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DATES: The approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 website addresses as of the date this document publishes in the *Federal Register*, but websites 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)).

Dated: November 24, 2017.

Leslie Kux,

[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).

Associate Commissioner for Policy.

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