practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on therapeutic drug assays that measure lamotrigine or zonisamide. 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 the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays," you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1654 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.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 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 809.10 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: August 2, 2010.

Nancy Stade,

Acting Associate Director for Regulations and Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–19419 Filed 8–5–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0495]

Draft Guidance for Industry and Food and Drug Administration Staff; Medical Devices; Neurological and Physical Medicine Device Guidance Document; Reopening of Comment Period; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 28, 2010 (75 FR 44267). The document reopened the comment period for a notice of availability of draft guidance documents for 11 neurological and physical medicine devices. The document was published with an inadvertent error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3208, Silver Spring, MD 20993, 301–796–9148.

SUPPLEMENTARY INFORMATION: In FR Doc. 2010–18406, appearing on page 44267, in the **Federal Register** of Wednesday, July 28, 2010, the following correction is made:

1. On page 44267, in the first column, the heading "[Docket No. FDA–2009–N–0495]" is corrected to read "[Docket No. FDA–2009–D–0495]".

Dated: July 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19355 Filed 8–5–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–D–0243] (formerly 2003D–0571)

Guidance for Industry on Drug Substance Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #169 entitled "Drug Substance Chemistry, Manufacturing, and Controls Information." This guidance provides recommendations on the chemistry, manufacturing, and controls (CMC) information for drug substances that should be submitted to support original new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs). The guidance is structured to facilitate the preparation of applications submitted in Common Technical Document (CTD) format.

DATES: Submit either electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments to *http://www.regulations.gov*. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Alem Ghiorghis, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8266, email: *alem.ghiorghis@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 1, 2006 (71 FR 31194), FDA published the notice of withdrawal and revision of seven guidances. CVM made Level II revisions to draft guidance entitled "Drug Substance Chemistry, Manufacturing, and Controls

Information" to support their continued use in CVM for the approval of new animal drugs (e.g., removed references to human drug and biological products). The guidance announced in this notice finalizes the draft guidance dated June 1, 2006.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the 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 the applicable statutes and regulations.

III. 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 section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) have been approved under OMB Control No. 0910–0032.

IV. Comments

Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

V. 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: July 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19360 Filed 8–5–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Vaccines and Related Biological Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products 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 September 21, 2010, from 2 p.m. to approximately 6 p.m.

Location: National Institutes of Health (NIH), Building 29B/Conference Room C. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room. Important information about transportation and directions to the NIH campus, parking, and security procedures is available on the Internet at *http://www.nih.gov/about/visitor/index.htm*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) Visitors must show two forms of identification, one of which must be a government-issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. Detailed information about security procedures is located at *http://www.nih.gov/about/visitorsecurity.htm*. Due to the limited available parking, visitors are encouraged to use public transportation.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On September 21, 2010, the committee will meet in open session to hear updates of the research programs in the Laboratory of Respiratory & Special Pathogens, Division of Bacterial, Parasitic, & Allergenic Products; Laboratory of Hepatitis Viruses, and Laboratory of Vector Borne Virus Diseases, Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA.

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 link.

Procedure: On September 21, 2010, from 2 p.m. to approximately 5:10 p.m., the meeting is open to the public. 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 September 15, 2010. Oral presentations from the public will be scheduled between approximately 4:10 p.m. and 5:10 p.m. Those desiring to make 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 September 9, 2010. 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,