Generic Drugs and The Orange Book

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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
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?

- Consumers
- Industry
- Healthcare Professionals
Contents of the Orange Book

• Prescription Products
• Over-the-Counter (OTC)
• Discontinued Drug Products
• Patents
• Exclusivity
Orange Book: Available Formats
Orange Book: Available Formats
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
**Drug Product Listing: Therapeutic Equivalence**

- Therapeutic Equivalence (TE) codes indicate FDA’s determination about the substitutability between products.
**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)
Finding a Generic Drug in the Orange Book

Orange Book EXPRESS

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
**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

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**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

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**BRAND**

**GENERIC**
Drug Product Listing:

- Example of a single source product in the Orange Book
- No TE code
**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 repackgage 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*. 
Questions

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