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.

[FR Doc. 2014–11513 Filed 5–16–14; 8:45 am]

BILLING CODE 4160–01–P

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

of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product ELELYSO (taliglucerase alfa). ELELYSO is indicated for long-term enzyme replacement therapy for adults with a confirmed diagnosis of Type 1 Gaucher disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ELELYSO (U.S. Patent No. 7,951,557) from Protalix Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 19, 2013, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ELELYSO represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ELELYSO is 2,483 days. Of this time, 1,746 days occurred during the testing phase of the regulatory review period, while 737 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* July 16, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 16, 2005.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 26, 2010. FDA has verified the applicant's claim that the new drug application (NDA) for ELELYSO (NDA 22–458) was submitted on April 26, 2010.

3. *The date the application was approved:* May 1, 2012. FDA has verified the applicant's claim that NDA 22–458 was approved on May 1, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 336 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 18, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 17, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. 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. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov*, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11516 Filed 5–16–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–E–1235; FDA–2012–E–1236; FDA–2012–E–1237]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PERJETA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product PERJETA (pertuzumab). PERJETA is indicated in combination with trastuzumab and docetaxel for treatment of patients with