at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at https://www.regulations.gov. Persons unable to download an electronic copy of “Recommendations for Dual 510(k) and CLIA Waiver by Application Studies” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 16038 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 54 have been approved under 0910–0396; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0755, the collections of information in 21 CFR 907 have been approved under 0910–0120; the collections of information in the guidance document entitled “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” have been approved under 0910–0598, the collections of information in the guidance document entitled “Requests for Feedback on Medical Device Submissions” have been approved under 0910–0756; and the collections of information in the guidance document entitled “Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization” have been approved under 0910–0607.

Dated: November 22, 2017.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2017–25774 Filed 11–28–17; 8:45 am]
Antidepressants for the treatment of schizophrenia.

Subsequent to this approval, the USPTO received a patent term restoration application for REXULITI (U.S. Patent No. 7,888,362) from Otsuka Pharmaceutical Co., Ltd., and the USPTO requested FDA’s assistance in determining this patent’s eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of REXULITI 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 REXULITI is 2,636 days. Of this time, 2,271 days occurred during the testing phase of the regulatory review period, while 365 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: April 23, 2008. The applicant claims April 20, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 23, 2008. The applicant claims April 20, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 23, 2008, which was 30 days after FDA receipt of the IND.

2. The date the application was submitted with respect to the human drug product under section 505(b) of the FD&C Act: July 11, 2014. FDA has verified the applicant’s claim that the new drug application (NDA) for REXULITI (NDA 205422) was initially submitted on July 11, 2014.

3. The date the application was approved: July 10, 2015. FDA has verified the applicant’s claim that NDA 205422 was approved on July 10, 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, the applicant seeks 868 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, pt 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 24, 2017.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2017–25772 Filed 11–28–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–E–1653]

Determination of Regulatory Review Period for Purposes of Patent Extension; SOLX 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 SOLX SYSTEM 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 the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

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, anyone interested person may petition FDA for a determination.