DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-719
NDA 50-719/S-006

Prometheus Labs
ATTN: Marilyn Carlson, D.M.D., M.D.
5739 Pacific Center Boulevard
San Diego, CA 92109

Dear Dr. Carlson:

Please refer to your supplemental new drug application dated August 25, 1999 received August 26, 1999, 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 30, 1999.

This supplemental new drug application provides for revision of the **Geriatric Use** subsection in the **PRECAUTIONS** section of the package insert as follows:

> **Geriatric Use:** Elderly patients may suffer from asymptomatic renal and hepatic dysfunction. Care should be taken when administering this therapy to this patient population.
>
> Replaced with
>
> **Geriatric Use:** Clinical studies of HELIDAC Therapy did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy in elderly patients should be considered when prescribing HELIDAC Therapy. As stated in the **CONTRAINDICATIONS** section, this therapy is contraindicated in patients with renal or hepatic impairment**.**

We have completed our review of this 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 labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to submitted labeling (text for the package insert submitted August 26, 1999).

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 mount individually 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 50-719/S-006." Approval of this submission by the FDA is not required before the labeling is used.

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

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

(b)(4)----------
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If you have any questions, call Kristen Miller, Regulatory Project Manager, 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

Enclosure: Revised labeling for prior approval supplement

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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