amendments thereto, is hereby withdrawn, effective December 27, 2005.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these NADAs.

Dated: December 7, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–24103 Filed 12–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Nonprescription Drugs Advisory Committee (NDAC) and the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC).

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 23, 2006, from 8 a.m. to 5 p.m.

Location: Holiday Inn Select Bethesda, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD. The hotel telephone number is 301–652–2000.

Contact Person: Darrell Lyons, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *lyonsd@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) codes 3014512541 or 3014512536. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committees will consider the safety and efficacy of new drug application (NDA) 21–887, proposing over-the-counter (OTC) use of ORLISTAT (tetrahydrolipstatin) capsules (60 milligrams (mg)), GlaxoSmithKline Consumer Healthcare, L.P., to promote weight loss in overweight adults when used along with a reduced calorie and low fat diet. The background material will become available no later than the day before the meeting and will be posted under NDAC or EMDAC's docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* (click on the year 2006 and scroll down to NDAC or EMDAC).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person by January 13, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 13, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Darrell Lyons at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 2, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. 05–24101 Filed 12–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–05–8000]

Memorandum of Understanding Between the United States Food and Drug Administration and the C–Path Institute

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the United States Food and Drug Administration and the C–Path Institute. The specific purpose of this MOU is to establish an overarching framework for collaboration between the parties. This framework will be based on mutually agreed upon programs and activities in the areas of applied scientific research and training/education to foster the development of new evaluation tools to inform medical product development. The parties shall each leverage its own expertise and resources to facilitate programs of shared interests across the diverse disciplines of therapeutics, biological sciences, engineering and medical devices in building applied research and training/education programs. The appropriate formal agreements will be executed as required by law for any activities that result from this collaboration.

DATES: The agreement became effective October 14, 2005.

FOR FURTHER INFORMATION CONTACT: *For C–Path Institute*: Raymond L. Woosley, The Critical Path Institute, 4280 N. Campbell Ave., #214, Tucson, AZ 85718, 520–547–3440, FAX: 520–547–3456, e-mail: *rwoosley@c-path.org*.

For The Food and Drug Administration: Mary I. Poos, Office of External Relations, Food and Drug Administration (HF–10), 5600 Fishers Lane, Rockville, MD 20857, 301–827–2825, FAX: 301–827–3042, e-mail: *mary.poos@fda.gov*.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: December 7, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

225-05-8000

MEMORANDUM OF UNDERSTANDING
BETWEEN THE
UNITED STATES FOOD AND DRUG ADMINISTRATION
AND THE
C-PATH INSTITUTE

This Memorandum of Understanding (MOU) between the U.S. Food and Drug Administration (FDA) and the Critical Path Institute (C-Path) (hereafter termed "the Parties") formalizes an agreement between the two parties to develop collaborative activities in the areas of applied research, training and education to enhance safe and efficacious medical product development.

I. Purpose

The specific purpose of this MOU is to establish an overarching framework for collaboration between the Parties. This framework will be based on mutually agreed upon programs and activities in the areas of applied scientific research and training/education to foster the development of new evaluation tools to inform medical product development. The Parties shall each leverage its own expertise and resources to facilitate programs of shared interests across the diverse disciplines of therapeutics, biological sciences, engineering and medical devices in building applied research and training/education programs. The appropriate formal agreements will be executed as required by law for any activities that result from this collaboration.

II. Background

The FDA is responsible for reviewing clinical research to ensure that marketed human medical products (drugs, biologics, and medical devices) have been shown to be safe and effective.

The C-Path Institute is a non-profit research and education organization located in Tucson, Arizona. The Institute's purpose is to create innovative programs in education and research to enable safe acceleration of medical product development. It also serves as a 'neutral ground' for academia, industry and government to test ideas that will result in optimal (safe, effective, timely) drug development processes. C-Path brings together faculty from the UAZ Colleges of Pharmacy, Medicine, Agriculture and Life Sciences, and the School of Management as well as clinicians and researchers from the UAZ Comprehensive Cancer Center, the Sarver Heart Center, the Pima Community College, Arizona State University and the Translational Genomics Research Institute in programs related to pharmaceutical discovery and development, clinical research and good clinical practices (GCP) as well as scientific staff from SRI International (an independent, non-profit technology development organization), who have substantial experience in developing drugs for commercial manufacturing. SRI International is a contractor for NIH and has initiated a drug development consortium with other academic institutions, the purpose of which is to assist faculty investigators to translate research into clinical drug candidates.

III. Substance of Agreement

This MOU is intended as an overarching framework for joint collaboration between the Parties, toward the goal of developing new evaluative tools to inform medical product development. The areas of collaboration would include, but not be limited to:

Training/Education programs: Activities arising from complementary interests will be developed jointly by C-Path and FDA, and offered to academia, industry, and others as identified needs arise. The Parties will disseminate information through mutually agreed vehicles including training activities, meetings, and symposia.

Applied Research programs: Programs will be developed in areas of mutual complementary interest such as imaging, biomarkers and surrogate markers, proteomics and genomics, clinical trial design, and other areas that will enhance medical product development.

As specific topics for joint training/education and/or research are identified under this MOU they will be conducted under the appropriate formal agreements as required by law.

IV. Participation

It is anticipated that a wide range of faculty and graduate students, clinicians, and researchers from academic programs may participate in activities developed under this agreement, including, but not limited to, University of Arizona Comprehensive Cancer Care Center, the Sarver Heart Center, the Colleges of Pharmacy, Medicine, Management, and Agriculture and Life Sciences, Pima Community College, Arizona State University, Translational Genomics Research Institute, and SRI International. Other participants could include FDA staff, scientists from industry, field laboratories and others identified for joint training and outreach activities.

Each Party will appoint appropriate representatives to facilitate the planning, preparation, and implementation of the activities within the framework of this MOU. Meetings will be convened at a venue and time agreed between Parties, and each Party shall be responsible for its own expenses incurred in sending representatives to these meetings.

V. Resource Obligations

This MOU describes in general terms the basis upon which the Parties intend to cooperate. It does not create binding, enforceable obligations against any Party. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and appropriated funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Parties and does not affect the ability of the Parties to enter into other agreements or arrangements related to this MOU.

VI. Name and Address of Participating Parties and Liaisons

A. C-Path Institute
Raymond L. Woosley, M.D., Ph.D.
President
The Critical Path Institute
4280 N. Campbell Ave. # 214
Tucson, AZ 85718
Phone: 520-547-3440
Fax: 520-547-3456
Email: rwoosley@c-path.org

B. Food and Drug Administration
Mary I. Poos, Ph.D.
Director, Academic and Intellectual Partnerships
Office of External Relations
Food and Drug Administration
Parklawn Bldg, Room 14C-06 (HF-10)
5600 Fishers Lane
Rockville, MD 20857
Tel: (301) 827-2825
Fax: (301) 827-3042
Email: mary.poos@fda.gov

VII. Period of Agreement

This MOU becomes effective upon the date of the last Party to sign ("effective date") and will continue in effect for five years. It may be modified by mutual written consent or terminated by either party upon a 30-day advanced written notice to the other party. The Parties agree to evaluate the MOU periodically during the effective period, but at least once annually, on or before the anniversary of the effective date. Upon evaluation, either Party shall have the option of continuing, modifying, or canceling this agreement as provided for in Article VII of this MOU.

APPROVED AND ACCEPTED FOR THE C-PATH INSTITUTE

By Raymond L Woosley

Title President

Date September 14, 2005

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By

Title Deputy Commissioner for Operations

Food and Drug Administration

Date 10/17/05

Cleared: R. Garwood, ORM 5/18/05
Reviewed and cleared: R. Springer, OM/OAGS 5/18/05
Reviewed and edited: L. Mahler, OCC 8/23/05
Reviewed and cleared: P. Stannard, OS 9/12/05

[FR Doc. 05–24100 Filed 12–15–05; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: November 2005

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of November 2005, 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 name, address	Effective date
PROGRAM-RELATED CONVICTIONS	
BASONE, RENNAE AKRON, OH	12/20/2005
BERTIE, LIONEL TOLEDO, OH	12/20/2005
BRAVO, THERESA SAN DIEGO, CA	12/20/2005
BROUSSARD, JERRY BEAUMONT, TX	12/20/2005
BRUMBAUGH, JAY COLLINSVILLE, OK	12/20/2005
CABRERA, DAISY BRONX, NY	12/20/2005
CARTER, ANGELA OSKALOOSA, IA	12/20/2005
CHINI, JERI PORT CLINTON, OH	12/20/2005
CLOSE, CHRISTOPHER ATWATER, CA	12/20/2005
DYE, HEATHER MILWAUKEE, WI	12/20/2005
EDWARDS, TERRI GAHANNA, OH	12/20/2005
FRID, BORIS WOODLAND HILLS, CA	12/20/2005
GORELICK, STUART BLOOMFIELD HILLS, MI	12/20/2005
HARVEY, JAMES LAKEWOOD, WA	12/20/2005
HARVEY, RUBY LAKEWOOD, WA	12/20/2005
HATHAWAY, BRIAN REYNOLDSBURG, OH	12/20/2005
HOWARD, JULIE FULTON, MS	12/20/2005
KHANNA, ARUN STONE MOUNTAIN, GA	12/20/2005
LOCKE, STEPHANIE HOUSTON, TX	12/20/2005
MASON, CLINT FORK, SC	12/20/2005
MERRITT, RICKLEY GREER, SC	12/20/2005
MILLER, MICHELLE SHAKOPEE, MN	12/20/2005
MOORE, MERLYN RIALTO, CA	12/20/2005
MR J'S LIQUOR, INC LOS ANGELES, CA	12/20/2005
PABBATHI, RAMMOHAN TRENTON, NJ	12/20/2005
PROFESSIONAL AMBULANCE SVC OF NORWICH, INC NORWICH, CT	12/20/2005
PROVINCE, KIMBERLY CLARKSDALE, MS	12/20/2005
RINGGENBERG, JULIE OTTUMWA, IA	12/20/2005
ROBY, JARROD COLUMBUS, OH	12/20/2005
ROSEL, NICOLE COOPERSVILLE, MI	12/20/2005
SATTARI, PARI TARZANA, CA	12/20/2005
SAULTER, MONROE THREE RIVERS, TX	12/20/2005
SCHAEFER, CHRISTA MARICOPA, AZ	12/20/2005
TAMAYO, HEIROL MONTGOMERY, AL	12/20/2005
VALLE, LUIS GLENDALE, CA	12/20/2005
VUKASIN, ALAN COTTONWOOD, ID	12/20/2005
WEILAND, JEANETTE HURSON, SD	12/20/2005
WHITE, ROBERT WILSONVILLE, OR	12/20/2005
FELONY CONVICTION FOR HEALTH CARE FRAUD	
BUNKER, JASON SAN BERNARDINO, CA	12/20/2005
CATANZARO, DANIEL CARTERSVILLE, GA	12/20/2005
DENNETT, ROBIN AUGUSTA, ME	12/20/2005
HAMPTON, STACEY ST LOUIS, MO	12/20/2005
MOORE, MARK DAYTON, OH	12/20/2005
NJOROGE, GEOFFREY OKLAHOMA CITY, OK	12/20/2005
PALMER, CARLTON COLUMBUS, OH	12/20/2005
SIM, TOM SANTA CLARA, CA	12/20/2005
WHITE, JACQUESE MEMPHIS, TN	12/20/2005
FELONY CONTROL SUBSTANCE CONVICTION	
CHLYSTA, RUSSELL YANKTON, SD	12/20/2005
FERNANDEX, BRENDA NACOGDOCHES, TX	12/20/2005
GRAYS, SONYA WACO, TX	12/20/2005
HAAKE, DONNA BELLEVUE, NE	12/20/2005
HEIKENS, ANGELA BELLE FOURCHE, SD	12/20/2005
KUTZNER, JAMES LOUISVILLE, KY	12/20/2005
MARTENS, DALE LONDONDERRY, VT	12/20/2005
MCCARTNEY, LUANNE COAHOMA, TX	12/20/2005
NYMAN, CATHERINE DENVER, CO	12/20/2005
ODVODY, DAWN GREENVILLE, IL	12/20/2005
PALMER, MARTIN WASILLA, AK	12/20/2005
RIOJAS, JEANETTE DEER PARK, TX	12/20/2005
RYABIK, BRETT DORAVILLE, GA	12/20/2005
SCOTT, BRUCE QUINCY, IL	12/20/2005
SHULTZ, ALAN MOUNT STERLING, KY	12/20/2005
WAY, NANCY FT WORTH, TX	12/20/2005
WHITAKER, DARWIN HAZARD, KY	12/20/2005
PATIENT ABUSE/NEGLECT CONVICTIONS	
ANDERSON, ERNEIS CLINTON, SC	12/20/2005
BASSO, ALICIA ROCHESTER, NY	12/20/2005
CANTU, HELEN MADERA, CA	12/20/2005
CLARK, RUBY PIONEER, LA	12/20/2005
CLENDENEN, BRENDA HODGEN, OK	12/20/2005
COPES, RESHAWN LEESVILLE, LA	12/20/2005
HAWKINS, BRIAN FOUNTAIN HILLS, AZ	12/20/2005
JIMENEZ, ALICIA LOS ANGELES, CA	12/20/2005
LAMBERT, STEPHANIE JANESVILLE, WI	12/20/2005
MOENICH, KIM CLEVELAND, OH	12/20/2005
MOORE, MICHAEL HENNESSEY, OK	12/20/2005
NAVARRO, JEA VALLEJO, CA	12/20/2005
NORRIS, KIMBERLY CHILDRESS, TX	12/20/2005
POPPY, THOMAS SPRING HILL, FL	12/20/2005
PRADA, GERMAN SPRINGBORO, OH	12/20/2005
SAGUIBO, VERONICA	12/20/2005