CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022410Orig1s000

OTHER REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	June 8, 2010
To:	Bob Rappaport, MD, Division Director **Division of Anesthesia and Analgesia Products (DAAP)**
Through:	Mary Willy, PhD, Deputy Director **Division of Risk Management (DRISK)** Sharon R. Mills, BSN, RN, CCRP Senior Patient Labeling Reviewer, Acting Team Leader **Division of Risk Management**
From:	Latonia M. Ford, RN, BSN, MBA Patient Product Information Reviewer **Division of Risk Management**
Subject:	Addendum to DRISK Review of Patient Labeling (Medication Guide), dated August 6, 2009
Drug Name(s):	Suboxone (buprenorphine and naloxone) sublingual film
Application Type/Number:	NDA 22-410
Applicant/sponsor:	Reckitt Benckiser Pharmaceuticals Inc.
OSE RCM #:	2010-970

1 INTRODUCTION

This review is written as an addendum to the Division of Risk Management (DRISK) review of the MG for Suboxone (buprenorphine and naloxone) sublingual film, originally requested by the Division of Anesthesia and Analgesia Products (DAAP), and completed on August 6, 2009.

Please let us know if DAAP would like a meeting to discuss this review or any of our changes prior to sending to the Applicant.

2 MATERIAL REVIEWED

Draft Suboxone (buprenorphine and naloxone) sublingual flim Medication Guide (MG) submitted on October 20, 2008, revised by DRISK on August 6, 2009, and further revised by the review division and provided to DRISK on May 14, 2010.

3 RESULTS OF REVIEW

In our review of the MG, we have:

- simplified wording and clarified concepts where possible
- ensured that the MG is consistent with the PI
- removed unnecessary or redundant information
- ensured that the MG meets the Regulations as specified in 21 CFR 208.20
- ensured that the MG meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)

After the original MG review was completed on August 6, 2009, DAAP sent the Applicant a Complete Response (CR) letter on August 21, 2009 because the proposed REMS was not sufficient to ensure that the benefits of suboxone sublingual film outweigh the risks associated with the use of the drug. DRISK revisions of the MG from August 6, 2009 were not provided to the Applicant. We received comments from DAAP on May 14, 2010 in response to our MG review completed on August 6, 2009. These comments and revisions are the subject of this review addendum.

Our annotated MG is appended to this memo. We retained all of our previous comments as well as the comments from DAAP in the tracked changes version of the MG.

Any additional revisions to the PI should be reflected in the MG.

Please let us know if you have any questions.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22410	ORIG-1	RECKITT BENCKISER PHARMACEUTICALS INC	SUBOXONE (BUPRENORPHINE/NALOXONE) sublingual film

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/s/

LATONIA M FORD
06/08/2010
Suboxone Addendum to DRISK Review of Patient Labeling (Medication Guide), dated August 6, 2009

MARY E WILLY
06/08/2010
I concur

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	August 6, 2009
To:	Bob Rappaport, MD, Division Director **Division of Anesthesia, Analgesia, and Rheumatology Products (DAARP)**
Through:	Claudia Karwoski, PharmD, Director **Division of Risk Management (DRISK)** Jodi Duckhorn, MA, Team Leader **Division of Risk Management**
From:	Latonia M. Ford, RN, BSN, MBA Patient Product Information Reviewer **Division of Risk Management**
Subject:	DRISK Review of Patient Labeling (Medication Guide)
Drug Name(s):	Buprenorphine and Naloxone (Suboxone)
Application Type/Number:	NDA 22-410
Applicant/sponsor:	Reckitt Benckiser Pharmaceuticals INC.
OSE RCM #:	2009-2042

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