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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0462]

Determination That PREVACID NAPRAPAC (Copackaged Lansoprazole Delayed-Release 15–Milligram Capsules and Naproxen 250–Milligram Tablets) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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) has determined that PREVACID NAPRAPAC 250 (copackaged lansoprazole delayed-release 15-milligram (mg) capsules and naproxen 250-mg tablets) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for copackaged lansoprazole delayed-release 15-mg capsules and naproxen 250-mg tablets.

FOR FURTHER INFORMATION CONTACT: Marguerita B. Sims, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5041.

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 sponsors 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. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an 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 generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine 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. FDA may not approve an ANDA that does not refer to a listed drug.

PREVACID NAPRAPAC 250 is the subject of NDA 21–507 held by Tap Pharmaceuticals, Inc. (TAP). PREVACID NAPRAPAC 250 is a copackaged drug product that contains Prevacid (lansoperazole) 15-mg delayed-release capsules (a proton-pump inhibitor) and Naprosyn (naproxen) 250-mg tablets (a nonsteroidal anti-inflammatory drug product (NSAID) with analgesic and antipyretic properties). PREVACID NAPRAPAC 250 is indicated for reducing the risk of NSAID-associated gastric ulcers in patients with a history of documented gastric ulcer(s) who require the use of an NSAID for treatment

of the signs and symptoms of rheumatoid arthritis, osteoarthritis, and/or ankylosing spondylitis. TAP's PREVACID NAPRAPAC 250 was discontinued in October 2006.

In a citizen petition received on November 13, 2006 (Docket No. 2006P–0462/CP1), submitted under 21 CFR 10.30 and in accordance with § 314.161, Robert W. Pollock of Lachman Consultant Services, Inc., requested that FDA determine whether PREVACID NAPRAPAC 250 was withdrawn from sale for reasons of safety or effectiveness.

For the reasons outlined previously, FDA has determined that TAP's PREVACID NAPRAPAC 250 was not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, the agency notes that a higher strength of PREVACID NAPRAPAC 250 [PREVACID NAPRAPAC 500 (15 mg/ 500 mg)] is currently being marketed. In addition, the petitioner identified no data or information suggesting that PREVACID NAPRAPAC 250 was withdrawn from sale for reasons of safety or effectiveness. FDA's independent evaluation of relevant literature and data has not uncovered anything that would indicate that this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records concerning the withdrawal, FDA found no indication that the decision not to commercially market PREVACID NAPRAPAC 250 was a result of any safety or effectiveness concerns regarding the product. Accordingly, the agency will continue to list PREVACID NAPRAPAC 250 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

PREVACID NAPRAPAC 250 may be approved by the agency as long as they meet all relevant 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: 7/30/07
July 30, 2007.

Randall W. Lutter,
Deputy Commissioner for Policy.

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