DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

ANDA 65-131

Food and Drug Administration
Rockville MD 20857

APR 16 2003

Par Pharmaceutical, Inc.
Attention: Linda Kulick
One Ram Ridge Road
Spring Valley, NY 10977

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated May 31, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Minocycline Hydrochloride Tablets USP, 50 mg (base), 75 mg (base), and 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 November 5, 2002; and February 6, February 24, February 28, and March 20, 2003.

Reference is also made to the Federal Register notice of January 27, 1998, (Volume 63, Number 17, pages 3903-3904), stating that Minocycline Hydrochloride Tablets, USP were not withdrawn from sale for reasons of safety or effectiveness. Because Minocycline Hydrochloride Tablets USP, 50 mg (base) and 100 mg (base) currently appear in the discontinued section of the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", this determination was necessary to allow the agency to approve an ANDA for the drug product. Reference is also made to the suitability petition submitted under section 505(j)(2)(C) of the Act and approved on November 30, 1998, permitting you to file this ANDA to include a drug product that differs in strength from that of the reference listed drug product (RLD). Specifically, the 75 mg (base) tablet strength represents an intermediate strength between the 50 mg (base) and 100 mg (base) strengths of the RLD.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The drug product, Minocycline Hydrochloride Tablets USP, 50 mg (base), 75 mg (base), and 100 mg (base), 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. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth 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 that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 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 our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research