**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-692/S-002

Biovail Laboratories International SLR
c/o Keller and Heckman, LLP
1001 G. Street, N.W.
Suite 500 W
Washington, D.C. 20001

Attention: John B. Dubeck
U.S. Agent

Dear Mr. Dubeck:

Please refer to your supplemental new drug application dated January 16, 2006, received January 17, 2006 submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ULTRAM® ER (tramadol hydrochloride) 100, 200 and 300 mg tablet.

This "Changes Being Effected" supplemental new drug application provides for changes that strengthen the safe use of the product.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this/these submission(s) "**FPL for approved NDA 21-693/S-002**." Approval of this/these submission(s) by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Paul Z. Balcer, Regulatory Project Manager, at (301) 796-1173.

Sincerely,

*{See appended electronic signature page}*

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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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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Bob Rappaport

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