

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.*

[FR Doc. 05-1091 Filed 1-19-05; 8:45 am]

**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 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
<b>PROGRAM-RELATED CONVICTIONS</b>	
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		<b>FELONY CONVICTION FOR HEALTH CARE</b>	
HERMITAGE, TN		DINKMEIER, LOU ANN .....	8/20/2003	<b>FRAUD</b>	
MAKINS, KATETINE C .....	8/20/2003	LAMAR, MO		ORLANDER, ANDREW .....	8/20/2003
LAURENS, SC		BAZAZZADEGAN, JULIA		EGLIN AFB, FL	
BUCKMON, NATASHA .....	8/20/2003	ELAINE .....	8/20/2003	DESIMONE, ERIK DAVID .....	8/20/2003
COLUMBIA, SC		FORTH WORTH, TX		TUCKER, GA	
WILLIAMS, JULIUS III .....	8/20/2003	WIMBLEY, MARY E .....	8/20/2003	MINARCIK, JOHN ROBERT ....	8/20/2003
STONE MOUNTAIN, GA		ST LOUIS, MO		SKOKIE, FL	
ALLEN, JACK W .....	8/20/2003	STEPANYAN, ARTHUR .....	8/20/2003	SILVESTRO, CAROLINE L .....	8/20/2003
ESTILL, SC		STUDIO CITY, CA		MENTOR, OH	
REDLICH, DALE PALMER .....	8/20/2003	DANIELS, KAREN ANN .....	8/20/2003	LEON, FRANK A JR .....	8/20/2003
CORAL SPRINGS, FL		SACRAMENTO, CA		LORAIN, OH	
HAUGHT, BARRY D .....	8/20/2003	STEPANIAN, ASMIK .....	8/20/2003	NIELSEN, KATHERINE MARIE	8/20/2003
EGLIN AFB, FL		VAN NUYS, CA		LA JUNTA, CO	
NESPECA, THOMAS W .....	8/20/2003	CANCIO, MENELEO COMETA		BROWN, GLENN CECIL .....	8/20/2003
TAMPA, FL		LOMPOC, CA		ALPINE, UT	
STURSBURG, CHRISTOPHER		CANCIO, RAUL COMETA .....	8/20/2003	KLINK, LORETTA LEE .....	8/20/2003
C .....	8/20/2003	ELOY, AZ		AUBURN, CA	
VALRICO, FL		MIKAYELIAN, RAFIK .....	8/20/2003		
DAVID M MOSS, DPM, P C ....	8/20/2003	TERMINAL ISLAND, CA		<b>FELONY CONTROL SUBSTANCE</b>	
GARDEN CITY, MI		URFALIAN, SARKIS .....	8/20/2003	<b>CONVICTION</b>	
JACKSON, WAYNE D .....	8/20/2003	ALTADENA, CA		GARLAND, TAMI A .....	8/20/2003
		GOTTLIEB, JEFFREY .....	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
KINGSPOINT, TN		SMITH, DANNELLY C .....	8/20/2003	YREKA, CA	
HALL, DIXIELEE L .....	8/20/2003	WYANDOTTE, MI		DU, JOHN ZHENG .....	8/20/2003
VERO BEACH, FL		SONE, JANET LEE .....	8/20/2003	SACRAMENTO, CA	
GIOVINO, LAURA		PORTAGE, IN		BODY CARE CENTER, CLINIC	8/20/2003
GLASSGOW .....	8/20/2003	KAY, WILLIAM EZRA .....	8/20/2003	COSTA MESA, CA	
DUNEDIN, FL		PEPPER PIKE, OH		LACY, KAREN N .....	8/20/2003
HINTZ, GIGI T .....	8/20/2003	LINNMANN, BRUCE MI-		PASADENA, CA	
CLEARWATER, FL		CHAE L .....	8/20/2003	FREED, STEPHEN W .....	8/20/2003
JACKSON, MARGARET .....	8/20/2003	CINCINNATI, OH		IDAHO FALLS, ID	
PUNTA GORDA, FL		CUSMA, JOSEPH A .....	8/20/2003	WISE, LESLIE EUGENE .....	8/20/2003
WARREN, STEPHANIE .....	8/20/2003	MASSILLON, OH		NEWPORT BEACH, CA	
CENTERVILLE, TN		WOJCIK, DAVID G .....	8/20/2003	MASLANA, JOANNE ELIZA-	
PENCE, CRETIA .....	8/20/2003	ELGIN, IL		BETH .....	8/20/2003
BRADYVILLE, TN		VEACH, CAROLINE S .....	8/20/2003	TUCSON, AZ	
CRISPIN, JEANETTE .....	8/20/2003	OAKLAND, IL		PETERS, KATHERINE .....	8/20/2003
CAUTIER, MS		STEELE, JACQUELINE E .....	8/20/2003	ESCONDIDO, CA	
DOYLE, KAY S .....	8/20/2003	CHICAGO, IL		MC GEE-JONES, BARBARA	
VICKSBURG, MS		SEARS, JENNIFER L .....	8/20/2003	DALE .....	8/20/2003
GALIPAULT, JANE .....	8/20/2003	CHAMPAIGN, IL		DEL MAR, CA	
LAKELAND, FL		BLACKMOND, ANTONIO .....	8/20/2003	JESSE, ROSALIE C .....	8/20/2003
DUNCAN, THOMASA JOYCE		CHICAGO, IL		EL CAJON, CA	
FROSTPROOF, FL		BARRON, JOEL .....	8/20/2003	WEAVER, DEANNA E .....	8/20/2003
DONALDSON, DORA ELISA ...	8/20/2003	GLENDAL, AZ		TUCSON, AZ	
CHULUOTA, FL		BROWN, LAKISHA		DOYLE, WENDY ANN .....	8/20/2003
BELAGA, NATALIE ELIZA-		ANTONETTE .....	8/20/2003	LA CRESCENTA, CA	
BETH .....	8/20/2003	CHAMPAIGN, IL		SCHAVE, BARBARA .....	8/20/2003
UNIVERSITY PARK, FL		ANDERSON, TISHA L .....	8/20/2003	BEVERLY HILLS, CA	
BRANT, PATRICIA JO .....	8/20/2003	ROCKFORD, IL		ARIAS, KERRY LYNN .....	8/20/2003
PENSACOLA, FL		AALDERS, NANCY BLOCK ....	8/20/2003	TUCSON, AZ	
CITERA-DOWLER, FRANCINE		OAK LAWN, IL		HIMALAYA, JOLYN .....	8/20/2003
HOLLYWOOD, FL		DAVIDSON, MYSTI D .....	8/20/2003	RANCHO PALOS VERDES,	
COOK, DONALD CLARENCE		ROAMOK, TX		CA	
GREEN ACRES, FL		JONES, KAREN DENISE .....	8/20/2003		
TINDLE, LISA A .....	8/20/2003	MARRERO, LA			
RALEIGH, NC		WOOD, LISA KATHLEEN			
WISNEWSKI-JONES, TINA ....	8/20/2003	ADAIR .....	8/20/2003		
WEST MELBOURNE, FL		LITTLE ROCK, AR			
MILBUT, DEBORAH LYNN ...	8/20/2003	HEBERT, DAPHNE BROOK ....	8/20/2003	WEINSTEIN, LEONARD .....	5/29/2003
BOCA RATON, FL		KAPLAN, LA		MONROE TWP, NJ	
FORD-HAYES, CHRIS-		CHANDLER, MARY KATH-			
TOPHER E .....	8/20/2003	ERINE .....	8/20/2003		
ORLANDO, FL		SHREVEPORT, LA			
ROSS, CORNELIA R .....	8/20/2003	JONES, LESLIE ADELE .....	8/20/2003		
NASHVILLE, TN		METAIRIE, LA			
FEAZELL, CHRISTOPHER A ..	8/20/2003	DOWNS, DORIS IRENE .....	8/20/2003	BGF TRANSPORTATION, INC	8/20/2003
COOKEVILLE, TN		MARTHAVILLE, LA		BROOKLYN, NY	
STALLINGS, MARCELLA .....	8/20/2003	HART, DILLIS LEROY .....	8/20/2003	M & D FAMILY PHARMACY,	
COOKEVILLE, TN		BOISE CITY, OK		INC .....	8/20/2003
MORTON, AILEEN .....	8/20/2003	SNYDER, GARY LEE .....	8/20/2003	REGO PARK, NY	
ALCOA, TN		LITTLETON, CO		KENDALL BEHAVIORAL	
MCLAUGHLIN, GINGER C .....	8/20/2003	SKUZA, RICHARD S .....	8/20/2003	HEALTHCARE CTR, INC ....	8/20/2003
HENDERSONVILLE, TN		COLORADO SPRNGS, CO		COLEMAN, FL	
PADAWER, JAN E .....	8/20/2003	NOIPERMPOON, SAMAPORN	8/20/2003	KENDALL PHYSICAL	
				THERAPY CTR, INC .....	8/20/2003

**FRAUD/KICKBACKS/PROHIBITED ACTS/  
SETTLEMENT AGREEMENTS**

WEINSTEIN, LEONARD .....

**OWNED/CONTROLLED BY CONVICTED  
ENTITIES**

BGF TRANSPORTATION, INC

BROOKLYN, NY

M & D FAMILY PHARMACY,  
INC .....

REGO PARK, NY

KENDALL BEHAVIORAL  
HEALTHCARE CTR, INC ....

COLEMAN, FL

KENDALL PHYSICAL  
THERAPY CTR, INC .....

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	
<b>DEFAULT ON HEAL LOAN</b>	
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](mailto: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](mailto: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.<sup>9</sup>

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]

**BILLING CODE 4150-04-P**

**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