

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2014-0008]

Vessel Sanitation Program: Annual Program Status Meeting; Request for comment

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

ACTION: Notice of public meeting and request for comment

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announces the 2014 annual Vessel Sanitation Program (VSP) public meeting. The annual meeting serves as a forum for HHS/CDC to update interested persons on work completed in 2013 and plans for future activities. HHS/CDC is also opening a public docket so that additional comment and materials may be submitted. The official record of this meeting will remain open for 30 days (through July 10, 2014) so that additional materials or comments may be submitted and made part of the record.

DATES: Written comments must be received on or before July 10, 2014.

The meeting will be held on June 10, 2014, from 9:00 a.m. to 4:30 p.m. in the auditorium of the Port Everglades Administration Building, 1850 Eller Drive, Fort Lauderdale, FL 33316. Information regarding logistics is available on the VSP Web site (<http://www.cdc.gov/nceh/vsp/2014annualmeeting.htm>).

Deadline for Requests for Special Accommodations: Persons wishing to participate in the public meeting who need special accommodations should contact CAPT Jaret Ames (vsp@cdc.gov or 954-356-6650 or 770-488-3141) by Monday, June 2, 2014.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2014-0008 by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Vessel Sanitation Program, Centers for Disease Control and Prevention, 4770 Buford Highway NE., MS F-58, Atlanta, Georgia 30341.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://regulations.gov>, including any

personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

CAPT Jaret Ames, Vessel Sanitation Program, Centers for Disease Control and Prevention, 4770 Buford Highway NE., MS F-58, Atlanta, Georgia 30341, email: vsp@cdc.gov, phone: 954-356-6650 or 770-488-3141.

SUPPLEMENTARY INFORMATION:

The purpose of the meeting is to inform the public of VSP's activities in assisting the cruise industry to prevent the introduction and spread of gastrointestinal (GI) illness to U.S. ports from ships under VSP's jurisdiction (ships with 13 or more passengers and an itinerary that includes foreign and U.S. ports).

The meeting will include a review of HHS/CDC's public health support activities from 2013, provide perspective on VSP's approach to vessel sanitation, and offer industry the opportunity to provide input regarding industry efforts to exceed VSP requirements. Presentations will clarify the roles and responsibilities of VSP, cruise line public health management, and shipyards constructing cruise ships. Presentations will also include initiatives for improved epidemiologic study of disease outbreaks and strategic approaches to public health risk reduction for 2015 and the future.

Matters to be discussed:

- VSP year in review—operational and construction inspections, budget, and vessel sanitation training
- CDC Calicivirus Laboratory—norovirus projects
- GI illness data and epidemiology projects—VSP review and progress report
- Cruise line public health initiatives
- CDC Quarantine—Border Health Services Branch Update, including surveillance
- Shipyard construction—strengthening public health through engineering controls
- Cruise Lines International Association—industry public health challenges and response

Meeting Accessibility: The meeting is open to the public, but space is limited to availability. Visitors must present government-issued identification to pass through the vehicle port security checkpoint and enter the administration building.

Advanced registration is encouraged; the meeting room can accommodate approximately 100 persons. Information regarding logistics is available on the VSP Web site (<http://www.cdc.gov/>

nceh/vsp/2014annualmeeting.htm). Attendees at the annual meeting normally include cruise ship industry officials, private sanitation consultants, and other interested parties.

Dated: May 15, 2014.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0092]

Electronic Study Data Submission; Data Standards; Availability of Validation Rules for Standard for Exchange of Nonclinical Data Formatted Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), is announcing the availability of the Validation Rules for Standard for Exchange of Nonclinical Data (SEND) Formatted Studies document. CDER is making this document available to improve the standardization and quality of nonclinical data that are submitted to CDER as well as to improve the predictability of data quality and usefulness.

FOR FURTHER INFORMATION CONTACT: Office of Strategic Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1183, Silver Spring, MD 20993, email: edata@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On February 6, 2014, FDA issued a **Federal Register** notice (79 FR 7201) announcing the availability of a revised draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Standardized Study Data". The revised draft guidance incorporates by reference a technical specifications document entitled "Study Data Technical Conformance Guide." On February 6, 2014, FDA issued a **Federal Register** notice (79 FR 7204) announcing the availability of the Guide and an update to the Data Standards Catalog. The Guide is available at <http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf>.

Section 8.2.3 of the Guide, "Support on Data Validation Rules," states that "[t]he Standards Web page provides links to the validation rules needed to ensure data compliance with CDISC standards, such as SDTM, SEND, ADaM, and define.xml." In this notice, we are announcing the availability of the SEND validation rules.

The Validation Rules for SEND Formatted Studies is an Excel file that provides human readable description of a rule set for validation (*Nonclinical Validator Specifications (XLS)*). Submitters of nonclinical study data can use this information to identify how FDA validates the data. It is available from the FDA Study Data Standards Resources Web page: <http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>. The file contains a combination of conformance rules (i.e., how well the data conform to the standard) and business rules (i.e., quality checks; how well the data may support meaningful analysis). The file may be updated periodically as new or updated validation rules are developed. The Change History tab will provide a descriptive change history of the document.

The validation rules in the Nonclinical Validator Specifications document were created following the suggested human readable validation rule syntax published by a Computational Science Symposium workgroup. This document is available at: http://www.phusewiki.org/wiki/index.php?title=Guidelines_for_Validation_Rule_Developers.

Dated: May 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-11522 Filed 5-19-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues. *Date and Time:* The meeting will be held on June 12, 2014, from 8 a.m. to 6 p.m. *Location:* Holiday Inn Express/Highlands, 20260 Goldenrod Lane, Germantown, MD 20876. The hotel telephone number is 301-428-1300.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993 *Jamie.Waterhouse@fda.hhs.gov*, 301-796-3063, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On June 12, 2014, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the LUTONIX 035 Drug Coated Balloon PTA Catheter sponsored by Lutonix, Inc. The LUTONIX 035 Drug Coated Balloon PTA Catheter (LUTONIX DCB) is an over-the-wire percutaneous transluminal angioplasty (PTA) catheter with a paclitaxel-based drug coating on the surface of the balloon. The LUTONIX DCB is compatible with a 0.035" guidewire and has balloon sizes ranging from 4 millimeters (mm) to 6 mm in diameter and 40 mm to 100 mm in length. The LUTONIX DCB catheter is available in 75 centimeters (cm), 100 cm and 130 cm working lengths.

The proposed indications for use are for improving luminal diameter for the treatment of obstructive de novo or non-stented restenotic lesions (≤ 15 cm in length) in native femoropopliteal arteries having reference vessel diameters of 4 mm to 6 mm.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will

be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 4, 2014. On June 12, 2014, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 28, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 30, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at *Annmarie.Williams@fda.hhs.gov* or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm11462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).