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.*

Dated: October 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25048 Filed 10–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0710]

Guidance for Industry on Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection.'' The Food and Drug Administration Safety and Innovation Act (FDASIA) added a provision to the Food, Drug, and Cosmetic Act (the FD&C Act) concerning inspections that makes a drug adulterated. This guidance defines the types of actions, inaction, and circumstances that FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection for the purposes of making a drug adulterated.

DATES: Submit either electronic or written comments on Agency guidance at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., rm. 4138, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. 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: Emily M. Leongini, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 10902 New Hampshire Ave., Bldg. 32, rm. 4339, Silver Spring, MD 20903, 301–796–5300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection.'' On July 9, 2012, FDASIA (Pub. L. 112–144) was signed into law. Section 707 of FDASIA adds 501(j) to the FD&C Act to make a drug adulterated that ''has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.'' As required by Section 707, FDA is issuing this guidance to define the types of action, inaction, and circumstances that FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection for the purposes of Section 501(j) of the FD&C Act.

In July 2013, FDA issued a draft guidance for industry of the same title (78 FR 42387, July 15, 2013). In response to docket comments, we revised the guidance to clarify FDA's expectations regarding the types of action, inaction, and circumstances that make a drug adulterated under 501(j) of the FD&C Act. Among other things, we added examples that may constitute reasonable explanations for actions, inactions, or circumstances that could otherwise be considered delaying, denying, or limiting inspection, or refusing to permit entry or inspection.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on ''Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection.'' 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. 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.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/RegulatoryInformation/Guidances/ucm122044.htm* or *http://www.regulations.gov.*

Dated: October 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25033 Filed 10–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Seventh Annual Sentinel Initiative; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Seventh Annual Sentinel Initiative Public Workshop.'' Convened by the Engelberg Center for Health Care Reform at the Brookings Institution and supported by a cooperative agreement with FDA, this 1-day workshop will bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Topics will include an overview of the transition from the Mini-Sentinel pilot program to the full Sentinel System and what that means for patients and other critical stakeholders. Additionally, panelists will discuss the future of the Sentinel System and opportunities to expand its medical product surveillance capabilities. This workshop will also engage stakeholders to discuss current and emerging Sentinel projects.

Date and Time: The public workshop will be held on February 5, 2015, from 9 a.m. to 4 p.m. EST.

Location: The public workshop will be held at the Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005. For additional travel and hotel information, please refer to *http://events.SignUp4.com/sentinel2015.* (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

There will also be a live Webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Workshop*).

Contact Person: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6358, Silver Spring, MD 20993, 301–796–3714, FAX: 301–847–3529, email: *SentinelInitiative@fda.hhs.gov.*

Registration: To attend the public workshop, you must register before February 5, 2015, by visiting *http://events.SignUp4.com/sentinel2015.* You may also register for the live Webcast by visiting this Web page. There will be no onsite registration. When registering, please provide the following information: Your name, title, company or organization (if applicable), postal address, telephone number, and email address. Those without Internet access should contact Carlos Bell to register (see *Contact Person*). There is no registration fee for the public workshop. However, registration will be on a first-come, first-served basis because seating is limited. Therefore, early registration is recommended. A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of the Washington Plaza Hotel.

If you need special accommodations due to a disability, please contact Joanna Klatzman at the Brookings Institution (202–536–3634, email: *SentinelEvent@Brookings.edu*) at least 7 days in advance.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast (archived video footage will be available on the Brookings Institution Web site following the workshop). Persons interested in viewing the live Webcast must register online by February 4, 2015, at 5 p.m. EST. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements and a test link in advance of the event. Prior to joining the streaming Webcast of the public workshop, it is recommended that you review these technical system requirements and test your connection.

Meeting Materials: All event materials will be available to registered attendees via email before the workshop and will be posted after the event on the Brookings Institution event Web site at *http://www.brookings.edu//health/events.*

Transcripts: Please be advised that transcripts will not be available.

Dated: October 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25053 Filed 10–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1617]

Blood Products 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: Blood Products 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 December 2, 2014, from 8:30 a.m. to 4:30 p.m. and December 3, 2014, from 8:30 a.m. to 12:30 p.m.

ADDRESSES: FDA is opening a docket for person interested in presenting data, information, or views, orally or in writing, on issues pending before the committee. The docket number is FDA–2014–N–1617. Please see the procedure section of the notice for further information.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

For those unable to attend in person, the meeting will also be Web cast. The Web cast will be available at the following links:

- December 2, 2014, Blood Products Advisory Committee Web link: *https://collaboration.fda.gov/bpac1214/*
- December 3, 2014, Blood Products Advisory Committee Web link: *https://collaboration.fda.gov/bpacdecember3/*

Contact Person: Bryan Emery or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, Bldg. 71, Rm. 6132, 240–402–8054 or 240–402–8106, 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 December 2, 2014, the Committee will meet in open session to hear scientific data related to reconsideration of the current blood donor deferral policy for men who have had sex with another man (MSM) even one time since 1977. The Committee will be presented with an update on the November 13, 2014, meeting of the Advisory Committee on Blood and Tissue Safety and Availability where the MSM blood donor deferral policy will be discussed. In the afternoon, an informational presentation will be made regarding the emergence of chikungunya virus infections in the Western Hemisphere and potential implications for blood transfusion safety. The Committee will also hear an informational presentation on the first survey of the Rapid Donor Surveillance (RapidDOS) project on Middle Eastern Respiratory Syndrome coronavirus (MERS-CoV).

On December 3, 2014, the Blood Products Advisory Committee will be seated as a device classification panel. In open session, the panel will discuss