

The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. 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:**

Tami Belouin, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a document entitled "Guidance for Industry: Implementation of an Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma" dated February 2013. The guidance document recognizes the standardized full-length and abbreviated donor history questionnaires and accompanying materials, version 1.2 dated September 2012, prepared by the PPTA, as an acceptable mechanism that is consistent with FDA's requirements and recommendations for collecting Source Plasma donor history information. The SPDHQ documents will provide blood establishments that collect Source Plasma with a specific process for administering questions to Source Plasma donors to determine their eligibility to donate. The guidance also advises Source Plasma manufacturers who choose to implement the acceptable SPDHQ documents on how to report the manufacturing change consisting of the implementation of the SPDHQ under 21 CFR 601.12.

In the **Federal Register** of July 22, 2011 (76 FR 44013), FDA announced the availability of the draft guidance of the same title dated July 2011. FDA received no comments on the draft guidance. A summary of changes includes: Referencing the most current version of the acceptable SPDHQ documents, clarifying that the full-length and abbreviated questionnaires are designed to be implemented together, and making a few editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated July 2011.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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. 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 21 CFR 601.12 have been approved under OMB control number 0910-0338 and the collections of information in 21 CFR 640.63 have been approved under OMB control number 0910-0116.

**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 guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: February 21, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0001]

**Seventh Annual Drug Information Association/Food and Drug Administration Statistics Forum—2013; Public Conference**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public conference.

**SUMMARY:** The Food and Drug Administration (FDA), in cosponsorship with the Drug Information Association (DIA), is announcing a public conference entitled "Seventh Annual DIA/FDA Statistics Forum—2013." The purpose of the conference is to discuss relevant statistical issues associated with the development and review of therapeutic drugs and biologics. This meeting is intended to be an open forum for the timely discussion of topics of mutual theoretical and practical interest to statisticians and clinical investigators who are involved in the development of new drugs and biologics. A primary focus for this meeting will be to establish an ongoing dialogue regarding FDA's "Critical Path" initiative—emphasizing the regulatory and statistical challenges associated with innovative approaches to the design and analysis of clinical trials data and measuring the progress being made in designing and implementing innovative solutions.

**DATES:** The public conference will be held on April 28, 2013, to May 1, 2013, from 8:30 a.m. to 5 p.m.

**ADDRESSES:** The public conference will be held at the Marriott Bethesda North Hotel and Conference Center, 5701 Marinelli Rd., Bethesda, MD 20852, 1-301-822-9200.

**FOR FURTHER INFORMATION CONTACT:**

Constance Burnett, Drug Information Association, 800 Enterprise Rd., Horsham, PA 19044, 1-215-293-5800, email:

[Constance.Burnett@diahome.org](mailto:Constance.Burnett@diahome.org); or Stephen Wilson, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-0579, email: [Stephen.Wilson@fda.hhs.gov](mailto:Stephen.Wilson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This annual FDA/DIA statistics forum will establish a unique, open, international forum for statisticians and clinicians from industry, academia, contract research organizations, and

Government Agencies. Meeting participants will learn, discuss, and collaborate on the current and emerging statistical methodologies and quantitative approaches used by sponsors to provide evidence for the approval of new therapies.

The goals of the program are to:

- Explore and implement innovative statistical solutions to issues associated with the regulatory review of therapeutic drugs and biologics.

- Describe the application of statistical methodologies and thinking to the development of new therapeutic biologics and drugs.

- Assess the impact of regulations and guidance on statistical practice.

- Discuss ideas for improving the communication between industry statisticians and FDA reviewers.

A description of the planned activities of the working groups can be found at <http://www.diahome.org/en/Meetings-and-Training/Find-Meetings-and-Training/Meeting-Details.aspx?ProductID=30457&EventType=Meeting>.

## II. Registration and Accommodations

### A. Registration

To register, please submit the registration form online at <http://www.diahome.org/en/Meetings-and-Training/Find-Meetings-and-Training/Meeting-Details.aspx?ProductID=30457&EventType=Meeting> (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) Registration fees cover the cost of facilities, materials, and food functions. Seats are limited, and conference space will be filled in the order in which registrations are received. Onsite registration will be available to the extent that space is available on the day of the conference. The costs of registration for different categories of attendee are as follows:

Category	Cost
Industry Representatives .....	\$1,400
Charitable Nonprofit/Academic (Full time) .....	700
Government (Full time) .....	420
Tutorial Fees .....	405

Government and nonprofit attendees and exhibitors will need an invitation code to register at the discounted rate. An invitation code can be obtained by sending an email to:

[Constance.Burnett@diahome.org](mailto:Constance.Burnett@diahome.org). All registrants will pay a fee with the exception of a limited number of speakers/organizers who will have a complimentary registration.

### B. Accommodations

Attendees are responsible for their own accommodations. Attendees making reservations at the Marriott Bethesda North Hotel and Conference Center, Bethesda, MD, are eligible for a reduced conference rate of \$209, not including applicable taxes. Those making reservations online should use the group code "13008" to receive the special rate. If you need special accommodations because of disability, please contact [Constance.Burnett@diahome.org](mailto:Constance.Burnett@diahome.org) at least 7 days before the meeting.

Dated: February 21, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2012-1049]

#### Interim Guidance for Revised Implementation of the International Convention for the Prevention of Pollution From Ships (MARPOL), Annex V

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Coast Guard announces the availability of CG-CVC Policy Letter 13-01, "Interim Guidance for Revised MARPOL Annex V Implementation." On July 15, 2011, the International Maritime Organization's (IMO) Marine Environment Protection Committee (MEPC) formally adopted Resolution MEPC.201(62), which amends the International Convention for the Prevention of Pollution from Ships (MARPOL) Annex V, by establishing a general prohibition on discharges of garbage into the sea. The amendments in Resolution MEPC.201(62) entered into force on January 1, 2013. CG-CVC Policy Letter 13-01 provides interim guidance to assist U.S. flagged and foreign flagged oceangoing ships regarding compliance with the amendments in Resolution MEPC.201(62) until the Coast Guard updates the applicable regulations in 33 CFR part 151.

**DATES:** The effective date for the amendments in Resolution MEPC.201(62) was January 1, 2013. CG-CVC Policy Letter 13-01 is effective as of February 26, 2013.

**ADDRESSES:** This notice and the documents referenced within are

available in the docket and can be viewed by going to [www.regulations.gov](http://www.regulations.gov) and using "USCG-2012-1049" as your search term. CG-CVC Policy Letter 13-01 can also be viewed on the Coast Guard's Web site at <http://homeport.uscg.mil> by referring to the left side menu and following the links to "Domestic Vessels," "Domestic Vessel Policy," and "Office of Commercial Vessel Compliance (CG-CVC) Policy Letters."

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice or CG-CVC Policy Letter 13-01, call or email LT John Peterson, U.S. Coast Guard, Office of Commercial Vessel Compliance (CG-CVC-1), telephone (202) 372-1226, or email [CG-CVC-1@uscg.mil](mailto:CG-CVC-1@uscg.mil). If you have questions on viewing material in the docket, call Docket Operations, telephone (202) 366-9826.

### SUPPLEMENTARY INFORMATION:

#### Background and Purpose

The United States implements MARPOL Annex V through the Act to Prevent Pollution from Ships (33 U.S.C. 1901, *et. seq.*). On July 15, 2011, the IMO's MEPC formally adopted Resolution MEPC.201(62), which amends MARPOL Annex V by establishing a general prohibition on discharges of garbage into the sea. Under prescribed conditions, exceptions are provided for food wastes, cargo residues, cleaning agents or additives contained in cargo hold, deck, and external surface wash waters, and animal carcasses. The amendments in Resolution MEPC.201(62) entered into force on January 1, 2013.

The Coast Guard intends to revise its regulations in 33 CFR part 151 to conform with the amendments in Resolution MEPC.201(62). These conforming regulatory provisions were not finalized prior to January 1, 2013. The lack of updated regulations does not exempt ships from meeting the requirements of the amended MARPOL Annex V. CG-CVC Policy Letter 13-01 provides interim guidance to assist U.S. flagged and foreign flagged oceangoing ships regarding compliance with the amendments in Resolution MEPC.201(62) until the Coast Guard updates the applicable regulations.

As of January 1, 2013, all U.S. flagged ships and fixed or floating platforms are expected to meet the requirements of the amended MARPOL Annex V. This is particularly important for U.S. flagged ships (including recreational and uninspected ships) on international voyages that want to avoid Port State control actions. For U.S. ships operating