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

Dated: September 10, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–21574 Filed 9–15–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0484]

Preparation for International Conference on Harmonization Meetings in Brussels, Belgium; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH meetings in Brussels, Belgium'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Brussels, Belgium. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Groups meetings in Brussels, Belgium, November 10 to 13, 2008, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The meeting will be held on Tuesday, October 21, 2008, from 3 p.m. to 5:30 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3rd floor, Conference Rooms D and E, Rockville, MD 20857. For security reasons, all attendees are asked to arrive no later than 2:45 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to Conference Rooms D and E.

Contact Person: All participants must register with Tammie Jo Bell, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by email: *tammie.bell@fda.hhs.gov* or fax: 301–827–0003.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material and requests to make oral presentation, to the contact person by October 14, 2008.

If you need special accommodations due to a disability, please contact Tammie Jo Bell at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–66, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Background: The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States, without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufactures Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org*.

Dated: September 9, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21573 Filed 9–15–08; 8:45 am]

BILLING CODE 4160–01–S

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.

Use of Razoxane for the Treatment of Alzheimer's Disease

Description of Technology: Abnormalities in the metabolism of the transition metals, iron and copper, have been demonstrated to play a crucial role in the pathogenesis of various neurodegenerative diseases, including Alzheimer's disease (AD) and Parkinson's disease (PD). Excessive iron accumulation in the brain occurs in both AD and PD. High levels of reactive iron can increase oxidative stress-induced neuronal vulnerability, increase the toxicity of environmental or endogenous toxins, and accelerate hallmark pathologies of these diseases.

As an example among many, the expression level of amyloid-β precursor protein (APP) that generates the AD neurotoxic peptide, amyloid-β (Aβ), is

regulated in large part by iron levels. APP mRNA has an iron response element (IRE) in its 5′-untranslated region, and cleavage of APP to release different amyloidogenic and non-amyloidogenic peptide forms involves metalloproteases.

Elevated Aβ levels as well as plaques formed by aggregation of Aβ involve iron, and play a significant role in degeneration of the brain seen in AD. Chelators can reduce both the generation and aggregation of Aβ. Razoxane, a bisdioxopiperazine, is an orally active metal chelator approved for the treatment of cancer, where it and dexrazoxane have been effectively used for decades. In neuronal cell culture models, razoxane induced dose-dependent reductions in APP and Aβ levels without toxicity. In animal experiments (transgenic mice expressing human Aβ), razoxane substantially reduced Aβ 1–40 and 1–42 in brain by up to 46% without toxicity following once daily, 21 day administration.

The claimed invention is the novel use of razoxane and other bisdioxopiperazines to reduce amyloid-beta peptide levels, reduce aggregation of alpha-synuclein and tau protein, and reduce abnormal protein folding or aggregation for the treatment of AD and related diseases with protein aggregation pathology. Since razoxane has been approved for humans use, it could be more quickly developed as a treatment for AD, PD and other diseases.

Market:

• Up to 4.5 million Americans are estimated to suffer from AD, which usually strikes after the age of 60.

• Population longevity is increasing so AD is expected to be a growing health problem.

• Currently marketed drugs only delay the severity of AD so better solutions are needed.

Development Status: Clinical safety data and pre-clinical efficacy data for treatment of Alzheimer's disease.

Inventors: Nigel H. Greig (NIA).

Patent Status:

• U.S. Provisional Application No. 60/811,836 filed 08 Jun 2006 (HHS Reference No. E–216–2007/0–US–01).

• PCT Application No. PCT/US2007/013607 filed 08 Jun 2007, which published as WO 2007/146178 on 21 Dec 2007 (HHS Reference No. E–216–2007/0–PCT–02).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Norbert Pontzer, J.D., PhD; 301–435–5502; *pontzern@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute on Aging, Laboratory of Neurosciences, Section on Drug Design & Development, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize razoxane and analogues for the treatment of neurodegenerative disorders, such as Alzheimer's and Parkinson's diseases. Please contact Nigel H. Greig (*Greign@grc.nia.nih.gov*) for more information.

Prevention and Treatment of Multiple Sclerosis (MS) by Administering E–Selectin

Description of Technology: The invention is a method and composition for inhibiting or treating symptoms of inflammatory demyelination or inflammation associated with autoimmune disorders. This is accomplished by administering recombinant E-selectin protein intranasally and resulting in E selectin-specific regulatory T-cells. These regulatory T-cells suppress activation of blood vessels where E-selectin is normally expressed by the localized production of immunosuppressive cytokines, modulating the actions of otherwise pro-inflammatory T-cells that can aberrantly cause demyelination of neurons, which leads to diseases like MS.

Applications: In addition to MS, potentially effective in treating other autoimmune disorders such as rheumatoid arthritis, type 1 diabetes, psoriasis, and those that affect blood vessels.

Market: MS may affect more than 2.5 million people worldwide. Currently, it is estimated that approximately 400,000 Americans are afflicted with MS and 200 more are diagnosed weekly.

Development Status: In vitro and *in vivo* data are available.

Inventors: Jacqueline Shukaliak-Quandt *et al.* (NINDS).

Patent Status:

• U.S. Provisional Application No. 60/828,735 filed 09 Oct 2006 (HHS Reference No. E–153–2005/0–US–01).

• PCT Application No. PCT/2007/021682 filed 09 Oct 2007 (HHS Reference No. E–153–2005/2–PCT–02).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Norbert Pontzer, J.D., PhD; 301–435–5502; *pontzern@mail.nih.gov*.

Use of Pentosan Polysulfate To Treat Certain Conditions of the Prostate

Description of Technology: Benign prostatic hyperplasia (BPH), involving a proliferation of smooth muscle cells and increased deposition of extracellular matrix, is a common development: 50% of men over age 60 (about 12.5 million men), and as much as 80% of all men over age 80 (about 3.2 million men), have some enlargement of the prostate gland.

This technology is a method for treating BHP using the oral medication, pentosan polysulfate. Pentosan polysulfate is a well known semi-synthetic polysaccharide extracted from beech wood cellulose that is FDA approved for the treatment of interstitial fibrosis. The current technology builds on the surprising discovery that pentosan polysulfate can cause regression of scarring and lesions in prostatic tissue. Pentosan polysulfate reduces or eliminates both smooth muscle cell proliferation and extracellular matrix deposition, and thus reduces the size of the prostate gland and associated obstructive symptoms.

Applications and Advantages:

• A method of treating benign prostatic hyperplasia using pentosan polysulfate.

• The method treats the underlying pathology of BHP non-invasively.

• The method addresses associated conditions, such as chronic prostatitis, prostadynia, and irritative bladder conditions (other than interstitial cystitis).

• Pentosan polysulfate has been FDA approved for another use.

Development Status: In vitro studies on BPH biopsy samples that demonstrate the drug slows the growth of prostate cells and extracellular matrix have been completed.

Patent Status: U.S. Patent No. 6,828,309 issued 07 Dec 2004 (HHS Reference No. E–104–1997/0–US–03).

Inventor: Gary E. Striker (NIDDK).

Publication: SJ Elliot et al. Pentosan polysulfate decreases prostate smooth muscle proliferation and extracellular matrix turnover. Prostate Cancer Prostatic Dis. 2003;6(2):138–142.

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; *Fatima.Sayyid@nih.hhs.gov*.

Dated: September 9, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–21504 Filed 9–15–08; 8:45 am]

BILLING CODE 4140–01–P