9000–0079, Corporate Aircraft Costs, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

**FOR FURTHER INFORMATION CONTACT:** Ms. Kathy Hopkins, Federal Acquisition Policy Division, GSA, 202–969–7226 or via email *kathy.hopkins@gsa.gov*.

**SUPPLEMENTARY INFORMATION:**

**A. Purpose**

Government contractors that use company aircraft must maintain logs of flights containing specified information (*e.g.,* destination, passenger name, purpose of trip, etc.). This information, as required by FAR 31.205–46, Travel Costs, is used to ensure that costs of owned, leased or chartered aircraft are properly charged against Government contracts and that directly associated costs of unallowable activities are not charged to such contracts.

**B. Annual Reporting Burden**

*Number of Respondents:* 3,000.

*Responses per Respondent:* 1.

*Total Responses:* 3,000.

*Average Burden per Response:* 6 hours.

*Total Burden Hours:* 18,000.

**C. Public Comments**

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulation (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

*Obtaining Copies of Proposals:* Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0079, Corporate Aircraft Costs, in all correspondence.

Dated: April 23, 2015.

**Edward Loeb,**

*Acting Director, Federal Acquisition Policy Division, Office of Acquisition Policy, Office of Governmentwide Policy.*

[FR Doc. 2015–09983 Filed 4–28–15; 8:45 am]

**BILLING CODE 6820–EP–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–0001]**

### Transmissible Spongiform Encephalopathies Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Transmissible Spongiform Encephalopathies Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on June 1, 2015, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm.1503), Silver Spring, MD 20993–0002. For those unable to attend in person, the meeting will also be available via Webcast. The Webcast will be available at the following link: *https://collaboration.fda.gov/cbertseac/.* When accessing the Webcast please enter as a guest. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

*Contact Person:* Bryan Emery or Rosanna Harvey, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6132, Silver Spring, MD 20993–0002, 240–402–8054 or 240–402–8072; 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 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 June 1, 2015, the Transmissible Spongiform Encephalopathies Advisory Committee will meet in open session to hear update presentations on the following topics: (1) The variant Creutzfeldt-Jakob Disease (vCJD) situation worldwide and an update on the United Kingdom's Transfusion Medicine Epidemiological Review; (2) vCJD in the United States; and, (3) the bovine spongiform encephalopathy (BSE) situation worldwide and the United States Department of Agriculture's regulatory approaches to reduce the risk of food-borne exposure of BSE. Following the update presentations, in open session, the committee will hear presentations from FDA on current measures to reduce risk of vCJD from transfusion in the U.S., and a mathematical model of the risk reduction achievable under the current and alternative geographically based donor deferral policies when implemented in conjunction with the use of leukocyte reduction of blood components. The committee will then discuss FDA's geographically based donor deferral policies and other strategies, including leukocyte reduction of blood components, to reduce the risk of transfusion-transmitted vCJD. FDA will seek advice from the committee in developing future recommendations to reduce this risk.

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 May 25, 2015. Oral presentations from the public will be

scheduled between approximately 2:30 p.m. and 3:30 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 May 15, 2015. 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 May 18, 2015.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bryan Emery 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: April 24, 2015.

**Peter Lurie,**

*Associate Commissioner for Public Health Strategy and Analysis.*

[FR Doc. 2015–10026 Filed 4–28–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–D–0090]**

### Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the progress of the Center for Devices and Radiological Health (CDRH) on its 2014–2015 Strategic Priority ''Strike the Right Balance Between Premarket and Postmarket Data Collection.'' To achieve this priority, CDRH established a goal to assure the appropriate balance between premarket and postmarket data collection to facilitate and expedite the development and review of medical devices, in particular high-risk devices of public health importance, and established a target date of December 31, 2014, by which to review 50 percent of product codes subject to a premarket approval application (PMA) that are legally marketed to determine whether or not, based on our current understanding of the technology, to rely on postmarket controls to reduce premarket data collection, to shift some premarket data collection to the postmarket setting, or to pursue down-classification. CDRH has taken such actions periodically in the past consistent with the medical device statutory framework but typically has done so on an ad hoc basis. CDRH also will require more data or up-classify a device, if warranted, based on the current state of the science; however, up-classification is not warranted for the devices subject to this retrospective review because they are already in the highest risk classification. In this document, CDRH is providing its current thinking on reviewed product types to solicit comments on the product codes that have been identified as candidates for reclassification, for reliance on postmarket controls to reduce premarket data collection, or a shift in premarket data collection to the postmarket setting.

**DATES:** Submit either electronic or written comments by June 29, 2015. See section IV for more information on how to submit comments to this document and properly identify the device(s) the comment concerns.

**ADDRESSES:** Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document and with the product code(s) for the device(s) the comment concerns.

**FOR FURTHER INFORMATION CONTACT:** Nancy Braier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5454, Silver Spring, MD 20993–0002, 301–796–5676.

**SUPPLEMENTARY INFORMATION:**

## I. Background

One of three Strategic Priorities for 2014–2015 in CDRH is to ''Strike the Right Balance Between Premarket and Postmarket Data Collection'' (Ref. 1).[1] CDRH's vision is for patients in the United States to have first in the world access to high-quality, safe, and effective medical devices of public health importance. A key determinant of early U.S. patient access to high-quality, safe, and effective devices is the extent of premarket data that device developers provide to FDA. Once a device developer decides to seek U.S. marketing approval or clearance, the extent of data that is collected premarket has an impact upon the length of time needed to complete a premarket submission—the more data to be collected premarket, the longer it may take to acquire the data and make the submission. Consequently, such data collection issues affect when U.S. patients have access to a medical device. On the other hand, it is also important that there is sufficient data to demonstrate a reasonable assurance of safety and effectiveness before a device subject to a premarket approval application (PMA) is approved for marketing in the United States. For this reason, it is important that CDRH strike the right balance between premarket and postmarket data collection. If CDRH can shift—when appropriate—some premarket data collection to the postmarket setting, CDRH could improve patient access to high-quality, safe, and effective medical devices of public health importance. However, patient safety could be undermined if CDRH shifted some data collection from the premarket to the postmarket setting without adequate assurances that necessary and timely data collection will occur. For this reason, CDRH strives to balance the premarket data and postmarket collection, in accordance with section 513(a)(3)(C) (21 U.S.C. 360c(a)(3)(C)) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which directs CDRH to consider whether the extent of data that otherwise would be required for approval of a PMA with respect to effectiveness can be reduced through reliance on postmarket controls.

[1] CDRH's 2014–2015 Strategic Priorities include ''Strengthen the Clinical Trial Enterprise'' and ''Provide Excellent Customer Service,'' in addition to ''Strike the Right Balance Between Premarket and Postmarket Data Collection'' (Ref. 1).