DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville MD 20857

NDA 20-406/S-033

TAP Pharmaceutical Products Inc.
Attention: Ms Leslie Abelson
Assistant Director, Regulatory Affairs
675 North Field Drive
Lake Forest, IL 60045

Dear Ms. Abelson:

Please refer to your supplemental new drug application dated July 20, 1999, received July 22, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prevacid® (lansoprazole) Delayed-Release Capsules, 15mg and 30mg.

We acknowledge receipt of your submissions dated October 6, 1999 and January 17, February 15 and 23, March 3 and 17, April 4 and 20, June 2, August 23 and 29, October 4, and November 3, 2000. Your submission of June 2, 2000 constituted a complete response to our May 22, 2000 action letter.

This supplemental new drug application provides for the use of Prevacid® (lansoprazole) Delayed-Release Capsules for the following two new indications: 1) for the treatment of NSAID-associated gastric ulcer in patients who continue NSAID use; and 2) for reducing the risk of NSAID-associated gastric ulcers in patients with history of a documented gastric ulcer who require the use of a NSAID.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-406/S-033." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27).

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products. We note that you have previously notified us of your intent to pursue pediatric exclusivity. Our letter of August 8, 2000 informed you that more data and expert discussion is needed before initiating pediatric studies. Therefore, we are deferring submission of your pediatric studies under the rule. Please re-evaluate available information on this drug and the disease in children and submit your pediatric development plan by June 1, 2003.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Cheryl Perry, Regulatory Health Project Manager,
at (301) 827-7475.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research