DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-406 / IND 30,159

TAP Pharmaceutical Products, Inc.
Attention: Ms. Donna Helms
675 North Field Drive
Lake Forest, IL 60045

Dear Ms. Helms:

Please refer to our original Written Request dated August 26, 1999, and to our Amended Written Request dated December 31, 2001 for pediatric studies for lansoprazole.

As indicated in the letter dated June 14, 2002, we are amending the below listed section of the Written Request. All other terms stated in our Written Request issued on August 26, 1999, as amended on December 31, 2001, remain the same.

We are removing the word "randomized" from the following sentence:

> "Study 4: Clinical Outcome Study of lansoprazole in pediatric patients aged 12 to 17 years inclusive: multicenter, open-label, randomized, parallel group, 8 to 12-week study in at least 80 patients of both sexes with GERD symptoms for at least three months in whom gastrointestinal endoscopy has been performed."

To read:

> "Study 4: Clinical Outcome Study of lansoprazole in pediatric patients aged 12 to 17 years inclusive: multicenter, open-label, parallel group, 8 to 12-week study in at least 80 patients of both sexes with GERD symptoms for at least three months in whom gastrointestinal endoscopy has been performed."

Submit protocols for the above studies to an investigational new drug application (IND) and clearly mark your submission, **"PEDIATRIC PROTOCOL SUBMITTED FOR PEDIATRIC EXCLUSIVITY STUDY"** in large font, bolded type at the beginning of the cover letter of the submission. Notify us as soon as possible if you wish to enter into a written agreement by submitting a proposed written agreement. Please clearly mark your submission, **"PROPOSED WRITTEN AGREEMENT FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission.

Submit reports of the studies as a supplement to an approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, clearly mark your submission **"SUBMISSION OF PEDIATRIC STUDY REPORTS – PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED"** in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. In addition, send a copy of the cover letter of your submission, via fax (301-594-0183) or messenger to the Director, Office of Generic Drugs, HFD-600, Metro Park North II, 7500 Standish Place, Rockville, MD 20855-2773.

If you wish to discuss any amendments to this Written Request, submit proposed changes and the reasons for the proposed changes to your application. Clearly mark submissions of proposed changes to this request **"PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission. We will notify you in writing if we agree to any changes to this Written Request.

We hope you will fulfill this pediatric study request. We look forward to working with you on this matter in order to develop additional pediatric information that may produce health benefits to the pediatric population.

If you have any questions, call Melissa Furness, Regulatory Project Manager, at 301-827-7450.

Sincerely,

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Deputy Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Victor Raczkowski

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