commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: September 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23893 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2880]

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Microbiology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 9 and 10, 2016, from 8 a.m. to 6 p.m.

ADDRESSES: Gaithersburg Holiday Inn Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301–948–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2880 for ''Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, *aden.asefa@fda.hhs.gov,* 301–796–0400, 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.

SUPPLEMENTARY INFORMATION:

Agenda: On November 9, 2016, during session one, the committee will

discuss and make recommendations regarding the reclassification of quantitative Cytomegalovirus (CMV) viral load devices from class III (Premarket approval) to class II (510(k)). A nucleic acid-based in vitro diagnostic device for the quantitation of CMV viral load, within the context of transplant patient management, is a post-amendment device classified into class III under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)(21 U.S.C. 360c(f)(1). To date, the following product code has been established for CMV viral load devices: PAB (CMV DNA Quantitative Assay). During session two, the committee will discuss and make recommendations regarding the appropriate initial classification for qualitative or quantitative viral load devices for Epstein-Barr virus, BK virus, JC virus, Human Herpesvirus 6, and Adenovirus infections. FDA is seeking expert recommendations to assess the potential risks and benefits of these devices when used in patients following solid-organ or stem cell transplantation.

On November 10, 2016, the committee will discuss and make recommendations to FDA regarding how FDA might handle a future premarket notification (510(k)) submission for a Procalcitonin (PCT) test. One test that FDA previously reviewed and cleared was the VIDAS B·R·A·H·M·S PCT (Procalcitonin) test which is an in vitro diagnostic test for measuring procalcitonin from human serum or plasma. The test was cleared with an indication for use as follows:

- VIDAS B·R·A·H·M·S PCT (PCT) is an automated test for use on the instruments of the VIDAS family for the determination of human procalcitonin in human serum or plasma (lithium heparinate) using the Enzyme-Linked Fluorescent Assay technique.
- VIDAS B·R·A·H·M·S PCT (PCT) is intended for use in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock.
- VIDAS B·R·A·H·M·S PCT (PCT) is also intended for use to determine the change of PCT level over time as an aid in assessing the cumulative 28-day risk of all-cause mortality in conjunction with other laboratory findings and clinical assessments for patients diagnosed with severe sepsis or septic shock in the intensive care unit (ICU) or when obtained in the emergency department or other medical wards prior to ICU admission.
- Procalcitonin (PCT) is a biomarker associated with the inflammatory response to bacterial infection that aids in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock. The percent change in PCT level over time also aids in the prediction of cumulative 28-day mortality in patients with severe sepsis and septic shock.

PCT levels on the first day of ICU admission above 2.0 nanograms per milliliter (ng/mL) are associated with a higher risk for progression to severe sepsis and/or septic shock than PCT levels below 0.5 ng/mL.

- A PCT level that declines ≤80 percent from the day that severe sepsis or septic shock was clinically diagnosed (day 0) to 4 days after clinical diagnosis (day 4) is associated with higher cumulative 28-day risk of all-cause mortality than a decline >80 percent.
- The combination of the first PCT level (≤2.0 ng/mL or >2.0 ng/mL) at initial diagnosis of severe sepsis or septic shock with the patient's clinical course and the change in PCT level over time until day 4 provides important additional information about the mortality risk.
- The PCT level on day 1 (the day after severe sepsis or septic shock is first clinically diagnosed) can be used to calculate the percent change in PCT level at day 4 if the day 0 measurement is unavailable.

FDA anticipates receiving a 510(k) submission for PCT test in which the intended use could be modified to add an indication for use as an aid in the antibiotic management of patients with suspected lower respiratory tract infection, an indication for use as an aid in the antibiotic management of patients being treated with antibiotics for confirmed or documented sepsis, or both. FDA is seeking feedback from the committee and interested parties to assess the evidence in support of the hypothetical changes and the overall benefits and risks from this proposed new indication for use in clinical practice, including feedback on whether any additional mitigations are necessary.

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 October 27, 2016. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. on November 9, 2016, and between approximately 1 p.m. and 2 p.m. on November 10, 2016. 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 October 19, 2016. 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 October 20, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA is establishing a docket for public comment on this document. The docket number is FDA–2016–N–2880. The docket will close on December 6, 2016. Comments received on or before October 26, 2016, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301–796–9638, at least 7 days in advance of the meeting. For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

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: September 28, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–23895 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0519]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How To Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 3, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0454. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway—21 CFR 11.2 OMB Control Number 0910–0454—Extension

We accept certain types of submissions electronically with no requirement for a paper copy. These types of documents are listed in public docket 97S–0251 as required by 21 CFR 11.2. Our ability to receive and process information submitted electronically is limited by our current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. Our guidance entitled ''Guidance for Industry #108: How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway'' outlines general standards to be used for the submission of any electronic information to CVM using the FDA Electronic Submission Gateway (ESG). The likely respondents are sponsors for new animal drug applications.

In the **Federal Register** of April 8, 2016 (81 FR 20647), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment; however, it did not pertain to the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
11.2	3538	29	1.3	38	.08 (5 minutes)	3.0

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimates on our experience with the submission of electronic information to us using the FDA ESG and the number of electronic registration or change requests received between January 1, 2014, and December 31, 2014.

Dated: September 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–23897 Filed 10–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0376]

Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the revised draft guidance for industry entitled ''Dietary Supplements: New Dietary Ingredient Notifications and Related Issues,'' that appeared in the **Federal Register** of August 12, 2016. We are taking this action in response to requests to extend the comment period to allow interested persons additional time to submit comments.

DATES: We are extending the comment period on the draft guidance published August 12, 2016 (81 FR 53486). Submit either electronic or written comments by December 12, 2016.

ADDRESSES: You may submit comments as follows: