4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0198]

Xanodyne Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 8 New Drug Applications and 46 Abbreviated New Drug Applications for Propoxyphene Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of March 10, 2014 (79 FR 13308). The document withdrew approval of 8 new drug applications (NDAs) and 46 abbreviated new drug applications (ANDAs) for prescription pain medications containing propoxyphene from multiple applicants. The document failed to withdraw approval of NDA 017507, held by Xanodyne Pharmaceuticals, Inc. (Xanodyne). Xanodyne wrote to FDA asking the Agency to withdraw approval of NDA 017507 and waiving its opportunity for a hearing. FDA confirms the withdrawal of approval of NDA 017507.

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: In the Federal Register of Monday, March 10, 2014, FR Doc. 2014-05063, on page 13308, the following correction is made:

On page 13308, in table 1, the following entry is added in numerical order by Application No.:

Application No.	Drug	Applicant or Holder
NDA 017507	Darvocet-N 100 (propoxyphene napsylate and acetaminophen) Suspension, 100 milligrams (mg)/650 mg/15 milliliters.	Xanodyne Pharmaceuticals, Inc., One Riverfront Pl., Newport, KY 41071

Dated: April 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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