DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BLA 103691

OCT 16 2008

Johnson and Johnson Pharmaceutical R&D, LLC
Attention: Ilona Scott
Director, Global Regulatory Affairs
920 Route 202, P.O. Box 300
Raritan, NJ 08869

Dear Ms. Scott:

Please refer to your supplement to your biologics license application (BLA) dated June 5, 2008, received June 5, 2008 (103691/5074), for Regranex (becaplermin)Gel, 0.01%.

This supplemental application, submitted as a "Changes Being Effected Immediately" provides for changes regarding the risk of increased mortality to the CONTRAINDICATIONS and WARNINGS sections of the package insert and addition of a boxed warning.

We have completed our review of this supplemental application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We note your June 5, 2008 submission included final content of labeling [CFR 601.14(b)] in structured product labeling (SPL) format; we will transmit it to the National Library of Medicine for public dissemination. Within 21 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Pursuant to 21 CFR 201.57(c)(18) and 201.80(f)(2), patient labeling must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling.

This information will be included in your biologics license application file.

If you have any questions, call Catherine Carr, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

Susan J. Walker, M.D., F.A.A.D.
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure