CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-693

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-693

Biovail Laboratories, Inc.
Attention: John F. Weet, Ph.D.
Vice President, Regulatory Affairs
700 Route 202/206 North
Bridgewater, New Jersey 08807

Dear Dr. Weet:

Please refer to your new drug application (NDA) dated March 10, 2004, received March 11, 2004, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for tramadol hydrochloride orally disintegrating tablets, 50 mg.

We acknowledge receipt of your submissions dated March 7 and 8, April 14 and 20, and May 3 and 5, 2005.

The March 8, 2005 submission constituted a complete response to our January 11, 2005 action letter.

This new drug application provides for the use of tramadol hydrochloride orally disintegrating tablets, 50 mg for the treatment of moderate to moderately severe pain in adults.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling package insert submitted March 7, 2005, immediate container and carton labels submitted May 5, 2005.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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 deferring submission of your pediatric studies.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of moderate to moderately severe pain in pediatric patients.

   Final Report Submission: May 8, 2009.

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated **"Required Pediatric Study Commitments"**.

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 directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Kathleen Reedy, Regulatory Project Manager, at (301) 827-2533.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Division Director
Division of Analgesic, Anti-inflammatory,
and Ophthalmic Drug Products, HFD-550
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/

Sharon Hertz
5/5/05 05:37:44 PM
Signing for Bob Rappaport, M.D.