

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-P-0029]

DDM
Display Date 11-20-08
Publication Date 11-21-08
Certifier D. Hawkins

Determination That NUBAIN (Nalbuphine Hydrochloride) Injection, 10 and 20 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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) is announcing its determination that NUBAIN (nalbuphine hydrochloride) injection, 10 and 20 milligrams/milliliter (mg/ml), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for nalbuphine hydrochloride injection, 10 and 20 mg/ml, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6306, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved 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

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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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On January 11, 2008, West-Ward Pharmaceutical Corp., on behalf of Hikma Farmacêutica of Portugal, submitted a citizen petition (Docket No. FDA-2008-P-0029) to FDA under 21 CFR 10.30. The petition requests that the agency determine whether NUBAIN (nalbuphine hydrochloride) injection, 10 and 20 mg/ml (NDA 18-024), manufactured by Endo Pharmaceuticals (Endo), was withdrawn from sale for reasons of safety or effectiveness. NUBAIN was approved on May 15, 1979. NUBAIN is an analgesic drug product used for the relief of moderate to severe pain. NUBAIN may be used as a supplement

to balanced anesthesia, for preoperative and postoperative analgesia, and for obstetrical analgesia during labor and delivery. Manufacture of NUBAIN was discontinued in 2003, and the drug product was moved from the prescription drug product list to the "Discontinued Drug Product List" section of the Orange Book.

FDA has reviewed its records and, under § 314.161, has determined that NUBAIN (nalbuphine hydrochloride) injection, 10 and 20 mg/ml, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that NUBAIN (nalbuphine hydrochloride) injection, 10 and 20 mg/ml, was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list NUBAIN (nalbuphine hydrochloride) injection, 10 and 20 mg/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 NUBAIN (nalbuphine hydrochloride) injection, 10 and 20 mg/ml, may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated:

11/14/08
November 14th, 2008 *e*

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11-18-08



Jeffrey Shuren, Associate Commissioner for Policy and Planning,

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S/NOTICE *e*

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Dawn P. Hawkins