DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-258

JAN 28 2005

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 12, 2001, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fentanyl Transdermal Systems, 25 mcg/hour, 50 mcg/hour, 75 mcg/hour, and 100 mcg/hour.

Reference is also made to the tentative approval letter issued by this office on June 22, 2004, and your amendments dated October 14, 2002, and October 26, 2004.

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 that your Fentanyl Transdermal Systems, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, and 100 mcg/hr, are bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Duragesic Transdermal Systems, 25 mcg/hour, 50 mcg/hour, 75 mcg/hour and 100 mcg/hour, respectively, of Alza Corp.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

The dissolution testing should be conducted in [redacted] (b)(4) of [redacted] (b)(4) at [redacted] (b)(4) rpm. The test product should meet the following "interim" specifications:

Time (hours)	Percent
0.5	(b)(4)
1	
2	
8	

The "interim" dissolution tests and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement - Changes Being Effected" if there are no revisions to be made to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a "Prior Approval Supplement."

It should be noted that certain portions of the labeling for Alza's Duragesic Transdermal Systems are subject to a period of exclusivity resulting from recently approved changes pertaining to pediatric use of the product. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), Alza's entitlement to this exclusivity is scheduled to expire on November 20, 2006. Section 505A(l) of the Act allows certain portions of labeling that are subject to pediatric exclusivity protection to be omitted from the labeling of products approved under section 505(j) of the Act. Section 505A(l) also permits the incorporation of language in the labeling of products approved under section 505(j) that informs health care practitioners that Alza's Duragesic Transdermal Systems have been approved for pediatric use. The agency has determined that the final printed labeling you have submitted is in compliance with section 505A of the Act with respect to pediatric use protected by exclusivity.

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.

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
Division of Drug Marketing, Advertising, and
Communications (HFD-42)
5600 Fishers Lane
Rockville, MD 20857

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,

(b)(6)

(b)(6)

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