both the pilot project and the draft SEND implementation guide can be found on the FDA SEND Web page at *http://www.fda.gov/oc/datacouncil/send.html*. Before creating and submitting nonclinical datasets, pilot participants should ensure that they use the most recent draft version of the SEND implementation guide.

II. Pilot Project Description

This pilot project is part of an ongoing effort to improve the efficiency of the review of nonclinical data within CDER. Eventually, as experience from the ongoing pilot is gained with various types of nonclinical studies, CDER expects to recommend new technical specifications as part of a continuing process for the submission of nonclinical study data provided electronically and eliminate the need to provide paper/PDF-based data listing.

A. Approach

CDER is seeking a limited number of sponsors (i.e., approximately five to eight) to participate in the phase 2 pilot. The duration of the pilot is expected to be approximately 3 years, but it may be extended as needed. Participants should be familiar with SEND (e.g., from involvement in the phase 1 pilot) and be willing to provide the same nonclinical study data in both PDF and SEND formats to an existing IND. The PDF must comply with all applicable regulations, including those in part 11 (21 CFR part 11)[1]. To achieve the goals of the pilot, FDA intends to exercise additional enforcement discretion with regard to part 11 requirements as applied to data submitted in SEND format under this pilot. That is, we do not intend to take enforcement action against data submitted in SEND format, under this pilot, to enforce compliance with those portions of part 11 that remain in effect. The SAS transport files (version 5) should be based on the SEND format. Having the same data available in both PDF and SEND formats provides the best opportunity to compare the two and evaluate the accuracy and reliability of the SEND format. Although the PDF version will continue to be the version used for archival purposes during the pilot, both data formats (i.e., PDF and SEND) will be used by FDA for regulatory review purposes. Before receiving any SEND data, FDA and pilot participants will work with the SEND Consortium to update the SEND implementation guide, which will then be used during the pilot.

For the purposes of this phase 2 pilot, full study reports of the following types of animal toxicity studies will be requested for submission to an existing IND in the appropriate CDER review division: (1) Repeat-dose toxicity studies of 14 days duration to 12 months duration in any species, (2) life-time carcinogenicity studies in rats or mice, or (3) 6-month carcinogenicity studies in transgenic mice. Studies should include toxicokinetic data, if available. For submission of carcinogenicity studies, the appropriate CDER and International Conference on Harmonization (ICH) guidances should be consulted. The submission should contain both the ''Tumor Dataset for Statistical Analysis'' (i.e., tumor.xpt, as described in Appendix 1 of the Study Data Specifications document; version 1.3; dated 2006–11–27) as well as the SEND-formatted datasets for the entire study. Depending on the ongoing efforts of the SEND Consortium to expand the SEND implementation guide, additional nonclinical study types may be piloted in the future. If so, FDA will post on the FDA SEND Web page an updated list of study types the agency will accept in this and any future pilots. We anticipate that a successful phase 2 pilot, which includes implementation of any needed changes to the SEND implementation guide and/or the data validation, viewing, and analysis tools, will allow CDER to routinely accept specific types of nonclinical study data provided electronically as SAS transport file (XPT version 5) datasets based on the SEND format. In the case of carcinogenicity studies, a successful phase 2 pilot will enable submission of the entire carcinogenicity study data in the electronic SEND format, thus eliminating the need for a separate submission of the electronic tumor dataset (i.e., tumor.xpt).

B. How to Participate

Requests to participate in the pilot project should be submitted to the Division of Dockets Management (see **ADDRESSES**). Requests are to be identified with the docket number found in brackets in the heading of this document. As mentioned above, it is recommended that interested participants be familiar with SEND and/or have been involved in the previous phase 1 pilot.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this pilot project. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–19468 Filed 10–2–07; 8:45 am]

BILLING CODE 4160–01–S

[1] See, ''Guidance for Industry; Part 11, Electronic Records; Electronic Signatures—Scope and Application,'' August, 2003; *http://www.fda.gov/Cder/guidance/5667fnl.htm*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Draft Policy Document for Comment

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: This is a Notice of Availability and request for comments on a draft Agency Guidance (''Policy Information Notice'' (PIN)) to clarify program and application requirements of the Federally Qualified Health Center Look-Alike program and make them consistent with those requirements under section 330 of the Public Health Service Act. The PIN, ''Federally Qualified Health Center (FQHC) Look-Alike Guidelines and Application'' (''FQHC Look-Alike PIN'') is available on the Internet at *http://bphc.hrsa.gov/draftsforcomment/lookalike/*.

DATES: Comments must be received by close of business November 7, 2007.

ADDRESSES: Please send your comments to the following e-mail address: *DPDgeneral@hrsa.gov.*

SUMMARY: HRSA believes that community input is valuable to the development of policies and policy documents related to the implementation of BPHC programs, including the FQHC Look-Alike Program. Therefore, we are requesting comments on the PIN referenced above. After review and consideration of all comments received, the PIN may be amended to incorporate certain recommendations from the public. Once the PIN is finalized, it will be made available on HRSA's Web site, along with the Agency's ''Response to Public Comments.'' That document will summarize the major comments received and describe the Agency's response, including any corresponding

changes made to the PIN. Where comments do not result in a revision to the PIN, explanations will be provided.

Background: HRSA has received numerous requests for clarification regarding the program guidelines, requirements, and application process for the FQHC Look-Alike program. The purpose of the FQHC Look-Alike PIN is to respond to these requests for clarification and to make the application process more consistent with section 330 grant programs.

The Omnibus Budget Reconciliation Acts of 1989, 1990, and 1993 amended section 1905 of the Social Security Act to create a new category of facility under Medicaid and Medicare known as Federally Qualified Health Centers (FQHCs). The Social Security Act § 1905(l)(2)(B) definition of an FQHC included an entity which, based on the recommendation of HRSA, is determined to meet the requirements of the section 330 grant program but does not receive the grant. This category of health centers has been labeled FQHC Look-Alikes.

To ensure that there are appropriate numbers of health centers to serve the millions of uninsured and underinsured populations throughout the country, FQHC Look-Alike status was made available to those entities that do not receive funding under section 330 but operate and provide services similar to grant-funded programs. As such, FQHC Look-Alikes are expected to demonstrate a commitment to serve all populations residing in their respective medically underserved communities regardless of their ability to pay and to satisfy all of the administrative, management, governance and service-related requirements that apply to section 330 funded health centers. Benefits of obtaining FQHC Look-Alike status include eligibility for enhanced Medicaid and Medicare reimbursement, participation in the 340(b) Federal Drug Pricing Program, and automatic Health Professional Shortage Area designation.

HRSA is responsible for managing the FQHC Look-Alike program and submitting recommendations to the Centers for Medicare and Medicaid Services (CMS) for designation as FQHCs; however, CMS has the final authority to designate applicants as FQHCs. The organizations are recertified annually to assure they are in compliance with these regulations.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, please contact Cicely Nelson at (301) 594–4496.

Dated: September 24, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–19507 Filed 10–2–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Director's Council of Public Representatives.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Director's Council of Public Representatives.

Date: October 26, 2007.

Time: 8:30 a.m. to adjournment.

Agenda: Key topics for this meeting will focus on public engagement in the biomedical and behavioral research process. Further information will be available on the COPR Web site in mid-October at *www.copr.nih.gov.*

Place: National Institutes of Health, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Kelli L. Carrington, Executive Secretary/Public Liaison Officer, Office of Communications and Public Liaison, Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 1, Room 344, Bethesda, MD 20892, 301–594–4575, *carringk@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.copr.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: September 26, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–4864 Filed 10–2–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Clinical Trials Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Clinical Trials Advisory Committee.

Date: November 14, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: Update on the progress of the implementation of the Clinical Trials Working Group.

Place: National Institutes of Health, Building 31, 31 Center Drive, Room 10, Bethesda, MD 20892.

Contact Person: Sheila A. Prindiville, MD, Director, Coordinating Center for Clinical Trials, Office of the Director, National Cancer Institute, National Institutes of Health, 6120 Executive Blvd., Suite 507, Bethesda, MD 20892, 301–451–5048, *prindivs@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399,