PINEVILLE, LA		BADEN, PA	
SPROUL, MELANIE LAREE	8/20/2003	MILEA, ADRIAN VALERIU	8/20/2003	ALBRECHT, FRANK M	8/20/2003
MARIANNA, FL		SALT LAKE CITY, UT		EASTON, MD	
KEY, REBECCA LYNN	8/20/2003	COY, HEATHER RENEE	8/20/2003	DEPTULA, RICHARD	8/20/2003
ANDERSON, SC		RYE, CO		ELLICOTT CITY, MD	
MATTERA, DIANNA LYNN	8/20/2003	FRENCH, LYLE REID	8/20/2003	GRAFFUM, ANN E	8/20/2003
TALLAHASSEE, FL		LOUISVILLE, CO		RICHMOND, VA	
JONES, NINA J	8/20/2003	WILLARD, KARL TERRELL	8/20/2003	WHITLOCK, AIMEE D	8/20/2003
SPARTA, TN		BOWLING GREEN, MO		CHARLESTON, WV	
LOWE, WANDA KAY	8/20/2003	LANDRENEAU, MICHAEL		YOUNG, DENISE	8/20/2003
PLEASANT VIEW, TN		DOUGLAS	8/20/2003	WILLIAMSPORT, PA	
KING, VICKY M	8/20/2003	ST JOSEPH, MO		RUSSELL, JANET MARIE	8/20/2003
MOORESBURG, TN		VINZANT, ROBIN RENEE	8/20/2003	CHINCHILLA, PA	
IMHOFF, PATRICIA SUZANNE		MITCHELLVILLE, IA		HAMMOND, DEBORAH	8/20/2003
PHOENIX, AZ		CASTILLO, JULIO CESAR	8/20/2003	HOLLIDAYSBURG, PA	
ERB, CHRISTOPHER JOHN ...	8/20/2003	KENT, WA		DONOVAN, KEITH R	8/20/2003
W PALM BEACH, FL		NEAULT, CHARLES CAREY ...	8/20/2003	ADELPHI, MD	
DANIELS, KIM	8/20/2003	TEMECULA, CA		CANTRELL, PATRICIA A	8/20/2003
TAZEWELL, TN		HUSSAIN, SHEILA KAY	8/20/2003	INMAN, SC	
MYERS, LISA CHERYL	8/20/2003	KINGMAN, AZ		WEEKS, WILLIAM W	8/20/2003
LITHONIA, GA		HUSSAIN, RASHIDA		WINTER HAVEN, FL	
SCHEIDLER, JOSEPH STAN-		KHATTOON	8/20/2003	MCQUAIG, JAMES EDWARD	8/20/2003
LEY	8/20/2003	KINGMAN, AZ		ST AUGUSTINE, FL	
HAMITON, OH		GOODMAN, REBECCA KAYE	8/20/2003	MURPHY, LONNIE	8/20/2003
TOMKO, JOHN R	8/20/2003	N LAS VEGAS, NV		MIAMI, FL	
HUBBARD, OH		SMITH, DOLORES	8/20/2003	SCOTT, ERICA L	8/20/2003
MOLIERE-COSSE,		PHOENIX, AZ		JACKSON, MS	
REACHENELLE	8/20/2003			GUIDRY, KAREN MARY	8/20/2003
MARRERO, LA				ARCADIA, FL	
LITTELL, SANDRA JANE	8/20/2003			HUMPHREYS, JANIE F	8/20/2003
HOUSTON, TX				PEARL, MS	
HOUSTON, DONALD	8/20/2003			POSEY, LISA	8/20/2003
SALT LAKE CITY, UT				TERRY, MS	
CLISE, RICHARD KEITH	8/20/2003			STOKES, JOSEPH MICHAEL	8/20/2003
FORT MORGAN, CO				GREENWOOD, MS	
EVANS, ERIC ALLEN	8/20/2003			DAWSON, TRACIE LYNN	8/20/2003
SALT LAKE CITY, UT				BIRMINGHAM, AL	
BOYETTE, CARL JEFFREY	8/20/2003			LONIE, PAULA R	8/20/2003
CHICO, CA				LYLES, TN	
				QUALLS, MIA L	8/20/2003
				SAVANNAH, TN	
				WALKER, TAMMY	8/20/2003
				NASHVILLE, TN	
				BOWEN, VICKIE	8/20/2003
				COLLINS, MS	
				WALKER, THOMAS A	8/20/2003
				MERIDIAN, MS	
				BURNS, JACKIE A	8/20/2003
				RIDGELAND, MS	
				PERDOMO, ONELIO E	8/20/2003
				GADSDEN, AL	
				CHEATHAM, SHERYLE D	8/20/2003
				SHAWNEE, TN	
				BUTLER, MISTI D	8/20/2003
				OAK RIDGE, TN	
				BOONE, RONALD C	8/20/2003
				HERMITAGE, TN	
				BOONE, LISA	8/20/2003
				GALLATIN, TN	
				O'BRIAN, MELODY A	8/20/2003
				LANTANA, FL	
				BELVILLE-COATES, SARAH ...	8/20/2003
				BRANDON, FL	
				HILDRETH, HOLLY ANNE	8/20/2003
				HIGH SPRINGS, FL	
				RANKINE, CORAL ELONZ	8/20/2003
				FLAGLER BEACH, FL	
				RUNDELL, JENNIFER FAITH ..	8/20/2003
				OCALA, FL	
				WILLIAMS, KIMBERLY SUSAN	8/20/2003
				LANTANA, FL	
				GRIFFIN, MARJORIE	8/20/2003

PATIENT ABUSE/NEGLECT CONVICTIONS

VASILIU, VASILIOS	8/20/2003
GLEN HEAD, NY	
BRICE, MARK D	8/20/2003
TONAWANDA, NY	
CAULFIELD, SHARON A	8/20/2003
BALLSTON LAKE, NY	
RENDON, JAIRO	8/20/2003
MALONE, NY	
CORREA, JOHANNA	8/20/2003
ROCHESTER, NY	
GUZMAN, RUDLES FRANCIS	8/20/2003
BROOKLYN, NY	
HYKES, LISA	8/20/2003
OKOLONA, MS	
CORNELIUS, CYNTHIA	8/20/2003
JACKSON, MS	
CALDWELL, JOHNNIE M	8/20/2003
NEWBERRY, SC	
JIMENEZ, HENRY	8/20/2003
ORLANDO, FL	
ST JOHN, SHARON A	8/20/2003
CLIFTON, CO	
GILL, RODNEY P	8/20/2003
AKRON, OH	
BENOIT, LEAKISHA RENEE ...	8/20/2003
LAFAYETTE, LA	
PANOSKE, JASON B	8/20/2003
OKEMA, OK	
MARSHALL, VICTORIA K	8/20/2003

CONVICTION FOR HEALTH CARE FRAUD

FREDE, MICHAEL DENNIS	8/20/2003
HAZELWOOD, MO	

CONVICTION—OBSTRUCTION OF AN INVESTIGATION

NAHAS, FREDERICK J	8/20/2003
LONGPORT, NJ	

CONTROLLED SUBSTANCE CONVICTIONS

COMITO, LEE ANN	8/20/2003
UTICA, NY	
GARZA, PAMELA IRENE	8/20/2003
CROW AGENCY, MT	

LICENSE REVOCATION/SUSPENSION/SURRENDERED

SULLIVAN, COLLEEN A	8/20/2003
SAUGUS, MA	
TIMONS, JODIE LYNN	8/20/2003
BROOKFIELD, MA	
CLAIRE, KELLY	8/20/2003
RUTLAND, MA	
GREEN, JOYCE D	8/20/2003
WOODBINE, NJ	
MCINTYRE, JOHN G JR	8/20/2003
RARITAN, NJ	
DIFASI, LINDA C	8/20/2003
SYRACUSE, NY	
PIERRE, LOVELY JEUDY	8/20/2003
QUEENS VILLAGE, NY	
HARRIS-POOLE, IRENE	8/20/2003
VOORHEES, NJ	
LAWLER, PAUL J	8/20/2003
ALTAMONT, NY	
DUTTON, JIMMY LEE	8/20/2003
MT VERNON, NY	
MCCLERNON, JUNE LAW	8/20/2003

Subject, city, state	Effective date	Subject, city, state	Effective date	Subject, city, state	Effective date
LAKELAND, FL		MEMPHIS, TN		AURORA, CO	
LUND, PHYLLIS LOOBY	8/20/2003	RICHARDSON, GILBERT A	8/20/2003	KING, ROCHELLE SHAVON ...	8/20/2003
KEY WEST, FL		DEFUNIAK SPRINGS, FL		TOPEKA, KS	
MOULTON, LAURIE ABBY	8/20/2003	WELLS, JUDY E MUNCIE	8/20/2003	WAMBEKE, FLORENCE	8/20/2003
NAPLES, FL		WINCHESTER, KY		RAPID CITY, SD	
FREED, CHRYSYAL	8/20/2003	JOHNSON, STACEY MARIE		REILLY, SETH	8/20/2003
FT MYERS, FL		CAVOTE	8/20/2003	THERMOPOLIS, WY	
FITZGERALD, DONNA GIB- SON	8/20/2003	THE PLAINS, OH		ROSE, LINDA	8/20/2003
ESTERO, FL		BILLINGSLEY, RENEE	8/20/2003	MEETEETSE, WY	
O'DONNELL, CAROL JANET ..	8/20/2003	PRATTVILLE, AL		THORNTON, MICHAEL KENT	8/20/2003
PORT ORANGE, FL		MALCOMB, SHEILA RE-		ST PETERS, MO	
ONIEAL, JENNIFER I	8/20/2003	BECCA HOLLAND	8/20/2003	ELLIS, BRIAN J	8/20/2003
BRANDON, FL		TRUSSVILLE, AL		SPRINGFIELD, MO	
SRINIVASAN, GOVIND	8/20/2003	BLAKENEY, SHERRY JEAN		VILLARREAL, REINALDA R ...	8/20/2003
DELTONA, FL		MCMANUS	8/20/2003	COLLBRAN, CO	
PHILLIPS, JAMES WINSTON ..	8/20/2003	SWEETWATER, AL		MOORE, STACI L	8/20/2003
BOYNTON BEACH, FL		ESTOK, MARY	8/20/2003	PLEASANT HILL, MO	
MADRIGAL, JAYMA M	8/20/2003	SPRING HILL, FL		CURL, DENISE M	8/20/2003
MORRISTOWN, TN		ARANDIA, RODRIGO S	8/20/2003	DUBUQUE, IA	
MILLER, KIMBERLY M	8/20/2003	CHICAGO, IL		KING, TERESSA A	8/20/2003
MILLER, KIMBERLY M	8/20/2003	SMITH, DANNELLY C	8/20/2003	YREKA, CA	
KINGSPOUR, TN		WYANDOTTE, MI		DU, JOHN ZHENG	8/20/2003
HALL, DIXIELEE L	8/20/2003	SONE, JANET LEE	8/20/2003	SACRAMENTO, CA	
VERO BEACH, FL		PORTAGE, IN		BODY CARE CENTER, CLINIC	8/20/2003
GIOVINO, LAURA		KAY, WILLIAM EZRA	8/20/2003	COSTA MESA, CA	
GLASSGOW	8/20/2003	PEPPER PIKE, OH		LACY, KAREN N	8/20/2003
DUNEDIN, FL		LINNMANN, BRUCE MI-		PASADENA, CA	
HINTZ, GIGI T	8/20/2003	CHAEI	8/20/2003	FREED, STEPHEN W	8/20/2003
CLEARWATER, FL		CINCINNATI, OH		IDAHO FALLS, ID	
JACKSON, MARGARET	8/20/2003	CUSMA, JOSEPH A	8/20/2003	WISE, LESLIE EUGENE	8/20/2003
PUNTA GORDA, FL		MASSILLON, OH		NEWPORT BEACH, CA	
WARREN, STEPHANIE	8/20/2003	WOJCIK, DAVID G	8/20/2003	MASLANA, JOANNE ELIZA-	
CENTERVILLE, TN		ELGIN, IL		BETH	8/20/2003
PENCE, CRETIA	8/20/2003	VEACH, CAROLINE S	8/20/2003	TUCSON, AZ	
BRADYVILLE, TN		OAKLAND, IL		PETERS, KATHERINE	8/20/2003
CRISPIN, JEANETTE	8/20/2003	STEELE, JACQUELINE E	8/20/2003	ESCONDIDO, CA	
CAUTIER, MS		CHICAGO, IL		MC GEE-JONES, BARBARA	
DOYLE, KAY S	8/20/2003	SEARS, JENNIFER L	8/20/2003	DALE	8/20/2003
VICKSBURG, MS		CHAMPAIGN, IL		DEL MAR, CA	
GALIPAULT, JANE	8/20/2003	BLACKMOND, ANTONIO	8/20/2003	JESSE, ROSALIE C	8/20/2003
LAKELAND, FL		CHICAGO, IL		EL CAJON, CA	
DUNCAN, THOMASA JOYCE		BARRON, JOEL	8/20/2003	WEAVER, DEANNA E	8/20/2003
FROSTPROOF, FL		GLENDAL, AZ		TUCSON, AZ	
DONALDSON, DORA ELISA ...	8/20/2003	BROWN, LAKISHA		DOYLE, WENDY ANN	8/20/2003
CHULUOTA, FL		ANTONETTE	8/20/2003	LA CRESCENTA, CA	
BELAGA, NATALIE ELIZA-		CHAMPAIGN, IL		SCHAVE, BARBARA	8/20/2003
BETH	8/20/2003	ANDERSON, TISHA L	8/20/2003	BEVERLY HILLS, CA	
UNIVERSITY PARK, FL		ROCKFORD, IL		ARIAS, KERRY LYNN	8/20/2003
BRANT, PATRICIA JO	8/20/2003	AALDERS, NANCY BLOCK	8/20/2003	TUCSON, AZ	
PENSACOLA, FL		OAK LAWN, IL		HIMALAYA, JOLYN	8/20/2003
CITERA-DOWLER, FRANCINE		DAVIDSON, MYSTI D	8/20/2003	RANCHO PALOS VERDES,	
HOLLYWOOD, FL		ROAMOK, TX		CA	
COOK, DONALD CLARENCE		JONES, KAREN DENISE	8/20/2003		
GREEN ACRES, FL		MARRERO, LA			
TINDLE, LISA A	8/20/2003	WOOD, LISA KATHLEEN			
RALEIGH, NC		ADAIR	8/20/2003		
WISNEWSKI-JONES, TINA	8/20/2003	LITTLE ROCK, AR			
WEST MELBOURNE, FL		HEBERT, DAPHNE BROOK	8/20/2003		
MILBUT, DEBORAH LYNN ...	8/20/2003	KAPLAN, LA			
BOCA RATON, FL		CHANDLER, MARY KATH-			
FORD-HAYES, CHRIS-		ERINE	8/20/2003		
TOPHER E	8/20/2003	SHREVEPORT, LA			
ORLANDO, FL		JONES, LESLIE ADELE	8/20/2003		
ROSS, CORNELIA R	8/20/2003	METAIRIE, LA			
NASHVILLE, TN		DOWNS, DORIS IRENE	8/20/2003		
FEAZELL, CHRISTOPHER A ..	8/20/2003	MARTHAVILLE, LA			
COOKEVILLE, TN		HART, DILLIS LEROY	8/20/2003		
STALLINGS, MARCELLA	8/20/2003	BOISE CITY, OK			
COOKEVILLE, TN		SNYDER, GARY LEE	8/20/2003		
MORTON, AILEEN	8/20/2003	LITTLETON, CO			
ALCOA, TN		SKUZA, RICHARD S	8/20/2003		
MCLAUGHLIN, GINGER C	8/20/2003	COLORADO SPRNGS, CO			
HENDERSONVILLE, TN		NOIPERMPOON, SAMAPORN	8/20/2003		
PADAWER, JAN E	8/20/2003				
				FRAUD/KICKBACKS/PROHIBITED ACTS/ SETTLEMENT AGREEMENTS	
				WEINSTEIN, LEONARD	5/29/2003
				MONROE TWP, NJ	
				OWNED/CONTROLLED BY CONVICTED ENTITIES	
				BGF TRANSPORTATION, INC	8/20/2003
				BROOKLYN, NY	
				M & D FAMILY PHARMACY, INC	8/20/2003
				REGO PARK, NY	
				KENDALL BEHAVIORAL HEALTHCARE CTR, INC	8/20/2003
				COLEMAN, FL	
				KENDALL PHYSICAL THERAPY CTR, INC	8/20/2003

Subject, city, state	Effective date
MIAMI, FL CHUCK'S SUPER RITE DRUGS, INC	8/20/2003
ATLANTA, GA BEHAVIORAL HEALTH PRO- VIDERS	8/20/2003
ESTILL, SC ARLINGTON HOUSE, INC	8/20/2003
ESTILL, SC WEST MIAMI MEDICAL SUP- PLY, INC	8/20/2003
TALLAHASSEE, FL READY MEDICAL EQUIP- MENT CORP	8/20/2003
TALLAHASSEE, FL SUNSHINE MEDICAL ENTER- PRISE GROUP, INC	8/20/2003
MIAMI, FL ADVANCED FAMILY DENTAL CARE	8/20/2003
IDAHO FALLS, ID HEALTH PRO MEDICAL LABS LA HABRA, CA	8/20/2003
JOSEPH E COBBS CHIROPRACTIC	8/20/2003
SAN DIEGO, CA CHIRO ACU CENTER	8/20/2003
GARDEN GROVE, CA	
DEFAULT ON HEAL LOAN	
CLARK, FREEMAN L	5/16/2003
EGLIN AFB, FL BOWERS, JOHN BENJAMIN ..	8/20/2003
HAYSVILLE, KS DAVIS, GEORGIA A	6/12/2003
RANDALLSTOWN, MD MARK, JEFFREY	7/16/2003
PORTLAND, OR DOYLE, TIMOTHY P	7/22/2003
BELLEVUE, WA STRONG-FIELDS, MICHELLE A	6/23/2003
PHILADELPHIA, PA	

comment on the following Written Request issued by the Food and Drug Administration (FDA) for off-patent drugs as defined in the Best Pharmaceuticals for Children Act (BPCA). The Written Request was referred to the NIH by the FDA as required by the BPCA. The Written Request was developed following formulation of an NIH-generated priority list, which prioritizes certain drugs most in need of study for use by children. The priority list was produced in consultation with the FDA, other NIH Institutes and Centers, and pediatric experts, as mandated by the BPCA. The studies that are described in the Written Request are intended to characterize the safety, efficacy, and pharmacokinetics of the drug for optimum use in pediatric patients.

DATES: Comments are requested within 30 days of publication of this notice.

ADDRESSES: Submit comments to: Anne Zajicek, M.D., Pharm.D., National Institute of Child Health and Human Development (NICHD), 6100 Executive Boulevard, Suite 4B—09, Bethesda, MD 20892-7510, telephone 301-435-6865 (not a toll-free number), e-mail BestPharmaceuticals@mail.nih.gov.

FOR FURTHER INFORMATION CONTACT: Anne Zajicek, M.D., Pharm.D., National Institute of Child Health and Human Development (NICHD), 6100 Executive Boulevard, Suite 4B—09, Bethesda, MD 20892-7510, telephone 301-435-6865 (not a toll-free number), e-mail BestPharmaceuticals@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The NIH is providing notice of Written Requests issued by the FDA, and is requesting public comment. On January 4, 2002, President Bush signed into law the Best Pharmaceuticals for Children Act (BPCA). The BPCA mandates that NIH, in consultation with the FDA and experts in pediatric research, shall develop, prioritize, and publish an annual list of certain approved drugs for which pediatric studies are needed. In response to this list, the FDA then issues a Written Request to holders of the New Drug Application (NDA) or abbreviated New Drug Application (aNDA) to request that pediatric studies be performed to provide needed safety and efficacy information for pediatric labeling. If the Written Request is declined by the NDA/aNDA holder (s), the Written Request is referred to the NIH, specifically the NICHD. A Request for Proposal (RFP) is then issued based on the Written Request and proposals are reviewed by a peer-review process for contract award.

To assure that the most appropriate pediatric studies are delineated in the RFP, public comment on the Written Request for the use of Meropenem for the treatment of complicated intra-abdominal infections in preterm and term newborn and infant patients younger than 91 days of age is hereby requested by the NIH.

Duane Alexander,
Director, National Institute for Child Health and Human Development, National Institutes of Health.

Meropenem Written Request

Dear Contact:
To obtain needed pediatric information on the use of meropenem, the Food and Drug Administration (FDA) is hereby making a formal Written Request, pursuant to section 505A of the Federal Food, Drug, and Cosmetic Act that you submit information from studies in pediatric patients described below.

Rationale:
The last 30 years have seen a dramatic rise in antibiotic resistance by common bacterial pathogens. This increasing microbial drug resistance requires the use of antibiotics with broad spectrum activity that can be relied upon when first line antimicrobials fail.

Imipenem-cilastatin and meropenem are carbapenems with widespread pediatric use. Imipenem-cilastatin has been labeled for use in pediatric patients (including newborns) for many serious infections such as pneumonia, skin and skin structure infections, osteomyelitis and complicated intra-abdominal infections. Meropenem is labeled for pediatric patients from three months of age through adolescence as single agent antimicrobial therapy for meningitis and complicated intra-abdominal infections, and is a recommended option for monotherapy of high severity complicated intra-abdominal infections in adults.⁹

There is significant off-label use of meropenem in newborn and infant patients younger than three months of age. For example, in 2003, the Child Health Corporation of America Pediatric Health Information System dataset (inpatient data from 31 free-standing children's hospitals) mentions 589 uses in this population for serious infections such as necrotizing enterocolitis and peritonitis. This off-label use occurs despite the lack of adequate pharmacokinetic, dosing, tolerability and safety data for this vulnerable age group. Collecting this data through the study of newborns and young infants with complicated intra-abdominal infections will fill this knowledge gap.

Dated: January 6, 2005.

Katherine B. Petrowski,
Director, Exclusion Staff, Office of Inspector General.

[FR Doc. 05-1066 Filed 1-19-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Public Comment on a Written Request Issued by the Food and Drug Administration on the Use of Meropenem for the Treatment of Complicated Intra-Abdominal Infections in Preterm and Term Newborn and Infant Patients Younger Than 91 Days of Age

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is requesting public