The full text of document DA 07–4924 and copies of any subsequently filed documents in this matter will be available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. Document DA 07–4924 and copies of subsequently filed documents in this matter may also be purchased from the Commission's duplicating contractor at Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554; the contractor's Web site, *http://www.bcpiweb.com;* or by calling (800) 378–3160. Document DA 07–4924 and subsequently filed documents in this matter may also be found by searching ECFS at *http://www.fcc.gov/cgb/ecfs* (insert CG Docket No. 03–123 into the Proceeding block).

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). Document DA 07–4924 can also be downloaded in Word or Portable Document Format (PDF) at: *http://www.fcc.gov/cgb/dro/trs.html.*

Synopsis

On May 18, 2007, Hawk filed its *DBRS Petition* for clarification proposing DBRS as a form of TRS compensable from the Interstate TRS Fund. As described by Hawk, its proposed DBRS would use an interpreter (a ''Communications Facilitator'' (CF)) to sit with the deaf/blind user, place or receive conventional voice-to-voice telephone calls on his or her behalf, and interpret the ensuing conversation(s). The CF would travel to the DBRS consumer's location to assist in placing the call. Alternatively, a DBRS consumer could travel to a regional DBRS center to place a call through a CF.

The Bureau seeks comment on the *DBRS Petition*, including, specifically, whether DBRS falls within the definition of TRS as set forth in section 225(a)(3) of the Communications Act of 1934, 47 U.S.C. 225(a)(3). The Bureau notes, for example, that Hawk's proposed DBRS does not fit within the typical two-leg relay paradigm in which a relay center receives and places inbound and outbound calls between the end users to the relay call. Instead, the DBRS would employ a CF to assist the caller, in person, in making a telephone call.

Federal Communications Commission.

Nicole McGinnis,

Deputy Chief, Consumer & Governmental Affairs Bureau.

[FR Doc. E7–25648 Filed 1–3–08; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Meeting

ACTION: Amendment of Meeting Announcement, dated December 26, 2007.

SUMMARY: This notice amends the meeting date for the 19th meeting of the American Health Information Community in accordance with the Federal Advisory Committee Act (Pub. L. No. 92–463, 5 U.S.C., App.) The American Health Information Community will advise the Secretary and recommend specific actions to achieve a common interoperability framework for health information technology (IT).

Revised Meeting Date: January 22, 2008, from 8:30 to 12:00 p.m. (previously scheduled on January 15, 2008).

ADDRESSES: Hubert H. Humphrey building (200 Independence Avenue, SW., Washington, DC 20201), Conference Room 800.

SUPPLEMENTARY INFORMATION: The meeting will include presentations by the Population Health/Clinical Care Connections Workgroup and Electronic Health Records Workgroup on Recommendations to the Community; an update on the Health IT Physician Adoption Survey results; an update on the Healthcare Information Technology Standards Panel (HITSP) Interoperability Specifications; and an update on the findings from the *Enhancing Data Quality in EHRs Report.*

For further information, visit *http://www.hhs.gov/healthit/ahic.html.* A Web cast of the Community meeting will be available on the NIH Web site at: *http://www.videocast.nih.gov/.*

If you have special needs for the meeting, please contact (202) 690–7151.

Dated: December 27, 2007.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 07–6281 Filed 1–3–08; 8:45 am]

BILLING CODE 4150–45–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Public Law 92–463, notice is hereby given of the fifteenth meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to approximately 5:30 p.m. on Tuesday, February 12, 2008 and 8 a.m. to approximately 5 p.m. on Wednesday, February 13, 2008, at the Hubert H. Humphrey Building—200 Independence Avenue, SW., Washington, DC 20201. The meeting will be open to the public with attendance limited to space available. The meeting also will be Web cast.

The main agenda item will involve deliberations on the oversight of genetic testing, including an overview of public comments received on the Committee's draft report *U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of HHS* and the formulation of final recommendations to the Secretary.

As always, the Committee welcomes hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. Individuals who would like to provide public comment should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301–496–9838 or e-mail at *carrs@od.nih.gov.* The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892. Anyone planning to attend the meeting who is in need of special assistance, such as sign language interpretation or other reasonable accommodations, is asked to contact the Executive Secretary.

Under authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic and genomic technologies and, as

warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the Web cast, will be available at the following Web site: *http://www4.od.nih.gov/oba/sacghs.htm.*

Dated: December 21, 2007.

Jennifer Spaeth,

Director, NIH Office of Federal Advisory Committee Policy.

[FR Doc. 07–6274 Filed 1–3–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0485]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Food and Drug Administration Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements governing applications for FDA approval to market a new drug.

DATES: Submit written or electronic comments on the collection of information by March 4, 2008.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson,Office of the Chief Information Officer (HFA 250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Application for FDA Approval to Market a New Drug—(OMB Control Number 0910–0001)—Extension

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or 505(j) of the act is effective with respect to such drug. Under the act, it is the sponsor's responsibility to provide the information needed by FDA to make a scientific and technical determination whether the product is safe and effective for use.

This information collection approval request is for all information requirements imposed on sponsors by the regulations under part 314 (21 CFR part 314), who apply for approval of a new drug application (NDA) or abbreviated new drug application (ANDA) in order to market or to continue to market a drug.

Section 314.50(a) requires that an application form (Form FDA 356h) be submitted that includes introductory information about the drug as well as a checklist of enclosures.

Section 314.50(b) requires that an index be submitted with the archival copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that a summary of the application be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the NDA contain the following technical sections about the new drug: Chemistry, manufacturing, and controls; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; microbiology; clinical data; and statistical section.

Section 314.50(e) requires the applicant to submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that case report forms and tabulations be submitted with the archival copy.

Section 314.50(h) requires that patent information, as described under § 314.53, be submitted with the application. (The burden hours for § 314.50(h) are already approved by OMB under OMB control number 0910–0513 and are not included in the burden estimates in table 1 of this document.)

Section 314.50(i) requires that patent certification information be submitted in section 505(b)(2) applications for patents claiming the drug, drug product, or method of use.

Section 314.50(j) requires that applicants that request a period of marketing exclusivity submit certain information with the application.

Section 314.50(k) requires that an archival, review, and field copy of the application be submitted.

Section 314.52 requires that any notice of certification of invalidity or noninfringement of a patent to each patent owner and the NDA holder be sent by a section 505(b)(2) applicant that relies on a listed drug. A 505(b)(2) applicant is required to amend its application at the time notice is provided to include a statement certifying that the required notice has