

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").

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-2014-D-0218 for “Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery.” 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.

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 Bipolar Electrosurgical Vessel Sealers 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 bipolar electrosurgical vessel sealers intended for use in general surgery. These devices are designed to seal isolated blood and lymphatic vessels for hemostasis (as an alternative to ties) through the use of high-frequency electrical current between two electrodes in close proximity. 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*. This generic type of device includes bipolar vessel sealing instruments, associated electrosurgical generators, and accessories for use in open and minimally invasive general surgical procedures. This guidance is intended only to address bipolar electrosurgical vessel sealers that have general indications for use in general surgery.

In the **Federal Register** of March 24, 2014 (79 FR 16009), FDA announced the availability of the draft guidance. Interested persons were invited to comment by June 23, 2014. Four 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 Bipolar Electrosurgical Vessel Sealers 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 Bipolar Electrosurgical Vessel Sealers 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 1300048 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 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; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910-0119; 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Single-Award Deviation From Competition Requirements for the National Center for Medical Home Implementation Cooperative Agreement

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Single-Award Deviation from Competition Requirements for the National Center for Medical Home Implementation Cooperative Agreement.

SUMMARY: HRSA announces the award of a supplement in the amount of \$300,000 per year for two years for the National Center for Medical Home Implementation (NCMHI) Cooperative Agreement cooperative agreement. The purpose of the NCMHI cooperative agreement, as stated in the funding opportunity announcement, is to: (1) Support a national resource and assistance effort to implement and spread the medical home model to all children and youth, particularly children with special health care needs (CSHCN), children who are vulnerable and/or medically underserved, and pediatric populations served by state public health programs, MCHB and HRSA; and (2) support activities of the Healthy Tomorrows Partnership for Children Program (HTPCP) grantees to improve children's health through innovative community-based efforts, and community and statewide partnerships among professionals in health, education, social services, government, and business. The supplement will permit the American Academy of Pediatrics (AAP), the cooperative agreement awardee, during the budget periods of 7/1/2016-6/30/2017 and 7/1/2017-6/30/2018, to provide technical assistance to the Rural IMPACT communities as they employ two-generation strategies to more effectively support children living in poverty in rural communities, including the implementation and spread of the family-centered medical home model of health care.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: The American Academy of Pediatrics.

Amount of Non-Competitive Awards: \$600,000.

Period of Supplemental Funding: 7/1/2016-6/30/2017 and 7/1/2017-6/30/2018.

CFDA Number: 93.110.

Authority: Social Security Act, Title V, sections 501(a)(1)(D) and 501(a)(2), (42 U.S.C. 701(a)(1)(D) and 701(a)(2)).

Justification: The White House Rural Council initiated the Rural IMPACT project to support improved well-being and upward economic mobility of children in rural and tribal communities. Ideally, systems and services are designed to meet family's needs, and are linked together so that families can access them seamlessly through universal "no wrong door" intake processes and shared referral networks. Components of the Rural IMPACT project include Healthy Start, Early Head Start, Head Start, Home Visiting, WIC, Medical Home, Quality Child Care Education Job Training and income and nutrition supports such as TANF cash assistance, Supplemental Security Income, and the Supplemental Nutrition Assistance Program. The goal of Rural IMPACT is to ensure the healthy development of at-risk children and increase the education and employment opportunities of their parents, thereby improving the well-being of families.

Rural IMPACT project continues to be a high priority of the White House Rural Council, and support for the ten Rural IMPACT communities will continue to be an interagency effort including, in addition to HHS, the Departments of Agriculture, Education, Labor, and the Corporation for National and Community Service.

The purpose of the NCMHI cooperative agreement, as stated in the funding opportunity announcement, is to: (1) Support a national resource and assistance effort to implement and spread the medical home model to all children and youth, particularly children with special health care needs (CSHCN), children who are vulnerable and/or medically underserved, and pediatric populations served by state public health programs, MCHB and HRSA; and (2) support activities of the Healthy Tomorrows Partnership for Children Program (HTPCP) grantees to improve children's health through innovative community-based efforts, and community and statewide partnerships among professionals in health, education, social services, government, and business. The Rural IMPACT Project activities align with the

current project plan, as the NCMHI advances system changes and new initiatives at the community, state, and national levels, building on community partnerships to support family-centered medical home implementation for all children and youth, particularly those underrepresented and from diverse communities (Goal 3).

In 2013, following objective review of its application, HRSA awarded the NCMHI cooperative agreement to the American Academy of Pediatrics (AAP), a nonprofit, tax-exempt organization under Internal Revenue Code 501(c)(3). In 2015, HRSA awarded a \$300,000 supplement to the NCMHI cooperative agreement to allow the AAP to build on its existing work under the cooperative agreement to implement and spread the medical home model in Rural IMPACT project communities, thereby advancing the well-being of children in those communities.

From August 2015 to June 2016, AAP, as part of the NCMHI cooperative agreement, established an expert workgroup and operational structure to guide the initiative; developed and issued a solicitation and scoring process, and conducted a review of applications to make recommendations for participating communities. Since the identification of ten rural and tribal communities, the AAP has provided technical assistance to support their efforts to develop and begin implementing two-generation service delivery models to address the needs of both vulnerable children and their parents.

From July 2016 to June 2018, the ten participating communities will implement their action plans. Ongoing support is needed to assist the communities in implementation as well as evaluation, sustainability, and dissemination of information. This supplement will provide additional funds, through the NCMHI cooperative agreement, to provide technical assistance to the Rural IMPACT communities as they employ two-generation strategies to more effectively support children living in poverty in rural communities, including the implementation and spread of the family-centered medical home model of health care.

FOR FURTHER INFORMATION CONTACT:

Marie Y. Mann, MD, MPH, FAAP, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 13-103, Rockville, Maryland 20857; MMann@hrsa.gov.