Thermal therapy for brain tumors
Addenda (procedures)
ICD–10 update and effect on MS–DRGs
Cooperating Parties Update

FOR FURTHER INFORMATION CONTACT: Amy Blum, Medical Systems Specialist, Classifications and Public Health Data Standards Staff, NCHS, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, e-mail *alb8@cdc.gov*, telephone 301–458–4106 (diagnosis), Mady Hue, Health Insurance Specialist, Division of Acute Care, CMS, 7500 Security Blvd., Baltimore, Maryland, 21244, e-mail *marilu.hue@cms.hhs.gov*, telephone 410–786–4510 (procedures).

Notice: Because of increased security requirements CMS has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show an official form of picture I.D., (such as a drivers license), and sign-in at the security desk upon entering the building. Those who wish to attend a specific ICD–9–CM C&M meeting in the CMS auditorium must submit their name and organization for addition to the meeting visitor list. Those wishing to attend the September 24–25, 2008 meeting must submit their name and organization by September 12, 2008 for inclusion on the visitor list. This visitor list will be maintained at the front desk of the CMS building and used by the guards to admit visitors to the meeting. Those who attended previous ICD–9–CM C&M meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you attend.

Register to attend the meeting on-line at: *http://www.cms.hhs.gov/apps/events/*.

Notice: This is a public meeting. However, because of fire code requirements, should the number of attendants meet the capacity of the room, no additional attendees will be accepted into the meeting.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 5, 2008.

Elaine L. Baker,

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

[FR Doc. E8–21599 Filed 9–15–08; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Joint Meeting of the Antiviral Drugs Advisory Committee and the Nonprescription 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: Antiviral Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee.

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 October 29, 2008, from 8 a.m. to 5 p.m.

Location: Hilton, The Ballrooms, 1750 Rockville Pike, Rockville, MD. The hotel telephone number is 301–468–1100.

Contact Person: Paul Tran, 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, 301–827–6793, FAX: 301–827–6776, e-mail: *paul.tran@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), codes 3014512531 and 3014512541. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will provide advice on types of studies and trial designs needed for an influenza antiviral MedKit for the treatment or prophylaxis of pandemic influenza and discuss publicly the proposed development program that would support an application for such a MedKit. Issues such as the role of personal MedKits, home stockpiling, non-prescription availability of influenza medications, and interfaces of home readiness with public health systems, will be raised in the course of the discussions.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: 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 on or before October 15, 2008. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before October 6, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 7, 2008.

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 Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

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