Dated: March 5, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0768]

Determination That ZEFAZONE (Cefmetazole Sodium) Injection, Equivalent to 1 Gram Base/Vial and Equivalent to 2 Gram Base/Vial, and ZEFAZONE (Cefmetazole Sodium) Intravenous Solution, Equivalent to 20 Milligrams Base/Milliliter and Equivalent to 40 Milligrams Base/Milliliter, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ZEFAZONE (cefmetazole sodium) Injection, equivalent to (EQ) 1 gram (g) base/vial and EQ 2 g base/vial, and ZEFAZONE (cefmetazole sodium) Intravenous (IV) Solution, EQ 20 milligrams (mg) base/milliliter (mL) and EQ 40 mg base/mL, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for 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 40 mg base/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Kathy Schreier, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6246, Silver Spring, MD 20993–0002, 301–796–3432.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the Orange Book. Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ZEFAZONE (cefmetazole sodium) Injection, EQ 1 g base/vial and EQ 2 g base/vial, is the subject of NDA 50–637, held by Pharmacia & Upjohn, Inc., which was initially approved on December 11, 1989; and ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and EQ 40 mg base/mL, is the subject of NDA 50–683, held by Pharmacia & Upjohn, Inc., which was initially approved on December 29, 1992. ZEFAZONE is a semisynthetic cephem antibiotic that is indicated for treatment of urinary tract infections, lower respiratory tract infections, skin and skin structure infections, and intra-abdominal infections.

In a letter dated August 1, 2000, Pharmacia & Upjohn, Inc., notified FDA that 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, were no longer being marketed and requested withdrawal of NDA 50–637 and NDA 50–683. FDA moved the drug products to the ''Discontinued Drug Product List'' section of the Orange Book and, in the **Federal Register** of August 16, 2001 (66 FR 43017), announced that it was withdrawing approval of NDA 50–637 and NDA 50–683 effective September 17, 2001.

Salus Pharma LLC submitted a citizen petition dated June 17, 2013 (Docket No. FDA–2013–P–0768), under 21 CFR 10.30, requesting that the Agency determine whether ZEFAZONE (cefmetazole sodium) Injection, EQ 1 g base/vial and EQ 2 g base/vial, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not request that we determine whether ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and EQ 40 mg base/mL, approved under NDA 50–683, was withdrawn for safety or effectiveness, that product also has been discontinued. On our own initiative, we have also determined whether ZEFAZONE (cefmetazole sodium) IV Solution, EQ 20 mg base/mL and EQ 40 mg base/mL, was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that 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, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that 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, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of 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, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list 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, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons

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.