LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

1600 STEWART AVENUE, WESTBURY, NY 11590
(516) 222-6222 • FAX (516) 683-1887

November 9, 2006

OVERNIGHT COURIER 11/9/06

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

This petition is submitted in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations of 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Prevacid® NapraPAC™, 15 mg/250 mg (lansoprazole delayed-release, 15 mg capsules and naproxen, 250 mg tablets kit) (NDA No. 021507) by Tap Pharm, has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products, which are eligible for submission as abbreviated new drug applications in the Approved Drug Product with Therapeutic Equivalence Evaluations ("The Orange Book"). The current edition of the Orange Book includes Prevacid® NapraPAC™, 15 mg/250 mg, in the active Drug Product Section of the "List" (applicable page attached). A listing of the drug product in this section of the Orange Book usually indicates that the drug product has been shown to be safe and effective and is currently being marketed. However, the Agency has provided notice to our client that the application holder is not marketing the lower strength (15 mg/250 mg) of the Prevacid® NapraPAC™ drug product. The higher strengths of 15 mg/375 mg and 15 mg/500 mg are currently being marketed.

Under FDA regulations, drugs are withdrawn from market if the Agency withdraws or suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

As stated, Tap Pharm's Prevacid® NapraPAC™, 15 mg/250 mg, is not currently available for sale in the marketplace. Because there is no current commercial distribution of this drug product, and even though this drug product is listed in the active section of the current version of the electronic Orange Book (accessed November 9, 2006), based on the Agency's indication that this drug product is not being

marketed, it is requested that the FDA determine whether Tap Pharm's decision to discontinue marketing of their Prevacid® NapraPAC™, 15 mg/250 mg product was for reasons of safety or effectiveness.

Should the innovator reintroduce this product strength into the market, Lachman Consultant Services, Inc. will consider this petition to be moot and we will take appropriate action to withdraw this petition.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which is unfavorable to the petition.

Respectfully submitted,

Robert Pollock pk

Robert W. Pollock
Senior Vice President
Lachman Consultant Services, Inc.

RWP/pk

Attachment: Electronic Edition of the Orange Book

cc: Martin Shimer (Office of Generic Drugs)

R03P6313

Proprietary Name Search Results from "OB_Rx" table for query on "prevacid."

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
020406		No	LANSOPRAZOLE	CAPSULE, DELAYED REL PELLETS; ORAL	15MG	PREVACID	TAP PHARM
020406		Yes	LANSOPRAZOLE	CAPSULE, DELAYED REL PELLETS; ORAL	30MG	PREVACID	TAP PHARM
021281		No	LANSOPRAZOLE	FOR SUSPENSION, DELAYED RELEASE; ORAL	15MG/PACKET	PREVACID	TAP PHARM
021281		Yes	LANSOPRAZOLE	FOR SUSPENSION, DELAYED RELEASE; ORAL	30MG/PACKET	PREVACID	TAP PHARM
021566		Yes	LANSOPRAZOLE	INJECTABLE; INTRAVENOUS	30MG/VIAL	PREVACID IV	TAP PHARM
021428		No	LANSOPRAZOLE	TABLET, DELAYED RELEASE, ORALLY DISINTEGRATING; ORAL	15MG	PREVACID	TAP PHARM
021428		Yes	LANSOPRAZOLE	TABLET, DELAYED RELEASE, ORALLY DISINTEGRATING; ORAL	30MG	PREVACID	TAP PHARM
021507		No	LANSOPRAZOLE; NAPROXEN	CAPSULE, DELAYED REL PELLETS, TABLET; ORAL	15MG,N/A;N/A,250MG	PREVACID NAPRAPAC 250 (COPACKAGED)	TAP PHARM
021507		No	LANSOPRAZOLE; NAPROXEN	CAPSULE, DELAYED REL PELLETS, TABLET; ORAL	15MG,N/A;N/A,375MG	PREVACID NAPRAPAC 375 (COPACKAGED)	TAP PHARM
021507		Yes	LANSOPRAZOLE; NAPROXEN	CAPSULE, DELAYED REL PELLETS, TABLET; ORAL	15MG,N/A;N/A,500MG	PREVACID NAPRAPAC 500 (COPACKAGED)	TAP PHARM

Return to Electronic Orange Book Home Page

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through September, 2006

Patent and Generic Drug Product Data Last Updated: November 09, 2006