analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and does not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

Section 12.45 (21 CFR 12.45), issued under section 701 of the FD&C Act, sets forth the format and procedures for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, concerning disclosure of data and information by participants (21 CFR 13.25). In accordance with § 12.45(e) the presiding officer may omit a participant's appearance.

The presiding officer and other participants will use the collected information in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the prehearing conference and commits participation.

The respondents are individuals or households, State or local governments, not-for-profit institutions and businesses, or other for-profit groups and institutions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.30—Citizen petition	220	1	220	24	5,280
10.33—Administrative reconsideration of action	6	1	6	10	60
10.35—Administrative stay of action	6	1	5	10	50
10.85—Requests for Advisory opinions	4	1	4	16	64
12.22—Filing objections and requests for a hearing on a regulation or order	5	1	5	20	100
12.45—Notice of participation	5	1	5	3	15
Total					5,569

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

The burden estimates for this collection of information are based on Agency records and experience over the past 3 years. The increase in burden hours is due to an increase in the number of respondents under several provisions.

Dated: February 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03604 Filed 2–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0467]

Joint Meeting of the Blood Products Advisory Committee and the Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming joint public advisory committee meeting of the Blood Products Advisory Committee and the Microbiology Devices Panel of the Medical Devices Advisory Committee. The Committee will function as a medical device panel to provide advice and recommendations to the Agency on classification of devices. The Committee will also provide advice and recommendations to the FDA on research programs in the Office of Blood Research and Review. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on March 21, 2018, from 8 a.m. to 5:15 p.m. and March 22, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, sections B&C), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Bryan Emery or Joanne Lipkind, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, Bldg. 71, Rm. 6132, at 240–402–8054, *bryan.emery@fda.hhs.gov* and Rm. 6270 at 240–402–8106, *joanne.lipkind@fda.hhs.gov* respectively, 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 website at *https://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. For those unable to attend in person, the meeting will also be available via webcast. The webcast will be available at the following link for both days: *https://collaboration.fda.gov/bpacmdac2018/.*

SUPPLEMENTARY INFORMATION:

Agenda: During the morning session on March 21, 2018, the Joint Committee

will discuss and make recommendations regarding the device reclassification from Class III to Class II of nucleic acid and serology-based point-of-care and laboratory-based in vitro diagnostic devices indicated for use as aids in the diagnosis of human immunodeficiency virus (HIV) infection. In the afternoon session, the Committee will hear an overview of the research presentations on the research programs of the Laboratory of Emerging Pathogens, the Laboratory of Bacterial and Transmissible Spongiform Encephalopathy Agents, and the Laboratory of Molecular Virology in the Division of Emerging Transfusion-Transmitted Diseases, Office of Blood Research and Review Center for Biologics Evaluation and Research. After the open session, the meeting will be closed to the public to permit discussion where disclosure would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C 552b(c)(6).

On March 22, 2018, the Joint Committee will discuss and make recommendations regarding the reclassification from Class III to Class II of nucleic acid and serology-based in vitro diagnostic devices indicated for use as aids in diagnosis of hepatitis C virus (HCV) infection and/or for use as aids in the management of HCV infected patients.

All the devices that will be discussed by the Committee during the 2-day meeting are post-amendment devices that currently are classified into Class III under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)).

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 website 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 website after the meeting. Background material is available at *https://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 March 14, 2018. Oral presentations from the public will be scheduled between approximately 12:25 p.m. to 1:25 p.m. and from 4:25 p.m. to 4:40 p.m. on March 21, 2018, and between approximately 11:15 a.m. to 12:15 p.m. on March 22, 2018. 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 March 6, 2018. 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 March 7, 2018.

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

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 Bryan Emery at least 7 days in advance of the meeting (See, **FOR FURTHER INFORMATION CONTACT**).

Closed Committee Deliberations: On March 21, 2018, between 4:40 p.m. and 5:15 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making decisions regarding pay adjustments of service fellows or promotion of individual scientists who are permanent CBER staff.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://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.)

Dated: February 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03614 Filed 2–21–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0115]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry and Food and Drug Administration Staff—Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Principle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information concerning class II special controls for an automated blood cell separator device operating by centrifugal or filtration separation principle.

DATES: Submit either electronic or written comments on the collection of information by April 23, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 23, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 23, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to