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 The draft guidance, when finalized, will represent the agency's current thinking on therapeutic drug assays that measure lamotrigine or zonisamide.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Persons interested in obtaining a copy of the draft guidance may do so by using the Internet.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This draft guidance refers to previously approved collections of information found in FDA regulations.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Draft Guidance for Industry and Food and Drug Administration Staff; Medical Devices; Neurological and Physical Medicine Device Guidance Document; Reopening of Comment Period;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