DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-258

Food and Drug Administration
Rockville MD 20857

JUN 22 2004

Mylan Technologies Inc.
Attention: William E. Brochu, Ph.D.
10 Lake Street
St. Albans, VT 05478

Sent by Facsimile and U.S. Mail

Dear Dr. Brochu:

This letter is in reference to your Abbreviated New Drug Application (ANDA) for Fentanyl Transdermal System, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr and 100 mcg/hr, dated October 12, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act).[1] As you know, a decision was entered in *Alza Corporation and Jansen Pharmaceuticals, Inc. v. Mylan Laboratories, Inc., Mylan Technologies, Inc., and Mylan Pharmaceuticals Inc.*, 2004 U.S. Dist. LEXIS 4914 (D.Vt. March 25, 2004). We are writing to inform you that, in light of this decision, the Agency hereby rescinds the final approval of ANDA 76-258 issued on November 21, 2003, and regards ANDA 76-258 as tentatively approved.

The Agency notes that the court's order states that "[b]ecause infringement has occurred, the effective date of any approval of Mylan's ANDA product shall be no earlier than the date of the expiration of the '580 patent family." Because under FDA's regulations (21 C.F.R. 314.105), caselaw, and longstanding practice, an approval with a delayed effective date is tentative, after consideration of the court's order the Agency has determined that final approval for this application is rescinded.

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 products, and is subject to change on the basis of new information that may come to our attention. Final approval cannot be granted earlier than the date of a court decision

[1] The listed drug product referenced in your application (NDA 19-813, Duragesic (Fentanyl Transdermal System), held by Alza Corporation) is subject to a period of patent protection that expires on July 23, 2004. The relevant patent is U.S. Patent No. 4,588,580 (the '580 patent). The '580 patent is also subject to a period of pediatric exclusivity that expires on January 23, 2005. Your application contains patent certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of the Fentanyl Transdermal System will not infringe on the '580 patent or that the patents are otherwise invalid.

finding the patents invalid, not infringed or unenforceable, or the expiration date of the patent and any period of pediatric exclusivity granted to the NDA holder.[2]

Because the Agency is granting a tentative approval for this application, when you believe that your application may be considered for final approval, you must amend your application to notify the Agency regarding whether circumstances have or have not arisen that may affect the effective date of final approval. To reactivate your 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 product was tentatively approved, and should include updated information such as final printed labeling, chemistry, manufacturing, and controls data as appropriate. Please note that this amendment should be submitted even if none of these changes were made. 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 final date of approval that you submit an additional amendment containing the information described above. Any changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

The drug products that are the subject of this abbreviated application may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery or introduction into interstate commerce of this drug before the effective final approval date is prohibited under Section 301(d) of the Act. Also, until the Agency issues the final approval letter, these drug products will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book").

For further information regarding this issue, please contact Cecelia Parise, R.Ph., Regulatory Policy Advisor to the Director, Office of Generic Drugs, at (301) 827-5845.

Sincerely yours,

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

[2] ANDA 76-258 will be subject to ALZA's pediatric exclusivity for fentanyl transdermal system as explained in the June 22, 2004 letter from Gary J. Buehler to E. Anthony Figg and Peter O. Safir.

cc: Dan Troy, Office of the Chief Counsel
E. Anthony Figg, Rothwell, Figg, Ernst & Manbeck
Peter O. Safir, Covington & Burling