CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

63065/S14, S15

APPROVAL LETTER

ANDA 63-065/S-014, S-015

JUN 10 1999

Danbury Pharmacal, Inc.
Attention: Ann Mullarkey
Mt. Ebo Drive South
Brewster, NY 10509

Dear Madam:

Reference is made to your supplemental drug applications dated July 31, 1998, submitted pursuant to 21 CFR 314.70, regarding your abbreviated new drug application for Minocycline Hydrochloride Capsules USP, 100 mg (base). We note that this product is subject to the exception provisions of Section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated April 5 and April 13, 1999.

The supplemental applications provide for:

S-014: An additional strength of Minocycline Hydrochloride Capsules, USP [75 mg (base/capsule)]; and

S-015: Updated labeling to reflect the new 75 mg (base/capsule) strength.

We have completed the review of these supplemental applications and have concluded that the new strength of the drug product is safe and effective for use as recommended in the submitted labeling. Accordingly, the supplemental applications are approved. The new strength of the drug product, Minocycline Hydrochloride Capsules USP, 75 mg (base/capsule), can be expected to have the same therapeutic effect as that of the listed drug product upon which the Agency relied as the basis of safety and effectiveness.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns for the new 75 mg (base/capsule) strength. Please submit all proposed materials in draft or mock-up form, not final print.

Submit both copies together with a copy of the final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

The material submitted is being retained in our files.

Sincerely yours,

/S/

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

6/10/99