Trade Name: SUBOXONE

Generic Name: Buprenorphine Hydrochloride; Naloxone Hydrochloride

Sponsor: Reckitt Benckiser Pharmaceuticals, Inc.

Approval Date: 03/12/2014

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.
# Reviews / Information Included in this NDA Review.

<table>
<thead>
<tr>
<th>Reviews / Information</th>
<th>Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Letter</td>
<td>X</td>
</tr>
<tr>
<td>Other Action Letters</td>
<td></td>
</tr>
<tr>
<td>Labeling</td>
<td></td>
</tr>
<tr>
<td>Summary Review</td>
<td></td>
</tr>
<tr>
<td>Officer/Employee List</td>
<td></td>
</tr>
<tr>
<td>Office Director Memo</td>
<td></td>
</tr>
<tr>
<td>Cross Discipline Team Leader Review</td>
<td></td>
</tr>
<tr>
<td>Medical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Chemistry Review(s)</td>
<td>X</td>
</tr>
<tr>
<td>Environmental Assessment</td>
<td></td>
</tr>
<tr>
<td>Pharmacology Review(s)</td>
<td></td>
</tr>
<tr>
<td>Statistical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Microbiology Review(s)</td>
<td></td>
</tr>
<tr>
<td>Clinical Pharmacology/Biopharmaceutics Review(s)</td>
<td></td>
</tr>
<tr>
<td>Risk Assessment and Risk Mitigation Review(s)</td>
<td></td>
</tr>
<tr>
<td>Proprietary Name Review(s)</td>
<td></td>
</tr>
<tr>
<td>Other Review(s)</td>
<td></td>
</tr>
<tr>
<td>Administrative/Correspondence Document(s)</td>
<td>X</td>
</tr>
</tbody>
</table>
APPLICATION NUMBER:
NDA 022410/S-014

APPROVAL LETTER
NDA 22410/S-014

Reckitt Benckiser Pharmaceuticals, Inc.
Attention: Bruce Paolella
Director, Regulatory Strategy Category/ North America
10710 Midlothian Turnpike, Suite 430
Richmond VA 23235

Dear Mr. Paolella:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 20, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Suboxone® (buprenorphine HCl/ naloxone HCl) Sublingual film.

We acknowledge receipt of your amendment dated February 14, 2014.

This “Changes Being Effected in 30 Days” supplemental new drug application provides for the addition of MonoSol Rx’s (b)(4) as a (b)(4) site.

We have completed our review of this supplemental new drug application, as amended. 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
03/12/2014
APPLICATION NUMBER:
NDA 022410/S-014

CHEMISTRY REVIEW(S)
3. Name and Address of Applicant

Reckitt Benckiser Pharmaceuticals Inc.
Attention: Bruce Paolella, Director,
10710 Midlothian Turnpike Suite 430, Richmond, VA 23235

4. DATE

Submission        PDUFA
9/20/13               3/20/14

5. Name of Drug: Suboxone

6. Nonproprietary Name: Buprenorphine/Nalaxone

7. Supplement, CBE-30, Provides for:
The addition of a site, MonoSol Rx’s

8. Amendment Date


10. How Dispensed: Rx

11. Related Documents

12. Dosage Form: Sublingual

13. Potency(ies): 2/0.5 mg, 8/2 mg, 4/1 mg and 12/3 mg

14. Comments

The equipment used in the facilities has the same operating principle.

The process has been validated in the facility using three batches of Suboxone® (8 mg Buprenorphine/2 mg Naloxone) Sublingual Film manufactured in the facility. No changes were made to the former manufacturing process steps and the three batches were as approved in the NDA.

The three validation batches were release tested and met the registered finished product specifications.

Reckitt Benckiser Pharmaceuticals Inc. commits to present the stability data following three months accelerated and room-temperature stability storage as soon as it becomes available.

The new site was and was found acceptable based on profile. See EER below.

No changes to the specifications, manufacturing process, or controls are occurring as a result of the transfer.

15. Conclusions and Recommendations: Recommend approval.

17. Name: Review Chemist                Signature                Date
Bart Ho, Chemist
Branch Chief
Ramesh Raghavachari, Ph.D.

Doc ID: 22410S14 Reckitt Benckiser
### FDA CDER EES

**ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT**

**Application:** NDA 22410/014  
**Sponsor:** RECKITT BENCKISER  
**Org. Code:** 170  
**Brand Name:** SUBOXONE (BUPRENORPHINE/HALOXONE)  
**Priority:** 45  
**Establish. Name:**  
**Stamp Date:** 20-SEP-2013  
**Generic Name:**  
**PDUFA Date:** 20-MAR-2014  
**Product Number; Dosage Form; Ingredient; Strengths**  
004: FILM: NALOXONE HYDROCHLORIDE; EQ 3MG BASE  
004: FILM: BUPRENORPHINE HYDROCHLORIDE; EQ 12MG BF  
003: FILM: NALOXONE HYDROCHLORIDE; EQ 1MG BASE  
001: FILM: NALOXONE HYDROCHLORIDE; EQ 5MG BASE  
001: FILM: BUPRENORPHINE HYDROCHLORIDE; EQ 2MG BF  
002: FILM: NALOXONE HYDROCHLORIDE; EQ 2MG BASE  
002: FILM: BUPRENORPHINE HYDROCHLORIDE; EQ 8MG BASE  
**FDA Contacts:**  
- R. RAGHAVACHARI, Prod Qual Reviewer (HFD-820) 3017961738  
- L. RIVERA, Product Quality PM (HFD-170) 3017964913  
- M. SULLIVAN, Regulatory Project Mgr (HFD-510) 3017961245  
- M. GAUTAM BASAIK, Team Leader (HFD-510) 3017967712  
**Overall Recommendation:**  
- ACCEPTABLE on 11-NOV-2013 by J. WILLIAMS (HFD-510) 3017964196  
- PENDING on 03-OCT-2013 by EES_PROD 3017964196  
**Establishment:** CFN: MONOSOL RX LLC  
**FEI:**  
- MONOSOL RX LLC  
**DMF No:**  
- MONOSOL RX LLC  
**Responsibilities:**  
- NOT ELSEWHERE CLASSIFIED  
**Profile:**  
- GAI Status: NONE  
**Last Milestone:** BC RECOMMENDATION  
**Milestone Date:** 03-OCT-2013  
**Decision:** ACCEPTABLE  
**Reason:** BASED ON PROFILE
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BARTHOLOME C HO
03/11/2014

RAMESH RAGHAVACHARI
03/11/2014
Reckitt Benekiser Pharmaceuticals, Inc.
Attention: Bruce Paolella
Director, Regulatory Strategy Category/ North America
10710 Midlothian Turnpike, Suite 430
Richmond VA 23235

Dear Mr. Paolella:

We have received your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER: 22410
SUPPLEMENT NUMBER: 014
PRODUCT NAME: Suboxone® (buprenorphine HCl/ naloxone HCl) Sublingual film
DATE OF SUBMISSION: September 20, 2013
DATE OF RECEIPT: September 20, 2013

This supplemental application, submitted as a “Changes Being Effected in 30 days” supplement, proposes the addition of a [site] (b)(4) site.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on November 19, 2013 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be March 20, 2014.

Cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:
All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm.

If you have questions, call me, at (301) 796 4013.

Sincerely,

{See appended electronic signature page}

LCDR Luz E Rivera, Psy.D.
Regulatory Project Manager
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/

LUZ E RIVERA
10/25/2013