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

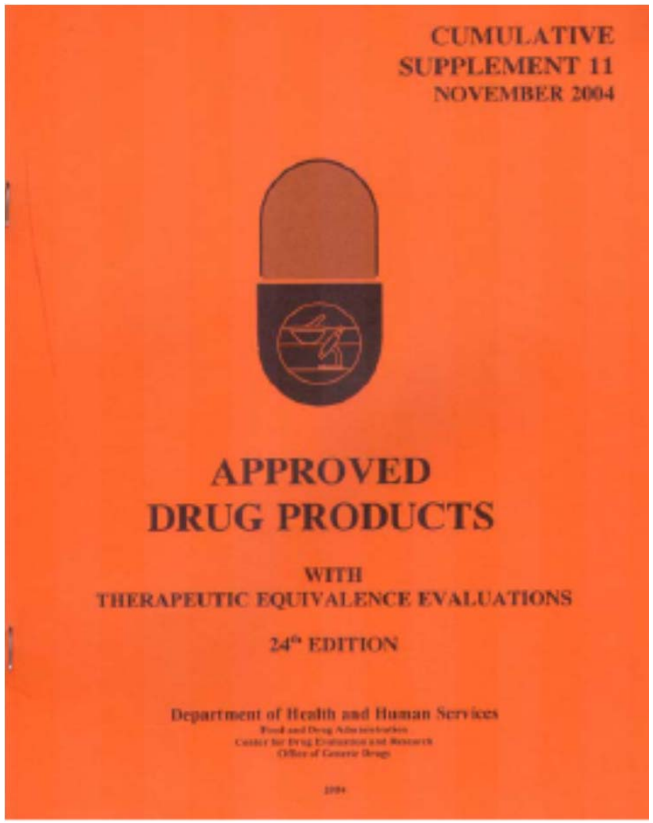
About the Orange Book

- 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

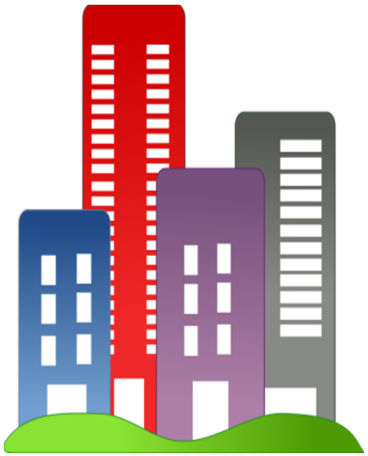
- Fulfills a mandate to list drug products approved as ***safe*** and ***effective*** under section 505(c) of the Federal Food, Drug, and Cosmetic Act

- 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



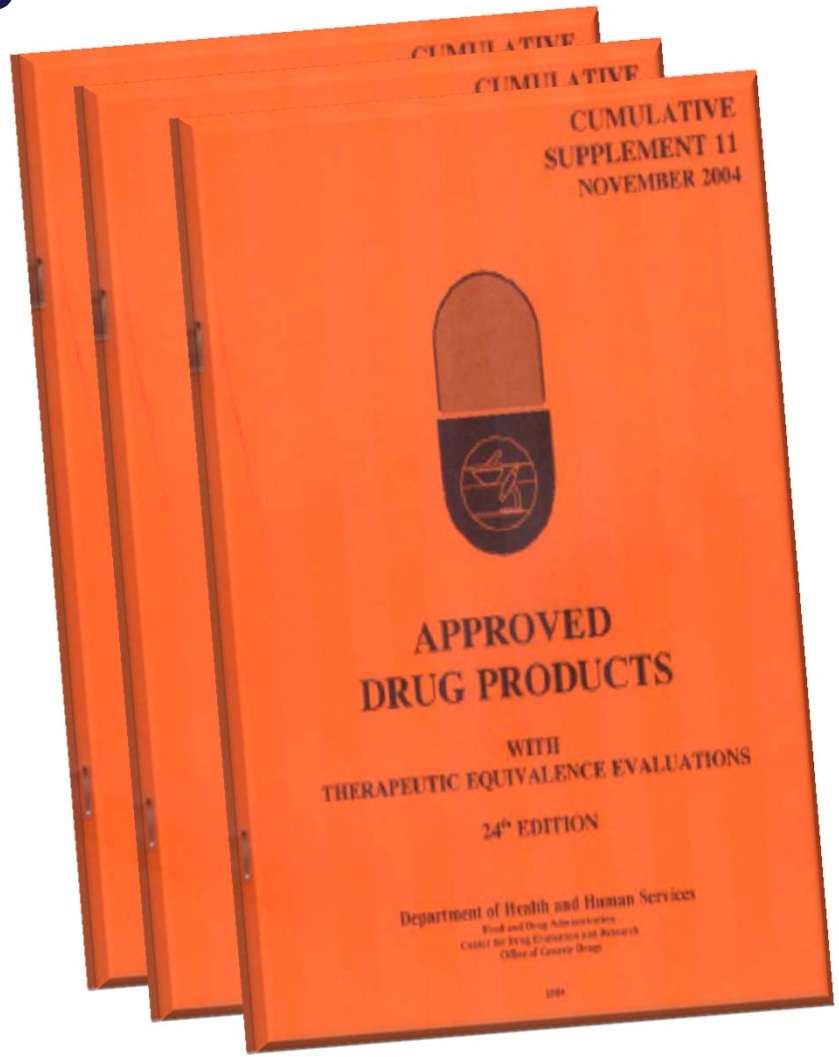
Industry

Healthcare Professionals

Contents of the Orange Book

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

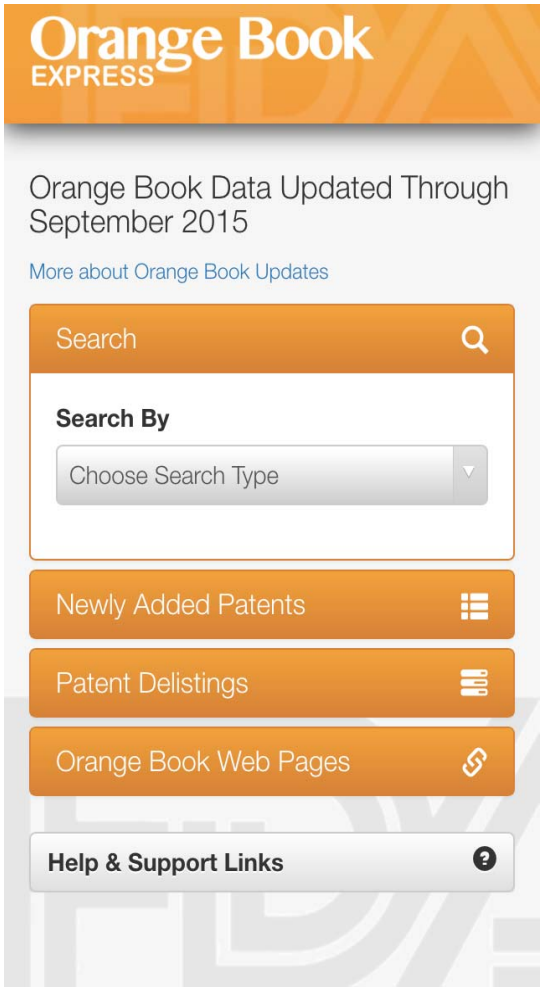
Orange Book: Available Formats



Orange Book: Available Formats

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

Orange Book: Available Formats

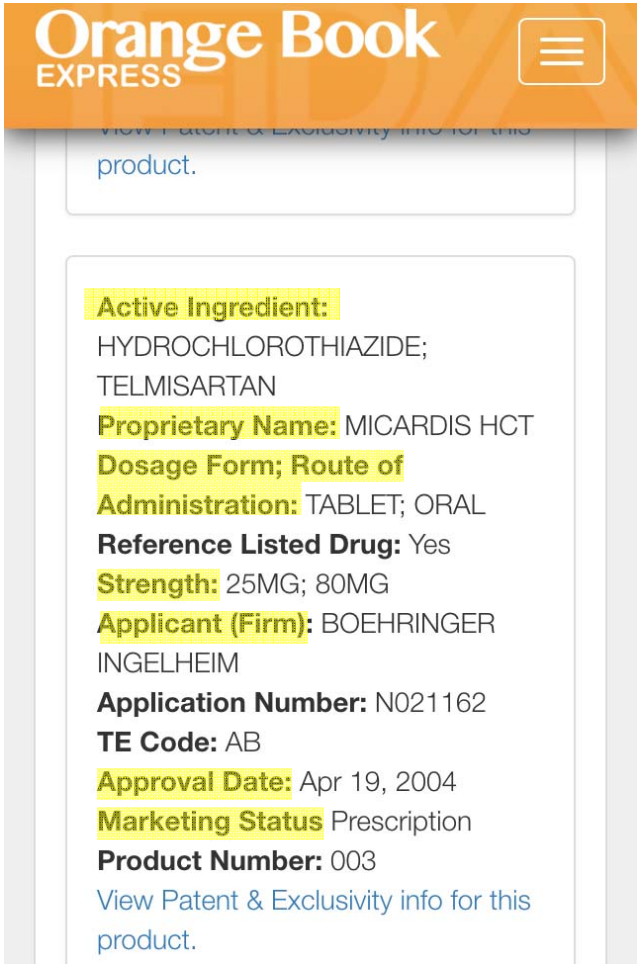


Updates to the Orange Book

- 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

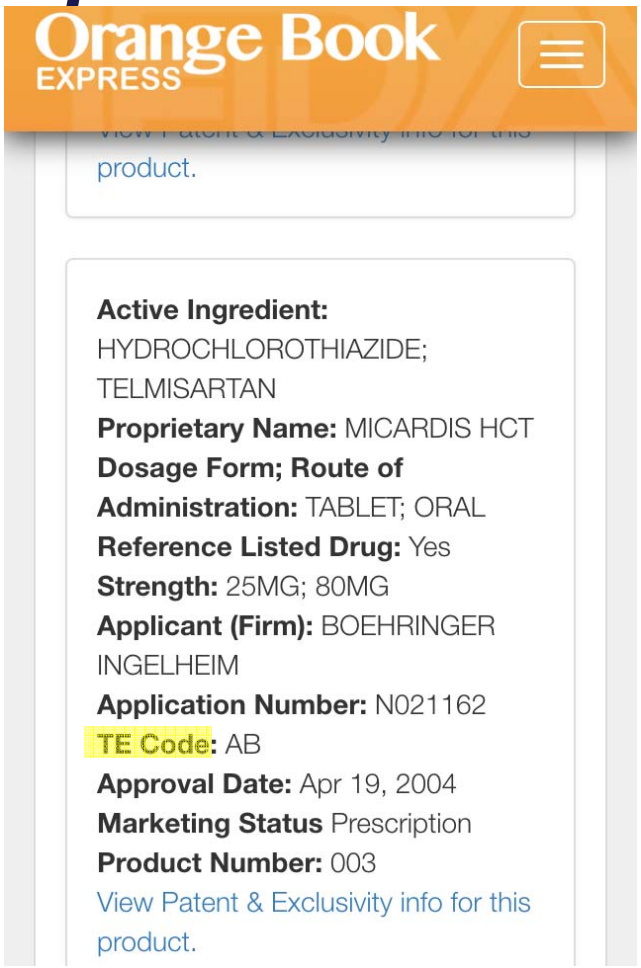
Drug Product Listing

- 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

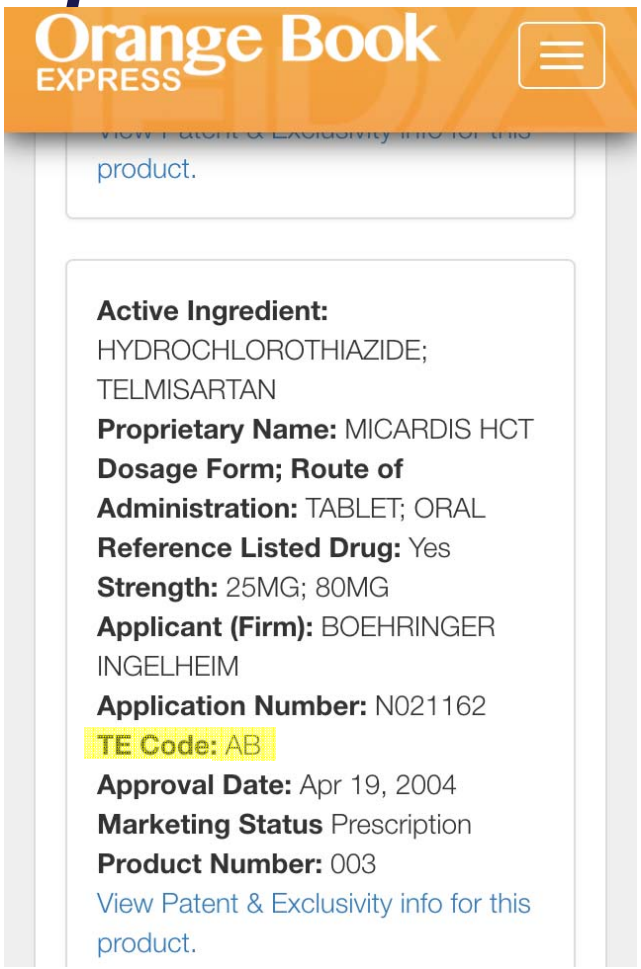


Drug Product List: Therapeutic Equivalence

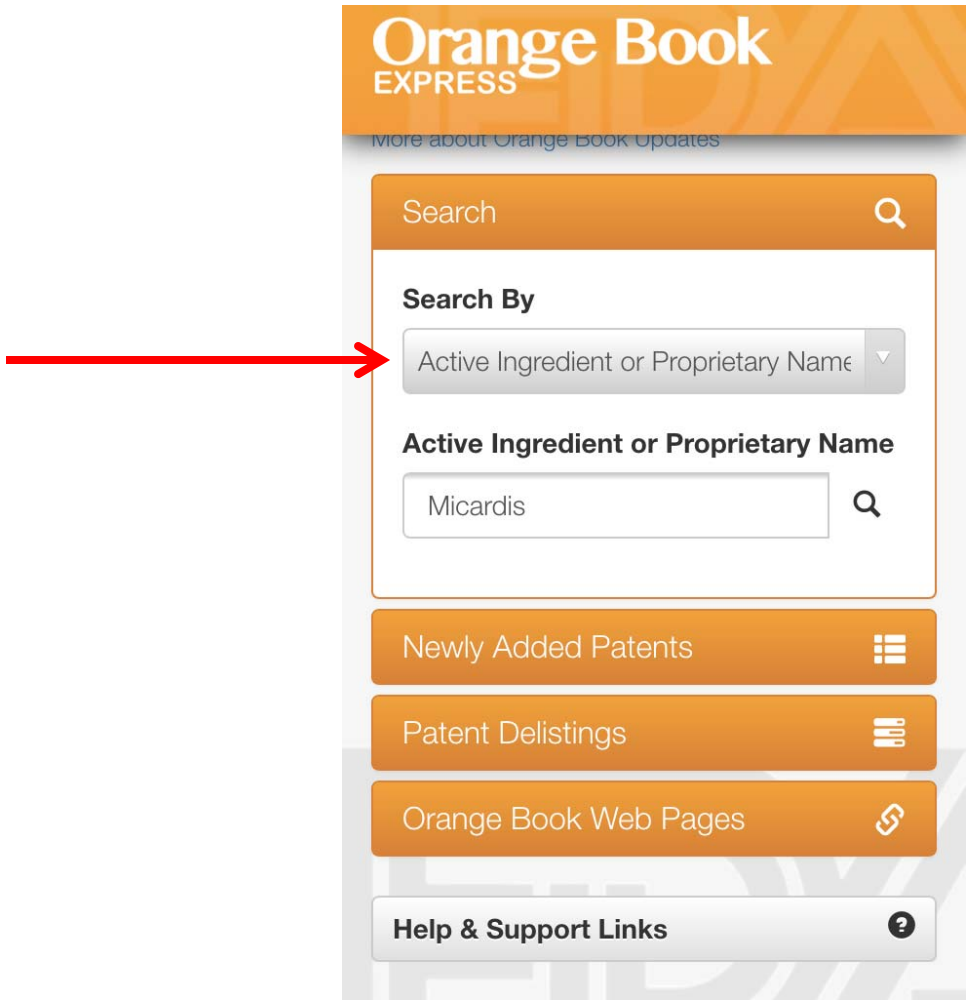
- Therapeutic Equivalence= pharmaceutically equivalent and bioequivalent for same use
- Pharmaceutically equivalent
  - **Contains the same active ingredient in the same dosage form, same strength** or **concentration and same route of administration**
- Bioequivalent – data shows the generic product 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



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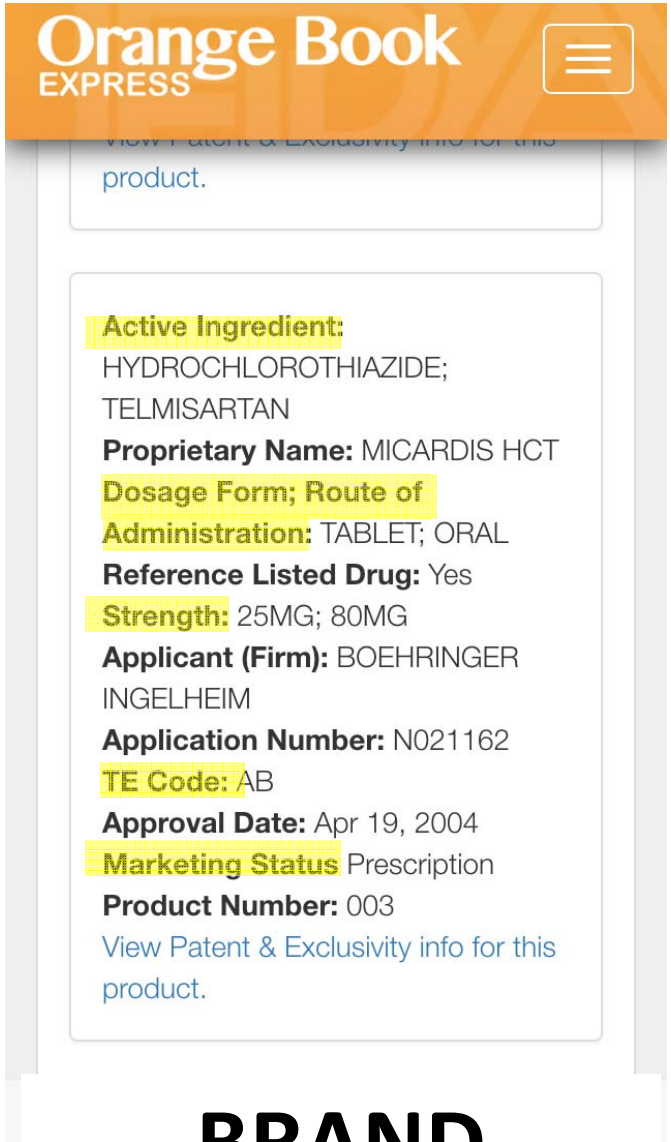
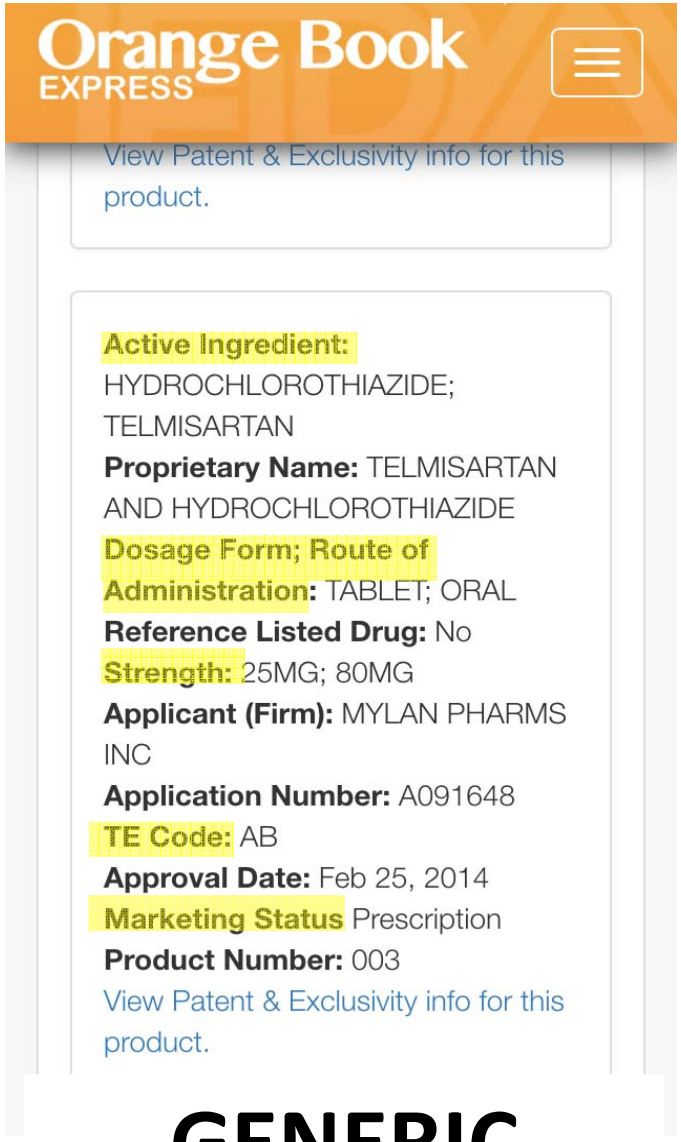


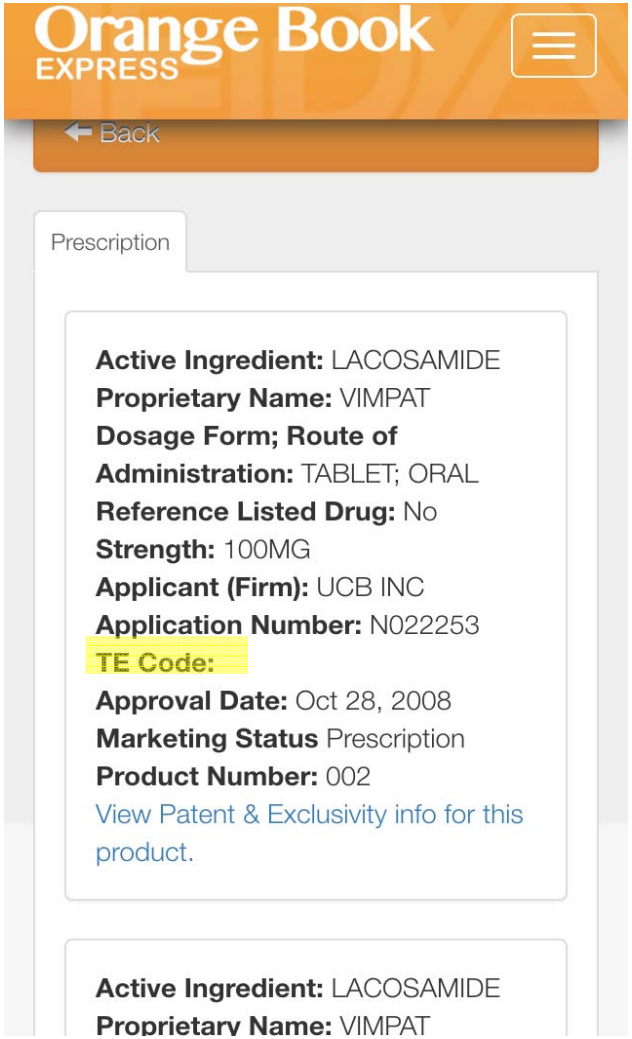
BRAND



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 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*.

Questions

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