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# ***Generic Drugs and The Orange Book***

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*U.S. Food and Drug Administration*



# *Objectives*

- What is a Generic Drug?
- About the Orange Book
- The Orange Book and Generic Drug Substitution
- Utilizing the Orange Book Express Mobile Application (“App”) to find drug product information



# ***What is a Generic Drug?***

- Generic drugs are FDA-approved copies of brand-name (“innovator”) drugs
- Meets the same high standards for quality as the innovator drug
- An affordable alternative



# ***What is a Generic Drug?***

In order for a generic drug to gain FDA approval, it must:

- contain the same active ingredients as the innovator drug
- come in the same dosage form
- be administered the same way.
- be identical in strength
- have the same conditions of use
- be bioequivalent (the generic product gets to the relevant part of the body at the same rate as the innovator)
- meet the same standards for identity, strength, purity and quality
- be manufactured under the same standards that FDA requires for the manufacture of brand products



# ***About the Orange Book***

- One of the key ways consumers can learn about available generic equivalents for a drug product is by searching the publication, ***Approved Drug Products with Therapeutic Equivalence Evaluations***
- Also known as the ***Orange Book***

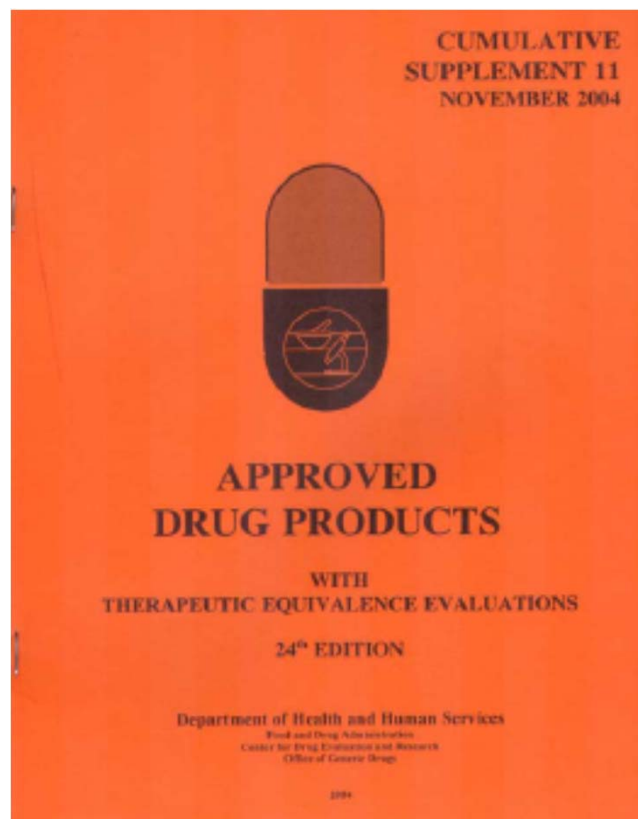


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# ***About the Orange Book***

## ***Approved Drug Products with Therapeutic Equivalence Evaluations***





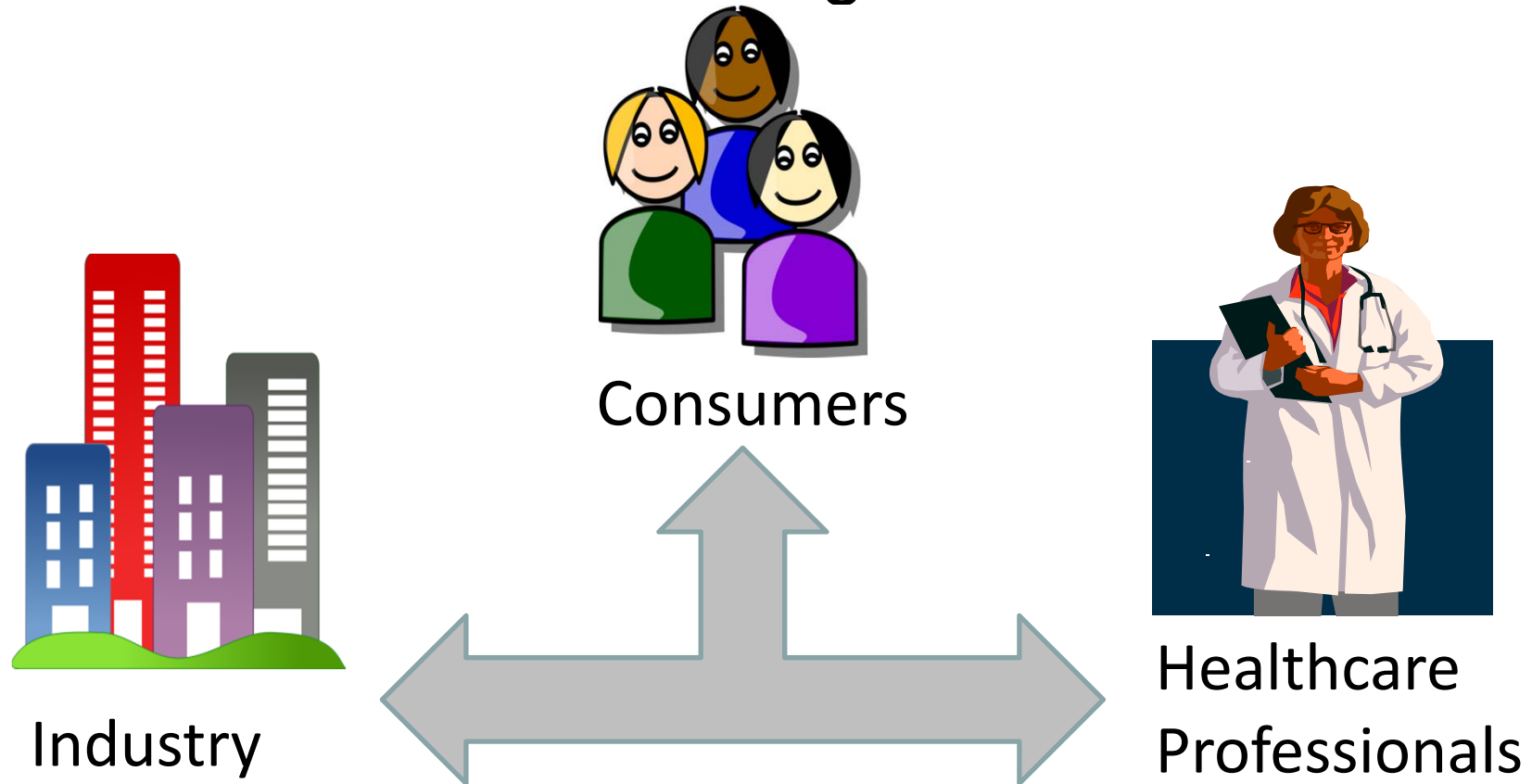
## ***About the Orange Book***

- Fulfills a mandate to list drug products approved as ***safe*** and ***effective*** under section 505(c) of the Federal Food, Drug, and Cosmetic Act
- Contains information with respect to substitution of generic drug products for brand- name (“innovator”) products



# *About the Orange Book*

- Who Utilizes the Orange Book?





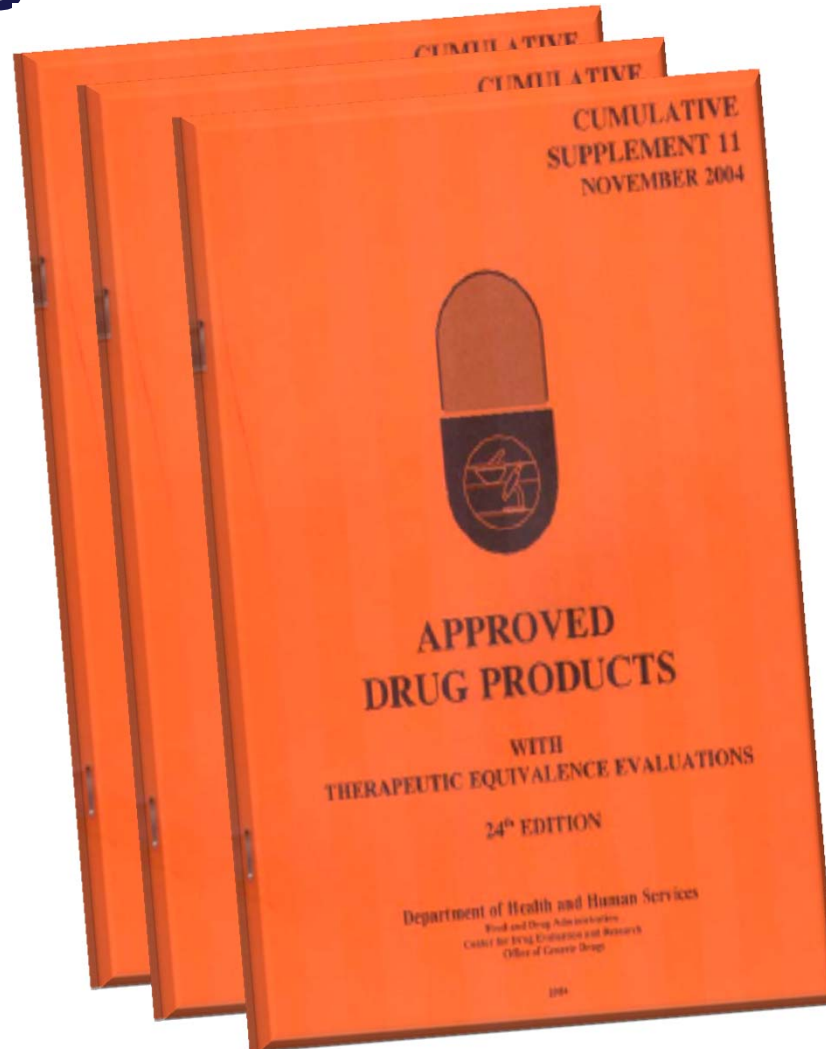


## ***Contents of the Orange Book***

- Prescription Products
- Over-the-Counter (OTC)
- Discontinued Drug Products
- Patents
- Exclusivity



# *Orange Book: Available Formats*





# Orange Book: Available Formats

Available on the internet: <http://www.fda.gov/cder/ob/default.htm>

The screenshot shows the FDA website header with the logo and navigation menu. The main heading is "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations". Below the heading is a breadcrumb trail: "FDA Home > Drug Databases > Orange Book". The text states "Current through September 2015" and "To provide timely consumer information on generic drugs, the Electronic Orange Book is updated daily as new generic approvals occur." There are two columns of search options under "Publications FAQ": "Search by Active Ingredient", "Search by Proprietary Name", and "Search by Patent" on the left; "Search by Applicant Holder" and "Search by Application Number" on the right. At the bottom, it says "The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act." and provides contact information for drug questions.

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## Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

FDA Home > Drug Databases > Orange Book

Current through September 2015

To provide timely consumer information on generic drugs, the Electronic Orange Book is updated daily as new generic approvals occur.

**Publications**  
**FAQ**

- Search by Active Ingredient
- Search by Proprietary Name
- Search by Patent
- Search by Applicant Holder
- Search by Application Number

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

Drug questions email: [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Pharmaceutical Science  
Office of Generic Drugs




# Orange Book: Available Formats


**Orange Book**  
EXPRESS


Orange Book Data Updated Through  
September 2015


[More about Orange Book Updates](#)


Search 


**Search By**

Choose Search Type 

Newly Added Patents 

Patent Delistings 

Orange Book Web Pages 

Help & Support Links 



# ***Updates to the Orange Book***

- Daily (Website and App)
  - Generic Drug approvals & Patents
- Monthly (Website, App, and Publication)
  - Additions: NDA approvals and New exclusivities
  - Changes: active ingredient, discontinued products, strength, dosage form, route, therapeutic equivalence (TE) code, Trade name
- Annually (Website, App, and Publication)
  - Annual Orange Book Edition Publication



# Drug Product Listing

- Active Ingredient
- Proprietary Name
- Dosage Form
- Route of Administration
- Strength
- Company Name
- Approval Date
- Marketing Status

**Orange Book**  
EXPRESS

View Patent & Exclusivity info for this product.

**Active Ingredient:**  
HYDROCHLOROTHIAZIDE;  
TELMISARTAN

**Proprietary Name:** MICARDIS HCT

**Dosage Form; Route of Administration:** TABLET; ORAL

**Reference Listed Drug:** Yes

**Strength:** 25MG; 80MG

**Applicant (Firm):** BOEHRINGER  
INGELHEIM

**Application Number:** N021162

**TE Code:** AB

**Approval Date:** Apr 19, 2004

**Marketing Status:** Prescription

**Product Number:** 003

[View Patent & Exclusivity info for this product.](#)



# Drug Product Listing: Therapeutic Equivalence

- Therapeutic Equivalence (TE) codes indicate FDA's determination about the substitutability between products

**Orange Book EXPRESS**

View Patent & Exclusivity info for this product.

**Active Ingredient:**  
HYDROCHLOROTHIAZIDE;  
TELMISARTAN

**Proprietary Name:** MICARDIS HCT

**Dosage Form; Route of Administration:** TABLET; ORAL

**Reference Listed Drug:** Yes

**Strength:** 25MG; 80MG

**Applicant (Firm):** BOEHRINGER INGELHEIM

**Application Number:** N021162

**TE Code:** AB

**Approval Date:** Apr 19, 2004

**Marketing Status:** Prescription

**Product Number:** 003

[View Patent & Exclusivity info for this product.](#)





## ***Drug Product List: Therapeutic Equivalence***

- Therapeutic Equivalence= pharmaceutically equivalent and bioequivalent for same use
- Pharmaceutically equivalent
  - Contains the **same active ingredient** in the **same dosage form**, **same strength** or **concentration** and **same route of administration**
- Bioequivalent – data shows the generic product gets to the relevant part of the body at the same rate as the innovator





# Drug Product Listing: Therapeutic Equivalence

- May substitute if “A” rated –therapeutically equivalent
- AB – (most common)

**Orange Book**  
EXPRESS

View Patent & Exclusivity info for this product.

**Active Ingredient:**  
HYDROCHLOROTHIAZIDE;  
TELMISARTAN

**Proprietary Name:** MICARDIS HCT

**Dosage Form; Route of Administration:** TABLET; ORAL

**Reference Listed Drug:** Yes

**Strength:** 25MG; 80MG

**Applicant (Firm):** BOEHRINGER INGELHEIM

**Application Number:** N021162

**TE Code:** AB

**Approval Date:** Apr 19, 2004

**Marketing Status:** Prescription

**Product Number:** 003


[View Patent & Exclusivity info for this product.](#)




# *Finding a Generic Drug in the Orange Book*

**Orange Book EXPRESS**


More about Orange Book Updates


Search 


**Search By**


Active Ingredient or Proprietary Name 


**Active Ingredient or Proprietary Name**

Micardis 

Newly Added Patents 

Patent Delistings 

Orange Book Web Pages 

Help & Support Links 



## Orange Book EXPRESS



[View Patent & Exclusivity info for this product.](#)

**Active Ingredient:**

HYDROCHLOROTHIAZIDE;  
TELMISARTAN

**Proprietary Name:** MICARDIS HCT

**Dosage Form; Route of**

**Administration:** TABLET; ORAL

**Reference Listed Drug:** Yes

**Strength:** 25MG; 80MG

**Applicant (Firm):** BOEHRINGER  
INGELHEIM

**Application Number:** N021162

**TE Code:** AB

**Approval Date:** Apr 19, 2004

**Marketing Status** Prescription

**Product Number:** 003

[View Patent & Exclusivity info for this product.](#)

**BRAND**

## Orange Book EXPRESS



[View Patent & Exclusivity info for this product.](#)

**Active Ingredient:**

HYDROCHLOROTHIAZIDE;  
TELMISARTAN

**Proprietary Name:** TELMISARTAN  
AND HYDROCHLOROTHIAZIDE

**Dosage Form; Route of**

**Administration:** TABLET; ORAL

**Reference Listed Drug:** No

**Strength:** 25MG; 80MG

**Applicant (Firm):** MYLAN PHARMS  
INC

**Application Number:** A091648

**TE Code:** AB

**Approval Date:** Feb 25, 2014

**Marketing Status** Prescription

**Product Number:** 003

[View Patent & Exclusivity info for this product.](#)

**GENERIC**



# Drug Product Listing:

- Example of a single source product in the Orange Book
- No TE code

The screenshot shows the 'Orange Book EXPRESS' interface. At the top, there is a navigation bar with the 'Orange Book EXPRESS' logo and a menu icon. Below the navigation bar is a 'Back' button. The main content area is titled 'Prescription' and contains a list of drug product details. The details are as follows:

- Active Ingredient:** LACOSAMIDE
- Proprietary Name:** VIMPAT
- Dosage Form; Route of Administration:** TABLET; ORAL
- Reference Listed Drug:** No
- Strength:** 100MG
- Applicant (Firm):** UCB INC
- Application Number:** N022253
- TE Code:** (highlighted in yellow)
- Approval Date:** Oct 28, 2008
- Marketing Status:** Prescription
- Product Number:** 002

Below the details, there is a link: [View Patent & Exclusivity info for this product.](#)

At the bottom of the screenshot, the following information is visible:

- Active Ingredient:** LACOSAMIDE
- Proprietary Name:** VIMPAT



## *In Conclusion*

- Generic drugs now represent 88 percent of drugs dispensed in the United States.
- The *Orange Book* is particularly critical in determining when generic drug versions can be substituted for the brand name product.
- Although some outside users repackage the information, the only definitive source for Therapeutic Equivalence (TE) and brand-name (“innovator”) drug data, as well as Patent and Exclusivity data, is the *Orange Book*.



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# *Questions*

CDER Division of Drug Information

[druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)