



NDA 18-401/S-015

Reckitt Benkiser Pharmaceuticals, Inc.
10710 Midlothian Turnpike
Richmond, VA 23235

Attention: Alan Young
Director, Regulatory Affairs

Dear Mr. Young:

Please refer to your supplemental new drug application dated March 20, 2003, received April 1, 2003, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Buprenex (buprenorphine hydrochloride) Injectable.

This "Changes Being Effected" supplemental new drug application provides for a revised ADVERSE REACTIONS section of the package insert. An "Allergic Reactions" subsection is added as requested in our November 20, 2002, letter.

We have completed our review of this application and it is approved, effective on the date of this letter.

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, HFD-410
FDA
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 Sara E. Stradley, Regulatory Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.,
Acting Division Director
Division of Anesthetic, Critical Care,
and Addiction Drug 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

6/10/03 03:00:58 PM