500), Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, 301–827–7175, e-mail: *gladys.Melendez-bohler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2011–16120, appearing on page 37817, in the **Federal Register** of Tuesday, June 28, 2011, the following correction is made:

1. On page 37819, in third column, section *A. Award Amount* is corrected to read as follows:

The total funding available is up to $360,000 (total costs including indirect costs) in fiscal year 2011 in support of this project. One award will be made. Funding will be provided for one year, with the possibility of up to four additional years of support, contingent upon successful performance and available funding.

Dated: July 21, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–18881 Filed 7–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0239]

Identifying the Center for Drug Evaluation and Research's Science and Research Needs; Availability of a Draft Report; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft report entitled ''Identifying CDER's Science and Research Needs.'' This document identifies current priorities in regulatory science related to the mission of the Center for Drug Evaluation and Research (CDER), and will guide strategic planning of internal research efforts. Through external communication of the science and research needs outlined in the report, CDER hopes to stimulate research and foster collaborations with external partners and stakeholders to address these priorities.

DATES: Although you can comment on the report at any time, to ensure that the Agency considers your comment on this report before it begins work on the final version of the report, submit either electronic or written comments on the report by September 26, 2011.

ADDRESSES: Submit written requests for single copies of this report 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 report.

Submit electronic comments on the draft report 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: Ruth Barratt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4540, Silver Spring, MD 20993–0002, 301–796–2600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft report entitled ''Identifying CDER's Science and Research Needs.'' This report is the result of an effort to identify regulatory science needs that, if addressed, would enhance CDER's ability to fulfill its regulatory mission. A publication entitled ''FDA Critical Path Opportunities Report and Critical Path Opportunities List'' was published in March 2006. That report focused on the scientific challenges underlying medical product development and served as a catalyst for CDER to launch an effort to identify specific areas that would benefit from additional regulatory science efforts. More recently, FDA released, ''Advancing Regulatory Science for Public Health'', which incorporates the Critical Path objectives into a broad framework for advancing regulatory science. In support of these initiatives, this report delineates major areas of scientific need that can contribute to the development of a strategic science and research agenda.

To begin an assessment of these needs, more than 200 representatives from CDER's offices were asked to identify: (1) Scientific challenges currently addressed on a case-by-case basis that might benefit from the development of a systematized approach; (2) recurrent science issues across teams, divisions, or offices; and (3) emerging scientific challenges. A comprehensive set of science and research needs was compiled from these discussions. Senior management from CDER offices reviewed and prioritized topics from their offices. These science and research needs were ultimately grouped into seven categories that were reviewed and endorsed by the CDER Science Prioritization and Review Committee and CDER senior management.

Seven major categories that crossed multiple disciplines were identified: (1) Improve access to postmarket data sources and explore feasibility of their use in different types of analyses; (2) improve risk assessment and management strategies to reinforce the safe use of drugs; (3) evaluate the effectiveness and impact of different types of regulatory communications to the public and other stakeholders; (4) evaluate the links among product quality attributes, manufacturing processes, and product performance; (5) develop and improve predictive models of safety and efficacy in humans; (6) improve clinical trial design, analysis, and conduct; and (7) enhance individualization of patient treatment.

The draft report is not intended to address the need to maintain a robust scientific readiness to respond rapidly to regulatory crises, but by communicating CDER's current science and research needs, CDER hopes to stimulate research and foster collaborations with external partners and stakeholders. CDER is disseminating this document externally and soliciting input on: (1) Research and initiatives that may be ongoing; and (2) opportunities to collaborate with external partners and stakeholders to maximize resources to address the areas for development discussed previously. The input will be reviewed and incorporated as appropriate into plans for collaborations and potential external partners will be contacted for further discussion.

II. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov.*

Dated: July 21, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–18880 Filed 7–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0465]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation Systems.'' This guidance document describes a means by which a repetitive transcranial magnetic stimulation (rTMS) system may comply with the requirement of special controls for class II devices. This guidance document is being immediately implemented as the special control for rTMS systems, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation Systems'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. 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 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: Ann H. Costello, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2460, Silver Spring, MD 20993–0002, 301–796–6493.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document will serve as the special control for rTMS systems. Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)) provides that any person who submits a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the FD&C Act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA will, within 60 days of receiving such a request, classify the device by written order. This classification will be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification. Because of the timeframes established by section 513(f)(2) of the FD&C Act, FDA has determined, under 21 CFR 10.115(g)(2), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is for immediate implementation. FDA will consider any comments that are received in response to this notice to determine whether to revise the guidance document. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying rTMS systems into class II (special controls), under section 513(f)(2) of the FD&C Act.

II. Significance of Special Controls Guidance

FDA believes that adherence to the recommendations described in this guidance, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of rTMS systems classified under 882.5805 (21 CFR 882.5805). In order to be classified as a class II device under 882.5805, a rTMS system must comply with the requirements of special controls; manufacturers must address the issues requiring special controls as identified in the guidance document, either by following the recommendations in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons interested in obtaining a copy of the 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.*

To receive ''Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems'' 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 paper copy. Please use the document number 1728 to identify the guidance you are requesting.

IV. 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 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 801 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.