how properties of the device may affect this demonstration; and (4) for the purpose of a HUD designation request, delineating a medically plausible subset (''orphan subset'') of persons with a given disease or condition that affects or is manifested in 4,000 individuals or more in the United States per year.

Devices that receive HUD designation may be eligible for marketing approval under an HDE application. An HDE application is a premarketing application that is similar to a premarket approval (PMA) application in that the applicant must demonstrate a reasonable assurance of safety, but in an HDE application, the applicant seeks an exemption from the PMA requirement of demonstrating a reasonable assurance of effectiveness. A device that has received HUD designation is eligible for HDE approval if, among other criteria, the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. (See section 520(m)(2)(C) of the FD&C Act; 21 CFR 814.104(b)(2).) Although a HUD designation from OOPD is a prerequisite to submitting an HDE application to the Center for Devices and Radiological Health or the Center for Biologics Evaluation and Research, it does not by itself guarantee approval of the HDE application.

In the **Federal Register** of December 13, 2011 (76 FR 77542), FDA issued for public comment ''Draft Guidance for Industry and Food and Drug Administration Staff on Humanitarian Use Devices Designations'' dated December 2011. The Agency issued this draft guidance with the aim of assisting sponsors in the preparation and submission of HUD designation requests by, among other things, providing clarity on particular elements of HUD designation requests that had historically caused confusion among sponsors. In particular, the draft guidance focused on the disease or condition that the device treats or diagnoses, population estimates, orphan subsets, device descriptions, scientific rationales, and supporting documentation.

We received several comments on the draft guidance. Most comments appreciated the clarification and explanation provided by the draft guidance. Several comments made recommendations to improve clarity.

FDA is issuing the draft guidance in final form with minor revisions to improve clarity. This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on HUD designation requests. 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 written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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 this guidance document at either: *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm,* or *http://www.regulations.gov.*

Dated: January 18, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–01420 Filed 1–23–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0046]**

### Clinical Flow Cytometry in Hematologic Malignancies; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Clinical Flow Cytometry in Hematologic Malignancies.'' The purpose of this public workshop is to seek public input from academia, Government, laboratorians, industry, clinicians, patients and other stakeholders on the role of clinical flow cytometry in hematologic malignancies, in order to develop a specific regulatory policy for this class of in vitro diagnostic devices.

*Date and Time:* The workshop will be held on February 25 and 26, 2013 from 8 a.m. to 5 p.m.

*Location:* The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Rm. 1503 (Section A of the Great Room) in Bldg. 31, Silver Spring, MD 20993–0002. All visiting public workshop participants (non- FDA employees) must enter through Building 1 for routine security check procedures. For parking and security information, please visit the following Web site: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

*Contact Person:* Carol Krueger, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5437, Silver Spring, MD 20993–0002, 301–796–3241, *Carol.Krueger@fda.hhs.gov.*

*Registration:* Registration is free and on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. on February 11, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, mailing address, email address, and telephone number. Those without Internet access should contact Carol Krueger to register (see Contact Person). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

If you need special accommodations due to a disability, please contact Susan Monahan (email: *Susan.Monahan@fda.hhs.gov* or phone:

301–796–5661) no later than February 11, 2013.

*Streaming Webcast of the Public Workshop:* This workshop will also be available via Webcast. Persons interested in viewing the Webcast must register online by 5:00 p.m. on February 11, 2013. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after February 20, 2013. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

*Requests for Oral Presentations:* This workshop includes public comment sessions. If you wish to present during a public comment session, you must indicate this at the time of registration. At the time of registration identify which discussion topic you wish to address. The topics under consideration for this workshop are identified in section II of this document. FDA will do its best to accommodate requests to present. Individuals and organizations with common interests are urged to consolidate or coordinate their comments, and request time to present a joint comment. Following the close of registration, the Agency will determine the amount of time allotted to each presenter, the approximate time each comment is to begin, and will select and notify speakers by February 20, 2013. All requests to make oral presentations must be received by the close of registration on February 11, 2013. No commercial or promotional material will be permitted to be presented or distributed at the workshop.

*Comments:* FDA is holding this public workshop to obtain information on the topics identified in section II of this document.

In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is March 29, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments. Submit electronic comments 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. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9:00 a.m. and 4:00 p.m., Monday through Friday and will be posted to the docket at *http://www.regulations.gov.*

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

**SUPPLEMENTARY INFORMATION:**

## I. Background

The earliest determination of B and T cell subsets was based on microscopic counting of cells expressing surface immunoglobulins for B cell enumeration, and sheep red blood cells rosette formation was used to enumerate T cells. The subsequent development of leukocyte-specific monoclonal antibodies and flow cytometry contributed to the automation of lymphocyte subset analysis. Flow cytometric lymphocyte subset analysis was initially used to immunophenotype hematological malignancies; however, the HIV epidemic led to a large number of 510(k) submissions addressing use for HIV immune monitoring in AIDS.

In response to these submissions, Draft Guidance for 510(k) Submission of Lymphocyte Immunophenotyping Monoclonal Antibodies was issued September 26, 1991. Prior to this draft document, reagents for CD2 and CD20 were 510(k) cleared based on methodological correlation with accepted reference methods. Following the issuance of the 1991 draft guidance, several test systems identifying CD3 T cells, CD4 and CD8 T cell subsets, NK cells and B cells were cleared under 510(k), with either single reagents or combination of reagents based on the previous clearance of CD2 and CD20 reagents. These clearances for flow cytometry system devices included flow cytometers, reagents, controls, and associated software for data acquisition and data analysis.

In 1997, the FDA issued the Analyte Specific Reagent (ASR) Rule (21 CFR 864.4020) to provide some assurance that 1) critical reagents manufacturers provided to laboratories for use in tests developed by the laboratories were made under current Good Manufacturing Practices (cGMP), 2) manufacturers registered with the FDA and listed such reagents, and 3) manufacturers reported malfunctions, injuries and deaths related to the use of such reagents to the FDA (62 FR 62260, November 21, 1997). Subsequent to publication of the ASR rule in 1997, some manufacturers began to bundle individual ASRs together in the form of reagent panels (''cocktails'') creating devices that went beyond the single reagent ASRs that the rule had anticipated. In 2007, the Agency reiterated and clarified the intentions of the ASR rule in the Guidance for Industry and FDA Staff on Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm078423.htm.* The 2007 guidance clarifies that the bundling of ASRs into a panel of multi-analytes is inconsistent with the definition of an ASR per 21 CFR 864.4020. Subsequent to issuance of the guidance, many uncleared, multi-analyte panels were withdrawn from distribution in order to comply with the interpretation of the ''ASR rule.''

Clinical flow cytometry plays a major role world-wide in the diagnosis of leukemia and lymphoma and more recently in the detection of minimal residual disease (MRD). Because there are currently no FDA cleared or approved in vitro diagnostics (IVD) panels for the diagnostic evaluation of hematological malignancies, FDA recognizes that there is an unmet need for such products to assist clinical laboratories in performing this testing. FDA has been working to define the regulatory guidelines for the review of this family of devices and has been actively working with industry and

academia to help bring additional products for clinical flow cytometry to market that are safe and effective.

In partnership with the National Institutes of Health (NIH) and National Institute of Standards and Technology (NIST), CDRH intends to utilize the findings of this workshop in the development of an appropriate, risk-based regulatory framework for Clinical Flow Cytometry, which promotes innovation and protects patient safety.

**II. Topics**

Topics for discussion during this workshop include: (1) Overview of Quality control and standardization issues associated with Clinical Flow Cytometry (FCM), including discussion of a NIST traceable standard; (2) Biological controls in Clinical FCM: The use of stabilized whole blood samples and cryopreserved cells for normals and chronic lymphocytic leukemia (CLL); (3) Third-party flow cytometry data analysis software; and (4) Overview of FDA regulation of Clinical FCM using the 510(k) clearance process.

The FDA is seeking representation from both North American and European clinical investigators at this workshop. This Clinical FCM Workshop is being planned to occur just prior to a CDER Workshop on the role of MRD in CLL which will be held February 27, 2013 (77 FR 76051, December 26, 2012). An FDA workshop for acute lymphocytic leukemia (ALL) MRD was held April 18, 2012, and a separate workshop on acute myelogenous leukemia (AML) MRD will be held March 4, 2013 (77 FR 76050, December 26, 2012).

Dated: January 17, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–01419 Filed 1–23–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection; Comment Request: The Jackson Heart Study (JHS)

*Summary:* Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 24, 2012, pages 65001–2, and allowed 60-days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Proposed Collection: Title:* The Jackson Heart Study: Annual Follow-up with Third Party Respondents. *Type of Information Collection Request:* Revision of a currently approved collection (OMB NO. 0925–0491). *Need and Use of Information Collection:* This project involves annual follow-up by telephone of participants in the JHS study, review of their medical records, and interviews with doctors and family to identify disease occurrence. Interviewers will contact doctors and hospitals to ascertain participants' cardiovascular events. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in African American men and women. Recruitment of 5,500 JHS participants began in September 2000 and was completed in March 2004. 5,302 participants completed a baseline Exam 1 that included demographics, psychosocial inventories, medical history, anthropometry, resting and ambulatory blood pressure, phlebotomy and 24-hour urine collection, ECG, echocardiography, and pulmonary function. JHS Exam 2 began September 26 2005, followed by a more comprehensive Exam 3 that began in February 2009. The two new exams include some repeated measures from Exam 1 and several new components, including distribution of self-monitoring blood pressure devices. The continuation of the study allows continued assessment of subclinical coronary disease, left ventricular dysfunction, progression of carotid atherosclerosis and left ventricular hypertrophy, and responses to stress, racism, and discrimination as well as new components such as renal disease, body fat distribution and body composition, and metabolic consequences of obesity. The JHS Community Health Advisor Networks (CHANs) comprise another component of the study. The JHS data shows high prevalence of risk factors: 73% of recruited participants are hypertensive, 29% are diabetic, 56% are obese (BMI > 30kg/m2), and 30% have the metabolic syndrome. Exploration of the impact on and interaction of high risk factor levels with other measures of clinical and subclinical disease will help identify unique approaches through epidemiology and prevention research to reduce the disproportionate burden of CVD in African-Americans. . The JHS CHANs play an important role to address CVD prevention by providing training to community members to spread health promotion and prevention messages within the Jackson community. The JHS Community Health Advisors (CHAs) are trained and certified to organize and conduct various outreach activities in five Jackson-area communities. Data on the JHS CHAs will be collected. *Frequency of Response:* One-time. *Affected Public:* Individuals or households; Businesses or other for profit; not-for-profit institutions. *Type of Respondents:* Middle aged and elderly adults; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number of Respondents:* 478; *Estimated Number of Responses per Respondent:* 1.0; *Average Burden Hours Per Response: 2.47);* and *Estimated Total Annual Burden Hours Requested:* 1253. The annualized cost to respondents is estimated at $24,206. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATE OF ANNUAL HOUR BURDEN

| Type of respondents | Number of respondents | Frequency of responses | Average time per response | Annual hour burden |
|---|---|---|---|---|
| Families | 200 | 1 | 1/6 | 33 |
| Physicians | 200 | 1 | 15/60 | 50 |
| Communities: | | | | |