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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

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 USPTO 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 XURIDEN (uridine triacetate). XURIDEN is indicated for the treatment of hereditary orotic aciduria. Subsequent to this approval, the USPTO received a patent term restoration application for XURIDEN (U.S. Patent No. 6,258,795) from Wellstat Therapeutics Corp., 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 XURIDEN 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 XURIDEN is 8,494 days. Of this time, 8,254 days occurred during the testing phase of the regulatory review period, while 240 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:* June 4, 1992. The applicant claims May 4, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 4, 1992, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* January 8, 2015. FDA has verified the applicant's claim that the new drug application (NDA) for XURIDEN (NDA 208169) was initially submitted on January 8, 2015.

3. *The date the application was approved:* September 4, 2015. FDA has verified the applicant's claim that NDA 208169 was approved on September 4, 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 5 years 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 21 CFR 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with 21 CFR 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 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25770 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–2017–N–6373]

Roxane Laboratories, Inc.; Withdrawal of Approval of a New Drug Application for ROXICODONE (Oxycodone Hydrochloride) Sustained-Release Tablets, 10 Milligrams and 30 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of new drug application (NDA) 020932 for ROXICODONE (oxycodone hydrochloride (HCl)) Sustained-Release Tablets, 10 milligrams (mg) and 30 mg, held by Roxane Laboratories, Inc. (Roxane). Roxane requested withdrawal of this application and waived its opportunity for a hearing.

DATES: The approval is withdrawn as of November 29, 2017.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993, 301–796–3601.

SUPPLEMENTARY INFORMATION: NDA 020932 for ROXICODONE SR (oxycodone HCl) Sustained-Release Tablets, 10 mg and 30 mg, was received on December 29, 1997, and approved on October 26, 1998, as safe and effective ''for the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days'' (see approval letter, available at *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20932ltr.pdf*). (FDA has verified the Web site addresses as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.) FDA later determined, however, that this application had serious deficiencies. Accordingly, on February 3, 2000, FDA granted Roxane's request for a stay of the effective date of the approval of NDA 020932 until such time as: (1) Roxane submits additional data; (2) FDA has reviewed those data; and (3) FDA has determined that the submitted data support a finding of safety and effectiveness without reliance on investigations to which Roxane does not have a right of reference.[1] Roxane has not submitted any additional information to support approval of NDA 020932, nor has it submitted any annual reports for this NDA since 2002. The product has never been marketed.[2] Roxane requested that FDA withdraw approval of NDA 020932 for ROXICODONE (oxycodone HCl) Sustained Release Tablets, and waived the opportunity for a hearing concerning this action.

For the reasons discussed above, approval of NDA 020932, and all amendments and supplements thereto, is withdrawn. Distribution of ROXICODONE (oxycodone HCl) Sustained-Release Tablets, 10 mg and 30 mg, in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

[1] February 3, 2000 FDA Response to Citizen Petition and Petition for Stay of Action, Docket FDA–1999–P–2921, available at *https://www.regulations.gov/document?D=FDA-1999-P-2921-0014.*

[2] Reflecting their non-marketed status, ROXICODONE (oxycodone HCl) Sustained-Release Tablets, 10 mg and 30 mg, are on the ''Discontinued Drug Products'' list in the Orange Book, where the drug is listed as ''Roxicodone'' and described as ''extended release'' (see *https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=020932*).

Dated: November 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25771 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–2017–D–5570]

Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications for Manufacturers of In Vitro Diagnostic Devices; Draft 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 draft guidance entitled ''Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices.'' FDA has developed this draft guidance to implement a section of the 21st Century Cures Act (Cures Act) that requires FDA to revise ''V. Demonstrating Insignificant Risk of an Erroneous Result—Accuracy'' of the guidance ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices'' (''2008 CLIA Waiver Guidance'') that was issued on January 30, 2008. This draft guidance updates FDA's thinking regarding the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by January 29, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2017–D–5570 for ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices.'' 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