DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-084/S-041

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

Dear Ms. Laudicina:

Please refer to your supplemental new drug application dated August 3, 1995, received August 4, 1995, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyloprim (allopurinol) Tablets.

This supplemental new drug application provides for revisions to the **Drug Interactions** subsection of the **PRECAUTIONS** Section of the package insert.

We have completed the review of this supplemental 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 final printed labeling submitted August 3, 1995. Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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

Please submit one market package of the drug product when it is available.

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

If you have any questions, call Lisa Hubbard, Interdisciplinary Scientist, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products
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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