## 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.*

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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)