DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-732/S-002
NDA 20-733/S-003

Reckitt Benckiser
10710 Midlothian Turnpike
Richmond, VA 23235

Attention: John D. Pitts, R.Ph., Ph.D.
Manager, Regulatory Affairs

Dear Dr. Pitts:

Please refer to your supplemental new drug applications dated April 13, 2005, received January 9, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Subutex (buprenorphine HCl) and Suboxone (buprenorphine HCl and naloxone HCl).

We acknowledge receipt of your submissions dated June 5, and July 31, 2006.

You were removed from the arrears list on January 9, 2006.

These "Changes Being Effected" supplemental new drug applications provide for changes to the immediate container labeling to reduce potential medication errors.

We have completed our review of these applications, as amended and these applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon carton/ container labeling text and with the minor editorial revisions listed below.

> Increase the prominence of the strength on the Suboxone labels to be commensurate with the size of the proprietary name.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (immediate container and carton labels). These revisions are terms of the approval of these applications.

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 these submissions "**FPL for approved supplement NDA 20-732/S-002**" and "**FPL for approved supplement NDA 20-733/S-003**". Approval of these submissions 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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Matt Sullivan, Regulatory Project Manager, at 301-796-1245.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
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/

Bob Rappaport

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