other than safety or effectiveness. ANDAs that refer to ZEFAZONE (cefmetazole sodium) Injection, EQ 1 g base/vial and EQ 2 g base/vial, and ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and EQ 40 mg base/mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05059 Filed 3–7–14; 8:45 am]

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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 March 10, 2014.

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 Propoxyphene HCl Tablets, 650 mg/65 mg.	Vintage Pharmaceuticals, 150 Vintage 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.

TABLE 1—PROPOXYPHENE DRUG PRODUCTS FOR WHICH APPLICATION HOLDERS REQUESTED WITHDRAWAL OF APPROVAL—Continued

Application No.	Drug	Applicant or holder
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 Propoxyphene Napsylate Tablets, 325 mg/50 mg and 650 mg/100 mg.	Vintage Pharmaceuticals.
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.
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.

TABLE 1—PROPOXYPHENE DRUG PRODUCTS FOR WHICH APPLICATION HOLDERS REQUESTED WITHDRAWAL OF APPROVAL—Continued

Application No.	Drug	Applicant or holder
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.

[FR Doc. 2014–05063 Filed 3–7–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0199]

MK Laboratories, Inc., et al.; Proposal To Withdraw Approval of Three Abbreviated New Drug Applications for Propoxyphene Products; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is proposing to withdraw approval of three abbreviated new drug applications (ANDAs) for propoxyphene drug products from multiple sources and is announcing an opportunity for holders of those ANDAs to request a hearing on this proposal.

DATES: Submit written requests for a hearing by April 9, 2014; submit data and information in support of the hearing request by May 9, 2014.

ADDRESSES: Requests for a hearing, supporting data, and other comments are to be identified with Docket No. FDA–2014–N–0199 and submitted to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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 first approved by FDA in 1957. It has been marketed as a single active ingredient drug product and in combination with other active ingredients such as acetaminophen. It has been marketed under brand names such as Darvon and Darvocet and in generic forms.

After receiving clinical data and other information showing that propoxyphene puts patients at risk of potentially serious and even fatal heart rhythm abnormalities, FDA determined that the risks of propoxyphene outweigh its benefits. On November 18, 2010, FDA asked Xanodyne Pharmaceuticals, Inc. (Xanodyne), the maker of Darvon and Darvocet, and manufacturers of then marketed generic propoxyphene drug products to voluntarily withdraw their products from the U.S. market. In a separate notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of 8 NDAs and 46 ANDAs from multiple sources, whose application holders have agreed in writing to permit FDA to withdraw approval of the applications and have waived their opportunity for a hearing.

Although the holders of the approved applications listed in Table 1 are believed to have discontinued marketing these products prior to November 2010, FDA has not received correspondence from these application holders requesting that the Agency withdraw approval of the identified applications. Hence, in accordance with section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), we hereby notify the application holders listed in Table 1 of their opportunity to request a hearing on CDER's proposal to withdraw approval of the listed applications.

TABLE 1—PROPOXYPHENE DRUG PRODUCT APPLICATIONS FOR WHICH FDA PROPOSES 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.

I. Safety Concern

NDAs 010996 and 010997 for propoxyphene HCl alone and in combination with aspirin and caffeine, both held by Xanodyne, were initially approved in 1957 solely on the basis of safety. The 1962 amendments to the FD&C Act required that drugs be shown to be effective as well as safe. To implement the 1962 amendments, FDA initiated the Drug Efficacy Study Implementation (DESI) review to evaluate the effectiveness of drugs that had been previously approved on safety grounds alone. In its DESI review of propoxyphene HCl; propoxyphene HCl with aspirin; and propoxyphene HCl with aspirin, phenacetin, and caffeine, FDA concluded that these drugs were effective for the relief of mild to moderate pain (34 FR 6264, April 8, 1969).