DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103691/5109

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

OMJ Pharmaceuticals, Inc.
c/o Johnson & Johnson Pharmaceutical R&D, L.L.C.
Attention: Ilona Scott
Director, Global Regulatory Affairs
920 Route 202 South
Raritan, NJ 08869

Dear Ms. Scott:

Please refer to your Supplemental Biologics License Application (sBLA), dated November 10, 2011, received November 10, 2011, submitted under section 351 of the Public Health Service Act for Regranex® (becaplermin) Gel, 0.01%.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated October 26, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved Regranex® REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Regranex® was originally approved on April 28, 2010, and the most recent REMS modification was approved on March 11, 2011. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Regranex®.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Regranex® outweigh its risks.

Therefore, we agree with your proposal, and a REMS for Regranex® is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling for Regranex® in accordance with 21 CFR 208.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Paul Phillips, Regulatory Project Manager, at (301) 796-3935.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, MD, MPH
Deputy Director for Safety
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

TATIANA OUSSOVA
04/30/2012