Orange Book 101

Camille Smith, PharmD, RPh, RAC
Orange Book Staff Pharmacist
Division of Legal and Regulatory Support (DLRS)
Office of Generic Drug Policy
CDER | U.S. FDA

Celebrating 40 Years: An In-Depth Examination of the FDA Orange Book – October 27-28, 2020

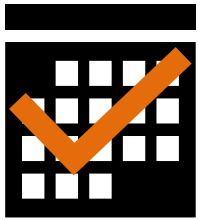
Learning Objectives

- Recognize timing for the Orange Book website and publication updates
- Explain how information is gathered and assessed for publication in the Orange Book
- Identify important aspects of Orange Book drug product listings
- Recognize the impact of the Orange Book publication on regulatory decision making

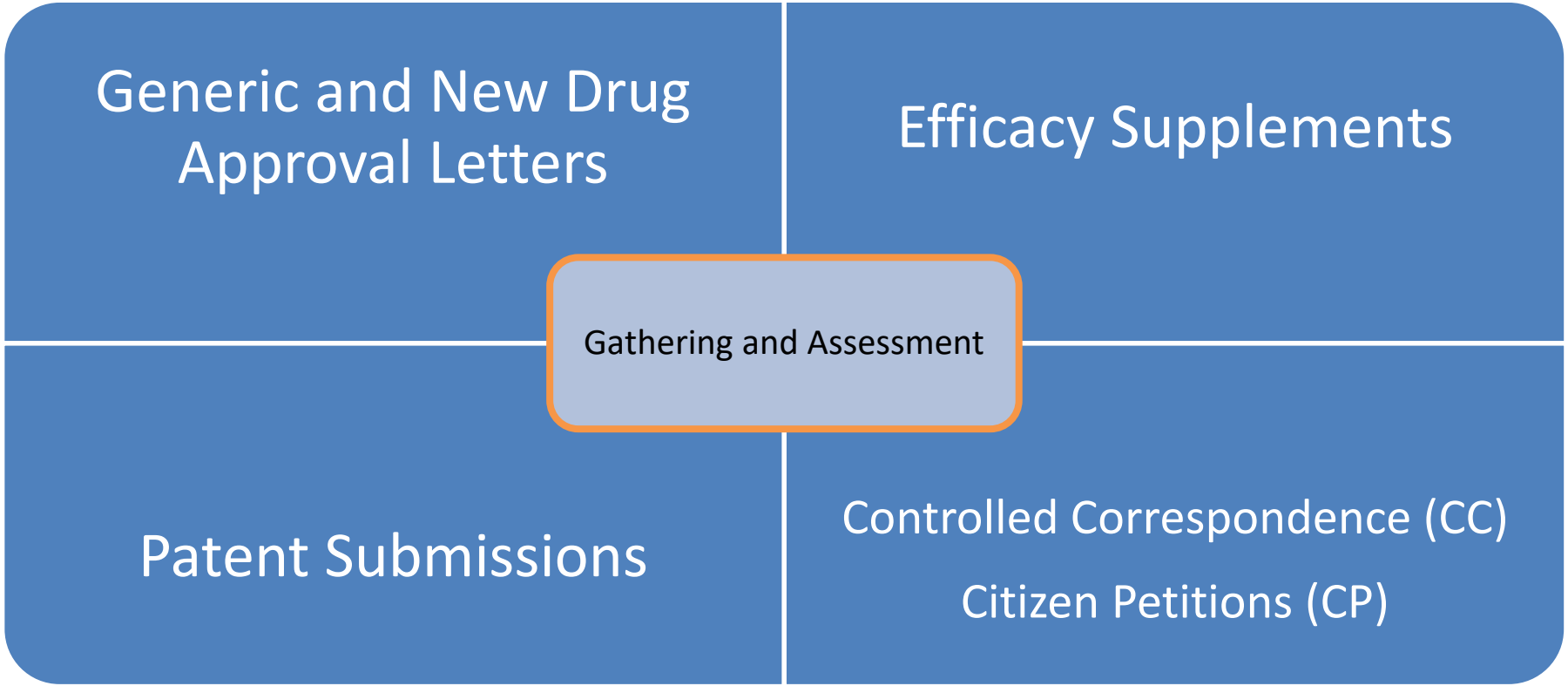
Timing for Updates

- Daily (Website and App)

- Monthly (Website, App, and Publication)
- Annually (Website, App, and Publication)
  - Annual Orange Book Edition Publication



Information Gathering and Regulatory Assessment



Information Gathering and Regulatory Assessment

Drug Approvals	• Daily web and monthly publication updates for drug product listings.
Patents	• Daily web and monthly publication updates for patent listings. Ongoing external correspondence in response to deficiencies and disputes.
Supplements	• Efficacy supplement reviews and monthly publication of exclusivity determinations.
Controlled Correspondence Citizen Petitions	• Written consults on drug status to support Agency's intended action.

Internal Collaboration and External Stakeholders

- Internal Agency Collaboration
  - Drug Approvals and Patents (OGD, OND, OPQ)
  - Exclusivity reviews (OND, OPQ)
  - CC and CP Consults (ORP)
  - Office of Communications (OCOMM) and others
- External stakeholders include
  - healthcare practitioners, industry representatives, regulatory professionals and consumers

Orange Book Publication Overview

- The Orange Book Staff gathers and reviews the information necessary to support Orange Book updates
- The Orange Book provides a list of drugs approved under Section 505 of the Federal Food, Drug, and Cosmetic Act organized into three sections (Prescription, Over-the-Counter (OTC), and Discontinued Drug Product Lists)
- The Orange Book is critical for determining which generic drug products can be substituted for particular brand name drug products
- The Orange Book is the only definitive source for therapeutic equivalence (TE) evaluations, reference listed drug (RLD) information, patent listings and exclusivity determinations

Orange Book Publication Overview

- The Orange Book does not contain
  - approved drug products that were discontinued either before the first edition was published in October 1980 or discontinued between 1980 and 1987 prior to the inclusion of the Discontinued Drug Product List in the Orange Book
  - drug products that do not have full approval
  - biological products licensed by FDA under the Public Health Service Act
  - marketed drug products that are not the subject of an approved New Drug Application or Abbreviated New Drug Application
  - drug products compounded by pharmacies and outsourcing facilities

Drug Product Listing Overview

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074951	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			JEROME STEVENS PHARMACEUTICALS INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075231	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			LGM PHARMA SOLUTIONS LLC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A203335	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			MAYNE PHARMA INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	FIORINAL W/CODEINE	N019429	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB	RLD	RS	ALLERGAN SALES LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075351	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				VINTAGE PHARMACEUTICALS LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074359	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				WATSON LABORATORIES INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Drug Product Listing Overview

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074951	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			JEROME STEVENS PHARMACEUTICALS INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075231	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			LGM PHARMA SOLUTIONS LLC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A203335	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			MAYNE PHARMA INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	FIORINAL W/CODEINE	N019429	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB	RLD	RS	ALLERGAN SALES LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075351	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				VINTAGE PHARMACEUTICALS LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074359	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				WATSON LABORATORIES INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Drug Product Listing Overview

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074951	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			JEROME STEVENS PHARMACEUTICALS INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075231	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			LGM PHARMA SOLUTIONS LLC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A203335	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			MAYNE PHARMA INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	FIORINAL W/CODEINE	N019429	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB	RLD	RS	ALLERGAN SALES LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075351	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				VINTAGE PHARMACEUTICALS LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074359	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				WATSON LABORATORIES INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Drug Product Listing Overview

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074951	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			JEROME STEVENS PHARMACEUTICALS INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075231	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			LGM PHARMA SOLUTIONS LLC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A203335	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			MAYNE PHARMA INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	FIORINAL W/CODEINE	N019429	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB	RLD	RS	ALLERGAN SALES LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075351	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				VINTAGE PHARMACEUTICALS LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074359	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				WATSON LABORATORIES INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Drug Product Listing Overview

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074951	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			JEROME STEVENS PHARMACEUTICALS INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075231	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			LGM PHARMA SOLUTIONS LLC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A203335	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			MAYNE PHARMA INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	FIORINAL W/CODEINE	N019429	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB	RLD	RS	ALLERGAN SALES LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075351	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				VINTAGE PHARMACEUTICALS LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074359	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				WATSON LABORATORIES INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Drug Product Listing Overview

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074951	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			JEROME STEVENS PHARMACEUTICALS INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075231	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			LGM PHARMA SOLUTIONS LLC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A203335	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			MAYNE PHARMA INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	FIORINAL W/CODEINE	N019429	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB	RLD	RS	ALLERGAN SALES LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075351	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				VINTAGE PHARMACEUTICALS LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074359	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				WATSON LABORATORIES INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Drug Product Listing Overview

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074951	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			JEROME STEVENS PHARMACEUTICALS INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075231	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			LGM PHARMA SOLUTIONS LLC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A203335	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			MAYNE PHARMA INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	FIORINAL W/CODEINE	N019429	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB	RLD	RS	ALLERGAN SALES LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075351	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				VINTAGE PHARMACEUTICALS LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074359	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				WATSON LABORATORIES INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Drug Product Listing Overview

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074951	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			JEROME STEVENS PHARMACEUTICALS INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075231	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			LGM PHARMA SOLUTIONS LLC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A203335	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			MAYNE PHARMA INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	FIORINAL W/CODEINE	N019429	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB	RLD	RS	ALLERGAN SALES LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075351	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				VINTAGE PHARMACEUTICALS LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074359	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				WATSON LABORATORIES INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Drug Product Listing Overview

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074951	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			JEROME STEVENS PHARMACEUTICALS INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075231	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			LGM PHARMA SOLUTIONS LLC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A203335	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			MAYNE PHARMA INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	FIORINAL W/CODEINE	N019429	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB	RLD	RS	ALLERGAN SALES LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075351	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				VINTAGE PHARMACEUTICALS LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074359	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				WATSON LABORATORIES INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Drug Product Listing Overview

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074951	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			JEROME STEVENS PHARMACEUTICALS INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075231	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			LGM PHARMA SOLUTIONS LLC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A203335	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			MAYNE PHARMA INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	FIORINAL W/CODEINE	N019429	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB	RLD	RS	ALLERGAN SALES LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075351	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				VINTAGE PHARMACEUTICALS LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074359	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				WATSON LABORATORIES INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Drug Product Listing Overview

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074951	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			JEROME STEVENS PHARMACEUTICALS INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075231	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			LGM PHARMA SOLUTIONS LLC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A203335	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			MAYNE PHARMA INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	FIORINAL W/CODEINE	N019429	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB	RLD	RS	ALLERGAN SALES LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075351	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				VINTAGE PHARMACEUTICALS LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074359	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				WATSON LABORATORIES INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Drug Product Listing Overview

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074951	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			JEROME STEVENS PHARMACEUTICALS INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075231	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			LGM PHARMA SOLUTIONS LLC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A203335	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB			MAYNE PHARMA INC
RX	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	FIORINAL W/CODEINE	N019429	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG	AB	RLD	RS	ALLERGAN SALES LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A075351	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				VINTAGE PHARMACEUTICALS LLC
DISCN	ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE	BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE	A074359	CAPSULE	ORAL	325MG; 50MG; 40MG; 30MG				WATSON LABORATORIES INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder

Patent Data Overview

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	8513263	12/23/2029	DS	DP			12/20/2018
001	8865698	10/21/2029			U-2469		12/20/2018
001	9127013	10/21/2029	DS	DP			12/20/2018
001	9447104	10/21/2029			U-2470		12/20/2018
001	9676783	10/21/2029			U-2469		12/20/2018
001	9782414	11/16/2035			U-2471		12/20/2018
001	10005783	10/21/2029			U-2472		12/20/2018
001	10045991	04/04/2037			U-2473		12/20/2018
001	10047097	10/21/2029			U-2474		12/20/2018
001	10137127	04/04/2037		DP			12/20/2018
001	10172861	11/16/2035	DS				06/13/2019
001	10668072	04/04/2037		DP			09/17/2020

Patent Data Overview

Patent Data

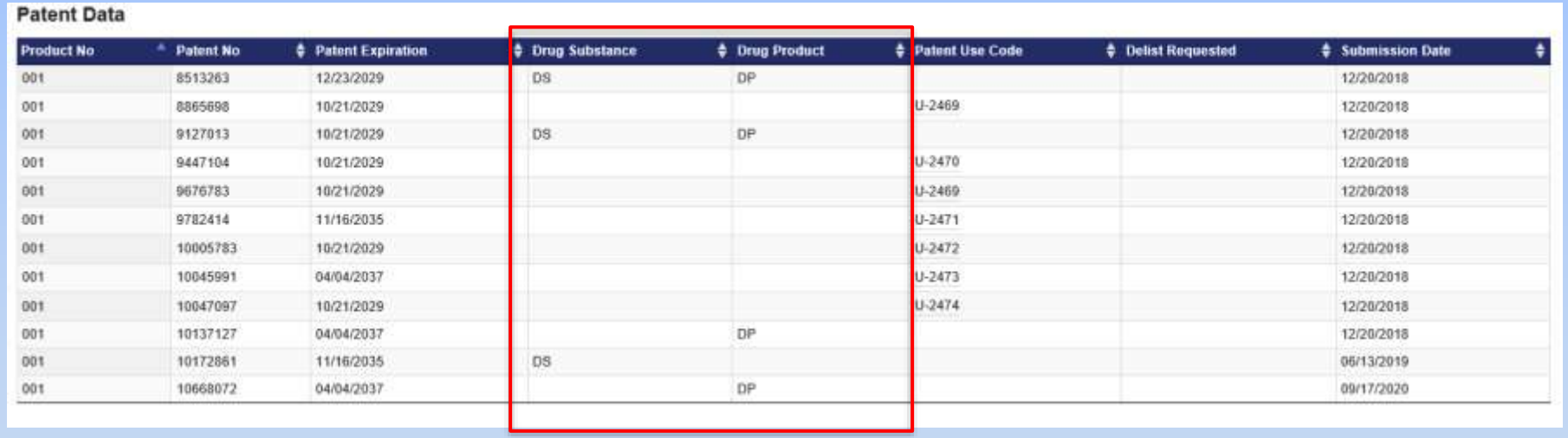
Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	8513263	12/23/2029	DS	DP			12/20/2018
001	8865698	10/21/2029			U-2469		12/20/2018
001	9127013	10/21/2029	DS	DP			12/20/2018
001	9447104	10/21/2029			U-2470		12/20/2018
001	9676783	10/21/2029			U-2469		12/20/2018
001	9782414	11/16/2035			U-2471		12/20/2018
001	10005783	10/21/2029			U-2472		12/20/2018
001	10045991	04/04/2037			U-2473		12/20/2018
001	10047097	10/21/2029			U-2474		12/20/2018
001	10137127	04/04/2037		DP			12/20/2018
001	10172861	11/16/2035	DS				06/13/2019
001	10668072	04/04/2037		DP			09/17/2020

Patent Data Overview

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	8513263	12/23/2029	DS	DP			12/20/2018
001	8865698	10/21/2029			U-2469		12/20/2018
001	9127013	10/21/2029	DS	DP			12/20/2018
001	9447104	10/21/2029			U-2470		12/20/2018
001	9676783	10/21/2029			U-2469		12/20/2018
001	9782414	11/16/2035			U-2471		12/20/2018
001	10005783	10/21/2029			U-2472		12/20/2018
001	10045991	04/04/2037			U-2473		12/20/2018
001	10047097	10/21/2029			U-2474		12/20/2018
001	10137127	04/04/2037		DP			12/20/2018
001	10172861	11/16/2035	DS				06/13/2019
001	10668072	04/04/2037		DP			09/17/2020

Patent Data Overview



Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	8513263	12/23/2029	DS	DP			12/20/2018
001	8865698	10/21/2029			U-2469		12/20/2018
001	9127013	10/21/2029	DS	DP			12/20/2018
001	9447104	10/21/2029			U-2470		12/20/2018
001	9676783	10/21/2029			U-2469		12/20/2018
001	9782414	11/16/2035			U-2471		12/20/2018
001	10005783	10/21/2029			U-2472		12/20/2018
001	10045991	04/04/2037			U-2473		12/20/2018
001	10047097	10/21/2029			U-2474		12/20/2018
001	10137127	04/04/2037		DP			12/20/2018
001	10172861	11/16/2035	DS				06/13/2019
001	10668072	04/04/2037		DP			09/17/2020

Patent Data Overview

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	8513263	12/23/2029	DS				12/20/2018
001	8865698	10/21/2029			U-2469		12/20/2018
001	9127013	10/21/2029	DS				12/20/2018
001	9447104	10/21/2029			U-2470		12/20/2018
001	9676783	10/21/2029			U-2469		12/20/2018
001	9782414	11/16/2035			U-2471		12/20/2018
001	10005783	10/21/2029			U-2472		12/20/2018
001	10045991	04/04/2037			U-2473		12/20/2018
001	10047097	10/21/2029			U-2474		12/20/2018
001	10137127	04/04/2037		DP			12/20/2018
001	10172861	11/16/2035	DS				06/13/2019
001	10668072	04/04/2037		DP			09/17/2020

METHOD OF TREATING CANCEROUS SOLID TUMORS

Patent Data Overview

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	8513263	12/23/2029	DS	DP			12/20/2018
001	8865698	10/21/2029			U-2469		12/20/2018
001	9127013	10/21/2029	DS	DP			12/20/2018
001	9447104	10/21/2029			U-2470		12/20/2018
001	9676783	10/21/2029			U-2469		12/20/2018
001	9782414	11/16/2035			U-2471		12/20/2018
001	10005783	10/21/2029			U-2472		12/20/2018
001	10045991	04/04/2037			U-2473		12/20/2018
001	10047097	10/21/2029			U-2474		12/20/2018
001	10137127	04/04/2037		DP			12/20/2018
001	10172861	11/16/2035	DS				06/13/2019
001	10668072	04/04/2037		DP			09/17/2020

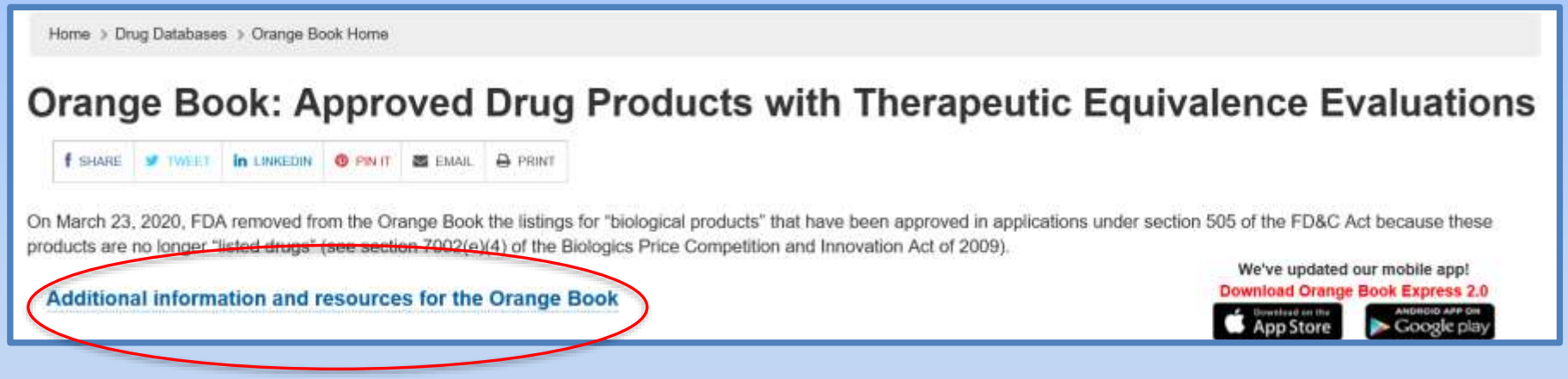
Exclusivity Data Overview

Exclusivity Data

Product No		Exclusivity Code	Exclusivity Expiration
001	NEW CHEMICAL ENTITY	NCE	08/07/2025

View a list of all patent use codes
View a list of all exclusivity codes

Additional Information and Resources



Additional Information and Resources

- Additions/Deletions for Prescription and OTC Drug Product Lists
- Orange Book Data Files
- Reference Listed Drugs by ANDA Reference Standard List
- Orange Book Patent Listing Dispute List
- BPCIA Orange Book Transition Edition
- Frequently Asked Questions on The Orange Book
- Frequently Asked Questions on Patents and Exclusivity
- Orange Book Preface
- FDA introduces reference standard data updates to the Orange Book

Challenge Question #1

The OB Staff uses generic drug approval information to update product listings in the Orange Book database daily.

A. TRUE

B. FALSE

Challenge Question #2

The Orange Book publication includes which of the following:

A. PRESCRIPTION DRUG PRODUCT LISTINGS

B. PATENT AND EXCLUSIVITY DATA

C. MARKETING STATUS

D. ALL OF THE ABOVE

The Orange Book Staff can be contacted by email at orangebook@fda.hhs.gov

Camille Smith, PharmD, RPh, RAC
Orange Book Staff Pharmacist
Division of Legal and Regulatory Support (DLRS)
Office of Generic Drug Policy
CDER | U.S. FDA

Celebrating 40 Years: An In-Depth Examination of the FDA Orange Book – October 27-28, 2020


FDA
U.S. FOOD & DRUG
ADMINISTRATION