CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 22410/S016

Trade Name: Suboxone® sublingual film

Generic Name: buprenorphine HCl & naloxone HCl dihydrate

Sponsor: Reckitt Benckiser Pharmaceuticals Inc.

Approval Date: 06/05/2014

Changes: addition of a new testing laboratory

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APPLICATION NUMBER:

NDA 22410/S016

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22410/S-016

APPROVAL LETTER

Reckitt Benckiser Pharmaceuticals Inc.
Attention: Bruce Paolella
Director Regulatory Strategy Category
10710 Midlothian Turnpike
Richmond VA 23235

Dear Mr. Paolella:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 6, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Suboxone (Buprenorphine HC1/ Naloxone HC1 Dihydrate) Sublingual Film.

This "Changes Being Effected in 30 Days" supplemental new drug application provides for addition of (b) (4) as an additional microbiological testing laboratory for the testing of raw material components and finished product

We have completed our review of this supplemental new drug application. This supplement is approved.

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 LCDR Luz E Rivera, Regulatory Project Manager, at (301) 796 4013.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Branch Chief, Branch IX,
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
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/

RAMESH RAGHAVACHARI
06/05/2014

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