IDENTIFYING THE CENTER FOR DRUG EVALUATION AND RESEARCH’S SCIENCE AND RESEARCH NEEDS: AVAILABILITY OF A DRAFT REPORT; REQUEST FOR COMMENTS

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 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.
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 requirements 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.


III. Electronic Access


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 document 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.