ANDA 75-863 April 5, 2002

Barr Laboratories, Inc.
Attention: Christine Mundkur
300 Corporate Drive, Suite 10
Blauvelt, NY 10913

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated May 5, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Kariva® Tablets [Desogestrel/Ethinyl Estradiol and Ethinyl Estradiol Tablets, 0.15 mg/0.02 mg and 0.01 mg, respectively, (28-day regimen)].

Reference is also made to our Tentative Approval letter dated November 29, 2001, and to your amendments dated October 20, 2000; February 16, and December 14, 2001; and February 15, February 20, and March 4, 2002.

The listed drug product (RLD) referenced in your application, Mircette® Tablets (28-day cycle) of Organon, Inc., is subject to a period of patent protection which expires on October 20, 2008, (U.S. Patent No. 4,921,843, the “Pasquale original patent”, and U.S. Patent No. RE 35724, the “Pasquale reissue patent”). Documentation submitted by the former owner of this ANDA, Duramed Pharmaceuticals, Inc. (Duramed), contains Paragraph IV Certifications to each of these patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that they are invalid, unenforceable, or will not be infringed by Duramed’s manufacture, use, or sale of this drug product. Section 505(j)(5)(B)(iii) of the Act provides that approval of this abbreviated new drug application shall be made effective immediately, unless an action is brought against Duramed for infringement of one or more of the patents. This action is to be brought before the expiration of forty-five days from the date the notice provided by Duramed under paragraph (2)(B)(I) is received by the patent and new drug application (NDA) holder.

You notified the agency that Duramed complied with the requirements of Section 505 (j)(2)(B) of the Act. Subsequently, you notified the agency that patent infringement litigation was underway in the United States District Court for the District of New Jersey involving a challenge to the '724 Pasquale reissue patent (Bio-Technology General Corp. v. Duramed Pharmaceuticals, Inc., Civil Action No. 00CV4509). On December 6, 2001, the District Court issued a summary judgement and court order concluding that Duramed did not infringe the claims of the '724 Pasquale reissue patent.

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 Division of Bioequivalence has determined your Kariva® Tablets to be bioequivalent and, therefore, therapeutically equivalent to the respective doses of the listed drug (Mircette® Tablets of Organon Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

In addition, we note that Duramed was the first ANDA applicant to submit a substantially complete ANDA containing Paragraph IV Certifications to the listed patents. Therefore, upon this approval, Barr Laboratories, Inc., the current owner of the application, is eligible for the remainder of the 180-day generic drug market exclusivity as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. This 180-day exclusivity commenced on December 6, 2001, the date of the district court ruling, and will end 180 days thereafter.

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 which 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 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 our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

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