DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 103691/5015

MAY 18 2005

OMJ Pharmaceuticals, Incorporated
Attention: Shirley Weisel
Senior Associate, Regulatory Affairs
Global Marketed Products
920 U.S. Highway Route 202
P.O.Box 300
Raritan, NJ 08869-0602

Dear Ms. Weisel:

Your request to supplement your biologics license application for Becaplermin to revise the Clinical Studies and Precautions sections of the package insert to include information regarding the treatment of venous stasis and pressure ulcers, to add a Geriatric Use subsection and to withdraw the 7.5 gram dose, has been approved.

This fulfills your commitment to submit final reports of clinical studies in venous stasis and pressure ulcers, as stated in commitment number 7 of the December 16, 1997, approval letter.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this supplement.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels). In addition, you may wish to submit draft copies of the proposed introductory advertising and promotional labeling with a cover letter requesting advisory comments to the Division of Drug Marketing, Advertising and Communication (HFD-42), Center for Drug Evaluation and Research, 5600 Fishers Lane/Room 8B45, Rockville, MD 20857. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by an FDA Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence to support that claim.

Please refer to http://www.fda.gov/cder/biologics/default.htm for important information regarding therapeutic biological products, including the addresses for submissions. Effective October 4, 2004, the new address for all submissions to this application is:

CDER Therapeutic Biological Products Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
12229 Wilkins Avenue
Rockville, Maryland 20852

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

Sincerely,

Marc Walton, M.D., Ph.D.
Director
Division of Therapeutic Biological Internal Medicine Products
Office of Drug Evaluation VI
Center for Drug Evaluation and Research

Enclosures: Package Insert
Patient Package Insert

CONCURRENCE PAGE

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