There are no costs to respondents except their time to participate in the survey.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hours)
Grantees	Annual Application	61	1	25	1525
	Annual Report	61	1	30	1830
Total					3355

Dated: July 20, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–14439 Filed 7–25–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Injury Prevention and Control (ACIPC), Science and Program Review Subcommittee

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces, the following meeting for the aforementioned committee and subcommittee:

Name: Science and Program Review Subcommittee (SPRS).

Times and Date: 11:30 a.m.–11:35 a.m., August 20, 2007 (Open). 11:35 a.m.–12:30 p.m., August 20, 2007 (Closed).

Place: CDC, Koger Center, Vanderbilt Building, Room 1006, 2939 Flowers Road, Atlanta, Georgia 30341–3724.

Purpose: The subcommittee provides advice on the needs, structure, progress, and performance of programs in the National Center for Injury Prevention and Control (NCIPC).

Matters To Be Discussed: The subcommittee will have a secondary review, discussion, and evaluation on the individual research grant and cooperative agreement applications submitted in response to the two Fiscal Year 2007 Requests for Applications (RFAs) related to the following individual research announcements: RFA–CE–05–020, Youth Violence Prevention through Community-Level Change; and RFA–CE–07–011, Multi-Level Parent Training Effectiveness Trial—Phase II (U49).

Following this meeting, the voting members of ACIPC will meet via teleconference to vote on the recommendations of the SPRS regarding the RFAs.

Name: Advisory Committee for Injury Prevention and Control.

Times and Date: 12:30 p.m.–12:55 p.m., August 20, 2007 (Open). 12:55 p.m.–1:30 p.m., August 20, 2007 (Closed).

Place: CDC, Koger Center, Vanderbilt Building, Room 1006, 2939 Flowers Road, Atlanta, Georgia 30341–3724.

Purpose: The committee advises and makes recommendations to the Secretary, Department of Health and Human Services, the Director, CDC, and the Director, NCIPC regarding feasible goals for the prevention and control of injury. The committee makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury prevention and control.

Matters To Be Discussed: Agenda items for the open portion include the call to order and introductions and request for public comments. The committee will vote on the results of the secondary review. This portion of the meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and (b), title 5 U.S.C., and the Determination of the Acting Director, Management Analysis and Services Office, CDC pursuant to Public Law 92–463.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Ms. Amy Harris, Executive Secretary, ACIPC, NCIPC, CDC, 4770 Buford Highway, NE., M/S K61, Atlanta, Georgia 30341–3724, Telephone (770) 488–4936.

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: July 17, 2007.

Elaine L. Baker,

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

[FR Doc. E7–14430 Filed 7–25–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0290]

Draft Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs)'' dated July 2007. The draft guidance document discusses certain cell selection devices that minimally manipulate autologous PBSCs at the point of care for specific clinical indications, and the applicability of the requirements to such PBSCs. The guidance also discusses the submission of data intended to support approval of cell selection devices.

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 written or electronic comments on the draft guidance by October 24, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–

800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs)'' dated July 2007. The draft guidance document discusses certain cell selection devices that minimally manipulate autologous PBSCs at the point of care for specific clinical indications, and the applicability of the requirements of 21 CFR part 1271 to such PBSCs. The guidance also discusses the submission of data intended to support approval of cell selection devices.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. 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 812 have been approved under 0910–0078; the collections of information in 21 CFR part 814 have been approved under 0910–0231; the collections of information in 21 CFR part 820 have been approved under 0910–0073; and the collections of information in 21 CFR part 822 have been approved under 0910–0449.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. 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 the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: July 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–3659 Filed 7–23–07; 12:02 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0347]

Draft Guidance for Industry and Food and Drug Administration Staff; In Vitro Diagnostic Multivariate Index Assays; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance entitled ''In Vitro Diagnostic Multivariate Index Assays.'' FDA is issuing this revised draft guidance to address the definition and regulatory status of a class of In Vitro Diagnostic Devices referred to as In Vitro Diagnostic Multivariate Index Assays (IVDMIAs). The revised draft guidance also addresses premarket and postmarket requirements with respect to IVDMIAs. The initial draft of this guidance was issued September 7, 2006.

DATES: Submit written or electronic comments on this draft guidance by August 27, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''In Vitro Diagnostic Multivariate Index Assays'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850 or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Courtney Harper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0694.

For further information concerning the guidance as it related to devices regulated by CBER: Martin Ruta, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3518.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 7, 2006 (71 FR 52800). FDA published a notice of availability of the initial draft guidance to address the definition and regulatory status of a class of in vitro diagnostic devices referred to as ''In Vitro Diagnostic Multivariate Index Assays (IVDMIAs).'' The initial draft guidance also addressed premarket and postmarket requirements with respect to IVDMIAs.

An IVDMIA, as defined in the draft guidance document, is a device within the meaning of the Federal Food, Drug, and Cosmetic Act (the act). Some IVDMIAs are laboratory-developed tests (LDTs); laboratory-developed IVDMIAs are a specific subset of LDTs. While FDA has stated that ''clinical laboratories that develop (in-house) tests