that a collection of information entitled ''Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On September 13, 2012, the Agency submitted a proposed collection of information entitled ''Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0754. The approval expires on December 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00872 Filed 1–16–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0485]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Premarket Approval of Medical Devices—21 CFR Part 814

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Premarket Approval of Medical Devices—21 CFR Part 814'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On November 22, 2013, the Agency submitted a proposed collection of information entitled ''Premarket Approval of Medical Devices—21 CFR Part 814'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0231. The approval expires on January 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00870 Filed 1–16–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0804]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Premarket Notification Submission 510(k)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Premarket Notification Submission 510(k), Subpart E'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On November 12, 2013, the Agency submitted a proposed collection of information entitled ''Premarket Notification Submission 510(k), Subpart E'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0120. The approval expires on January, 31 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00869 Filed 1–16–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0618]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Reporting and Recordkeeping for Electronic Products—General Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Reporting and Recordkeeping for Electronic Products—General Requirements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On November 20, 2013, the Agency submitted a proposed collection of information entitled ''Reporting and Recordkeeping for Electronic Products—General Requirements'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0025. The approval expires on January 31, 2017. A copy of the supporting statement for this information collection is available on

the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00871 Filed 1–16–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1530]

Reporting of Computational Modeling Studies in Medical Device Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Reporting of Computational Modeling Studies in Medical Device Submissions.'' Computational modeling and simulation (CM&S) studies are often used by sponsors as a tool to support medical device applications. The purpose of this draft guidance document is to provide recommendations to industry on the formatting, organization, and content of reports of CM&S studies that are used as valid scientific evidence to support medical device submissions, and to assist FDA staff in the review of computational modeling and simulation studies by improving the consistency and predictability of the review and facilitating full interpretation and complete review of those studies. This draft guidance is not final nor is it in effect at this time.

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 comment 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 April 17, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Reporting of Computational Modeling Studies in Medical Device Submissions'' 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 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: Tina Morrison, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1272, Silver Spring, MD 20993–0002, 301–796–6310.

SUPPLEMENTARY INFORMATION:

I. Background

There has been an increased interest in the use of CM&S studies as a tool to support medical device applications, as evidenced by the increase in the number of computer modeling test reports submitted in medical device applications. The Center for Devices and Radiological Health (CDRH) recognizes that use of CM&S studies are an innovative means to design, develop, and evaluate medical devices, and has held five public meetings on the topic in recent years. Information regarding the most recent meeting, ''FDA/NIH/NSF Workshop on Computer Models and Validation for Medical Devices,'' June 11–12, 2013, is available at: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm346375.htm.*

CM&S studies have traditionally been used in the areas of fluid dynamics (e.g., shear stress and stagnation calculations in ventricular assist devices), solid mechanics (e.g., maximum stress locations in a hip implant), electromagnetics and optics (e.g., radiofrequency dosimetry in magnetic resonance imaging, fluence for fiber optic spectroscopy devices), ultrasound propagation (e.g., absorbed energy distribution for therapeutic ultrasound), and thermal propagation (e.g., radiofrequency and laser ablation devices). The purpose of this draft guidance document is to provide recommendations to industry on the formatting, organization, and content of reports of CM&S studies that are used as valid scientific evidence to support medical device submissions. Moreover, this draft guidance is intended to help improve the consistency and predictability of the review of computational modeling and simulation studies and to better facilitate full interpretation and complete review of those studies.

The draft guidance provides a general outline of information that should be included in a CM&S report, written in general terms to capture reporting for any modality. The guidance also includes five subject matter appendices that provide more background, structure, and specific terminology for modeling and simulation modalities that are widely used in regulatory submissions, including fluid dynamics and mass transport; solid mechanics; electromagnetics and optics; ultrasound; and heat transfer.

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 ''Reporting of Computational Modeling Studies in Medical Device Submissions.'' 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.* To receive ''Reporting of Computational Modeling Studies in Medical Device Submissions,'' 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 1807 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 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807 subpart E have been approved