DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 2, 2013.

ADDRESSES: Submit written requests for single printed copies of the draft guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129; Silver Spring, MD 20993. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the Office of Combination Products at 301–796–8930. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Patricia Y. Love, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040–4.'' This document provides guidance to sponsors seeking to rely on conformity to ISO Standard 11040–4 in submissions for glass syringes products. FDA has become aware of adverse events and product quality events related to connectivity problems when certain glass syringes are used with connecting devices, including connecting devices to conform to the FDA-recognized ISO 594–2 standard. Accordingly, FDA has determined that, for glass syringes, demonstrating conformity to the ISO 11040–4 standard alone does not ensure that the glass syringe can be properly connected to connecting devices. Therefore, this guidance document identifies additional, technical information that should be included in an investigational device exemption (IDE), humanitarian device exemption (HDE), 510(k), or postmarket application (PMA) for a glass syringe product, or in an investigational new drug application (IND), a biologics license application (BLA), new drug application (NDA), or abbreviated new drug application (ANDA) for a drug or biological product that is delivered with such a glass syringe product, to demonstrate that the glass syringe can be properly connected to connecting devices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040–4.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 for NDAs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for BLAs have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 814 subpart B for PMAs have been approved under OMB control number 0910–0231. The collections of information in FD&C Act subpart E for 510(k) notifications have been approved under OMB control number 0901–0120.

Dated: March 28, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07685 Filed 4–2–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: Primary Care Faculty Development Initiative (OMB No. 0915-xxxx)—[New].

Abstract: HRSA's Bureau of Health Professions, Division of Medicine and Dentistry, has contracted with Oregon Health and Science University (OHSU), contract HHSH250201200023C, to conduct the planning, execution, and evaluation of a nationally based, longitudinal Primary Care Faculty Development Initiative (PCFDI) demonstration project. OHSU has developed web-based survey

instruments which will be used to evaluate the effectiveness of the planned curriculum and its implementation and to make recommendations to improve teaching and competency assessment in primary care educational activities. The two web-based surveys are Irvine's Leadership Behavior Survey and the Faculty Skill & Program Feasibility Survey. The objectives of the survey instruments are to: assess the feasibility and acceptability of an inter-disciplinary faculty development pilot program targeting primary care physicians; to measure the leadership skills of PCFDI faculty participants; and to assess the initial impact of faculty receiving training from an inter-disciplinary faculty development pilot program on their perception of skill development in the core content areas of leadership, change management, teamwork, panel or population management, competency assessment, and clinical microsystems.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Irvine's Leadership Behavior Survey	36	1	36	.167	6.01
Faculty Skill & Program Feasibility Survey	36	1	36	.167	6.01
Total	72		72		12.02

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Deadline: Comments on this Information Collection Request must be received within 60 days of this notice.

Dated: March 27, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–07650 Filed 4–2–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIAMS.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIAMS.

*Date:*April 23–24, 2013.

Time: 6:00 p.m. to 5:20 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 4C32, Bethesda, MD 20892.

Contact Person: John J. O'Shea, MD, Ph.D., Scientific Director, National Institute of Arthritis & Musculoskeletal and Skin Diseases, Building 10, Room 9N228, MSC 1820, Bethesda, MD 20892, (301) 496–2612, *osheaj@arb.niams.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: March 28, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–07659 Filed 4–2–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Cancer Biology and Therapy.

Date: April 17, 2013.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 9609 Medical Center Drive, 7–W–106, Rockville, MD, (Telephone Conference Call).

Contact Person: Eun Ah Cho, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7–W–106, Bethesda, MD 20892, 240–276–6342, *choe@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting date due to scheduling conflicts.

(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, Cancer Control, National Institutes of Health, HHS)