DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-719/S-013

Prometheus Laboratories, Inc.
Attention: Henry Pan, M.D., Ph.D.
Executive VP, Chief Scientific and Chief Medical Officer
9410 Carroll Park Dr.
San Diego, CA 92121

Dear Dr. Pan:

Please refer to your supplemental new drug application dated December 26, 2007, received December 27, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for HELIDAC® Therapy (bismuth subsalicylate/metronidazole/tetracycline hydrochloride). This application is subject to the exemption provisions contained in section 125(d)(2) of Title 1 of the FDA Modernization Act of 1997.

We acknowledge receipt of your submission dated June 13, 2008.

This "Changes Being Effected" supplemental new drug application provides for the following changes to the HELIDAC® Therapy package insert (deletions are indicated by ~~strikethrough~~ and additions are indicated by underline):

1. In the **DESCRIPTION** section, the following revisions were made:

   Metronidazole tablets, USP: Each convex, round, white to off-white ~~round~~ tablet contains 250 mg metronidazole. Metronidazole is 2-Methyl-5-nitroimidazole-1-ethanol, with the following structural formula:

   Inactive Ingredients: Each metronidazole tablet contains ~~lactose monohydrate, magnesium stearate,~~ colloidal silicon dioxide, crospovidone, hydrogenated vegetable oil and microcrystalline cellulose~~, povidone, sodium starch glycolate, and stearic acid.~~

2. In the **HOW SUPPLIED** section, the following changes were made:

   4 metronidazole 250-mg tablets, each convex, round, white to off-white tablet with "~~Z 2971~~DAN" imprinted on one side and "5540" imprinted on the other side.

3. At the end of the label, the following changes were made:

   Bismuth subsalicylate tablets are manufactured by OSG Norwich Pharmaceuticals. Metronidazole 250-mg tablets, USP ~~and tetracycline~~are manufactured by Watson Laboratories, Inc. Tetracycline hydrochloride 500-mg capsules, USP are manufactured by IVAX Pharmaceuticals, Inc.

for

Prometheus Laboratories Inc.
San Diego, CA 92121
REVISED ~~MAY~~JULY 2007

~~HE006G07~~ HE006I07

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the labeling submitted on June 13, 2008.

In addition, your description of the Metronidazole product should be consistent with the description of the Metronidazole tablets, USP in the Watson Laboratories, Inc. label for ANDA 18-764. Therefore, we request that in the **DESCRIPTION** section and **HOW SUPPLIED** section of the package insert, the Metronidazole tablets, USP be described as "unscored" instead of "convex." These changes can be submitted in the next annual report as per 21 CFR 314.70 (d).

We also acknowledge the inclusion in this submission of a revised carton label with updated information on the new manufacturer of Metronidazole tablets, USP.

"Submit revised content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website."

If you have any questions, please call Christine Lincoln, RN, M.S., MBA, Regulatory Health Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE (Package Insert)

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

6/27/2008 04:10:39 PM