ANDA 75-671 October 23, 2000

Par Pharmaceutical, Inc.
Attention: Michelle Bonomi-Huvala
One Ram Ridge Road
Spring Valley, New York 10977

Dear Madam:

This is in reference to your abbreviated new drug application dated July 14, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Megestrol Acetate Oral Suspension, 40 mg/mL.

Reference is also made to your amendment dated September 13, 2000.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product). It is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product referenced in your application, Megace Oral Suspension of Bristol Myers Squibb, is subject to a period of patent protection which expires on August 16, 2011, (U.S. Patent No. 5,338,732 [the ‘732 patent]). Your application contains a Paragraph IV Certification to the ‘732 patent under Section 505(j)(2)(A)(vii) (IV) of the Act. This certification states that your manufacture, use, or sale of this drug product will not infringe upon the ‘732 patent. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated new drug application shall be made effective immediately, unless an action is brought against Par

Pharmaceutical, Inc. (Par) for infringement of the patent that is the subject of the certification (the '732 patent). You have notified the agency that Par has complied with the requirements of Section 505(j)(2)(B) of the Act. As a result, Bristol Myers Squibb Company initiated a patent infringement suit against Par in the United States District Court for the Southern District of New York involving a challenge to the '732 patent (Bristol-Myers Squibb Company v. Par Pharmaceutical, Inc., Civil Action No. 99 CIV.10822). Therefore, final approval cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii) since the date of receipt of the 45-day notice required under section 505(j)(2)(B)(i), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or,

   b. the date of a court decision [505(j)(5)(B)(iii)(I), (II), or (III)], or,

   c. the patent has expired, and

2. The Agency is assured there is no new information that would affect whether final approval should be granted.

Because the Agency is granting a tentative approval for this application, please submit an amendment at least 60-days (but not more than 90-days) prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the drug product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data appropriate. This amendment also serves to reactivate this application within the Office of Generic Drugs and should also be submitted even if none of these changes were made. The amendment should also provide a copy of an order or judgement, settlement agreement between the parties, or a licensing agreement between you and the patent holder, if applicable, or any other relevant information to address the status of the '732 patent. The amendment should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the agency may request at any time prior to the date of final approval that your submit an additional amendment containing the information described above. Failure to submit either or, if requested, both amendments may result in

rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application, as well as the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

Furthermore, this drug product may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in "Approved Drug Products with Therapeutic Equivalence Evaluations" list, the “Orange Book”, published by the agency.

Prior to submitting the amendment(s), please contact Michelle Dillahunt, Project Manager, (301) 827-5848, for further instructions.

Sincerely yours,

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