DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-324/S-026
NDA 17-391/S-011

Prometheus Laboratories Inc.
Attention: Malvina Laudicina
5739 Pacific Center Blvd.
San Diego, California 92121

Dear Ms Laudicina:

Please refer to your supplemental new drug applications dated October 2, 1995 received October 3, 1995 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imuran (azathioprine) Injection and Tablets.

These "Changes Being Effected " supplemental new drug applications provide for multiple changes to the label.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted October 2, 1995).

> Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 16-324/S026 and NDA 17-391/S-011". 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, HF-2
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 Ms Nancy Halonen, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, MD
Division Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
HFD-550
Office of Drug Evaluation V
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/

Lee Simon

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