

“THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Unique Device Identification: Convenience Kits; Draft Guidance for Industry and Food and Drug Administration Staff” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3303, Silver Spring, MD 20993-0002, 301-796-5995, email: gudidsupport@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 226 of the Food and Drug Administration Amendments Act of 2007 and section 614 of the Food and Drug Administration Safety and Innovation Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to add and amend section 519(f) (21 U.S.C. 360i(f)), which directs FDA to publish regulations establishing a unique device identification system for medical devices. The UDI system final rule was published on September 24, 2013 (78 FR 58786) (the UDI Rule).

The overarching objective of the UDI Rule, as required by section 519(f) of the FD&C Act, is to provide a system to adequately identify medical devices through distribution and use. We interpret this to mean that the form of a UDI should, in conformity with 21 CFR 801.40, be available to identify a device in both easily readable plain-text and in a form that can be entered into an electronic patient record or other computer system via an automated process when the device is used by an end user.

The term “convenience kit” is defined at 21 CFR 801.3 as “two or more different medical devices packaged together for the convenience of the user.” Under 21 CFR 801.30(a)(11), individual devices packaged within a convenience kit are excepted from the UDI labeling requirements, provided the UDI is on the label of the immediate container of the convenience kit. The preamble to the UDI Rule expressed our thinking at the time that medical procedure kits, including orthopedic procedure kits, are convenience kits.

Since the publication of the UDI Rule, we have determined that interpreting the term “convenience kit” at § 801.3 to include implantable devices and instruments that are provided by the labeler in sets or trays as non-sterile and repeatedly reconfigured and sterilized (or cleaned and sterilized) prior to use would be inconsistent with the purpose of the exceptions at § 801.30 and the UDI Rule generally. In this draft guidance, FDA proposes to interpret the term “convenience kit” at § 801.3 as applying solely to two or more different medical devices packaged together for the convenience of the user where they are intended to remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user.

II. Significance of Guidance

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 Unique Device Identification for Convenience Kits. It does not establish any rights for any person is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <http://www.regulations.gov>. Persons unable to download an electronic copy of “Unique Device Identification: Convenience Kits; Draft Guidance for Industry and Food and Drug Administration Staff” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500010 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This 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 part 801, subpart B have been approved under OMB control number 0910-0720.

Dated: December 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-33008 Filed 12-31-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review: Notice of Closed Meetings

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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; PAR15-306: Lymphatics in Health and Disease in the Digestive System, Kidney and Urinary Tract.

Date: January 26, 2016.

Time: 1:30 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Patricia Greenwel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301-435-1169, greenwep@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Mouse Models for Translational Research.

Date: January 28, 2016.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lambratu Rahman Sesay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301-451-3493, rahmanl@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 28, 2015.

Sylvia Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-32974 Filed 12-31-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NRNL-19936;
PPWOCRADIO, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance

of properties nominated before December 5, 2015, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by January 19, 2016.

ADDRESSES: Comments may be sent via U.S. Postal Service to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th Floor, Washington, DC 20005; or by fax, 202-371-6447.

SUPPLEMENTARY INFORMATION:

The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before December 5, 2015. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

ALABAMA

Jefferson County

Pinson Hills Historic District, Roughly Cedar Church, Main, Mountain, Pinson & Walnut Sts., Pinewood & Leslie Drs., Center Point & Silver Lake Rds., Pinson, 15000975
Pinson Main Street Historic District, Roughly Clayton, Lane, Main & Spring Sts., Elm & Powell Aves., Marvin's Way, Old Bradford Rd. & Pinson Plz., Pinson, 15000976

DELAWARE

New Castle County

Grantham—Edwards—McComb House, 217 Park Ave., New Castle, 15000977

DISTRICT OF COLUMBIA

District of Columbia

Lexington, The, (Apartment Buildings in Washington, DC, MPS) 1114 F St. NE., Washington, 15000978

ILLINOIS

Johnson County

Dupont, John, House, 130 W. 5th St., New Burnside, 15000979

MASSACHUSETTS

Bristol County

Berkley Common Historic District, N. Main, S. Main, Porter & Locust Sts., Berkley, 15000980

Middlesex County

Six Moon Hill Historic District, (Mid-Century Modern Houses of Lexington, Massachusetts MPS) 4, 8 Bird Hill & 1-40 Moon Hill Rds, 16, 24 Swan Ln., Lexington, 15000981

MINNESOTA

Waseca County

Hoffman Apiaries, 4661 420th Ave., Janesville, 15000982

MISSISSIPPI

Copiah County

Brewer Place, (Copiah County MPS) 3101 Utica Rd., Crystal Springs, 15000983

Georgetown Methodist Church, (Copiah County MPS) 1002 Lane Ave., Georgetown, 15000984

Hancock County

House at 5098 MS 604, 5098 MS 604, Pearlinton, 15000985

Harrison County

Central Gulfport Historic District, Roughly bounded by 24th & 17th Sts., 18th & 23rd Aves., Gulfport, 15000986

Second Street Historic District, Along 2nd St., Gulfport, 15000987

Holmes County

Durant Illinois Central Railroad Depot, 436 E. Mulberry St., Durant, 15000988

WISCONSIN

Winnebago County

Equitable Fraternal Union Building, 116 S. Commercial St., Neenah, 15000989

Authority: 60.13 of 36 CFR part 60

Dated: December 8, 2015.

J. Paul Loether,

*Chief, National Register of Historic Places/
National Historic Landmarks Program.*

[FR Doc. 2015-32999 Filed 12-31-15; 8:45 am]

BILLING CODE 4312-51-P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Computing or Graphics Systems, Components Thereof, and*