DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-719/S-008

Prometheus Laboratories, Inc.
Attention: Huy Nguyen
Manager, Regulatory Affairs
5739 Pacific Center Blvd.
San Diego, CA 92121

Dear Mr. Nguyen:

Please refer to your supplemental new drug application dated March 22, 2004, received March 23, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Helidac® Therapy ((bismuth subsalicylate/metronidazole/tetracycline hydrochloride).

We acknowledge receipt of your submission dated August 19, 2004.

This "Changes Being Effected" supplemental new drug application provides for revised labeling to comply with the Final Rule entitled "**Labeling Requirements for Systemic Antimicrobial Drug Products Intended for Human Use"** (68FR 6062, February 6, 2003) and respond to our CBE request letter dated September 11, 2003. Labeling changes were also made under the **HOW SUPPLIED** section.

This "Changes Being Effected" supplemental new drug application provides for the following additions to the package insert:

Location	**Text**
At the beginning of the label, under "**PRODUCT NAME"**	To reduce the development of drug-resistant bacteria and maintain the effectiveness of HELIDAC Therapy and other antibacterial drugs, HELIDAC Therapy should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.
INDICATIONS AND USAGE	To reduce the development of drug-resistant bacteria and maintain the effectiveness of HELIDAC Therapy and other antibacterial drugs, HELIDAC Therapy should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
PRECAUTIONS section, under "General"	Prescribing HELIDAC Therapy in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication it is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

PRECAUTIONS section, under **"Information for Patients"**	Patients should be counseled that antibacterial drugs including HELIDAC Therapy should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When HELIDAC Therapy is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of Therapy, the medication should be taken exactly as directed. Skipping doses or not competing the full courses of Therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by HELIDAC Therapy or other antibacterial drugs in the future.
HOW SUPPLIED	For the metronidazole 250 mg tablet embossment, "PG" on the upper half of the tablet and "10" on the lower half of the tablet were deleted and replaced with "Z 2971".

We completed our review of this application and it is approved effective on the date of this letter.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Robin Anderson, R.N., M.B.A., Labeling Reviewer at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
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/

Renata Albrecht

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