DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0432]

Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3–D Printing; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3–D Printing.'' The purpose of this workshop is to provide a forum for FDA, medical device manufactures, additive manufacturing companies, and academia to discuss technical challenges and solutions of 3–D printing. The Agency would like input regarding technical assessments that should be considered for additively manufactured devices to provide a transparent evaluation process for future submissions.

Dates and Times: The public workshop will be held on October 8 and 9, 2014, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Matthew Di Prima, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 2214, Silver Spring, MD 20993, 301–796–2507, email: *matthew.diprima@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by September 30, 2014, 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4321, Silver Spring, MD 20993–0002, 301–796–5661, email: *susan.monahan@fda.hhs.gov* no later than September 23, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events-Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select the appropriate public workshop from the events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see Registration). Registrants will receive confirmation after they have been accepted and will be notified if they are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by September 30, 2014, 4 p.m. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after October 1, 2014. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to obtain information on the technical challenges of additively manufacturing medical devices. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is November 10, 2014.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. 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.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Additive manufacturing, also known as 3–D printing, is a fast-growing manufacturing technique that builds devices from computerized blueprints or models, by layering material only where it is needed as if building with interlocking bricks. Traditional methods of manufacturing remove material from larger pieces by cutting, drilling, and carving to create a final part. Through additive manufacturing designers can alter products quickly for rapid prototype iteration or produce small batches of multiple product designs in each batch. The 3–D computer models used to build each part can be created using traditional computer aided design techniques or they can be made directly from 3–D image sources, such as computed tomography scans or magnetic resonance imaging. Designers can also use a combination of techniques. Consequently, 3–D printers can create truly anatomically matched

devices or surgical guides by utilizing a patient's own medical imaging.

Additive manufacturing is just beginning to enter mainstream use in medical devices. This technology unlocks new avenues for creativity and innovation for medical device designers. For example, it can facilitate the production of devices with intricate structures that were previously impractical or impossible. Current industry applications include using it as an alternative device production method for traditional components or as a primary method to create patient-matched devices. As the technology matures, additional capabilities may be incorporated into medical devices. FDA has begun to receive submissions using additive manufacturing for both traditional and patient-matched devices, and we see many more on the horizon. Industry forecasts project significant growth of additive manufacturing in both traditional and innovative environments by 2025.

Additive manufacturing may or may not present new questions depending on its use. However, there are technical challenges associated with the process from design to final product that need to be properly addressed in all cases to ensure patient safety and to promote innovation in a fast-moving field. Process verification and validation are especially important when devices are produced individually or in very small batches. By discussing and addressing these technical challenges through an open forum, FDA would like to foster innovation with a transparent process and shared expectations for stakeholders. Participants in the workshop will include researchers, scientists, and engineers involved with the research and development of products using additive manufacturing as one or more steps of the manufacturing process. The intent is to address scientific and technical challenges posed by additive manufacturing process but not address specific printing technologies or medical device types. The latter will still be covered by their respective standards and guidance documents. Ideas generated during this workshop may facilitate development of new draft guidances and/or standards for additive manufacturing of medical devices.

II. Topics for Discussion at the Public Workshop

At this public workshop, participants will engage in open dialogue and discuss the following factors that contribute to additively manufactured medical devices.

- Preprinting considerations, including but not limited to:
  - material chemistry;
  - physical properties;
  - recyclability;
  - part reproducibility; and
  - process validation.
- Printing considerations, including but not limited to:
  - printing process characterization;
  - software used in the process;
  - post-processing steps (hot isostatic pressing, curing); and
  - additional machining.
- Post-printing considerations, including but not limited to:
  - cleaning/excess material removal;
  - effect of complexity on sterilization and biocompatibility;
  - final device mechanics;
  - design envelope; and
  - verification.

This is not an inclusive list. There will be discussion time and breakout sessions to bring up topics that are not listed.

The goals of the public workshop are to:

- Develop a more complete understanding of the technical challenges and solutions in additive manufacturing across a variety of materials and printing technologies that will affect safety and effectiveness of medical devices;
- Create awareness of these technical challenges and collaboratively develop solutions and best practices to ensure the performance and reliability of these devices; create a forum for open dialogue among stakeholders to share lessons learned and best practices for overcoming the technical challenges presented by additive manufacturing;
- Promote innovation in technology and processes to ensure and improve device performance and reliability; and
- Coordinate future collaborations in the development of educational materials, standards, and guidance.

Dated: May 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–0057]

Determination of Regulatory Review Period for Purposes of Patent Extension; ELELYSO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ELELYSO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination