

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>.