Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For information concerning the guidance as it relates to devices regulated by CDRH: Mary Brady, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5426, Silver Spring, MD 20993–0002, 301–796–6089.

For information concerning the guidance as it relates to devices regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

I. Background

For a variety of reasons, use of devices outside professional healthcare facilities or clinical laboratories is on the rise. First, the U.S. population is aging, and the elderly are more likely to live with chronic diseases that require daily medical care at home. Second, due to medical advancements, many individuals with chronic diseases are living longer, but are dependent on home medical care. Finally, an increasing focus on reducing healthcare costs for patients of all ages has spurred the growth of the home health care market. Integral to the home health care market are home use devices. Although home use devices provide significant benefits to patients and families, including quality of life improvements and cost savings, home use devices are also associated with unique risks. Reducing or minimizing the risks posed by home use devices can greatly improve the public health.

This draft guidance provides recommendations for designing and developing medical devices intended for home use through considerations involving the physical environment, the user, the device or system, the labeling, and the utilization of human factors. This should result in a safe and easier-to-use device, minimize use error, and reduce the likelihood that adverse events will occur. The recommendations in the guidance apply to both prescription and over-the-counter medical devices that are intended for home use.

II. Significance of Guidance

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 the total product life cycle for devices intended for home use. 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. 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* or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive ''Design Considerations for Devices Intended for Home Use'' from CDRH, you may either send an email 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 1750 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently 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 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; 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 part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in Form FDA 3500A have been approved under OMB control number 0910–0291.

V. 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.*

Dated: December 5, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30033 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–D–1005]

Draft Guidance for Industry on Safety Considerations for Product Design To Minimize Medication Errors; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Safety Considerations for Product Design to Minimize Medication Errors.'' The draft guidance provides sponsors of investigational new drug applications, new drug applications, biologics licensing applications, abbreviated new drug applications, and nonprescription drugs marketed without an approved application (e.g., monograph) with a set of principles for developing drug products using a systems approach to minimize medication errors relating to product design. The draft guidance includes recommendations intended to improve the drug product and container closure design at the earliest stages of product development for all prescription and nonprescription drug products.

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