received a patent term restoration application for YONDELIS (U.S. Patent No. 7,420,051) from Pharma Mar, S.A., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 25, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of YONDELIS represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for YONDELIS is 7,107 days. Of this time, 6,773 days occurred during the testing phase of the regulatory review period, while 334 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:* May 10, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 10, 1996.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* November 24, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for YONDELIS (NDA 207953) was initially submitted on November 24, 2014.

3. *The date the application was approved:* October 23, 2015. FDA has verified the applicant's claim that NDA 207953 was approved on October 23, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,471 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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.

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

Dated: November 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25683 Filed 11–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0384]

Pediatric Information for X-Ray Imaging Device Premarket Notifications; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Pediatric Information for X-ray Imaging Device Premarket Notifications.'' This guidance document outlines FDA's current thinking on information that should be provided in premarket notification submissions for x-ray imaging devices that are indicated for pediatric populations or general use x-ray imaging devices for which considerable pediatric application is anticipated. FDA intends for this guidance to minimize uncertainty during the premarket review process of premarket notification submissions for x-ray imaging devices for pediatric use to encourage the inclusion of pediatric indications for use for x-ray imaging device premarket notification submissions and to provide recommendations on information to support such indications. Both new devices and modifications of existing x-ray imaging devices that require submission of a new premarket notification are included within the scope of this guidance document, regardless of whether the device is a complete x-ray imaging system, a component part of an x-ray imaging device, or an accessory (*e.g.,* detectors and software).

DATES: The announcement of the guidance is published in the **Federal Register** on November 28, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–

2012–D–0384 for ''Pediatric Information for X-ray Imaging Device Premarket Notifications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Pediatric Information for X-ray Imaging Device Premarket Notifications'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Laurel Burk, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4268, Silver Spring, MD 20993–0002, 301–796–5933.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document outlines the current thinking of FDA regarding information that should be provided in premarket notification submissions (510(k)s) and device labeling for x-ray imaging devices that are indicated for pediatric populations or general use x-ray imaging devices for which considerable pediatric application is anticipated. General use x-ray imaging devices typically neither include nor exclude specific populations in the indications for use and may be expected to be used in any population. Because a large percentage of the hundreds of millions of x-ray examinations performed annually in the United States are exams of pediatric patients, FDA expects that most general use x-ray imaging devices will be used for a considerable quantity of pediatric examinations unless a device's design precludes use in smaller sized patients. This guidance is intended to enhance clarity regarding the premarket review process of 510(k)s for x-ray imaging devices, to encourage the inclusion of pediatric indications for use for x-ray imaging device 510(k)s, and to provide recommendations regarding labeling, including the instructions for use.

In February 2010, FDA launched an ''Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging'' (*https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm2007191.htm*); and on March 30 and 31, 2010 (75 FR 8375, February 24, 2010), the Agency held a public meeting entitled ''Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging'' (*https://www.federalregister.gov/documents/2010/02/24/2010-3674/device-improvements-to-reduce-unnecessary-radiation-exposure-from-medical-imaging-public-meeting*). At the meeting, FDA sought advice on ''steps that manufacturers of computerized tomography (CT) and fluoroscopic devices could take to reduce unnecessary radiation exposure through improved product design, enhanced labeling, or improved instructions and training for equipment use and quality assurance at medical imaging facilities.'' The Agency asked whether manufacturers should incorporate special provisions for pediatric patients, particularly with regard to hardware and software features. Recommendations received by FDA, which apply to all general-use x-ray imaging modalities, included making available pediatric protocols and control settings, targeted instructions, and educational materials emphasizing pediatric dose reduction, quality assurance tools for facilities emphasizing radiation dose management, and dose information applicable to pediatric patients. Many of the recommendations from pediatric experts focused on expanding the flexibility or range of features already available on x-ray imaging devices, which may also improve adult imaging for nonstandard applications.

In the **Federal Register** of May 10, 2012 (77 FR 27461), the Agency announced the issuance of the draft guidance entitled ''Pediatric Information for X-ray Imaging Device Premarket Notifications'' and interested persons were invited to comment by September 7, 2012. On July 16, 2012 (77 FR 27463, May 10, 2012), the Agency held a public meeting entitled ''Device Improvements for Pediatric X-ray Imaging'' (*https://www.regulations.gov/document?D=FDA-2012-N-0385-0002*) where FDA also solicited public feedback on the draft of this guidance. FDA has considered the comments received and has incorporated changes suggested by the comments, as appropriate. In addition, FDA requested help in identifying issues relevant to radiation safety in pediatric x-ray imaging that might benefit from standards development or further research at this workshop. FDA requested specific comments on technical device design and pediatric safety questions. Since the 2012 meeting, many recommended device design improvements have been incorporated into FDA-recognized consensus standards, and others are under consideration for future revisions of such standards.

In 2014, the Agency issued a revised general pediatric guidance entitled ''Premarket Assessment of Pediatric Medical Devices.'' The guidance, which applies to all devices, defines pediatric subpopulations and the general information that should be provided for

different types of premarket submissions for devices intended for use in pediatric populations.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on pediatric information for x-ray imaging device 510(k)s. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Pediatric Information for X-ray Imaging Device Premarket Notifications'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1771 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR parts 1002, 1010, 1020, 1030, 1040, and 1050 have been approved under OMB control number 0910–0025. The collections of information in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756. In addition, FDA concludes that the Indications for Use warning label does not constitute a ''collection of information'' under the PRA. Rather, the labeling statements are ''public disclosure(s) of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public.'' (5 CFR 1320.3(c)(2).)

Dated: November 21, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25632 Filed 11–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2016–E–1195 and FDA–2016–E–1534]

Determination of Regulatory Review Period for Purposes of Patent Extension; Senza Spinal Cord Stimulation System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Senza Spinal Cord Stimulation System 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 the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 29, 2018. 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 May 29, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 29, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 29, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2016–E–1195 and FDA–2016–E–1534 for Determination of Regulatory Review Period for Purposes of Patent Extension; SENZA SPINAL CORD STIMULATION SYSTEM. Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.