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

information on the surface of fresh, intact citrus fruit for commercial marketing as specified in 21 CFR 179.43. Subsequent to this approval, USPTO received patent term restoration applications for CARBON DIOXIDE LASER (U.S. Patent Nos. 5,660,747 and 5,897,797) from Durant Wayland, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated February 13, 2013, FDA advised the USPTO that this product had undergone a regulatory review period and that FDA's granting of the food additive petition for CARBON DIOXIDE LASER represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CARBON DIOXIDE LASER is 1,950 days. The applicant has not asserted a testing phase. All 1,950 days of the regulatory review period occurred during the approval phase. This period of time was derived from the following dates:

1. *The date a major health or environmental effects test on the food additive was initiated:* No date claimed. The applicant has not asserted a testing period.

2. *The date the application was initially submitted with respect to the food additive under section 409 of the FD&C Act:* February 9, 2007. FDA has determined that the food additive petition (FAP) for Carbon Dioxide Laser for Etching Food (FAP 7M4768) was submitted on February 9, 2007.

3. *The date a regulation for use of the food additive became effective:* June 11, 2012. FDA has verified the applicant's claim that FAP 7M4768 was granted through FDA's issuance of a responsive food additive regulation, effective June 11, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by December 22, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 20, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. 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. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25032 Filed 10–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, Program on Biosecurity and Biosafety Policy; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the meeting of the National Science Advisory Board for Biosecurity (NSABB).

Name of Committee: National Science Advisory Board for Biosecurity.

Date: October 22, 2014.

Time: 8:00 a.m.–4:00 p.m. Eastern Time (Times are approximate and subject to change).

Agenda: Presentations and discussions regarding: (1) Overview of recent Federal policies regarding biosafety and biosecurity; and (2) other business of the Board.

Place: National Institutes of Health, Building 31; 6th Floor, Conference Room 6, Bethesda, Maryland.

Contact Person: Carolyn Mosby, NSABB Program Assistant, NIH Program on Biosecurity and Biosafety Policy, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892, (301) 435–5504, *carolyn.mosby@nih.gov.*

Under authority 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established the NSABB to provide advice regarding federal oversight of dual use research, defined as biological research that generates information and technologies that could be misused to pose a biological threat to public health and/or national security.

The meeting will be open to the public, however pre-registration is strongly recommended due to space limitations. Persons planning to attend may register online at: *http://palladianpartners.cvent.com/d/KY8f5UlwH0WnoisQD81oFg/8nfg/P1/1Q* or by calling Palladian Partners, Inc. (Contact: Joel Yaccarino at 301–650–8660). Online registration will close at 12:00 p.m. Eastern the day before the meeting. After that time, you will need to register onsite on the day of the meeting, from 7:15 a.m. Eastern. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate these requirements upon registration.

This meeting will also be webcast. To access the webcast and meeting information, including the draft meeting agenda and the registration link, connect to: *http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/nsabb/nsabb-meetings-and-conferences.* Please check this site for updates.

Time will be allotted on the agenda for oral public comment, with presentations limited to three minutes per speaker. Sign-up for oral public comments will begin at approximately 7:45 a.m. on October 22, 2014, and will be restricted to one sign-in per person. In the event that time does not allow for all those interested to present oral comments, any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. In addition, any interested person may submit written comments to the NSABB prior to the meeting by sending the comments to the Contact Person listed on this notice by 5:00 p.m. Eastern on October 20, 2014. Written comments should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Any written comments received after the deadline will be provided to the Committee either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.