B. REMS Data Elements

For REMS with ETASU, the REMS data elements describe REMS requirements using a standardized, machine-readable format that permits integration of REMS information into electronic health information technology, including clinical decision support, e-Prescribing systems, and electronic pharmacy systems. FDA has developed terminology to assist in the coding of REMS data elements. This terminology is available as part of the Draft REMS SPL Implementation Guide Excerpt on FDA's SPL Web site (*http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm).* The REMS Data Elements do not replace the approved REMS document, which will continue to be the enforceable document establishing the REMS requirements.

III. How To Participate in the REMS SPL Pilot

A. Participation

Volunteers interested in participating in the pilot should contact pilot staff by email at *REMS_Standardization@fda.hhs.gov.* The following information should be included in the request: Contact name, contact phone number, and contact email address. FDA will contact interested applicants to discuss the pilot. FDA is seeking a limited number of participants (no more than nine) to participate in this pilot. FDA is also seeking comment from any stakeholder on its proposed approach for capturing REMS information in SPL format in this pilot, as described in section II.

B. Procedures

To create an SPL file and submit it to FDA, a participant will need the following tools: Appropriate software, knowledge of terminology and standards, and access to FDA's Electronic Submissions Gateway (ESG) (*http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm*). The ESG is an Agency-wide means of accepting electronic regulatory submissions. The FDA ESG enables the secure submission of regulatory submissions. Instructions and information regarding the creation of an SPL file and the converting of REMS information into SPL can be found at *http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm*. There should be no additional cost associated with obtaining the software. In 2010, FDA collaborated with Pragmatic Data, LLC (*http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm189651.htm*), to make available free SPL authoring software that SPL authors may use to create new SPL documents or edit previous versions.

After the SPL is created, the participant would upload the file through the ESG. The Internet portal can be found at *http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm*. Prior to uploading an SPL file, one must obtain a digital certificate. Instructions regarding obtaining a digital certificate used with FDA's ESG and uploading the SPL file for submission can be found at *http://www.fda.gov/esg/default.htm*. The digital certificate binds together the owner's name and a pair of electronic keys (a public and a private key) that can be used to encrypt and sign documents. A fee of up to approximately $20 is charged for the digital certificate. Application holders should have already secured a digital certificate because they are required to do so when they register and list.

During the pilot, FDA staff will be available to answer any questions or concerns that may arise. Pilot participants will be asked to comment on and discuss their experiences converting their REMS into SPL format. Their comments are expected to assist FDA in its completion of the REMS SPL project.

IV. Duration of the REMS SPL Pilot

FDA will accept requests for participation in the REMS SPL pilot from October 6, 2015 to December 7, 2015. The pilot will proceed for 4 months, from October 6, 2015 to February 3, 2016. This pilot may be extended as resources and needs allow.

V. Paperwork Reduction Act of 1995

This notice 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 314 have been approved under OMB control number 0910–0001.

Dated: September 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25349 Filed 10–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–M–1064, FDA–2015–M–1065, FDA–2015–M–1177, FDA–2015–M–1178, FDA–2015–M–1325, FDA–2015–M–1326, FDA–2015–M–1460, FDA–2015–M–1461, FDA–2015–M–1557, FDA–2015–M–1708, FDA–2015–M–1709, FDA–2015–M–1956, FDA–2015–M–1957, FDA–2015–M–1958, FDA–2015–M–1959, FDA–2015–M–2077, FDA–2015–M–2078, FDA–2014–M–2247]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Melissa Torres, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–5576.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that

FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2015, through June 30, 2015. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM APRIL 1, 2015 THROUGH JUNE 30, 2015

PMA No., Docket No.	Applicant	Trade name	Approval date
P140003, FDA–2015–M–1177	ABIOMED, Inc	Impella® 2.5 System	3/23/2015
P130014, FDA–2015–M–1065	HyperBranch Medical Technology, Inc.	Adherus® AutoSpray Dural Sealant	3/30/2015
P130021/S010, FDA–2015–M–1064.	Medtronic CoreValve, LLC	Medtronic CoreValve® System	3/30/2015
P110015, FDA–2015–M–1178	Advanced Breath Diagnostics, LLC.	Gastric Emptying Breath Test (GEBT)	4/6/2015
P040020/S050, FDA–2015–M–1325.	Alcon Research, Ltd	AcrySof IQ ReSTOR +2.5 D Multifocal Intraocular Lens	4/13/2015
P120023, FDA–2015–M–1326	AcuFocus™, Inc	KAMRA™ inlay	4/17/2015
H130007, FDA–2014–M–2247	CVRx®, Inc	Barostim neo™ Legacy System	12/12/2014
P140011, FDA–2015–M–1460	Siemens Medical Solutions USA, Inc.	MAMMOMAT Inspiration with Tomosynthesis Option	4/21/2015
P120017, FDA–2015–M–1461	Medtronic, Inc	Model 5071 Lead	4/27/2015
P130012, FDA–2015–M–1557	Greatbatch Medical	Myopore Sutureless Myocardial Pacing Lead	4/30/2015
P140023, FDA–2015–M–1708	Roche Molecular Systems, Inc	cobas® KRAS Mutation Test	5/7/2015
P130022, FDA–2015–M–1709	Nevro Corp	Nevro Senza Spinal Cord Stimulation (SCS) System	5/8/2015
P140026, FDA–2015–M–1956	Silk Road Medical, Inc	ENROUTE™ Transcarotid Stent System	5/18/2015
P140004, FDA–2015–M–1957	Vertiflex®, Inc	Superion® InterSpinous Spacer	5/20/2015
P140002, FDA–2015–M–1958	Terumo Medical Corp	Misago® Peripheral Self-expanding Stent System	5/22/2015
P120005/S031, FDA–2015–M–1959.	Dexcom, Inc	Dexcom G4®PLATINUM (Pediatric) Continuous Glucose Monitoring System.	5/22/2015
P110010/S096, FDA–2015–M–2077.	Boston Scientific Corp	PROMUS® Element™ Plus and Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Monorail™ and Over-the-Wire).	6/1/2015
P050052/S049, FDA–2015–M–2078.	Merz North America	Radiesse® Injectable Implant	6/4/2015

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: September 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25352 Filed 10–5–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0748]

Agency Information Collection Activities; Proposed Collection; Submission for Office of Management and Budget Review; Guidance for Industry on Generic Drug User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 5, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0727. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.