FDA Home<sup>3</sup> Drug Databases<sup>4</sup> Orange Book<sup>5</sup>

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
Patent and Exclusivity Search Results from query on Appl No 022410 Product 001 in the OB\_RX list.

#### **Patent Data**

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N022410	001	8017150	Feb 13, 2023		Υ		
N022410	001	8475832	Mar 26, 2030		Υ	U - 1411	
N022410	001	8603514	Apr 3, 2024		Υ	U - 1464	

#### **Exclusivity Data**

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N022410	001	NDF	Aug 30, 2013

#### Additional information:

- 1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
- 2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

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**Evaluations** Search results from the "OB\_Rx" table for query on "022410."

Active Ingredient:

BUPRENORPHINE HYDROCHLORIDE; NALOXONE

HYDROCHLORIDE FILM;SUBLINGUAL

Proprietary Name: SUBOXONE

Applicant: RECKITT BENCKISER

Strength: EQ 2MG BASE; EQ 0.5MG BASE

Application Number: N022410
Product Number: 001

Approval Date: Aug 30, 2010

Reference Listed Drug No RX/OTC/DISCN: RX

TE Code:

Dosage Form; Route:

Patent and Exclusivity Info for this

product: View

Active Ingredient:

BUPRENORPHINE HYDROCHLORIDE; NALOXONE

Dosage Form; Route: HYDROCHLORIDE FILM; SUBLINGUAL

Proprietary Name: SUBOXONE

Applicant: RECKITT BENCKISER

Strength: EQ 8MG BASE; EQ 2MG BASE

Application Number: N022410
Product Number: 002

Approval Date: Aug 30, 2010

Reference Listed Drug No RX/OTC/DISCN: RX

TE Code:

Patent and Exclusivity Info for this

product: View

Active Ingredient:

BUPRENORPHINE HYDROCHLORIDE; NALOXONE

Dosage Form; Route: HYDROCHLORIDE FILM; SUBLINGUAL

Proprietary Name: SUBOXONE

Applicant: RECKITT BENCKISER

Strength: EQ 4MG BASE; EQ 1MG BASE

Application Number: N022410
Product Number: 003

Approval Date: Aug 10, 2012

Reference Listed Drug No RX/OTC/DISCN: RX



TE Code:

Patent and Exclusivity Info for this

product:

View

Active Ingredient:

BUPRENORPHINE HYDROCHLORIDE; NALOXONE

HYDROCHLORIDE FILM; SUBLINGUAL

Dosage Form; Route: FILM; SUBLING
Proprietary Name: SUBOXONE

A II - - BESTATE BENCH

Applicant: RECKITT BENCKISER

Strength: EQ 12MG BASE;EQ 3MG BASE

Application Number: N022410
Product Number: 004

Approval Date: Aug 10, 2012

Reference Listed Drug Yes RX/OTC/DISCN: RX

TE Code:

Patent and Exclusivity Info for this

product:

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FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

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