CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022410Orig1s000

Trade Name: Suboxone (sublingual film)

Generic Name: buprenorphine and naloxone

Sponsor: Reckitt Benckiser Pharmaceuticals Inc.

Approval Date: 8/30/2010

Indications: For use in the maintenance treatment of opioid dependence when used as part of a complete treatment plan to include counseling and psychosocial support.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022410

NDA APPROVAL

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

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

Dear Dr. Pitts:

Please refer to your New Drug Application (NDA) submitted October 20, 2008, received October 21, 2008, 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 October 22 and 30, and December 1, 3, 8, and 11, 2008, and January 8, February 4 (2), March 3, 20, 25, and 26, April 6, 20, 28, and 30, June 9, July 24, August 7 and 14, and November 2, 12, 24, 2009, and January 25, March 5 (2), April 29, May 17, July 21, and August 20, 23, 24, and 27, 2010.

The November 24, 2009, submission constituted a Complete Response to our August 21, 2009, Action Letter.

This new drug application provides for the use of Suboxone (buprenorphine and naloxone) sublingual film for use in the maintenance treatment of opioid dependence when used as part of a complete treatment plan to include counseling and psychosocial support.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert and Medication Guide). 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your April 29, 2010, submission containing final printed carton and container labels.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o)(3) of the FDCA authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute.

During the review of this NDA we have become aware of a placebo-controlled thorough QT study employing another buprenorphine containing product, Butrans, approved on June 30, 2010. (b) (4)

Therefore, Suboxone sublingual film may have the potential to cause QT prolongation at therapeutic doses that could result in increased risk for serious cardiac events, including life-threatening arrhythmias. Further, we note that patients with hepatic impairment may have delayed clearance of, and increased exposure to, buprenorphine which could lead to an increase in adverse effects, including the potential for QT prolongation.

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to identify the unexpected serious

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