Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Guidance on Electronic Standards for Transfer of Data

In the **Federal Register** of September 15, 2011 (76 FR 57060), FDA published a notice of availability for a draft guidance document entitled ''Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data'' (VICH GL35). Interested persons were given until November 14, 2011, to comment on the draft guidance. FDA received a few comments on the draft guidance, and those comments, as well as those received by other VICH member regulatory agencies, were considered as the guidance was finalized. The guidance announced in this document finalizes the draft guidance dated September 15, 2011. The final guidance is a product of the Pharmacovigilance Expert Working Group of the VICH.

In order to allow for electronic exchange of this information between stakeholders, further specification of the field descriptors and their relationships, including agreement on format of the electronic message is essential. This VICH guidance document is intended to provide recommended standards to construct a single electronic message to transmit data elements for submission of AERs to all member regions. The need to transfer and disseminate information quickly, accurately and easily between Regulatory Authorities and Marketing Authorization Holders on a worldwide scope is especially pertinent to the notification and assimilation of information for pharmacovigilance. Whereas the recommended definition of the pharmacovigilance information has been set forth within the draft guidance entitled, ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' (VICH GL24), and the final guidances entitled ''Pharmacovigilance of Veterinary Medicinal Products: Controlled Lists of Terms'' (VICH GL30) and ''Pharmacovigilance of Veterinary Medicinal Products: Data Elements for Submission of Adverse Event Reports'' (VICH GL42), this guidance defines recommended electronic standards for transfer of data. Please note that VICH GL42 has been harmonized in GFI #188, ''Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine.''

III. Significance of Guidance

This guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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 this guidance have been approved under OMB control number 0910–0645.

V. Comments

Interested persons may submit either electronic comments regarding this document to *www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: December 4, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28830 Filed 12–9–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Postponement of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory scheduled for December 12, 2014. The meeting was announced in the **Federal Register** of September 22, 2014 (79 FR 56589). The meeting is postponed from December 12, 2014, until February 20, 2015. The location of the meeting has also changed.

Date and Time: The meeting will be held February 20, 2015, from 8 a.m. to 6 p.m.

Location: Hilton/Washington DC North, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

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 February 13, 2015. Oral presentations from the public will be scheduled 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 4, 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 February 6, 2015.

Contact Person: Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1611, Silver Spring, MD 20993–0002, 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.

Dated: December 4, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–28881 Filed 12–9–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1998]

Patient-Focused Drug Development Public Meeting on Chagas Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for Chagas disease. Patient-Focused Drug Development is part of FDA's performance commitments in the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The meeting is intended to allow FDA to obtain patients' perspectives on the impact that Chagas disease has on their daily lives, as well as their perspectives on the available therapies for Chagas disease. FDA is also interested in discussing issues related to scientific challenges in developing drugs to treat Chagas disease. In the afternoon, FDA will provide information for and gain perspective from patients and patient advocacy organizations, health care providers, academic experts, and industry on various aspects of clinical development of drug products intended to treat Chagas disease. The input from this public meeting will help in developing topics for further discussion.

DATES: The meeting will be held on April 28, 2015, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by April 20, 2015. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the meeting. Submit electronic or written comments by June 29, 2015.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Sections B and C of the Great Room (Rm. 1503), Silver Spring, MD 20993. Participants must enter through Building 1 and undergo security screening. For more information on parking and security procedures, please visit *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

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, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at *http://www.fda.gov/Drugs/NewsEvents/ucm420130.htm.*

FOR FURTHER INFORMATION CONTACT: Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1144, Silver Spring, MD 20993, 301–796–0684, FAX: 301–847–8443, *Pujita.Vaidya@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected Chagas disease as the focus of a meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patients' perspectives on the severity of the disease and the available therapies for the condition. Patient-Focused Drug Development is being conducted to fulfill FDA's performance commitments made as part of the authorization of PDUFA V under Title I of the Food and Drug Safety and Innovation Act (Public Law 112–144). The full set of performance commitments is available on the FDA Web site at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA has committed to obtain the patient perspective in 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

On April 11, 2013, FDA published a notice (78 FR 21613) in the **Federal Register** announcing the disease areas for meetings in fiscal years (FYs) 2013 through 2015, the first 3 years of the 5-year PDUFA V time frame. To develop the list of disease areas, the Agency used several criteria that were outlined in the April 11 notice. The Agency obtained public comment on these criteria and potential disease areas through a notice for public comment published in the **Federal Register** on September 24, 2012 (77 FR 58849), and through a public meeting held on October 25, 2012. In selecting the disease areas, FDA carefully considered the public comments received and the perspectives of its review divisions. On October 8, 2014, FDA published a notice in the **Federal Register** to initiate another public process to determine the disease areas for FYs 2016 through 2017 (79 FR 60857). More information, including the list of disease areas and a general schedule of meetings, is posted at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.*

II. Public Meeting Information

A. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will obtain patient and patient stakeholder input on symptoms of Chagas disease (American trypanosomiasis) that matter most to patients and on current approaches to treating Chagas disease. When left untreated, acute Chagas disease may progress to chronic Chagas disease. There are currently no FDA-approved drug therapies to treat acute or chronic Chagas disease. FDA is committed to working with all stakeholders to develop safe and effective therapies for affected individuals.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section and organized by topic. For each topic, a brief patient panel discussion will begin the dialogue, followed by a facilitated discussion inviting comments from other patients and patient stakeholders. In addition to input received through this public meeting, FDA is interested in receiving patient input addressing these