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

the appropriate device classification of blood establishment computer software (BECS) and accessories to BECS. Blood establishment computer software is currently subject to the premarket notification [510(k)] provisions of the Federal Food, Drug and Cosmetic Act.

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 November 25, 2014. On December 2, 2014, oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. On December 3, 2014, oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.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 November 18, 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 November 19, 2014.

FDA has opened a docket for the public who are 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. The docket will close November 25, 2014. Interested persons are encouraged to use the docket to submit electronic or written comments regarding this meeting. Submit electronic comments to *http://www.regulations.gov.*

Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Comments are to be identified 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.*

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 Bryan Emery 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/ucm111462.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).

Dated: October 16, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–25067 Filed 10–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–E–1242; FDA–2012–E–1243]

Determination of Regulatory Review Period for Purposes of Patent Extension; CARBON DIOXIDE LASER

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CARBON DIOXIDE LASER and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the United States Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that food additive.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For food additives, the testing phase begins on the date when a major health or environmental effects test is begun and runs until a petition relying on the test and requesting the issuance of a regulation for use of the additive under section 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348) is initially submitted to FDA. The approval phase begins on the date a petition requesting the issuance of a regulation for use of the additive under section 409 of the FD&C Act is initially received. The approval phase continues until the regulation for the additive becomes effective or until commercial marketing is permitted (21 CFR 60.22). Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a food additive will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has amended the food additive regulations to provide for the safe use of CARBON DIOXIDE LASER for etching