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[FR Doc. 2013-21604 Filed 9-4-13; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0477]

Center for Devices and Radiological Health: Draft Standard Operating Procedure for Level 1, Immediately in Effect Guidance Documents on Premarket Data Issues; Availability and 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 the Draft Standard Operating Procedure (SOP) for Level 1, Immediately in Effect (IIE) Guidance Documents on Premarket Data Issues. The SOP describes the Center for Devices and Radiological Health's (CDRH's or the Center's) draft process to clarify and more quickly inform stakeholders when CDRH has changed its expectations relating to, or otherwise has new scientific information that could affect, data submitted as part of an Investigational Device Exemption (IDE) or premarket submission, including a Premarket Notification 510(k), a Premarket Approval (PMA), or a Humanitarian Device Exemption (HDE) that needs to be disseminated in a timely manner.

DATES: The Agency encourages interested parties to submit information and either electronic or written comments by October 21, 2013.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document. Submit electronic comments on the draft SOP 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:
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SUPPLEMENTARY INFORMATION:

I. Background

The Task Force on the Utilization of Science in Regulatory Decision Making (the Task Force) published a Preliminary Report and Recommendations in August 2010. In the report, the Task Force noted that when new scientific information changes CDRH's regulatory thinking, it has been challenging for the Center to communicate the change and its basis to all affected parties in a meaningful and timely manner. The Task Force recommended that the Center make use of more rapid tools for broad communication on regulatory matters, including establishing a standard practice for communicating to all manufacturers of a particular group of devices for which the Center has changed its regulatory expectations on the basis of new scientific information.

Currently, manufacturers typically learn of changes CDRH implements regarding what data or how to gather specific data in support of an IDE or premarket submission, including a Premarket Notification 510(k), a PMA, or an HDE at the time of or soon after a decision is made through individual engagement with the Center, often not until after they have prepared that submission. Reviewers may implement these changes, such as requesting new clinical data or using a new test method, on a case-by-case basis, with immediate supervisory concurrence when it is necessary to protect the public health. For example, a reviewer may request that sponsors test their implantable device for durability because new data demonstrate that this type of device is prone to failure due to premature wear and tear of the technology. Although CDRH may issue a detailed guidance document, the document may not be published until a year or more after a Branch- or Division-level decision has been made to request the information because of the resource constraints in developing guidance documents.

CDRH believes that timely communication with industry about changes in premarket regulatory expectations is important. FDA's Good Guidance Practices regulation provides a mechanism for communicating and implementing certain changes in regulatory expectations quickly, without requiring prior public comment. Under 21 CFR 10.115(g)(2), FDA may issue a Level 1, IIE Guidance Document when prior public participation is not "feasible or appropriate." Under these circumstances, CDRH intends to use the

procedures described in § 10.115(g)(2) to issue guidance documents addressing changes in premarket regulatory expectations. CDRH has developed this SOP to facilitate issuance of such guidance documents.

On July 21, 2011 (76 FR 43693), CDRH issued a Standard Operating Procedure for "Notice to Industry" Letters, which outlined a similar process to clarify and quickly inform stakeholders of new CDRH expectations (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259172.pdf>). After considering the comments received on that proposal, CDRH is now announcing a draft SOP that meets the Center's needs and addresses concerns raised regarding the original "Notice to Industry" proposal.

II. Electronic Access

Persons interested in obtaining a copy of the draft SOP may do so by using the Internet. The Draft Standard Operating Procedure for Level 1, Immediately in Effect Guidance Documents on Premarket Data Issues is available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259172.pdf>. The draft SOP is also available from <http://www.regulations.gov> and can be located using the docket number found in brackets in the heading of this document.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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: August 28, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-21544 Filed 9-4-13; 8:45 am]

BILLING CODE 4160-01-P