Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Request for Applications: OH–04–001.

Contact Person for More Information: Pervis C. Major, Ph.D., Scientific Review Administrator, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, WV 26505, telephone 304–285–5979.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: January 14, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 04–1303 Filed 1–21–04; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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 Committee: Vaccines and Related Biological Products Advisory Committee.

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

Date and Time: The meeting will be held on February 18, 2004, from 8:30 a.m. to 4:30 p.m.; and on February 19, 2004, from 8:30 a.m. to 12:30 p.m.

Location: The meeting will be held at the Sheraton Four-Points Hotel, 8400 Wisconsin Ave., Bethesda, MD.

Contact Person: William Freas or Denise H. Royster, Food and Drug Administration, Center for Biologics Evaluation and Research (CBER) (HFM–71), 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will review and discuss the selection of strains to be included in the influenza virus vaccine for the 2004–2005 season. The committee and CBER will begin a discussion of the potential suitability for use in vaccine manufacture of influenza isolates that have been passaged through mammalian cells (e.g., Madin-Darby Canine Kidney cells or Vero cells).

Procedure: On February 18 and 19, 2004, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 4, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. to 1:30 p.m. on February 18, 2004, and between 8:45 a.m. to 9:15 a.m. on February 19, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 13, 2004, 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 William Freas or Denise H. Royster 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: January 12, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–1264 Filed 1–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Memorandum of Understanding Between the Food and Drug Administration and the Environmental Protection Agency, Office of Research and Development

[FDA 225–04–4000]

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 FDA and the U.S. Environmental Protection Agency (EPA), Office of Research and Development. The purpose of the MOU is to expedite research and development of new methods and technologies that can be implemented in support of Homeland Security efforts by Federal, State or local government entities as well as authorized private sector organizations to avert and/or mitigate the effects of terrorist activities in the United States.

DATES: The agreement became effective February 19, 2003.

FOR FURTHER INFORMATION CONTACT: Frederick L. Fricke, Jr., Forensic Chemistry Center (HFR–CE500), Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513–679–2700, ext. 180.

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: January 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

Memorandum of Understanding
Between
United States Environmental Protection Agency
Office of Research and Development
and
United States Food and Drug Administration
Office of Regulatory Affairs
for
Collaborative Research and Development and Emergency Response Triage Efforts for Homeland Security

I. Purpose, Objectives and Goals:

a. **Purpose.** This Memorandum of Understanding (MOU) establishes the framework for collaborative research and development and emergency triage response efforts between the U.S. Environmental Protection Agency's (EPA's) Office of Research and Development (EPA and its Laboratories and Centers) and the Food and Drug Administration (FDA) Office of Regulatory Affairs (FDA and its Laboratories) on the subject of Homeland Security. Research and development and emergency triage efforts specifically targeted under this MOU are focused on, but not limited to, safe buildings, water security, food safety and rapid risk assessment. The MOU is intended to expedite research and development of new methods and technologies that can be implemented in support of Homeland Security efforts by federal, state or local government entities as well as authorized private sector organizations to avert and/or mitigate the effects of terrorist activities in the United States.

Both EPA and FDA believe that this collaboration will contribute to more efficient resource utilization, avert or minimize duplication, and accelerate method and technology advancement in the Homeland Security arena. The two organizations further believe that successful collaboration will leverage beneficial results via method and technology transfer and emergency triage response in support of human health and environmental protection, while ensuring a safe food and water supply for the United States of America.

b. **Objectives.** FDA and EPA will work collaboratively to expedite development of methods and technologies that are needed to address Homeland Security issues.

c. **Goals.**

i. Identify method and technology needs, formulate research and development projects that address emergency response triage needs, and establish Interagency Agreements (IAGs) or other extramural arrangements that describe how personnel and resources

of FDA and EPA will be effectively utilized to perform research and development projects addressing Homeland Security issues such as early detection of impending terrorist attacks or the aftermath of terrorist attacks.

ii. Perform collaborative research and development projects in an expeditious manner.

iii. Provide products from the research and development projects in a form and format that can be easily used and understood by the targeted public and private sector organizations involved in Homeland Security activities.

II. Background and Program Scope:

a. **Background.** Terrorist attacks against the United States and the consequent war on terrorism being waged by the U.S., its allies and many countries around the world have provided great impetus for the development of methods and technologies that can be utilized to detect and/or neutralize terrorist threats. One of the greatest concerns facing the United States and other nations is the deliberate use of chemical, biological, nuclear or radiological weapons by terrorist organizations. Following the tragic events of September 11, 2001, the U.S. Food and Drug Administration, the U.S. Environmental Protection Agency, and other federal agencies, as well as universities and emergency response organizations in the public and private sector, began addressing the need for new methods and technologies related to Homeland Security.

b. **Program Scope.** Under this MOU the two organizations - EPA and FDA - will meet on an annual basis to identify areas of research and development, and emergency response triage activities related to Homeland Security that can be efficiently addressed through a collaborative approach.

III. Responsibilities:

a. **The Food and Drug Administration agrees to:**

i. Work with EPA to exchange information consistent with agency regulations governing the release of information to other federal agencies and identify research and development needs and emergency response triage activities in the area of Homeland Security. Develop, formulate and establish IAGs [this MOU will be incorporated by reference in each related IAG] between specific EPA Laboratories and Centers and one or more FDA Laboratories. Describe specific research and development projects, and emergency response triage activities that will be jointly pursued by FDA and EPA.

ii. Participate in joint technical activities (e.g., inspections, workgroups, scientific or engineering panels) with representatives from EPA, and other organizations which may be established to provide technical advice and guidance on issues related to Homeland Security.

iii. Enter into IAGs that address research and development needs, under which FDA personnel from one or more FDA Laboratories will work cooperatively on projects of mutual interest and formulated as described above with EPA as time (the Food and Drug Administration has priority) and resources permit.

iv. In special cases and subject to approval by the Director of the appropriate FDA Laboratory, work con-jointly with EPA to address the research and development needs, and emergency response triage activities of a third party (either public or private).

v. Assign a Management Point of Contact and Technical Lead(s) for interactions with the EPA.

vi. Provide, in cooperation with EPA's Management Point of Contact, an annual executive summary report on the progress made under this MOU for each of the IAGs, or other cooperative activities, that are developed as part of this agreement (MOU).

vii. Record, produce and maintain minutes of meetings as described in this MOU.

b. **The Environmental Protection Agency agrees to:**

i. Work with FDA to exchange information consistent with agency regulations governing the release of information to other federal agencies and identify research and development needs, and emergency response triage activities in the area of Homeland Security. Develop, formulate and establish IAGs [this MOU will be incorporated by reference in each related IAG] between one or more FDA Laboratories and EPA Laboratories and Centers. Describe specific research and development projects, and emergency response triage activities that will be jointly pursued by EPA and FDA.

ii. Participate in joint technical activities (e.g., inspections, workgroups, scientific or engineering panels) with representatives from EPA, and other organizations which may be established to provide technical advice and guidance on issues related to Homeland Security.

iii. Enter into IAGs that address research and development needs, under which EPA personnel will work cooperatively on projects of mutual interest and formulated as described above with FDA as time (the EPA mission has priority) and resources permit.

iv. In special cases and subject to approval by the Director of the appropriate EPA Laboratory or Center, work con-jointly with FDA to address the research and development needs, and emergency response triage activities of a third party (either public or private).

v. Cooperate in making facilities available in cases where emergency response activities are required.

vi. Assign a Management Point of Contact and Technical Lead(s) for interactions with the FDA.

vii. Provide, in cooperation with FDA's Management Point of Contact, an annual executive summary report on the progress made under this MOU for each of the IAGs, or other cooperative activities, that are developed to carry out his MOU.

IV. Memorandum of Understanding (MOU) Administration:

a. **Reports.** The status of work performed under this MOU will be reviewed on an annual basis. The FDA Coordinator of Counter Terrorism Laboratory Response Development/ Office of Regulatory Affairs, will take the lead and be responsible for organizing meetings (planning meetings and annual meetings), developing agenda and recording results of the meetings. Minutes of the meetings will be produced by FDA and be distributed to meeting participants as well as to the Director of the appropriate FDA Laboratory and in turn the Commissioner, FDA and to the EPA. A central file (retained by FDA) will be maintained.

b. **Information Releases:** The Associate Commissioner for Regulatory Affairs, FDA, and the Assistant Administrator, EPA (or their designees) will jointly review and approve information regarding MOU activities (meetings, new developments, etc.) prior to public release. IAGs prepared under this agreement will stipulate specific procedures for the coordination, handling and public disclosure of information. All information disclosures concerning activities under this MOU or subsequent IAGs will comply with agency regulations governing the release of information. Where particular information protocols apply to a particular laboratory, or network of laboratories, those protocols will be followed by both parties to this MOU.

c. **Security Classification:** The highest security classification applied by either FDA or EPA will govern the handling of information and reports under this MOU, as appropriate. The security classification and procedures will be stipulated in each IAG.

d. **Facility Security, Health, Safety and Environmental Compliance:** The host facility's security, health, safety and environmental compliance programs will be followed by personnel when engaged in work activities as outlined in this MOU. Workers Compensation Claims shall be covered by the employee's agency.

e. **Reimbursement Policy:** Each party to this agreement will handle and expend its own funds. The responsibilities assumed by each party are contingent upon funds being available from which expenditures legally may be met.

f. **Annual Management Meetings:** EPA and FDA will meet yearly to plan and coordinate research and development activities, and emergency response triage activities under this MOU. Such meetings will be held at a mutually agreed upon location and on a date that is compatible with the planning and budgeting cycle of each organization. At this meeting, recommendations for adjustments to current activities, projects, and budget priorities will be proposed and agreed upon by the Management Points of Contact for submission to the appropriate EPA and FDA administrators for further action.

g. **Semi-Annual Technical Discussions:** EPA and FDA will meet twice a year to discuss technical progress under each IAG or activity. These reviews will require technical information exchange by EPA and FDA Technical Leads. These meetings may include individuals from outside of EPA and FDA as mutually agreed to by the respective Management Points of Contact.

h. **Technical Lead Responsibilities:** Technical Leads for each IAG or activity will strive to engage in:

- Providing technical information exchange consistent with agency regulations governing the exchange or release of information
- Delivering written or verbal technical evaluations of progress
- Conducting visit to sites where research is underway
- Organizing and Participating in technical workshops and scientist-to-scientist meetings
- Reporting on any exceptional accomplishments from, or impediments to, successful program or project execution
- Recommending improvements for the MOU activities

i. **Approvals:** All IAGs and activities conducted to carry out this MOU must be agreed to and approved by the EPA and FDA prior to commencement of any technical work.

j. **Inventions and Licensing:** Activities conducted to carry out this MOU and any IAGs or other extramural arrangements may result in products or processes that are patentable or otherwise proprietary. The organization whose work results in the invention shall disclose the invention to the other organization and then prepare, file, and prosecute patent applications. If protection is granted, the inventing organization will manage the invention in accordance with its rules and regulations. Inventions resulting from joint research and development by both EPA and FDA employees shall be handled as jointly agreed to at the time of the disclosure.

V. Period of Agreement:

a. This MOU shall be effective for seven years from the date of the last signature unless canceled in writing by (either/any) of the participating organizations with 90 days notice.

b. Conflicts that may arise after the MOU is in effect will be resolved by EPA and FDA Management Points of Contact. If conflicts cannot be resolved at this level, then they will be taken to the respective Points of Contacts Directors in the EPA and FDA Laboratories. If conflicts cannot be resolved at this level, then the signatory authorities for this MOU will resolve the conflicts either by coming to informal agreement or by amending the MOU.

c. This MOU will be reviewed annually by the Management Points of Contact to determine if any changes or amendments should be incorporated. Such changes or amendments will be formally incorporated in the MOU within 90 days of the annual review.

VI. Names and Addresses of Parties:

Environmental Protection Agency
26 West Martin Luther King Drive
Cincinnati, Ohio 45268

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

VII. General Provisions:

a. Nothing in this MOU supersedes any other memorandum of understanding held by either party.

b. This MOU in no way restricts the parties from participating in similar activities or arrangements with other public or private agencies, organizations, or individuals.

c. 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.

Approved and Accepted for the Food and Drug Administration by

John M. Taylor
Associate Commissioner for Regulatory Affairs
U.S. Food & Drug Administration

2/14/03
Date

Approved and Accepted for the Environmental Protection Agency by:

E. Timothy Oppelt
Director, National Homeland Security Research Center
U. S. Environmental Protection Agency

2/19/03
Date

[FR Doc. 04–1263 Filed 1–21–04; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Inhibitors of Formation of Protease Resistant Prion Protein

Bruce Chesebro, Byron Caughey, Joelle Chabry, Susette Priola (NIAID). U.S. Patent 6,211,149 issued on 03 Apr 2001 (DHHS Reference No. E–189–1998/0–US–02); U.S. Patent 6,355,610 issued on 12 Mar 2002 (DHHS Reference No. E–189–1998/0–US–03); U.S. Patent Application No. 10/096,080 filed 11 Mar 2002 (DHHS Reference No. E–189–1998/0–US–04).

Licensing Contact: Michael Ambrose; 301/594–6565; *ambrosem@mail.nih.gov*.

Protease-resistant prion proteins are actively associated with various transmissible spongiform encephalopathies (TSEs). These include Creutzfeldt-Jakob disease in humans and Bovine spongiform encephalopathy (''mad cow disease'') in cattle.

The present invention discloses proprietary peptides and potential pharmaceutical compositions using such peptides that inhibit the formation of protease-resistant prion protein aggregates. These aggregates develop into amyloid deposits in the brain of affected patients, leading to the development of the spongiform encephalopathy. The peptides, when used in vitro inhibit such aggregation. Furthermore, when used in pharmaceutical compositions and medically relevant dosages, may be used for therapies for TSEs.

Inhibitors of Amyloid Formation

Winslow S. Caughey, Byron Caughey, Lynne D. Raymond, Motohiro Horiuchi (NIAID). U.S. Patent 6,632,808 issued on 14 Oct 2003 (DHHS Reference No. E–205–1998/0–US–03).

Licensing Contact: Michael Ambrose; 301/594–6565; *ambrosem@mail.nih.gov*.

This invention discloses methods, compounds and compositions for therapeutic treatment of amyloidogenic diseases, like Alzheimer's disease, type 2 diabetes and, particularly, transmissible spongiform encephalopathies (prion diseases) such as CJD, Kuru in humans and BSE (''Mad Cow Disease'') in cattle.

The invention is based on the findings that cyclic tetrapyrroles and derivatives inhibit the formation of protease-resistant prion protein (PrP-res) the pathologic, amyloidogenic protein aggregates of the prion diseases. These methods and compounds have the potential for the development of pharmaceutical therapies for the treatment and prevention of progression of such TSEs.

Inhibition of Diseases Associated With Amyloid Formation

Byron Caughey, Richard E. Race (NIAID).

U.S. Patent 5,276,059 issued on 04 Jan 1994 (DHHS Reference No. E–107–1992/0–US–01).

Licensing Contact: Michael Ambrose; 301/594–6565; *ambrosem@mail.nih.gov*.

Amyloid deposition in brain samples is diagnostic for several serious and fatal diseases. These include Alzheimer's disease as well as several transmissible spongiform encephalopathies (prion diseases) such as CJD and BSE (''Mad Cow Disease''). Together, these diseases having amyloid depositions are termed amyloidogenic diseases.

This invention covers and discloses the method and compositions of using Congo Red in the treatment of such amyloidogenic diseases. Congo Red is shown to inhibit the accumulation of PrP-res, the amyloidogenic and pathologic protein or the transmissible spongiform encephalopathies. The potential therapeutics covered by this invention includes Congo Red and its derivatives.

Dated: January 14, 2004.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 04–1258 Filed 1–21–04; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Codon-Optimization of the HIV–1 Vif Gene

Klaus Strebel, Stephan Bour, Kim-Lien Nguyen (NIAID); DHHS Reference No. E–041–2004/0—Research Tool/Biological Material; Licensing Contact: Michael Ambrose; 301/594–6565; *ambrosem@mail.nih.gov*.

Expression of the HIV–1 Vif protein in the absence of other viral factors such a Tat and Rev is extremely inefficient due to the presence of inhibitory sequences on its mRNA. This invention uses codon optimization to remove such inhibitory sequences without altering the amino acid sequence of the protein. The modified vif gene in the resulting pcDNA -hVIF vector is expressed under the control of the CMV promoter. In this, the protein functions as wild type and is more amendable to high-level expression in mammalian cells.

Currently this vector is used in on-going studies of HIV infection and its