CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

22-410/S006/S007

Trade Name: SUBOXONE®

Generic Name: buprenorphine hydrochloride; naloxone hydrochloride

Sponsor: Reckitt Benckiser Pharmaceuticals, Inc.

Approval Date: 8/10/2012

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APPLICATION NUMBER:

22-410/S006/S007

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Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:

22-410/S006/S007

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022410/S-006
NDA 022410/S-007

SUPPLEMENT APPROVAL

Reckitt Benckiser Pharmaceuticals, Inc.
10710 Midlothian Turnpike, Suite 430
Richmond, VA 23235

Attention: Clorey Toombs
CMC Manager, Regulatory Affairs

Dear Ms. Toombs:

Please refer to your Supplemental New Drug Applications (sNDA) dated September 29 and 30, 2011, and received September 30, 2011, and identified as S-006 and S-007, respectively. These sNDAs were submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Suboxone (buprenorphine and naloxone) sublingual film.

We acknowledge receipt of your amendments dated January 26, March 8, and June 4, 2012, to Supplement S006, and January 27 and 31, March 8, and June 4, 2012, to Supplement S007, and to your risk evaluation and mitigation strategy (REMS) assessment dated August 29, 2011.

These "Prior Approval" supplemental new drug applications provide for the following:

S-006: addition of a 4 mg/1 mg (buprenorphine/naloxone) strength

S-007: addition of a 12 mg/3 mg (buprenorphine/naloxone) strength

These supplemental new drug applications also provide for proposed modifications to the approved risk evaluation and mitigation strategy (REMS).

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide), with the addition of any labeling changes in pending

"Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your June 4, 2012, submission containing final printed carton and container labels.

We remind you of the following:

Pouch Labels (Currently marketed strengths: 1 mg/0.5 mg, 8 mg/2 mg)
At next printing revise the statement "Do not chew or swallow sublingual films" to read "Do not cut, chew or swallow sublingual film" and relocate to the Principal Display Panel to increase its prominence

Carton Labeling (Currently marketed strengths: 1 mg/0.5 mg, 8 mg/2 mg)
At next printing revise the statement "Do not chew or swallow sublingual films" to read "Do not cut, chew or swallow sublingual film" and relocate to the Principal Display Panel to increase its prominence.

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