DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-543/S-002 **CBE-30 SUPPLEMENT**

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

Dear Mr. Mills:

Please refer to your supplemental new drug application dated May 4, 2004, received May 6, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Striant® (testosterone buccal system) mucoadhesive.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following:

- Changes in the (b)(4) a soft paperback push through aluminum foil blister card package of the Striant drug product.
- Changes to the label on the immediate container, which is the blister card package.
- Changes to the labeling on Package Insert and Patient Package Insert

We completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the submitted labeling text and with the minor editorial revisions listed below/indicated in the enclosed labeling.

- Under PRECAUTIONS, in the *Pediatric Use* section, a period is needed at the end of the sentence, "Safety and effectiveness in pediatric male patients below the age of 18 have not yet been established."
- Under ADVERSE REACTIONS, a period is needed at the end of the sentence, "In all clinical studies combined, a total of 308 patients were treated with Striant® for up to 12 months."
- The periods should be inside the quotes of "bad taste in mouth" and "sleep apnea" found under ADVERSE REACTIONS, in the "*Gum-related adverse events and gum examinations*" section, and in "What are the possible side effects of testosterone replacement therapy?" section of the Patient Package Insert, respectively.

The final printed labeling (FPL) must be identical to submitted labeling for immediate container label (blister card) submitted May 4, 2004, and enclosed labeling (text for the package insert and text for the patient package insert), which includes minor editorial revisions. These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-543/S-002." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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}*

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products, HFD-580
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Proposed PI & PPI with editorial changes

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Daniel A. Shames

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