DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 11, 2013.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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: Carol Holquist, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4416, Silver Spring, MD 20993–0002, 301–796–0171.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Safety Considerations for Product Design to Minimize Medication Errors.'' In Title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85), Congress reauthorized and expanded the Prescription Drug User Fee Act program for fiscal years (FYs) 2008 through 2012 (PDUFA IV). As part of the performance goals and procedures set forth in an enclosure to the letter from the Secretary of Health and Human Services referred to in section 101(c) of FDAAA, FDA committed to certain performance goals and procedures. (See *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm*). In that letter, FDA stated that it would use fees collected under PDUFA to implement various measures to reduce medication errors related to look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose designations, and error-prone label and packaging designs. Among these measures, FDA agreed that by the end of FY 2010, after public consultation with academia, industry, other stakeholders, and the general public, the Agency would publish draft guidance describing practices for naming, labeling, and packaging drugs and biologics to reduce medication errors. On June 24 and 25, 2010, FDA held a public workshop and opened a public docket (Docket No. FDA–2010–N–0168) to receive comments on these measures.

This draft guidance document, which addresses safety achieved through drug product design, is the first in a series of planned guidance documents to minimize risks contributing to medication errors. The second guidance will focus on minimizing risks with the design of drug product container labels, carton labeling, and packaging configurations, and the third guidance will focus on minimizing risks with drug product nomenclature.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on addressing safety achieved through drug product design to minimize medication errors. 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.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. 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. 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 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: December 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30034 Filed 12–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; 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 Friday, December 7, 2012 (77 FR 73034). The product name in the document was incorrect. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5290, *Natasha.Facey@fda.hhsgov.*

SUPPLEMENTARY INFORMATION: In FR doc. 2012–29538, appearing on page 73034 in the **Federal Register** of Friday, December 7, 2012, the following correction is made:

1. On page 73034, in the second column under the section entitled ''Agenda'', the product name ''NeuroPace Responsive Neurostimulation (RNS) System'' is corrected to read ''NeuroPace RNS System''.

Dated: December 7, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–30024 Filed 12–12–12; 8:45 am]

BILLING CODE 4160–01–P