d. The overall framework to evaluate the quality of the meta-analysis; whether there is a basis for establishing a hierarchy of evidence for judging the quality of the meta-analysis.

Dated: October 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–24939 Filed 10–23–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Peripheral and Central Nervous System Drugs 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: Peripheral and Central Nervous System Drugs 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 November 13, 2013, from 8 a.m. to 5 p.m.

Location: Sheraton Silver Spring Hotel, Cypress Ballroom, 8777 Georgia Ave., Silver Spring, MD 20910. The hotel's telephone number is 301–589–0800.

Contact Person for More Information: Glendolynn S. Johnson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *PCNS@fda.hhs.gov,* 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: The committee will discuss supplemental biologics license application (sBLA) 103948–5139, alemtuzumab injection, proposed trade name LEMTRADA, submitted by Genzyme Corporation, a Sanofi Company. The proposed indication is for the treatment of patients with relapsing forms of multiple sclerosis to slow or reverse the accumulation of physical disability and reduce the frequency of clinical exacerbations.

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 November 6, 2013. 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 October 30, 2013. 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 October 31, 2013.

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 Glendolynn S. Johnson 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: October 18, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–24908 Filed 10–23–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1277]

Therapeutic Area Standards Initiative Project Plan; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the Therapeutic Area Standards Initiative Project Plan. This therapeutic area (TA) Project Plan will be the primary document for guiding all major aspects of FDA's multi-year initiative to develop and implement TA standards to support the regulatory review process for drugs and biologics. The TA Project Plan will be updated annually and made available for public comment.

DATES: Although you can comment on this TA Project Plan at any time, to ensure that the Agency considers your comment on this TA Project Plan before it begins work on the next version of the TA Project Plan, submit either electronic or written comments on the TA Project Plan by December 23, 2013.

ADDRESSES: Submit written requests for single copies of the TA Project Plan to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002 or Office of Communication, Outreach and Development (HFM–40). Send one self-addressed adhesive label to assist that

office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the TA Project Plan.

Submit electronic comments on the TA Project Plan 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.

FOR FURTHER INFORMATION CONTACT: Colleen Ratliffe, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1158, Silver Spring, MD 20993, email: *CDERDataStandards@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the TA Project Plan. This TA Project Plan will be the primary document for guiding all major aspects of FDA's multi-year initiative to develop and implement TA standards to support the regulatory review process for drugs and biologics. Updated annually and made available for public comment, the plan will provide the overall management framework for addressing and accomplishing the PDUFA V objectives to develop and adopt clinical terminology standards for TAs.

Standardized data elements and terminologies enable data from multiple trials to be grouped for analysis, and meta-analyses within and across drug classes. In 2011, in response to an urgent need to further standardize study data terminologies and concepts for efficacy analysis, FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) compiled a prioritized list of disease and TAs and made it available on FDA's Web site.[1] Several factors were considered in the identification and prioritization of these TAs: (1) Active investigational new drug applications (INDs), (2) existing standardization projects underway, and (3) industry input on drug development pipeline activity.

The Food and Drug Administration Safety and Innovation Act (FDASIA) reauthorized the Prescription Drug User Fee Act (PDUFA V) in July 2012. The PDUFA V Reauthorization Performance Goals and Procedures (Section XII)[2] states that FDA will prepare a project plan for developing distinct TA terminology standards, using a public process that allows for stakeholder input through open standards development organizations.

In November 2012, FDA requested public input relevant to study data standards by: (1) Convening a public meeting on November 5, 2012, entitled ''Regulatory New Drug Review: Solutions for Study Data Exchange Standards'' to receive input from stakeholders on the advantages and disadvantages of current and emerging alternatives for the exchange of regulated study data, and (2) issuing a notice in the August 14, 2012 **Federal Register** (77 FR 48491), informing the public of FDA's intent to prioritize and develop study data standards for identified TAs, and requesting public comment on the TA roadmap as well as recommendations on how the effort could be accomplished most efficiently. The TA Project Plan was developed based upon information from the November 5, 2012, public meeting and public comments submitted in response to the November 20, 2012, **Federal Register** notice on the prioritization of TAs.

The TA standards should enable and enhance the ability to integrate, analyze, report, and share study data. As described in the TA Project Plan, CBER and CDER are actively collaborating with external stakeholders to support the development of these TA standards. Stakeholders are encouraged to engage in and support these data standardization efforts where possible, including providing feedback on the TA Project Plan.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://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, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov.*

Dated: October 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–24909 Filed 10–23–13; 8:45 am]

BILLING CODE 4160–01–P

[1] *http://www.fda.gov/TherapeuticAreaStandards.*

[2] *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Application for the Postdoctoral Research Associate Program

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 23, 2013, pages 44135–44136, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of General Medical Sciences (NIGMS), National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Ms. Tammy Dean-Maxwell, NIGMS, NIH, Natcher Building, Room 3AN–44, 45 Center Drive, MSC 6200,