CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 022410/S-011

Trade Name:	**SUBOXONE**
Generic Name:	**Buprenorphine Hydrochloride; Naloxone Hydrochloride**
Sponsor:	**Reckitt Benckiser Pharmaceuticals, Inc.**
Approval Date:	08/08/2013
Indications:	SUBOXONE sublingual film is indicated for maintenance treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support.

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APPLICATION NUMBER:

NDA 022410/S-011

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Reviews / Information Included in this NDA Review.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDAs 18401/ S-019, 20732/S-009, 20733/ S-011 & 22410/ S-011bundle

APPROVAL LETTER

Reckitt Benckiser Pharmaceuticals, Inc.
Attention: Vanita Dimri, RAC, ASQ-CQA
Regulatory Affairs-RegEx NA
10710 Midlothian Turnpike, Suite 430
Richmond VA 23235

Dear Ms. Dimri:

Please refer to your Supplemental New Drug Application (sNDA), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA	Supplement	Drug Product	Dated	Received
18401	S-019	Buprenex® (buprenorphine HCI) Injection	March 15, 2013	March 18, 2013
20732	S-009	Subutex® (buprenorphine HCI) Sublingual Tablet	March 15, 2013	March 18, 2013
20733	S-011	Suboxone® (buprenorphine HCI/ naloxone HCI) Sublingual Tablet	March 15, 2013	March 18, 2013
22410	S-011	Suboxone® (buprenorphine HCI/ naloxone HCI) Sublingual film	March 15, 2013	March 15, 2013

These "Changes Being Effected" supplements provide to register post approval drug substance changes made to the manufacture of drug substance Buprenorphine HCl, in DMF 12412.

We have completed our review of these supplemental new drug applications. These supplements are 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.
Acting Branch Chief, Branch IX
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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