• 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.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jismi Johnson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1524, Silver Spring, MD 20993–0002, 301–796–6424.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this guidance document to assist industry in preparing premarket notification (510(k)) submissions for electrosurgical devices intended for use in general surgery. These devices are designed to cut and/or remove tissue and control bleeding through the use of high-frequency electrical current. For the purpose of this guidance, electrosurgical devices may also be called radiofrequency devices or high-frequency devices. The scope of this document is limited to the class II electrosurgical devices and accessories classified under 21 CFR 878.4400, *Electrosurgical cutting and coagulation device and accessories.*

In the **Federal Register** of March 24, 2014 (79 FR 16008), FDA announced the availability of the draft guidance. Interested persons were invited to comment by June 23, 2014. A total of six sets of comments were received. FDA reviewed and considered all the public comments received and revised sections of the guidance, where applicable.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on premarket notification (510(k)) submissions for electrosurgical devices for general surgery. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1835 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; and the collections of information in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

Dated: August 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–19404 Filed 8–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Request for Nominations on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of a nonvoting member to represent the interests of tobacco growers to serve on the Tobacco Products Scientific Advisory Committee for the Center for Tobacco Products (CTP), notify FDA in writing. FDA is also requesting nominations for a nonvoting member to represent the interests of tobacco growers to serve on the Tobacco Products Scientific Advisory Committee, and an alternate to this representative. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations

will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent the interests of tobacco growers must send a letter stating that interest to FDA by *September 14, 2016* (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by September 14, 2016.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process should be sent to Caryn Cohen (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal at: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site at: *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373 (choose Option 5), email: *TPSAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency intends to add nonvoting industry representatives to the following advisory committee:

I. Tobacco Products Scientific Advisory Committee

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent the interests of tobacco growers should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent the interests of tobacco growers for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent the interests of tobacco growers.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting member to represent the interests of tobacco growers. Contact information, current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA seeks to include the views of women, and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 9, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–19312 Filed 8–12–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0218]

Premarket Notification Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery.'' FDA has developed this guidance document to assist industry in preparing premarket notification (510(k)) submissions for bipolar electrosurgical vessel sealers intended for use in general surgery.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: 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'').