- limitations for use of the *Galactomannan* assay;
- considerations for sample acquisition and documentation;
- analysis of study results; and
- performance characteristics of the assay.

Innovative and improved DDTs can help streamline the drug development process, improve the chances for clinical trial success, and yield more information about a treatment and/or disease. DDTs include, but are not limited to, biomarkers, clinical outcome assessments and animal models. Refer to DDTs Qualification Programs at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentTools QualificationProgram/default.htm* for additional information.

As stated previously in the **Federal Register** of January 7, 2014 (79 FR 831), FDA announced the availability of the guidance for industry entitled ''Qualification Process for Drug Development Tools,'' which described the process that would be used to qualify DDTs and to make new DDT qualification recommendations available on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* CDER has developed this formal process to work with developers of these biomarker DDTs to guide the developers as they refine the tools and rigorously evaluate them for use in the regulatory context. Once qualified, DDTs will be publicly available for use in any drug development program for the qualified context of use. As described in the January 2014 guidance, biomarker DDTs should be developed and reviewed using this process.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on *Galactomannan* in serum and BAL fluid. 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. The Paperwork Reduction Act of 1995

This guidance contains an information collection that is 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 information collection has been approved under the OMB control numbers 0910–0001 and 0910–0014. The information requested in the guidance is currently submitted to FDA to support medical product effectiveness (see 21 CFR 312.30, 21 CFR 314.50(d)(5), and 21 CFR 314.126(b)(6)).

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

V. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.*

1. De Pauw, B., T.J. Walsh, J.P. Donnelly, et al., ''Revised Definitions of Invasive Fungal Disease from European Organization for Research and Treatment of Cancer/Invasive Fungal Infections Cooperative Group and the National Institute of Allergy and Infectious Diseases Mycoses Study Group (EORTC/MSG) Consensus Group,'' *Clinical Infectious Diseases* (2008) 46: 1813–1821.

Dated: October 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25532 Filed 10–24–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2013–1078]

National Offshore Safety Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of Federal Advisory Committee meetings.

SUMMARY: The National Offshore Safety Advisory Committee and its Subcommittees will meet on November 18 and 19, 2014, in Houston, TX, to discuss the safety of operations and other matters affecting the offshore oil and gas industry. These meetings are open to the public.

DATES: Subcommittees of the National Offshore Safety Advisory Committee will meet on Tuesday, November 18, 2014, from 1 p.m. to 4 p.m. and the full Committee will meet on Wednesday, November 19, 2014, from 8:30 a.m. to 4:30 p.m. These meetings may end early if the Committee has completed its business, or they may be extended based on the number of public comments. All submitted written materials, comments, and requests to make oral presentations at the meetings should reach the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**) by November 1, 2014. Any written material submitted by the public will be distributed to the Committee and become part of the public record.

ADDRESSES: The meetings will be held in the conference room of the American Bureau of Shipping, 15011 Katy Freeway, Suite 100, Houston, TX, 77094, 832–391–3300, *http://www.eagle.org.*

For information on facilities or services for individuals with disabilities, or to request special assistance at the meetings, contact the individuals listed in **FOR FURTHER INFORMATION CONTACT** section, as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Committee as listed in the ''Agenda'' section below. Written comments for distribution to Committee members must be submitted no later than November 1, 2014, if you want the Committee members to be able to review your comments before the meeting, and must be identified by docket number USCG–2013–1078 and submitted by *one* of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments

(preferred method to avoid delays in processing).

• Fax: (202) 493–2251.

• Mail: Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

• Hand Delivery: Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please submit comments using only one of the above methods.

Instructions: All submissions must include the words ''Department of Homeland Security'' and the docket number for this action, USCG–2013–1078. All comments submitted will be posted without alteration at *http://www.regulations.gov* including any personal information provided. You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Docket: For access to the docket to read documents or comments related to this notice, go to *http://www.regulations.gov,* insert USCG–2013–1078 in the Search box, press Enter, and then click on the item you wish to view.

A public oral comment period will be held during the meeting on November 19, 2014, and speakers are requested to limit their comments to 3 minutes. Contact one of the individuals listed below to register as a speaker.

FOR FURTHER INFORMATION CONTACT: Commander Thomas Kaminski, Designated Federal Official of the National Offshore Safety Advisory Committee, Commandant (CG–OES–2), U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE., Stop 7509, Washington, DC 20593–7509; telephone (202) 372–1410, fax (202) 372–8382 or email *Thomas.J.Kaminski@uscg.mil*, or Mr. Scott Hartley, telephone (202) 372–1437, fax (202) 372–8382 or email *Scott.E.Hartley@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826 or 1–800–647–5527.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act*, Title 5 United States Code Appendix. The National Offshore Safety Advisory Committee provides advice and recommendations to the Department of Homeland Security on matters and actions concerning activities directly involved with or in support of the exploration of offshore mineral and energy resources insofar as they relate to matters within U.S. Coast Guard jurisdiction.

A copy of all meeting documentation will be available at *https://homeport.uscg.mil/NOSAC.* Alternatively, you may contact Mr. Scott Hartley as noted in the **FOR FURTHER INFORMATION CONTACT** section above.

Agenda

Day 1

The National Offshore Safety Advisory Committee Subcommittees will meet on November 18, 2014, from 1 p.m. to 4 p.m. to review, discuss and formulate recommendations on the following matters:

• Commercial Diving Safety on the Outer Continental Shelf;

• Offshore Supply Vessel Purpose and Offshore Workers; and

• Training of personnel on Mobile Offshore Units and Offshore Supply Vessels working on the Outer Continental Shelf.

Day 2

The National Offshore Safety Advisory full Committee will meet on November 19, 2014, from 8:30 a.m. to 4:30 p.m. to review and discuss Subcommittee progress, reports and recommendations received from the above listed Subcommittees from their deliberations on November 18, 2014. The Committee will then use this information and consider public comments in formulating recommendations to the U.S. Coast Guard. Public comments or questions will be taken at the discretion of the Designated Federal Officer during the discussion and recommendation portion of the meeting as well as during the public comment period. A complete agenda for November 19, 2014, is as follows:

(1) Current Business—Presentation and discussion of progress reports, final reports and recommendations from the Subcommittees and subsequent actions on:

(a) Commercial Diving Safety on the Outer Continental Shelf;

(b) Offshore Supply Vessel Purpose and Offshore Workers; and

(c) Training of personnel on Mobile Offshore Units and Offshore Supply Vessels working on the Outer Continental Shelf.

(2) Presentations and discussions of the following matters:

(a) Offshore Service Vessel Dynamic Positioning Authority and Dynamic Positioning Operator Certification;

(b) NorSafe U.S.A. Lifeboat Fall Testing;

(c) American Bureau of Shipping Liquefied Natural Gas Bunkering;

(d) Center for Offshore Safety Activities; and

(e) American Petroleum Institute Recommended Practice 2D Operation and Maintenance of Offshore Cranes.

(3) Public comment period.

The agenda, progress reports, draft final reports, new task statements and presentations will be available approximately 7 days prior to the meeting at the *https://homeport.uscg.mil/NOSAC* Web site or by contacting Mr. Scott Hartley.

Minutes

Meeting minutes will be available for public view and copying within 90 days following the meeting at the *https://homeport.uscg.mil/NOSAC* Web site.

Notice of Future 2014 National Offshore Safety Advisory Committee Meetings

To receive automatic email notices of future National Offshore Safety Advisory Committee meetings in 2014, go to the online docket, USCG–2013–1078 (*http://www.regulations.gov/#!docketDetail:D=USCG-2013-1078*), and select the sign-up-for-email-alerts option.

Dated: October 22, 2014.

J.G. Lantz,

Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2014–25472 Filed 10–24–14; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2014–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to