at home for lack of an appropriate caregiver are provided care in a facility of 20 or fewer beds that offers, within its walls, the full range of services provided by hospice programs under section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)).

Under the demonstration project, the hospice program shall comply with otherwise applicable requirements, except that it shall not be required to offer services outside of the hospice facility or to meet the requirements of section 1861(dd)(2)(A)(iii) of the Social Security Act (SSA) regarding the 20-percent cap on inpatient care days.

The Secretary may require the hospice demonstration to comply with additional quality assurance standards for provision of services. Upon completion of the project, the Secretary shall submit a report to the Congress on the project including recommendations regarding extensions to hospice programs serving rural areas.

B. The Rural Hospice Demonstration

The demonstration will be offered to up to three hospice programs and will not exceed a period of 5 years. The demonstration is designed to test whether hospice services provided by a demonstration hospice program to Medicare beneficiaries who lack an appropriate caregiver and who reside in rural areas results in wider access, improved hospice services, benefits to the rural community, and a sustainable pattern of care. Hospice provides palliative care to individuals who have a terminal illness with a prognosis of 6 months or less. The care is provided typically in the individual's home or place of residence with family members present. Individuals who lack family or someone to serve as the primary caregiver need proportionately more support from hospice staff. Due to long distances and difficult terrain, it can be particularly difficult to provide the Medicare hospice benefit efficiently in rural areas. There may be situations where the hospice benefit could be provided to beneficiaries who would not otherwise be able to receive these services if the location of hospice care is altered. This demonstration will allow a hospice with up to 20 beds to provide all levels of hospice services within its walls to individuals who reside in rural areas and lack an appropriate caregiver, while not having to provide services outside of the hospice facility or comply with the 20-percent cap on inpatient care days.

While the demonstration provider will not have to meet the limit on inpatient care days or provide care outside of the facility, it will not alter the level of care requirements for general inpatient care. In order to provide general inpatient care to hospice patients, a hospice participating in the demonstration must assure that the need for general inpatient care is met according to Medicare guidelines. The demonstration will test whether hospice services provided by a facility that does not meet the limit on inpatient care days or provide services outside of the facility for hospice individuals residing in rural areas who lack an appropriate caregiver results in wider access, improved hospice services, benefits to the rural community, and a sustainable pattern of care.

The demonstration is designed for a demonstration hospice to provide the full range of services within its facility to Medicare beneficiaries who reside in rural areas and lack an appropriate caregiver. If a demonstration hospice provides care to any patient who either lives outside a rural area or has an appropriate caregiver, then the hospice must comply with all of Medicare hospice requirements at 1861(dd) of the SSA for these patients since they are not considered part of the demonstration.

We plan to make up to three awards. Interested parties can obtain complete solicitation and supporting information on the CMS Web site at: *http://www.cms.hhs.gov/researchers/demos/rmbh/default.asp.* Paper copies can be obtained by writing to Cindy Massuda at the address listed in the **ADDRESSES** section of this notice.

II. Collection of Information Requirements

Since CMS will receive less than 10 applications to this solicitation, the information collection requested reference in this solicitation are not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Authority: Section 409 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173).

(Domestic Assistance No. 93.773 Medicare—Hospital insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: March 10, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–6861 Filed 4–1–05; 4:42 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0119]

Preparation for the 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 to provide information and receive comments on the International Conference on Harmonization (ICH) in advance of its next next Steering Committee and Expert Working Group meetings in Brussels, Belgium, May 9 through 12, 2005. Scheduled for the ICH meetings is an Efficacy Brainstorming Session focusing on the review of the existing efficacy guidelines and their need for updating as well as potential new topics for consideration. To promote a fuller discussion of this topic the public meeting will be expanded to include public input on initiatives related to current ICH efficacy guidelines and consider needs for further information both within and between existing guidances. These initiatives include electronic source data, clinical development plan summaries, Health Level 7 structured product labeling, and other initiatives including information exchange standards (e.g., Electronic Common Technical Document (eCTD) and terminology standards).

Date and Time: The meeting will be held on April 20, 2005, from 9 a.m. to 5:30 p.m.

Location: The meeting will be held at The DoubleTree Hotel and Executive Meeting Center, 1750 Rockville Pike, Rockville, MD. A block of rooms for those wishing to attend the meeting have been set aside at the government rate. Please contact the hotel directly for your reservation: DoubleTree Hotel and Executive Meeting Center, 301–468–1100, FAX: 301–468–0308.

Contact Person: Sema Hashemi, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3050, FAX: 301–480–0716, e-mail: *Sema.Hashemi@fda.hhs.gov*.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and FAX number), and written material and

requests to make oral presentations, to the contact person by April 14, 2005.

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–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

If you need special accommodations due to a disability, please contact Sema Hashemi at least 7 days in advance.

SUPPLEMENTARY INFORMATION: 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 the following 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 Manufacturers 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. 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*. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by April 14, 2005, and submit a brief statement of the general nature of the evidence or arguments they which to present, the names and addresses, phone number, FAX, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting and ICH Expert Working Groups. One of the topics for the upcoming ICH meeting is an Efficacy Brainstorming Session focusing on the review of the existing efficacy guidelines and their need for updating as well as potential new topics for consideration. The complete set of ICH Efficacy Guidelines may be found at *http://www.ich.org/* or *http://www.fda.gov/cder/guidance/index.htm*. To promote a fuller discussion of this topic the public meeting will be expanded to include public input on initiatives related to current ICH efficacy guidelines and consider needs for further information both within and between existing guidances. These initiatives include electronic source data, clinical development plan summaries, Health Level 7 structured product labeling, and other initiatives including information exchange standards (e.g., eCTD and terminology standards).

The agenda for the public meeting will be made available on April 15, 2005, via the internet at *http://www.fda.gov/cder/meeting/ICH_Spring2005.htm*.

Dated: April 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7020 Filed 4–5–05; 11:53 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, 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.

Methods for High-Efficiency Single Genome Sequencing of HIV

Drs. John Coffin, Mary Kearney, Frank Maldarelli and Sarah E. Palmer (NCI), *et al.*

U.S. Provisional Application filed 25 Jan 2005 (DHHS Reference No. E–022–2005/0–US–01).

Licensing Contact: Sally Hu; 301/435–5606; *hus@mail.nih.gov*.

The invention is directed to a method for efficiently obtaining single genome sequences (SGS) of HIV from a biological sample. The invention has the following advantages over the current commercial genotyping in use: (1) It might improve the sensitivity of diagnosis of drug resistant HIV in newly infected HIV patients; (2) It might provide a more affordable diagnostic tool for early detection of drug resistance since the invention is adaptable to an automated approach for the high-throughput processing of a large number of patient sample; (3) It might improve patient outcome since SGS has the ability to identify low level mutation and will permit a more comprehensive evaluation of resistance in patients and might potentially change the clinical approach to treating resistant virus. In summary, this