

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 Harmonised 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@cdrh.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
PROGRAM-RELATED CONVICTIONS	
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
FELONY CONVICTION FOR HEALTH CARE FRAUD	
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	
FELONY CONTROL SUBSTANCE CONVICTION		CAVANAUGH, TRACIE	11/20/2005	MAESTRE, NANCY	11/20/2005
BROWN, MARY	11/20/2005	RENSELAER, 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
PATIENT ABUSE/NEGLECT CONVICTIONS		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	FENSKO, 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	
CONVICTION FOR HEALTH CARE FRAUD		GOEPP, JULIUS	11/20/2005	RICHARD, MARY	11/20/2005
BROWNING, MISTY	11/20/2005	ROCHESTER, NY		SPRINGFIELD, IL	
WALKER, LA		GOODLUCK-JONES, KANDY		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	MOUNDVILLE, AL		HOUSTON, TX	
VERNON, TX		HANSON, ROBIN	11/20/2005	SCHIRMER, BARBARA	11/20/2005
LICENSE REVOCATION/SUSPENSION/ SURRENDERED		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	SHAFFER, 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		ALIQUIPPA, PA	
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	

OWNED/CONTROLLED BY CONVICTED ENTITIES

INTEGRITY OXYGEN & MEDICAL EQUIPMENT, INC SHREVEPORT, LA	11/20/2005
JACKSONVILLE HEALTH CARE SYSTEMS INC JACKSONVILLE, FL	11/20/2005
OK MEDICAL EQUIPMENT & SUPPLY COMPANY LLC SOUTHFIELD, MI	11/20/2005
OLD TOWNE CHIROPRACTIC CHISAGO CITY, MN	11/20/2005

DEFAULT ON HEAL LOAN

ESTE-MCDONALD, JAIME ANDOVER, MA	11/20/2005
RATLIFF, CYNTHIA APTOS, CA	11/20/2005
SNOW, EDDIE OAKLAND, CA	11/20/2005
WELLMAN, FRED FLORENCE, MA	11/20/2005
WOODS, REBEKAH LOUISVILLE, KY	11/20/2005

OWNERS OF EXCLUDED ENTITIES

ZAGERMAN, RHEA FARMINGTON HILLS, MI	11/20/2005
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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.nidDK.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.

(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