DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-324/S-030
NDA 17-391/S-013

Prometheus Laboratories, Inc.
Attention: Becky Donahue
Director, Regulatory Affairs
5739 Pacific Center Blvd.
San Diego, CA 92121-4203

Dear Dr. Koda:

Please refer to your supplemental new drug applications dated October 27, 2004, received October 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for IMURAN® (azathioprine), 50 mg Tablets and 100 mg Injection.

We acknowledge receipt of your submission dated May 10, 2005, which constituted a complete response to our April 28, 2005 action letter.

We have completed our review of these applications, as amended and they are approved, effective on the date of this letter, with the minor editorial revisions listed below.

In the third paragraph of the CLINICAL PHARMACOLOGY section a substitution of "-" for "6-MeMP" was missed in the draft labeling text.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert). These revisions are terms of the approval of these applications.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually please mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 16-324/S-030, and 17-391/S-013**." Approval of these submissions by FDA is not required before the labeling is used.

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 Paul Z. Balcer, Regulatory Project Manager, at (301) 827 2090.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Division 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

7/26/05 12:15:02 PM