Legislation, and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2014–13290, appearing on page 32964, in the **Federal Register** of Monday, June 9, 2014, the following correction is made:

On page 32964, in the second column, in the headings section of the document, [Docket No. FDA–2014–N–0736]'' is corrected to read ''FDA–2015–N–2781''.

Please be aware that this new docket is no longer open for comment.

Dated: August 12, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015–20397 Filed 8–18–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–2458]**

### Center for Devices and Radiological Health Participation in International Medical Device Regulators Forum, Regulated Product Submission, Table of Contents Pilot Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH), Offices of Device Evaluation (ODE) and In Vitro Diagnostics and Radiation (OIR) are announcing their participation in the International Medical Device Regulators Forum's (IMDRF) Regulated Product Submission Table of Contents Pilot Program. Participation in the Pilot is voluntary and open to applicants who submit premarket approval (PMA) applications or premarket notification (510(k)) to either ODE or OIR. The Pilot project is intended to provide industry, IMDRF, and CDRH staff the opportunity to evaluate the Table of Contents structure and to receive input from industry participants. Participants will be asked to submit their submissions electronically using IMDRF's Table of Contents (ToC) format.

**DATES:** The IMDRF is seeking interest for participation in the voluntary IMDRF Regulated Product Submission, Table of Contents Pilot Program. See section II.A. for instructions on how to submit a request to participate. The Pilot project will accept submissions with the ToC structure starting September 2015 through September 2016.

**FOR FURTHER INFORMATION CONTACT:** Jodi Hope N. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1520, Silver Spring, MD 20993, 301–796–9299, *Jodi.Anderson@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

The IMDRF was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization. It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force. The Forum aims to accelerate international medical device regulatory harmonization and convergence.

The Regulated Product Submission (RPS) proposal was endorsed as a new work item by IMDRF at its 2012 inaugural meeting in Singapore. The Work Group, consisting of regulatory authorities from the United States, European Union (EU), Australia, Brazil, Japan, China, and Canada, created a comprehensive Table of Contents for Non-In Vitro Diagnostics (nIVD) and also for IVD Marketing Authorizations, which were formalized in August 2014.

The ToC provides a comprehensive submission structure that can be used as a harmonized international electronic submission format while minimizing regional divergences and indicating where regional variation exists. This document is intended to provide guidance regarding the location of submission elements. These documents can be found on IMDRF's Web site (Refs. 1 and 2).

This document is intended to work together with a regional classification matrix, a separate document created for each participating jurisdiction. The classification matrix defines whether a heading is required, not required, optional, conditionally required, etc., for the given submission type. FDA's Classification Matrices can be found on FDA's Web site (Ref. 3).

The ToC Work Group has previously conducted Pilots for both of the ToC structures, using historical submissions. These Pilots provided valuable feedback regarding the ToC structure and completeness; however, there were limitations to using historical submissions and also a limited number of samples involving submission to more than one jurisdiction. Furthermore, there were no specific guidelines regarding the means of building a submission in a non-standard implementation. Additional IMDRF testing is considered necessary to both evaluate the ToC structures using real regulatory submissions and also evaluate the ToC structure from an industry perspective.

#### II. CDRH Participation in IMDRF Regulated Product Submission Table of Contents (ToC) Implementation Pilot

FDA's participation in the IMDRF RPS ToC Implementation Pilot will provide both local and international benefits for FDA, as it will provide FDA feedback into decisions regarding the ToC's suitability.

CDRH is participating in the Pilot. In doing so, CDRH will receive premarket submissions from the medical device regulated industry using the IMDRF ToC and FDA Regional Classification Matrices. Applications are to be real regulatory submissions—either PMAs or 510(k) applications—that will result in regulatory decisions by CDRH. PMAs exclude combination products and bundled submissions. The 510(k)s exclude special, abbreviated, and third-party submissions, as well as combination products, bundled submissions, and amendments after a final decision. Pilot participation requires that an application submitted to FDA also be submitted sequentially or simultaneously to at least one additional participating IMDRF region. Currently the participating regulating authorities are Australia (Therapeutic Goods Administration), Brazil (ANVISA), Canada (Health Canada), China (China Food and Drug Administration), and the European Union (Notified Bodies).

The Pilot is described in greater detail in the IMDRF/RPS WG/N26 Informational Document ''IMDRF Table of Contents (ToC) Pilot Plan'' (Ref. 4).

The Regulators participating in this Pilot intend to use submissions only for the requested regulatory activity and objectives of this Pilot. Any submissions generated in relation to this testing will not be distributed to other manufacturers or other regulators. Industry participants should share any submission content directly with the appropriate regulators through the official regulatory processes in place—*i.e.*, submission content will be shared across regulators directly by regulated industry.

Feedback provided on the ToC structure, experience developing regulatory submissions, or suggestions

for additional ToC headings may be shared and made public, excluding any confidential content. Basic applicant and submission identifying information (*e.g.*, Applicant/Correspondent/Manufacturer Name, Device Name, Device Type, and Submission Type) will be shared among IMDRF Regulators for the purpose of conducting the Pilot. The invitation to participants will provide the specific details of the information to be shared among the Regulators as it is a condition for Pilot participation. Any information provided in the resulting Pilot findings should only disclose information explicitly stated as releasable.

This Pilot will be evaluated in accordance with current FDA protocols and performance standards. Feedback from reviewers will be provided on the reviewability of the submission, based on the IMDRF ToC and FDA classification matrix, and any observations regarding issues in the submission content elements of the ToC Pilot. Feedback from industry will be accepted throughout the submission building process.

The Pilot project is intended to provide industry, IMDRF, and CDRH staff the opportunity to evaluate the ToC structure, through the receipt of input from industry participants and CDRH staff. Comments received during the Pilot project will be used to evaluate the usability of the ToC format. FDA will be reviewing the contents of each submission as part of this Pilot; however, Pilot participation for the manufacturer will end after successfully passing the refuse to accept criteria. Subsequently, a complete scientific review, outside of the scope of the Pilot, will commence.

*A. Participation*

Volunteers interested in participating in the Pilot project should provide expressions of interest to the IMDRF ToC working group at the IMDRF ToC email account *imdrftoc@gmail.com.* Confirmation of your interest in participation in the IMDRF ToC Pilot plan is requested. If notification is received by August 21, 2015, then the manufacturer will be invited to participate in a ''participation teleconference'' to answer remaining questions. After August 21, 2015, contact FDA Pilot staff by email at *Jodi.Anderson@fda.hhs.gov* with any questions. The following information should be included in the request: Applicant, trade name, primary product code, submission type, contact name, and contact email. FDA will contact interested applicants to discuss the Pilot project. FDA is seeking a limited number of participants (no more than nine) to participate in this Pilot project. Participants must adhere to FDA's submission requirements (*i.e.*, eCopy) and Refuse to Accept (RTA) requirements (Refs. 5 and 6).

*B. Procedures*

After reading the ToC Pilot Plan document, applicants use either the nIVD or IVD ToC documents, as well as the respective Classification Matrix to construct their submission. The submission, placed into a single .zip file with the name ''MISC FILES.zip'' is then loaded onto media via eCopy (*e.g.*, CD, DVD, SD card, USB drive). No paper copy of the submission is needed. All submissions are still expected to comply with the respective PMA or 510(k) RTA guidance documents. All submissions are still expected to comply with the *FDA's* eCopy Program for Medical Device Submissions Final Guidance (Ref. 5), except for the following: (1) With the exception of the cover letter, all sections discussing paper copy requirements may be disregarded; (2) sections outside the scope of the Pilot (*e.g.*, sections pertaining to Bundled Submissions) may be disregarded; and (3) Attachment A, Part B of the eCopy Guidance is superseded by the ToC document. Applicants are required to provide a paper cover letter, meeting the technical guidance provided in the eCopy Guidance Document, Attachment 1, Part A. In addition, the following statement must be included in *bold:*

*This submission is part of the IMDRF ToC Pilot, and is organized according to the IMDRF ToC. Accordingly, special eCopy processing applies. As per the agreement for this ToC Pilot, no full paper copies are required, and the specially-formatted submission is zipped and placed within a MISC FILES folder in the eCopy.*

The cover letter and media should be sent via mail to the Document Control Center (DCC) to: Food and Drug Administration, Center for Devices and Radiological Health, Document Control Center, Bldg. 66, Rm. G609, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002 ATTN: IMDRF ToC Pilot Submission.

During the Pilot, CDRH staff will be available to answer any questions or concerns that may arise. Pilot project participants will be asked to comment on and discuss their experiences with the Pilot submissions process. Their input and discussions will assist both IMDRF and CDRH in their use of the ToC in future electronic submission formats.

## III. Duration of the IMDRF Regulated Product Submission ToC Implementation Pilot

FDA intends to accept requests for participation in the IMDRF's Regulated Product Submission, ToC Implementation Pilot for 12 months, from September 2015 through September 2016. This Pilot program may be extended as resources and needs allow.

## IV. 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.FDAC. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR part 814, subparts A through E have been approved under OMB control number 0910–0231.

## V. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. IMDRF Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC) Final Document, *http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140630-rps-nivd-toc.pdf.*
2. IMDRF In Vitro Diagnostic Device Market Authorization Table of Contents (IVD MA ToC) Final Document, *http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140630-rps-ivd-toc.pdf.*
3. FDA/IMDRF Documents, Regulated Product Submission (RPS) Work Item, *http://www.fda.gov/MedicalDevices/InternationalPrograms/IMDRF/ucm417027.htm.*
4. IMDRF Table of Contents (ToC) Pilot Plan, *http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-150708-toc-pilot-plan.pdf.*
5. FDA's eCopy Program for Medical Device Submissions Final Guidance, October 10, 2013, *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/*

*UCM313794.pdf.*

6. FDA's Refuse to Accept Policy for 510(k)s Final Guidance, December 31, 2012, *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.*

Dated: August 13, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–20430 Filed 8–18–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–0001]**

### Arthritis Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Arthritis Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on October 23, 2015, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

*Contact Person:* Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *AAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* The committee will discuss new drug application (NDA) 207988, lesinurad oral tablets, submitted by Ardea Biosciences, Inc., for the treatment of hyperuricemia associated with gout, in combination with a xanthine oxidase inhibitor.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 8, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 30, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 1, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Philip Bautista at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 12, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015–20398 Filed 8–18–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–2817]**

### Medical Devices; Export Certificates; Food and Drug Administration Export Reform and Enhancement Act of 1996; Certification Fees

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revised fees the Agency will assess for issuing export certificates for devices. The FDA Export Reform and Enhancement Act of 1996 (EREA) provides that any person who exports a device may request FDA certify in writing that the exported device meets certain specified requirements. It further provides that FDA shall issue such a certification within 20 days of the receipt of a request for such certification and that FDA may charge up to $175 for each certification that is issued within the 20 days. Since February 2003, FDA's costs to process the device certificates have increased; however, the export certificate fee for subsequent certificates has not changed. Because of the increase, FDA is raising the fees for subsequent certificates, from the current fee of $15 to $85, and revising the formula used to calculate the number of original and subsequent device export certificates issued. These changes are necessary to ensure that the program remains self-sustaining and to cover FDA's increased costs, which are