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	11/20/2005

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

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. 05–22479Filed 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