DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-324/S-031
NDA 17-391/S-014

Prometheus Laboratories, Inc.
9410 Carroll Park Drive
San Diego, CA 92121

Attention: R. Wayne Frost, PharmD, JD
Vice President, Regulatory Affairs and Quality Systems

Dear Dr. Frost:

Please refer to your supplemental new drug applications dated May 13, 2008, received May 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imuran® (azathioprine) 100 mg Injection and 50 mg Tablets.

These "Changes Being Effected" supplemental new drug applications, which are in response to our February 14, 2008, supplement request letter, revise the package insert to include an additional adverse reaction to the **Others** subsection of **ADVERSE REACTIONS** section.

We have completed our review of these applications, and they are approved, effective on the date of this letter, for use as recommended in the attached content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on May 13, 2008. We will transmit this version to the National Library of Medicine for public dissemination.

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
Food and Drug Administration
Suite 12B05
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 Margarita Tossa, Regulatory Project Manager, at (301) 796-4053.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Bob Rappaport

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