



NDA 21-543/S-001

Columbia Laboratories, Inc.  
Attention: Susan Witham  
Vice President, Regulatory Affairs  
354 Eisenhower Parkway  
Plaza 1, Second Floor  
Livingston, NJ 07039

Dear Ms. Witham:

Please refer to your supplemental new drug application dated September 3, 2003, received September 4, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Striant™ (testosterone buccal system) mucoadhesive.

We acknowledge receipt of your submission containing “Changes Being Effected” supplemental new drug application, which provides for the Final Printed Label for the blister card that will contain 10 Striant™ placebo buccal systems.

We completed our review of this application, as amended. This application is approved, effective on date of letter, based on the enclosed label.

If you have any questions, call John C. Kim, R.Ph., J.D., Regulatory Health Project Manager, at (301) 827-3003.

Sincerely,

{See appended electronic signature page}

Moo-Jhong Rhee, Ph.D.  
Chemistry Team Leader, for the  
Division of Reproductive and Urologic Drug  
Products, HFD-580  
DNDC II, Office of New Drug Chemistry  
Center for Drug Evaluation and Research

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/s/

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Moo-Jhong Rhee  
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