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4160-01-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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 8 new drug applications (NDAs) and 46 abbreviated new drug applications (ANDAs) for prescription pain medications containing propoxyphene. The holders of these applications have agreed in writing to permit FDA to withdraw approval of the applications and 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:

Propoxyphene is an opioid pain relief medication marketed under brand names such as Darvon and Darvocet. In 1957, FDA approved NDAs 010996 and 010997 for propoxyphene hydrochloride (HCl), alone and in combination with other active ingredients, both of which are currently held by Xanodyne Pharmaceuticals, Inc. (Xanodyne).

In 2010, after receiving new clinical data showing that when propoxyphene is taken at therapeutic doses, the drug puts patients at risk of potentially serious or even fatal heart rhythm abnormalities, and other information including new epidemiological data, FDA concluded that the risks of propoxyphene outweigh its benefits as a pain reliever. In separate telephone conversations on November 18, 2010, FDA asked Xanodyne and the holders of marketed generic propoxyphene drug products to permit FDA to withdraw approval of their applications and to waive their opportunity for a hearing. In a separate notice published elsewhere in this issue of the Federal Register, FDA notifies other holders of ANDAs for pain medications containing propoxyphene of their opportunity to request a hearing if they wish to challenge the Agency's proposal to withdraw approval of their applications.

Xanodyne and manufacturers of generic propoxyphene products identified in table 1 have written to FDA asking the Agency to withdraw approval of their applications for propoxyphene-containing products and have waived their opportunity for a hearing. Some products approved under the applications identified in table 1 were discontinued in the past, before FDA's November 2010 determination that the risks of propoxyphene outweigh its benefits. Not included in table 1 are NDAs and ANDAs for which Federal Register notices were previously published announcing withdrawal of approval.

Table 1.--Propoxyphene Drug Products for Which Application Holders Requested Withdrawal of Approval

Application No.	Drug	Applicant or Holder
NDA 010996	Darvon Compound (aspirin, caffeine, and propoxyphene HCl) Capsules, 389 milligrams (mg)/32.4 mg/32 mg Darvon Compound-65 (aspirin, caffeine, and propoxyphene HCl) Capsules, 389 mg/32.4 mg/65 mg Darvon with ASA (aspirin and propoxyphene HCl) Capsules, 325 mg/65 mg	Xanodyne Pharmaceuticals, Inc., One Riverfront Pl., Newport, KY 41071
NDA 010997	Darvon (propoxyphene HCl) Capsules, 32 mg and 65 mg	Do.
NDA 016829	Darvon-N with ASA (aspirin and propoxyphene napsylate) Capsules, 325 mg/100 mg	AAIPharma Inc., 2320 Scientific Park Dr., Wilmington, NC 28405
NDA 016844	Darvocet (acetaminophen and propoxyphene HCl) Tablets, 325 mg/32.5 mg	Do.
NDA 016861	Darvon-N (propoxyphene napsylate) Suspension, 50 mg/5 milliliters	Do.
NDA 016862	Darvon-N (propoxyphene napsylate) Tablets, 100 mg	Do.
NDA 016863	Darvon-N with ASA (aspirin and propoxyphene napsylate) Tablets, 325 mg/100 mg	Do.
NDA 017122	Darvocet-N 50 (acetaminophen and propoxyphene napsylate) Tablets, 325 mg/50 mg Darvocet-N 100 (acetaminophen and propoxyphene napsylate) Tablets, 650 mg/100 mg	Xanodyne Pharmaceuticals, Inc.
ANDA 040139	Acetaminophen and Propoxyphene HCl Tablets, 650 mg/65 mg	Watson Laboratories, Inc., 400 Interpace Pkwy., Parsippany, NJ 07054
ANDA 040507	Acetaminophen and	Vintage Pharmaceuticals, 150 Vintage

Application No.	Drug	Applicant or Holder
	Propoxyphene HCl Tablets, 650 mg/65 mg	Dr., Huntsville, AL 35811
ANDA 040569	Propoxyphene HCl Capsules, 65 mg	Mylan Pharmaceuticals, 781 Chestnut Ridge Rd., Morgantown, WV 26505
ANDA 040908	Propoxyphene HCl Capsules, 65 mg	Vintage Pharmaceuticals
ANDA 070115	Acetaminophen and Propoxyphene Napsylate Tablets, 325 mg/50 mg	Mutual Pharmaceutical Co., Inc., 1100 Orthodox St., Philadelphia, PA 19124
ANDA 070116	Acetaminophen and Propoxyphene Napsylate Tablets, 650 mg/100 mg	Do.
ANDA 070145	Acetaminophen and Propoxyphene Napsylate Tablets, 650 mg/100 mg	Mylan Pharmaceuticals
ANDA 070146	Acetaminophen and Propoxyphene Napsylate Tablets, 650 mg/100 mg	IVAX Pharmaceuticals, Subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 070443	Acetaminophen and Propoxyphene Napsylate Tablets, 650 mg/100 mg	Sandoz Inc., 2555 W. Midway Blvd., Broomfield, CO 80038
ANDA 070615	Acetaminophen and Propoxyphene Napsylate Tablets, 650 mg/100 mg	Mutual Pharmaceutical Co., Inc.
ANDA 070771	Acetaminophen and Propoxyphene Napsylate Tablets, 650 mg/100 mg	Do.
ANDA 070775	Acetaminophen and Propoxyphene Napsylate Tablets, 650 mg/100 mg	Do.
ANDA 070910	Acetaminophen and Propoxyphene Napsylate Tablets, 650 mg/100 mg	Actavis Elizabeth LLC, 200 Elmora Ave., Elizabeth, NJ 07202
ANDA 072195	Acetaminophen and Propoxyphene Napsylate Tablets, 650 mg/100 mg	Mylan Pharmaceuticals
ANDA 074119	Acetaminophen and Propoxyphene Napsylate Tablets, 650 mg/100 mg	Teva Pharmaceuticals, 1090 Horsham Rd., North Wales, PA 19454
ANDA 074843	Acetaminophen and	Vintage Pharmaceuticals

Application No.	Drug	Applicant or Holder
	Propoxyphene Napsylate Tablets, 325 mg/50 mg and 650 mg/100 mg	
ANDA 075738	Acetaminophen and Propoxyphene Napsylate Tablets, 650 mg/100 mg	Mallinckrodt Inc., 675 McDonnell Blvd., Hazelwood, MO 63042
ANDA 076429	Darvocet A500 (acetaminophen and propoxyphene napsylate) Tablets, 500 mg/100 mg	Xanodyne Pharmaceuticals, Inc.
ANDA 076609	Acetaminophen and Propoxyphene Napsylate Tablets, 650 mg/100 mg	Watson Laboratories, Inc., 4955 Orange Dr., Fort Lauderdale, FL 33314
ANDA 076743	Acetaminophen and Propoxyphene Napsylate Tablets, 325 mg/100 mg	Cornerstone Therapeutics Inc., 1255 Crescent Green Dr., Cary, NC 27518
ANDA 076750	Acetaminophen and Propoxyphene Napsylate Tablets, 500 mg/100 mg	Do.
ANDA 077196	Acetaminophen and Propoxyphene Napsylate Tablets, 500 mg/100 mg	Watson Laboratories, Inc.
ANDA 077677	Acetaminophen and Propoxyphene Napsylate Tablets, 325 mg/50 mg and 650 mg/100 mg	Wockhardt USA LLC, 20 Waterview Blvd., Parsippany, NJ 07054
ANDA 077821	Acetaminophen and Propoxyphene Napsylate Tablets 650 mg/100 mg	Mirror Pharmaceuticals LLC, 140 New Dutch Ln., Fairfield, NJ 07004
ANDA 080044	Aspirin, Caffeine, and Propoxyphene HCl Capsules, 389 mg/32.4 mg/65 mg	Sandoz, Inc., 4700 Sandoz Dr., Wilson, NC 27893
ANDA 080269	Propoxyphene HCl Capsules, 65 mg	Par Pharmaceuticals, Inc., 1 Ram Ridge Rd., Spring Valley, NJ 10977
ANDA 080530	Dolene (propoxyphene HCl) Capsules, 65 mg	Heritage Pharmaceuticals Inc., 105 Fieldcrest Ave., Edison, NJ 08837
ANDA 080783	Propoxyphene HCl Capsules, 65 mg	Valeant Pharmaceuticals North America LLC, 700 Route 202/206 North, Bridgewater, NJ 08807
ANDA 083101	Aspirin, Caffeine, and Propoxyphene HCl Capsules, 389 mg/32.4 mg/65 mg	Sandoz, Inc., 2555 W. Midway Blvd., Broomfield, CO 80038

Application No.	Drug	Applicant or Holder
ANDA 083113	Propoxyphene HCl Capsules, 65 mg	Private Formulations Inc.
ANDA 083125	Propoxyphene HCl Capsules, 65 mg	Sandoz, Inc.
ANDA 083185	Propoxyphene HCl Capsules, 65 mg	Nexgen Pharma, Inc., 17802 Gillette Ave., Irvine, CA 92614
ANDA 083186	Propoxyphene HCl Capsules, 65 mg	Mutual Pharmaceutical Co. Inc.
ANDA 083464	Propoxyphene HCl Capsules, 32 mg	Private Formulations Inc.
ANDA 083501	Propoxyphene HCl Capsules, 65 mg	West-Ward Pharmaceutical Corp., 435 Industrial Way West, Eatontown, NJ 07724
ANDA 083528	Propoxyphene HCl Capsules, 32 mg	Mylan Pharmaceuticals, 781 Chestnut Ridge Rd., Morgantown, WV 26505
ANDA 083688	Propoxyphene HCl Capsules, 65 mg	Sandoz Inc., 506 Carnegie Center, Princeton, NJ 08540
ANDA 083689	Acetaminophen and Propoxyphene HCl Tablets, 325 mg/32 mg	Mylan Pharmaceuticals
ANDA 083870	Propoxyphene HCl Capsules, 65 mg	Sandoz, Inc.
ANDA 083978	Acetaminophen and Propoxyphene HCl Tablets, 650 mg/65 mg	Mylan Pharmaceuticals
ANDA 084014	Propoxyphene HCl Capsules, 32 mg	Sandoz, Inc., 4700 Sandoz Dr., Wilson, NC 27893
ANDA 084999	Wygesic (acetaminophen and propoxyphene HCl) Tablets, 650 mg/65 mg	Caraco Pharmaceutical Laboratories, Ltd., 1150 Elijah McCoy Dr., Detroit, MI 48202
ANDA 086495	Propoxyphene HCl Capsules, 65 mg	Sandoz, Inc.
ANDA 088615	Propoxyphene HCl Capsules, 65 mg	Teva Pharmaceuticals
ANDA 089025	Aspirin, Caffeine, and Propoxyphene HCl Capsules, 389 mg/32.4 mg/65 mg	Do.
ANDA 089959	Acetaminophen and Propoxyphene HCl Tablets, 650 mg/65 mg	Sandoz Inc., 2555 W. Midway Blvd., Broomfield, CO 80038

Therefore, under sections 505(e) and 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e) and 355(j)(6)) and under authority delegated to the Director of the Center for Drug Evaluation and Research 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. 355(a) and 331(d))).

Dated: March 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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