



NDA 21-504/S-003

Vyteris, Inc.  
13-01 Pollitt Drive  
Fair Lawn, NJ 07410

Attention: George M. Baskinger  
Associate Director, Regulatory Affairs

Dear Mr. Baskinger:

Please refer to your supplemental new drug application dated December 15, 2004, received December 16, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LidoSite™ Patch (Lidocaine HCl /Epinephrine topical iontophoretic patch) 10%/0.1% and the LidoSite™ Controller.

We acknowledge receipt of your submission dated February 28, 2005.

This “Changes Being Effected” supplemental new drug application provides for changes to your package insert and the system instructions sheet as requested in the Division’s May 6, 2004, NDA Approval Letter, in addition to other minor changes to clarify the safe use of the system.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 28, 2005 (package insert/system instructions, printed patch film, patch, pouch patch carton, shelf carton, controller, and controller carton labels.)

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kimberly Compton, Regulatory Project Manager, at (301) 827-7432.

Sincerely,

*{See appended electronic signature page}*

Bob Rappaport, M.D.  
Director  
Division of Anesthesia, Analgesia and  
Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/

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Bob Rappaport  
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