4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0199]

MK Laboratories, Inc., et al.; Withdrawal of Approval of 3 Abbreviated New Drug Applications for Propoxyphene Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three abbreviated new drug applications (ANDAs) for products containing propoxyphene. The basis for the withdrawals is that the products are no longer shown to be safe because propoxyphene puts patients at risk of potentially serious and even fatal heart rhythm abnormalities. The holders of these ANDAs have waived their opportunity for a hearing.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6254, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: On November 18, 2010, after receiving clinical data and other information showing that propoxyphene puts patients at risk of potentially serious and even fatal heart rhythm abnormalities, FDA asked manufacturers of then marketed branded and generic propoxyphene drug products to voluntarily withdraw the products from the U.S. market. In a notice published in the Federal Register of March 10, 2014 (79 FR 13308), FDA withdrew approval of 8 new drug applications (NDAs) and 46 ANDAs for propoxyphene drug products

from multiple sources whose application holders agreed in writing to waive their opportunity for a hearing and permit FDA to withdraw approval of the applications. In a separate notice published in the Federal Register of March 10, 2014 (79 FR 13310), FDA's Center for Drug Evaluation and Research (CDER) notified the holders of 3 other approved ANDAs for propoxyphene drug products of their opportunity to request a hearing on CDER's proposal to issue an order, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)), withdrawing approval of 3 ANDAs for propoxyphene drug products. The following products, all of which FDA believes were discontinued prior to November 2010, were listed in the notice.

Table 1: -- Propoxyphene Drug Product Applications for Which FDA Proposed to Withdraw Approval

Application No.	Drug	Applicant or Holder
ANDA 083544	Kesso-Gesic (propoxyphene hydrochloride (HCl)) Capsules, 65 milligrams (mg)	MK Laboratories Inc., 424 Grasmere Ave., Fairfield, CT 06430.
ANDA 084551	Propoxyphene HCl Capsules, 65 mg	Whiteworth Towne Paulsen Inc.
ANDA 084553	Compound 65 (aspirin, caffeine, and propoxyphene HCl) Capsules, 389 mg/32.4 mg/65 mg	Alra Labs, 3850 Clearview Ct., Gurnee, IL 60031.

In its March 10, 2014, notice of opportunity for a hearing, CDER provided these ANDA holders an opportunity to request a hearing to show why approval of the ANDAs should not be withdrawn. No timely request for a hearing on this matter was received following publication of the notice in the Federal Register.

Therefore, under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs, approval of the applications listed in table 1 and all amendments and supplements thereto is withdrawn (see DATES). Introduction or delivery for introduction of these products into 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. 331(d))).

Dated: September 5, 2014

Leslie Kux,

Assistant Commissioner for Policy.

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