# Generic Drugs: *Busting the Myths*


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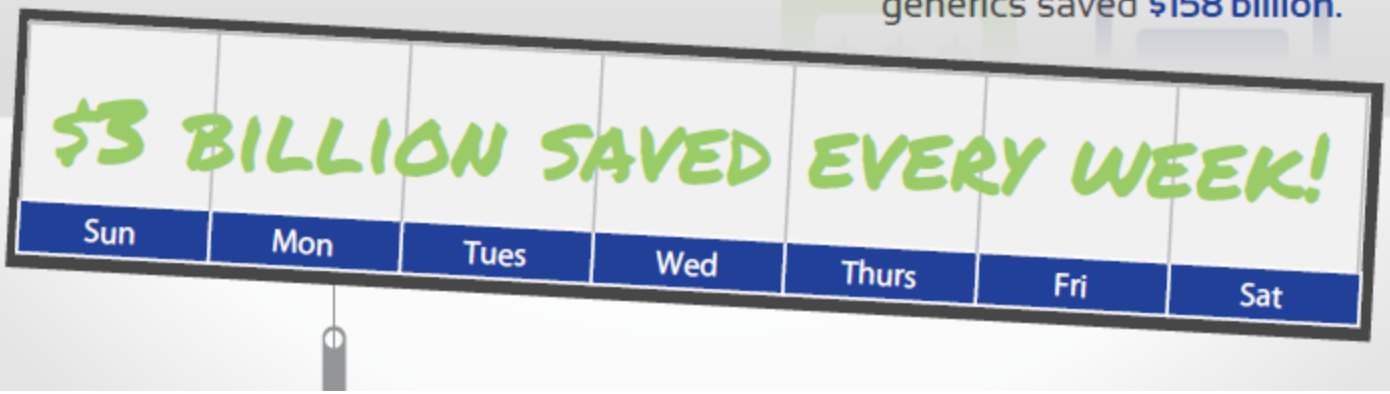
# FACTS ABOUT GENERIC DRUGS

## 80-85% LESS

Average cost of a generic drug vs. its brand-name counterpart


**In 2010 alone**, the use of FDA-approved generics saved **$158 billion.**



# FACTS ABOUT GENERIC DRUGS

Today, nearly **8 in 10** prescriptions filled in the U.S. are for generic drugs.

# FACTS ABOUT GENERIC DRUGS

- FDA requires generic drugs to have the **same active ingredient**, **strength**, **dosage form**, and **route of administration** as the brand-name drug.
- The generic manufacturer **must prove its drug is the same** (bioequivalent) as the brand-name drug.
- All manufacturing, packaging, and testing sites **must pass the same quality standards** as those of brand-name drugs.
- Many generic drugs are made in the same manufacturing plants as the brand-name drugs.

# FACTS ABOUT GENERIC DRUGS

## FDA MONITORS ADVERSE EVENTS REPORTS FOR GENERIC DRUGS.

The monitoring of adverse events for all drug products, including generic drugs, is one aspect of the overall FDA effort to evaluate the safety of drugs after approval. Many times, reports of adverse events describe a known reaction to the active drug ingredient.

Reports are monitored and investigated, when appropriate. Investigations may lead to changes in how a product is used or manufactured.

**Date:**
May 20, 2016

**Time:**
9:00 a.m. to 5:00 p.m.



**Generic Drug User Fee Amendments of 2012**

- Backlog Fee
- Facility Fees
- Drug Master File Fee
- Abbreviated New Drug Application (ANDA) and Prior Approval Supplement (PAS) Fees
- Generic Drug User Fee Cover Sheet and Payment Information
- Other Fee Related Questions

# FY 2016 Regulatory Science Initiatives Part 15 Public Meeting



The Food and Drug Administration (FDA or the Agency) will hold a public meeting that will provide an overview of the current status of the regulatory science initiatives for generic drugs and will provide an opportunity for public input on research priorities in these topic areas. FDA is seeking input from a variety of stakeholders—industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2012 (GDUFA) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public meeting into account in developing the fiscal year (FY) 2017 Regulatory Science Plan.

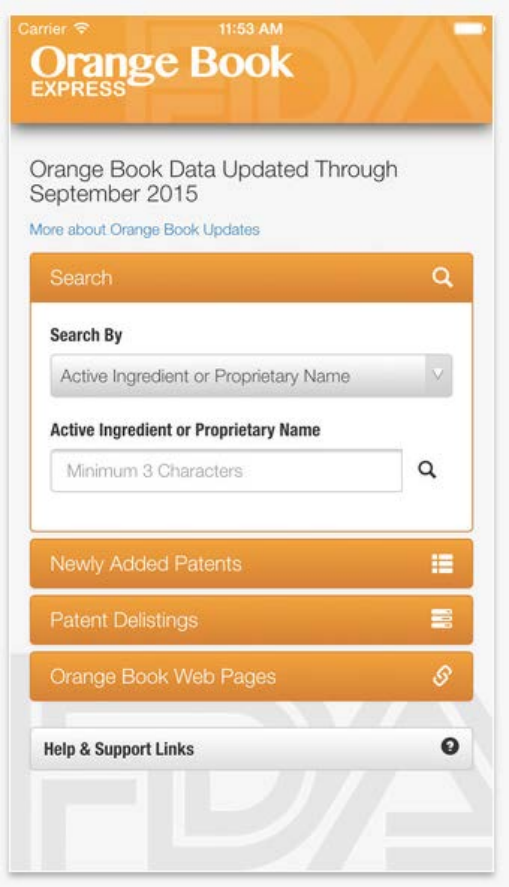
FDA wants your input as we develop an annual list of regulatory science initiatives specific to generic drugs. We will take the information from the public meeting into account in developing the FY 2017 Regulatory Science Plan.

# GDUFA Regulatory Science Priorities for Fiscal Year 2016

In the Generic Drug User Fee Amendments (GDUFA) of 2012, FDA committed to prepare a yearly list of regulatory science priorities for generic drugs based on input from industry and other stakeholders. To comply with this GDUFA requirement, the FDA Office of Generic Drugs developed the following fiscal year (FY) 2016 regulatory science priorities for generic drugs:

- **Post-market evaluation of generic drugs**
- **Equivalence of complex products**
- **Equivalence of locally-acting products**
- **Therapeutic equivalence evaluation and standards**
- **Computational and analytical tools**

# Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)




The publication ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (the List, commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act). (For more information, see the Orange Book Preface.)

Orange Book EXPRESS

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**

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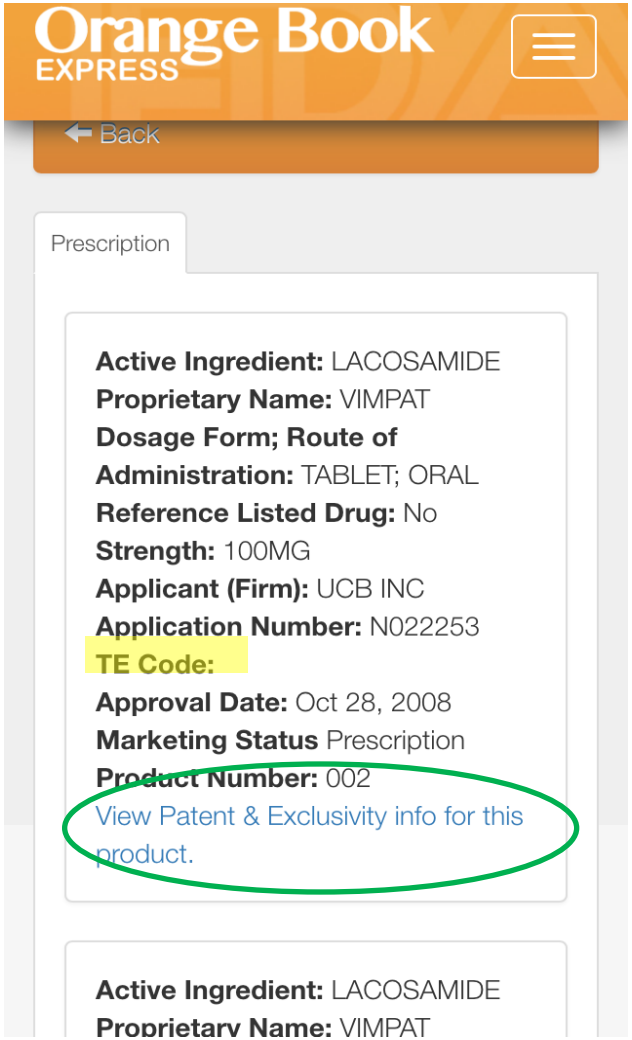
View Patent & Exclusivity info for this product.

**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



# Generic Drug User Fee Amendments of 2012



**Latest News:**

- Overview of the Generic Drug User Fee Amendments of 2012 (GDUFA)
- GDUFA Self-Identification (SPL) Submission – Part 1
- GDUFA Self-Identification (SPL) Submission – Part 2

**GDUFA, an historic first: Providing user fees for FDA to ensure timely review of applications for generic drugs**

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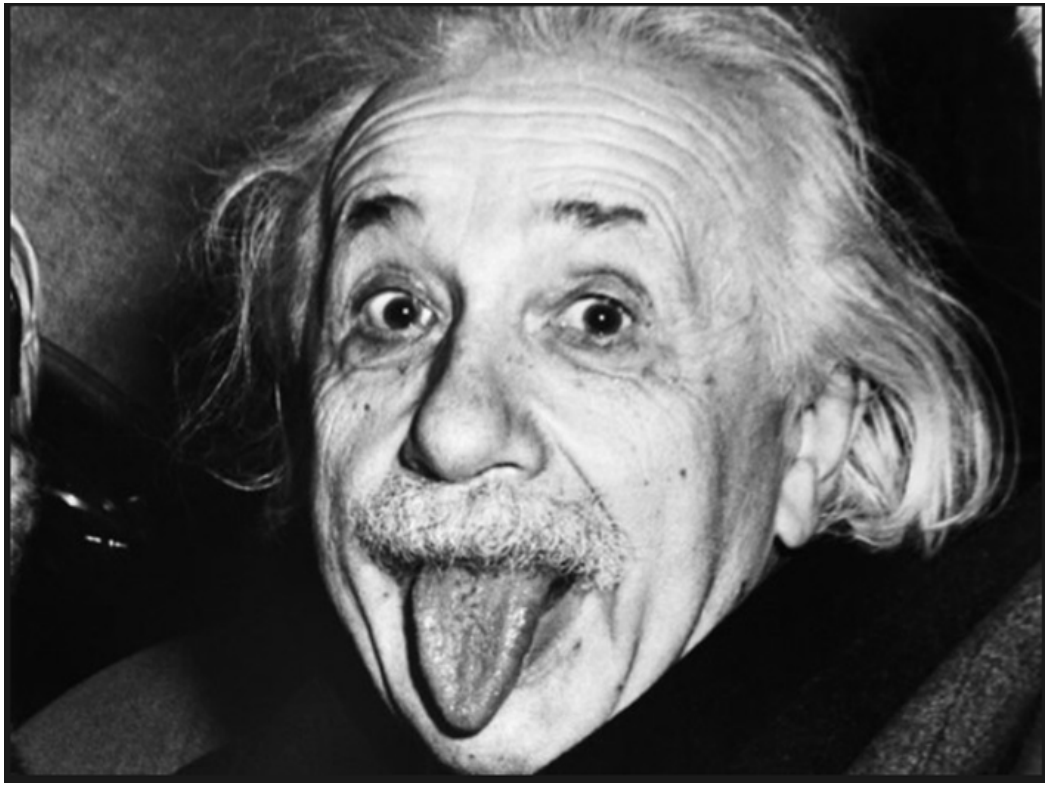
# Questions?



# Challenge Question:

- Who determines <u>when</u> a generic drug may be approved?