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 19, 2021.

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 19, 2021. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 19, 2021. 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.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Committee. The Committee is a non-discretionary Federal advisory committee established to provide advice to the Commissioner.

The Commissioner is charged with the administration of the Radiation Control for Health and Safety Act of 1968. This Act creates the Committee and requires the Commissioner to consult with the Committee before prescribing standards for radiation emissions from electronic products. This Committee provides advice and consultation to the Commissioner on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products and may recommend electronic product radiation safety standards to the Commissioner for consideration.

The Committee shall consist of 15 voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of science or engineering applicable to electronic product radiation safety. Members will be invited to serve for overlapping terms of up to 4 years. Voting members will include five members selected from governmental agencies, including State and Federal Governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative of organized labor. A quorum shall consist of 10 members, of which at least 3 shall be from the general public, 3 from the government agencies, and 3 from the affected industries.

Further information regarding the most recent charter and other information can be found at https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/default.htm or by contacting the Designated Federal Officer (see FOR FURTHER INFORMATION CONTACT). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at https://www.fda.gov/AdvisoryCommittees/default.htm.


Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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