DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-692/S-009

Bioavail Laboratories International SRL
c/o Keller and Heckman, LLP
Attention: John Dubeck, Agent for Bioavail Laboratories International SRL
1001 G Street, N.W., Suite 500 West
Washington, DC 20001

Dear Mr. Dubeck:

Please refer to your supplemental new drug application dated September 16, 2008, received September 17, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Ultram®ER (tramadol hydrochloride) Tablets, Extended Release.

This "Changes Being Effected in 30 days" supplemental new drug application provides for addition of (b) (4) an alternate packaging facility for the 200 mg physician samples.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as submitted on September 17, 2008.

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 Swati Patwardhan, Regulatory Project Manager, at (301) 796-4085.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure:

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

/s/

Jim Vidra

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