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.

Agenda: On March 15, 2016, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the Absorb GT1 Bioresorbable Vascular Scaffold (BVS) System sponsored by Abbott Vascular. The Absorb GT1 BVS System is a temporary scaffold that will fully resorb over time and is indicated for improving coronary luminal diameter in patients with ischemic heart disease due to de novo native coronary artery lesions (length ≤ 24 millimeters (mm)) with a reference vessel diameter of ≥ 2.5 mm and ≤ 3.75 mm.

On March 16, 2016, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the AngelMed Guardian System sponsored by Angel Medical Systems, Inc. The AngelMed Guardian System is an implantable cardiac monitor intended to alert patients to ST segment shifts indicating coronary ischemia. The AngelMed Guardian System is intended for use in patients with prior acute coronary syndrome events, and at risk for recurrent events, to ST segment changes indicating cardiac ischemia.

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 March 1, 2016. Oral presentations from the public will be scheduled on March 15 and 16, 2016, between approximately 1 p.m. and 2 p.m. 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 February 22, 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 February 24, 2016.

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 Artair Mallett at *artair.mallett@fda.hhs.gov,* 301–796–9638, at least 7 days in advance of the meeting.

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: January 11, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–00824 Filed 1–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0073]

Request for Information on Psychosocial Predictors of Uptake of Tobacco and Other Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is opening a docket to obtain data and information related to psychosocial predictors of uptake and continued use of tobacco products, including specific categories of tobacco products and specific individual tobacco products, as well as other products from which predictors may be adapted for or extrapolated to tobacco products. FDA is seeking data and information in the form of reports and manuscripts that are unpublished or not available through indexed bibliographic databases. The purpose of this request for information (RFI) is to gather additional information that could help identify and evaluate predictors of consumer initiation, uptake, and use of tobacco products. FDA has already searched the publicly available scientific literature and is now seeking to supplement that with information that is not included in the published scientific literature.

DATES: Submit either electronic or written comments or information by March 4, 2016.

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–2016–N–0073 for ''Request for Information on Psychosocial Predictors of Uptake of Tobacco and Other Products.'' 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: Shireen Ahmad, Office of Science, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 4462, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act) into law. The Tobacco Control Act grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors. FDA is conducting a systematic review and meta-analysis of the scientific literature in an effort to identify the best psychosocial predictors that longitudinally predict initiation of tobacco product use, uptake of specific types of tobacco products, and uptake of specific individual tobacco products. This information may be used by FDA in future rulemaking and review of industry submissions.

II. Request for Information

FDA seeks information related to psychosocial predictors of uptake of tobacco and other products. FDA has searched the publicly available scientific literature and is now looking to supplement that search with information from other sources, specifically unpublished data or other information. For the purpose of this RFI, FDA considers ''psychosocial predictors'' to include constructs that can be measured at the level of the individual, such as beliefs, attitudes, perceptions, intentions, willingness/openness, curiosity, or other measures that have been used in longitudinal research and demonstrated to be associated with product uptake or initiation. In addition to studies reporting on tobacco products, FDA also would accept information on uptake and use of other products from which predictors may be adapted for or extrapolated to tobacco products. If such information is submitted, it should include an explanation of why the predictor and product could be extrapolated to tobacco products.

For this RFI, FDA is requesting unpublished data (summarized); unpublished or prepublication copies of manuscripts, conference presentations, and/or posters; dissertations and/or theses; and white papers or other unpublished reports. FDA is requesting both data that show associations as well as data that fail to show an association (*i.e.,* null findings). Specifically, FDA is requesting unpublished data from studies on human subjects (including youth, young adults, and older adults) that include:

• A longitudinal design (observational or experimental) in which there is at least one month between assessments and data are reported for at least two time points;

• At least one psychosocial predictor; and

• A quantifiable (continuous or categorical) outcome measure of actual product use (not intentions to use) related to initiation or uptake.

Outcomes may include:

• Initiation;

• Continued use;

• Progression to more frequent use;

• Choice of a specific product; or

• Other similar outcomes.

Data may come from studies outside of the United States; however, we prefer that reports be submitted in English.

For this RFI, FDA is seeking only quantitative scientific data presented in report or manuscript format, and not data from qualitative studies (*e.g.,* interviews, focus groups), anecdotes, or testimonials. FDA is requesting data and information from all interested parties, including, but not limited to, academic and government researchers, industry, and any other sources.

When submitting information, please include details about how the data were collected, including the sample composition, year(s) of data collection, and a detailed summary of the methods and measures used. For data summaries, please include both point estimates and measures of variance, as well as effect sizes (if available).

Please also note that when submitting information and data to the docket, certain compressed file formats (*e.g.,* zip files) are not allowed. Acceptable file formats include: .doc, .docx, .pdf, .ppt, .pptx, .rtf, .txt, .xls, .xlsx, .xlsm, .xlsb, and .wpd.

Dated: January 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–00836 Filed 1–15–16; 8:45 am]

BILLING CODE 4164–01–P