DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 16-324/S-34
NDA 16-324/S-35
NDA 17-391/S-15

SUPPLEMENT APPROVAL

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

Attention: Michael C. Scaife, Ph.D.
Vice President, Regulatory Affairs

Dear Dr. Scaife:

Please refer to your Supplemental New Drug Applications (sNDA) dated March 18, 2011, received March 21, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Imuran (azathioprine) Tablets and Imuran (azathioprine) Injection.

We also acknowledge your submissions dated May 12, 2011.

We refer to our letter dated February 24, 2011, requesting that you submit a prior approval supplement to add Sweet's Syndrome (acute febrile neurotphilic dermatosis) to the "Others" subsection of the Adverse Reaction section of the Imuran (azathioprine) label.

We also refer to our letter dated April 13, 2011, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Imuran (azathioprine). This information pertains to the risk of hepatosplenic T-cell lymphoma (HSTCL).

Your supplemental new drug application (16-324/34) provides for the addition of Sweet's Syndrome (acute febrile neutrophilic dermatosis) to the "Others" subsection of the Adverse Reaction section of the labeling for Imuran (azathioprine) Tablets

Your supplemental new drug application (16-324/35) provides for revisions to the labeling for Imuran (azathioprine) Tablets consistent with our April 13, 2011, SAFETY LABELING CHANGE NOTIFICATION LETTER.

Your supplemental new drug application (17-391/15) provides for the addition of Sweet's Syndrome (acute febrile neutrophilic dermatosis) to the "Others" subsection of the Adverse Reaction section of the labeling for Imuran (azathioprine) Injection. This submission also provides for revisions to the labeling consistent with our April 13, 2011, SAFETY LABELING CHANGE NOTIFICATION LETTER.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

REPORTING REQUIREMENTS

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 Michelle Jordan, Regulatory Project Manager, at (301) 796-4786.

Sincerely,

{See appended electronic signature page}

Sally Seymour, M.D.
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling

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

/s/

SALLY M SEYMOUR
05/24/2011