DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Availability of Final Environmental Assessment (FINAL EA) and a Finding of No Significant Impact (FONSI) for Metropolitan Sewer District of Greater Cincinnati Easement on HHS/CDC/NIOSH Taft North Campus, Cincinnati, OH

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of Availability of Final Environmental Assessment (FINAL EA) and a Finding of No Significant Impact (FONSI) for Metropolitan Sewer District of Greater Cincinnati Easement on HHS/CDC/NIOSH Taft North Campus, Cincinnati, Ohio.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) is issuing this notice to advise the public that HHS/CDC has prepared, and signed on January 3, 2013, a Finding of No Significant Impact (FONSI) based on the Final Environmental Assessment (FINAL EA) for Metropolitan Sewer District of Greater Cincinnati Easement on the HHS/CDC/NIOSH Taft North Campus, Cincinnati, Ohio. HHS/CDC prepared the final EA, dated November 2012, in accordance with the National Environmental Policy Act (NEPA).

DATES: The FONSI and/or Final EA are available as of the publication date of this notice.

ADDRESSES: Interested parties may request copies of the FONSI and/or Final EA, from: Mr. Sam Tarr, Centers for Disease Control and Prevention, Buildings and Facilities Office, 1600 Clifton Road NE., Mailstop K96, Atlanta, GA, 30333. Telephone Number (770) 488–8170.

SUPPLEMENTARY INFORMATION: The Final EA evaluated the granting of an easement to the Metropolitan Sewer District of Greater Cincinnati (MSD) for the sole purpose of installing sanitary sewer and storm sewer improvements to the MSD's existing sewer system and the rehabilitation and expansion of an existing storm water detention basin. The proposed easement covers approximately 0.64 acres located adjacent to the intersection of Grandin Road and Grand Beech Lane, Cincinnati, Ohio. The EA also evaluated the construction activities associated with the MSD's sanitary sewer and storm sewer improvements. The purpose and need of the proposed easement is to provide access to MSD to implement/construct MSD sanitary sewer and storm sewer improvements on Federally-owned land in the custody and control of HHS/CDC.

The Final EA has been prepared in accordance with the National Environmental Policy Act (NEPA) of 1969. Based on the results of the EA, HHS/CDC has issued a Finding of No Significant Impact (FONSI) indicating that the proposed action will not have a significant impact on the environment. Minimization and mitigating measures will include: Compliance with applicable regulatory laws, procedures, and permits for all construction activities; development and implementation of Erosion and Sedimentation Control Plan; conduct potential habitat survey for identified wildlife; site review by state historic preservation office before construction to avoid disturbance of any site with the potential for archeological significance; and the application of best management practices (BMP) to minimize short term air quality and noise impact during construction activities.

Dated: January 16, 2013.

J. Ronald Campbell,

Director, Division of Executive Secretariat, Centers for Disease Control and Prevention.

[FR Doc. 2013–01390 Filed 1–23–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0847]

Guidance for Industry and Food and Drug Administration Staff; Humanitarian Use Device (HUD) Designations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for the industry and FDA staff entitled ''Humanitarian Use Device (HUD) Designations.'' Devices are eligible for HUD designation if they are designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. Devices that receive HUD designations may be eligible for marketing approval under the Humanitarian Device Exemption (HDE) marketing pathway. This guidance document is intended to assist applicants in the preparation and submission of HUD designation requests and FDA reviewers in evaluating such requests. This guidance finalizes the draft guidance of the same title dated December 2011.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Orphan Products (OOPD), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5271, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling OOPD at 301–796–8660. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Eric Chen, Office of Orphan Products Development (OOPD), Food and Drug Administration, Bldg. 32, Rm. 5222, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6327, email: *eric.chen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Humanitarian Use Device (HUD) Designations.'' Devices are eligible for HUD designation if they are designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. (See section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 360j(m); 21 CFR 814.102.) This guidance document is intended to assist applicants in the preparation and submission of HUD designation requests to OOPD. This guidance is also intended to assist FDA reviewers in the evaluation and analysis of HUD designation requests.

Topics addressed in this guidance include: (1) Demonstrating in HUD designation requests that the device is designed to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year; (2) how this demonstration varies depending on whether the device is intended for therapeutic or diagnostic purposes; (3)

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.

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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: