

of medical devices; (2) promote technological innovation; and (3) facilitate international trade. GHTF provides further information concerning the structure, goals, and procedures at the GHTF Web site and can be accessed at <http://ghtf.org>.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's Good Guidance Practice (GGP) regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the GHTF recommendations as related to premarket submission to FDA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

To receive a copy of "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff," by fax call CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1347) followed by the pound sign #. Follow the remaining voice prompts to complete your request.

To receive "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff," you may either send a fax request to 301-443-8818 to receive a hard copy of the document, or send an e-mail request to [gwa@cdhrh.fda.gov](mailto:gwa@cdhrh.fda.gov) to receive a hard copy or an electronic copy. Please use the document number 1347 to identify the guidance you are requesting.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes: Device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's, information on video conferencing, and electronic submissions, Mammography Matters, and other device-related information. The CDRH web site home page may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance

documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

## IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 2, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-22387 Filed 11-9-05; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### Program Exclusions: October 2005

**AGENCY:** Office of Inspector General, HHS.

**ACTION:** Notice of program exclusions.

During the month of October 2005, 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 name/address	Effective date
<b>PROGRAM-RELATED CONVICTIONS</b>	
ADAIR, KARISTA ..... LEWISBURG, TN	11/20/2005
AUSTIN, HOWARD ..... OAKDALE, LA	11/20/2005
BAILEY, LAWRENCE ..... SHREVEPORT, LA	11/20/2005
BESAW NALEN, KIMBERLY ... MANCHESTER, NH	11/20/2005
BLACK, ANTONIA ..... FLINT, TX	11/20/2005
CONVENIENT DENTAL CARE CENTER, PC ..... OKEMOS, MI	11/20/2005
DE LA CRUZ, ALFONSO ..... LOS ANGELES, CA	11/20/2005
ERLICH, RUSSELL ..... BROOKLYN, NY	11/20/2005
FLORES, SILVIA ..... ONTARIO, CA	11/20/2005
GARCIA, ROSEMARIE ..... SAN DIEGO, CA	11/20/2005
HAMILTON BENNETT, MAISHA ..... CHICAGO, IL	11/20/2005
HAWKINS, KIMBERLY ..... SHAKOPEE, MN	11/20/2005
HERNANDEZ, KAREN ..... OKLAHOMA CITY, OK	11/20/2005
KATZ, RONALD ..... OTISVILLE, NY	11/20/2005
KEMMETT, BARBARA ..... BRIDGEWATER, MA	11/20/2005
KUBRICKY, MARK ..... OGDEN, UT	11/20/2005
LAKHTER, ALEXANDER ..... E STROUDSBURG, PA	11/20/2005
LEBEL, ALEXANDER ..... BROOKLYN, NY	11/20/2005
LEEDS, LORI ..... SHAKOPEE, MN	11/20/2005
LITTLE, MARK ..... ANTHONY, TX	11/20/2005
MALVAREZ, NORBERTO ..... MIAMI, FL	11/20/2005
MARTINEZ, CESAR ..... MIAMI, FL	11/20/2005
MORAN, PAT ..... WICHITA FALLS, TX	11/20/2005
SHUMATE, TAMMY ..... LOUISVILLE, KY	11/20/2005
UTUK, BECALO ..... BRYAN, TX	11/20/2005
VU, PHOUA ..... SAN DIEGO, CA	11/20/2005
WALLACE, SHIRLEY ..... JONESBORO, AR	11/20/2005
WILLIAMS-WRIGHT, MYRA .... MIAMI, FL	11/20/2005
<b>FELONY CONVICTION FOR HEALTH CARE FRAUD</b>	
CHAVEZ, WILLIAM ..... MIAMI, FL	11/20/2005
GONZALEZ, DUVIEL ..... MIAMI, FL	11/20/2005
GORRIN, EDDY ..... MIAMI, FL	11/20/2005
KRZYS, PENNY ..... MIAMI, FL	11/20/2005

Subject name/address	Effective date	Subject name/address	Effective date	Subject name/address	Effective date
ASHTABULA, OH		FLATWOODS, KY		WEST HOLLYWOOD, CA	
<b>FELONY CONTROL SUBSTANCE CONVICTION</b>		CAVANAUGH, TRACIE .....	11/20/2005	MAESTRE, NANCY .....	11/20/2005
BROWN, MARY .....	11/20/2005	RENSSELAER, NY		KEYSTONE HEIGHTS, FL	
MARICOPA, AZ		CHAN, DENNIS .....	11/20/2005	MARRON, TIMOTHY .....	11/20/2005
CASTAGNETTI, LEINA .....	11/20/2005	SACRAMENTO, CA		APACHE JUNCTION, AZ	
HILO, HI		CLAYTON, MICHELLE .....	11/20/2005	MARTIN, ELIZABETH .....	11/20/2005
GUY, CRYSTAL .....	11/20/2005	VERNON, VT		DOTHAN, AL	
COLUMBIA, MS		COLBY, JULIE .....	11/20/2005	MARTINEZ, SYNTHIA .....	11/20/2005
ILIADES, EMMANUEL .....	11/20/2005	BYFIELD, MA		TYLER, TX	
CENTERVILLE, MA		CORBETT, KELLY .....	11/20/2005	MCBRIDE, MARGO .....	11/20/2005
MASCOLO, JOSEPHINE .....	11/20/2005	LAGUNA BEACH, CA		ANNAPOLIS, MD	
ELMWOOD PARK, NJ		CUNNINGHAM, RICHARD .....	11/20/2005	MCCALL, STEVEN .....	11/20/2005
MEHTA, DONNA .....	11/20/2005	DAPHNE, AL		GOODYEAR, AZ	
CHATTANOOGA, TN		DAVIS, LACIANA .....	11/20/2005	MCCOY, TIERRA .....	11/20/2005
THATCHER, GILIE .....	11/20/2005	METAIRIE, LA		RICHMOND, VA	
CHARLOTTESVILLE, VA		DENHALTER, MARY .....	11/20/2005	MCGEORGHEAN, ANTOINETTE	11/20/2005
WELCH, PAUL .....	11/20/2005	CLEARFIELD, UT		GILFORD, NH	
EDGEFIELD, SC		DENTON, TAMMY .....	11/20/2005	MCHUGH, LAURA .....	11/20/2005
<b>PATIENT ABUSE/NEGLECT CONVICTIONS</b>		MORTON, MS		CHELMSFORD, MA	
ACKLEY, CHRISTINE .....	11/20/2005	DINKINS, LINDA .....	11/20/2005	MCMAHON, KATHY .....	11/20/2005
CANON CITY, CO		JACKSONVILLE, FL		MOSA POINT, MS	
BEDDIE, ELIZABETH .....	11/20/2005	DOVE, LAURA .....	11/20/2005	MIRANNE, CHRISTOPHER .....	11/20/2005
BURLINGTON, VT		SHREVEPORT, LA		OAKLAND, CA	
COLBY, DEBORAH .....	11/20/2005	DUBRULE, ROSAIRE .....	11/20/2005	MORRIS, LAWRENCE .....	11/20/2005
EAST PROVIDENCE, RI		TIPTONVILLE, TN		FT LAUDERDALE, FL	
COOK, SHANNON .....	11/20/2005	ECKLUND, DAN .....	11/20/2005	O'DAY, JAMES .....	11/20/2005
FRESNO, CA		SILVERHILL, AL		CANTON, MI	
CRUZ, EVELYN .....	11/20/2005	FARCHIONE, LOUIS .....	11/20/2005	PALUMBO, TAMARA .....	11/20/2005
BROOKLYN, NY		PITTSFORD, NY		GOLDEN, CO	
HALLMARK NURSING CEN- TER, INC .....	11/20/2005	FENSKE, JOANA .....	11/20/2005	PATTERSON, ENOLA .....	11/20/2005
SCHENECTADY, NY		TUCSON, AZ		SPRINGFIELD, IL	
MANLAPAZ, CARLOS .....	11/20/2005	FLOYD, AMANDA .....	11/20/2005	PAYTON, JEAN .....	11/20/2005
CERRITOS, CA		MARIETTA, MS		GRENADA, MS	
PRIMO, ROFINO .....	11/20/2005	FRANKS, SUSANN .....	11/20/2005	PEEPLER, DEBRA .....	11/20/2005
LONDON, OH		TOWN CREEK, AL		DINSMORE, FL	
SANDY, ANJI .....	11/20/2005	GIRARDI, DEBORAH .....	11/20/2005	PETERS, ALONZO .....	11/20/2005
MCCLOUD, OK		NAPLES, FL		HOUSTON, TX	
YOUNG, LAKEYSHA .....	11/20/2005	GIROUARD, MARGARET .....	11/20/2005	RAINEY, APRIL .....	11/20/2005
MONTGOMERY, AL		BEDFORD, MA		DAYTON, NV	
<b>CONVICTION FOR HEALTH CARE FRAUD</b>		GOEPP, JULIUS .....	11/20/2005	RICHARD, MARY .....	11/20/2005
BROWNING, MISTY .....	11/20/2005	ROCHESTER, NY		SPRINGFIELD, IL	
WALKER, LA		GOODLUCK-JONES, KANDY	11/20/2005	SANDS, VANESSA .....	11/20/2005
JUNKINS, MICHELLE .....	11/20/2005	PHOENIX, AZ		PHOENIX, AZ	
HAMPTON, ME		GULLEDGE, WILLIAM .....	11/20/2005	SCALLY, MICHAEL .....	11/20/2005
SPOTWOOD, JEFFREY .....	11/20/2005	MOUNDEVILLE, AL		HOUSTON, TX	
VERNON, TX		HANSON, ROBIN .....	11/20/2005	SCHIRMER, BARBARA .....	11/20/2005
<b>LICENSE REVOCATION/SUSPENSION/ SURRENDERED</b>		LOGANSPOUT, LA		DUDLEY, NC	
ABBINANTE, ROBIN .....	11/20/2005	HARRIS, KANDY .....	11/20/2005	SCHWARTZ, MONTY .....	11/20/2005
MADISON, AL		MAYFIELD, KY		OAKLAND, FL	
ALOISI, MARTHA .....	11/20/2005	HAVARD, REBA .....	11/20/2005	SHAFER, CYNTHIA .....	11/20/2005
WORCESTER, MA		MOBILE, AL		CLEARWATER, FL	
ANDREWS, TRACIE .....	11/20/2005	HOLLAND, ANNISSA .....	11/20/2005	SINDERS, DONITTA .....	11/20/2005
ORMOND BEACH, FL		MILLRY, AL		DUGGER, IN	
BAIRD, TIMOTHY .....	11/20/2005	JOHNSON, ROSIE .....	11/20/2005	STREETER, WILBERT .....	11/20/2005
PARKERS LAKE, KY		HATTIESBURG, MS		TOPEKA, IN	
BILODEAU, JOHN .....	11/20/2005	JONES, CINDY .....	11/20/2005	URSIDA, JOSEPH .....	11/20/2005
HOOKSETT, NH		LONE WOLF, OK		ALBUQUERQUE, NM	
BRINSER, STACEY .....	11/20/2005	KASH, CONNIE .....	11/20/2005	VOIT, SHARON .....	11/20/2005
PINETOP, AZ		CAMPTON, KY		DWIGHT, IL	
CARTER, BRENDA .....	11/20/2005	KINCHEN, STACEY .....	11/20/2005	WARD, TINIKA .....	11/20/2005
HOOVER, AL		NEW BERLIN, WI		HATTIESBURG, MS	
CAUDILL, TAMMY .....	11/20/2005	KROL, GERALD .....	11/20/2005	WEISS, LEENA .....	11/20/2005
		EVERGREEN PARK, IL		MERRITT ISLAND, FL	
		LANDRUM, DEBORAH .....	11/20/2005	WILLIAMS, LEANNE .....	11/20/2005
		FT MYERS, FL		TUPELO, MS	
		LONGWOOD MASSAGE AND TANNING STUDIO .....	11/20/2005	WILLIAMS, SUSAN .....	11/20/2005
		LONGWOOD, FL		WAKE FOREST, NC	
		LOPEZ, LISA .....	11/20/2005	WILMSHURST, SANDRA .....	11/20/2005
		WILDWOOD, FL		VAN NUYS, CA	
		MABE, MARY .....	11/20/2005	WOODALL, JOHN .....	11/20/2005
		LAKE FOREST, CA			
		MACKAY, CHARLOTTE .....	11/20/2005		

Subject name/address	Effective date
PARIS, KY	
<b>OWNED/CONTROLLED BY CONVICTED ENTITIES</b>	
INTEGRITY OXYGEN & MEDICAL EQUIPMENT, INC .....	11/20/2005
SHREVEPORT, LA	
JACKSONVILLE HEALTH CARE SYSTEMS INC .....	11/20/2005
JACKSONVILLE, FL	
OK MEDICAL EQUIPMENT & SUPPLY COMPANY LLC .....	11/20/2005
SOUTHFIELD, MI	
OLD TOWNE CHIROPRACTIC CHISAGO CITY, MN	11/20/2005
<b>DEFAULT ON HEAL LOAN</b>	
ESTE-MCDONALD, JAIME .....	11/20/2005
ANDOVER, MA	
RATLIFF, CYNTHIA .....	11/20/2005
APTOS, CA	
SNOW, EDDIE .....	11/20/2005
OAKLAND, CA	
WELLMAN, FRED .....	11/20/2005
FLORENCE, MA	
WOODS, REBEKAH .....	11/20/2005
LOUISVILLE, KY	
<b>OWNERS OF EXCLUDED ENTITIES</b>	
ZAGERMAN, RHEA .....	11/20/2005
FARMINGTON HILLS, MI	

Dated: November 1, 2005.

**Katherine B. Petrowski,**

*Director, Exclusions Staff, Office of Inspector General.*

[FR Doc. 05-22438 Filed 11-9-05; 8:45 am]

**BILLING CODE 4152-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Program Project Review Meeting.

*Date:* December 5, 2005.

*Time:* 8 a.m. to 2 p.m.

*Agenda:* To Review and evaluate grant applications.

*Place:* Hyatt Arlington, 1325 Wilson Boulevard, Arlington, VA 22209.

*Contact Person:* John F. Connaughton, PhD., Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 757, 6707 Democracy Boulevard, Bethesda, MD 20892-5452. (301) 594-7797, [connaughtonj@extra.nidk.nih.gov](mailto:connaughtonj@extra.nidk.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 2, 2005.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 05-22479 Filed 11-9-05; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Microbiology, Infectious Diseases and AIDS Initial Review Group, Acquired Immunodeficiency Syndrome Research Review Committee. AIDS Research Review Committee.

*Date:* November 28-29, 2005.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Latham Hotel, 3000 M Street, NW., Washington, DC 20007.

*Contact Person:* Leyla S. Diaz, PhD, Scientific Review Administrator, Scientific

Review Program, Division of Extramural Activities, National Institutes of Health/ NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, (301) 451-3679, [diazl@niaid.nih.gov](mailto:diazl@niaid.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 2, 2005.

**Anne Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 05-22480 Filed 11-9-05; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Environmental Health Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Environmental Health Sciences Special Emphasis Panel, November 15, 2005, 1 p.m. to November 15, 2005, 3:30 p.m. Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC, 27709 which was published in the **Federal Register** on October 24, 2005, FR 70 204 61464.

The meeting will be held December 6, 2005 instead of November 15, 2005. The meeting is closed to the public.

Dated: November 2, 2005.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 05-22481 Filed 11-9-05; 8:45am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose