DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-693/S-001

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 December 23, 2005, received December 27, 2005 submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ULTRAM® ODT (tramadol hydrochloride) 50-mg tablet.

This "Changes Being Effected" supplemental new drug application provides for final revised Prescribing Information, commercial packaging and the global change of the trade name TRAMADOL ODT to ULTRAM® ODT.

We have completed our review of this supplemental new drug application and have the following minor edits:

1. Under **WARNINGS**, "Seizure Risk," first sentence, the word "within" needs to be bolded.
2. Under **WARNINGS**, "Seizure Risk," second sentence, an underline needs to be removed after the word "ODT."
3. Under **OVERDOSE**, a period needs to be added at the end of the first sentence.

The application with the minor edits is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 23, 2006.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 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

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

/s/

Bob Rappaport

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