DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 75-182/S-015 and 016

JUL 20 2006

Mylan Technologies, Inc.
Attention: William E. Brochu, Ph.D.
Vice President, Regulatory Affairs and Quality
110 Lake Street
St. Albans, VT 05478

Dear Sir:

This is in reference to your supplemental abbreviated new drug applications dated September 9, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Estradiol Transdermal System, 0.025 mg/24 hours, 0.075 mg/24 hours, and 0.1 mg/24 hours.

Reference is also made to your amendments dated October 4, 2005, and March 21, 2006. We acknowledge receipt of your correspondence dated September 28, and November 14, 2005, addressing the patent issues associated with these supplemental applications.

The supplemental applications, submitted as "Prior Approval Supplements," provide for:

S-015: Two additional dosage strengths, Estradiol Transdermal System 0.0375 mg/24 hours and Estradiol Transdermal System 0.06 mg/24 hours.

S-016: Labeling revisions associated with the additional strengths.

We have completed the review of these supplemental applications, and have concluded that your Estradiol Transdermal System 0.0375 mg/24 hours and Estradiol Transdermal System 0.06 mg/24 hours are safe and effective for use as recommended in the submitted labeling. Accordingly the supplemental applications are approved. The Division of Bioequivalence has determined your Estradiol Transdermal System 0.0375 mg/24 hours and your Estradiol Transdermal System 0.06 mg/24 hours to be bioequivalent and, therefore, therapeutically equivalent to the

reference listed drug (RLD), Climara Transdermal System 0.0375 mg/24 hours and Climara Transdermal System 0.06 mg/24 hours, respectively, of Berlex Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The RLD upon which you have based your supplemental applications, Berlex's Climara Transdermal System, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,223,261 (the '261 patent), is scheduled to expire on June 29, 2010. Your supplemental applications contain a paragraph IV certification to the '261 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Estradiol Transdermal System, 0.0375 mg/24 hours and/or 0.06 mg/24 hours, under these supplemental applications. Section 505(j)(5)(B)(iii) of the Act provides that approval of supplemental applications shall be made effective immediately, unless an action was brought against Mylan Technologies, Inc. (Mylan Tech) for infringement of the '261 patent. You have notified the agency that Mylan Tech complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '261 patent was brought against Mylan Tech within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that Mylan Tech was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '261 patent for these drug products. Therefore, with this approval, Mylan Tech is eligible for 180 days of generic drug exclusivity for Estradiol Transdermal System, 0.0375 mg/24 hours and for Estradiol Transdermal System 0.06 mg/24 hours. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to these supplemental applications informing the agency of the date the exclusivity begins to run.

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

Postmarketing reporting requirements for this ANDA 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.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly 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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Robert L. West / for

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