The ABCs of OTCs

Little-Known Facts About Over-the-Counter Drugs

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Little-Known Fact?

There are over 100,000 marketed over-the-counter drug products.

Little-Known Fact?

OTC drugs save billions of dollars in healthcare costs every year.

Little-Known Fact?

The bill that “created” the class of over-the-counter drugs was sponsored by two Senators who were also pharmacists.

Bonus if you know the name of either Senator!

This Week In FDA History - Oct. 26, 1951

Photo courtesy of Kremers Reference Files University of Wisconsin

Former vice president and senator Hubert H. Humphrey Jr., who was a pharmacist in South Dakota before beginning his political career, co-sponsored the 1951 Durham-Humphrey Amendment.

October 26, 1951: The Durham-Humphrey Amendment is passed. The bill requires any drug that is habit-forming or potentially harmful to be dispensed under the supervision of a health practitioner as a prescription drug and must carry the statement, "Caution: Federal law prohibits dispensing without prescription."

Durham-Humphrey Amendment (1951)

Establishment of Two Drug Classes

- Rx legend (prescription)
  - Requires practitioner supervision, because of the drug's toxicity or potentiality for harmful effect, or method of use
  - Labeling indicates that it is by prescription-only
- OTC (nonprescription)
  - Drugs that do not meet the definition for an Rx drug

Little-Known Fact?

Technically, all drugs are OTC

unless they are specifically determined to be prescription (not the other way around).

General Characteristics of OTC Drugs

- Safe (acceptable safety margin) and efficacious
- Low misuse and abuse potential
- Condition to be treated is self-diagnosable
- Does not require a health care practitioner for safe and appropriate use
- Adequate labeling so that consumers can
  - Self-diagnose
  - Self-select
  - Self-administer
  - Know when to stop using

Little-Known Fact?

For some products, you might be surprised to learn they are considered drugs.


SUN
SCREEN
SPF
10
SUN PROTECTION CREAM
SUN
SCREEN
SPF
30
SUN PROTECTION LOTION


#1 BRAND in HOSPITALS
Purell
ADVANCED
HAND SANITIZER
KILLS THE MOST GERMS
REFRESHING GEL
Kills More Than 99.99% of Germs
Leaves Hands Feeling Soft
8 FL OZ (236 mL)

Definition of a Drug

A substance intended for use in the

- diagnosis,
- cure,
- mitigation,
- treatment, or
- prevention

of disease.


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Little-Known Fact?

Everything a consumer needs to know about how to use an OTC drug safely and effectively (and without any help from a healthcare provider) has to fit into a pretty small space.

OTC Labeling: "Drug Facts" (21 CFR 201.66)

Drug Facts

Active ingredient(s) ***Purpose***

.....

Use(s)

Warnings

Do not use

Ask a doctor before use if you have

Ask a doctor or pharmacist before use if you are

When using this product

Stop use and ask a doctor if

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

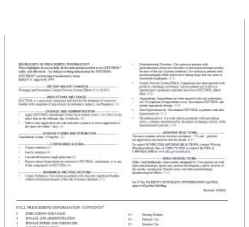
Directions

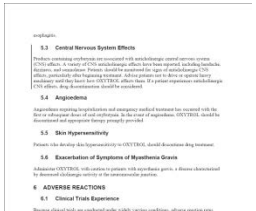
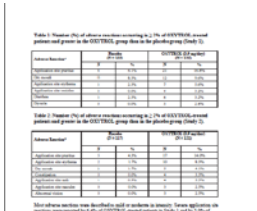
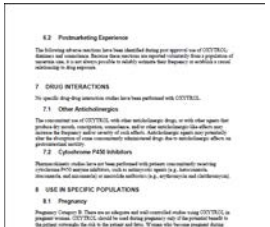
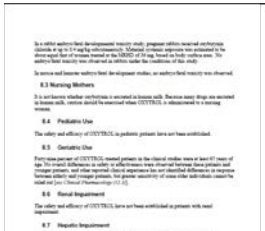
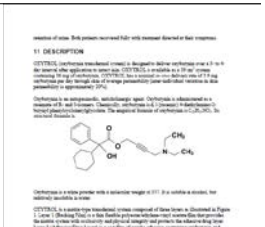
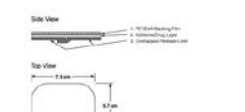
Other information

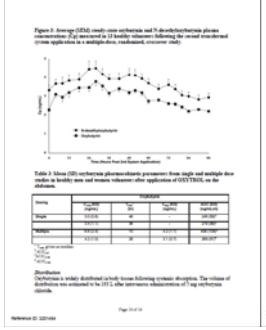
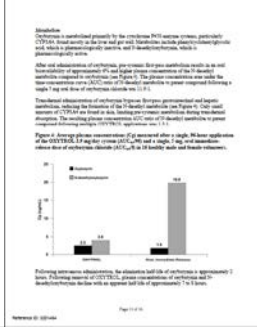
Inactive ingredients

Questions or comments?

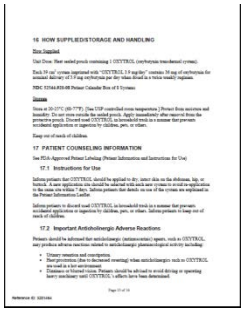
Rx Full Prescribing Information







Little-Known Fact?

OTC drugs are regulated in two different ways, one of which surprises many people.

Regulatory Pathways for OTC Drugs

NDA or Monograph

Types of OTC New Drug Applications (NDAs)

- Sponsors submit applications, and they must be approved before the product can be marketed (also true for prescription drugs)
- Rx-to-OTC Switch
  - full switch
  - partial switch
- Direct-to-OTC

Partial Rx-to-OTC Switch

- Topical antifungals for athlete's foot, ringworm, and jock itch (treatment of Tinea versicolor remains Rx indication)
- Proton pump inhibitors for heartburn (treatment of ulcers, erosive esophagitis remain Rx)
- Second-generation antihistamines (e.g. Claritin® or loratidine) for hay fever or other upper respiratory allergies (chronic idiopathic urticaria remains Rx)
- Flonase® (fluticasone), also for hay fever or other upper respiratory allergies (non-allergic rhinitis remains Rx)

Full Rx-to-OTC Switch

- Miralax® (polyethylene glycol)
- Rhinocort® Allergy Spray (budesonide)
- Nasacort® Allergy 24 HR (triamcinolone)

Direct-to-OTC

Ecamsule-containing sunscreens
(reduce UVA exposure)

Little-Known Fact?

There are special consumer studies that are sometimes done for OTC drugs, but not for prescription drugs.

OTC Consumer Studies

- In addition to safety/efficacy study requirements
- Assess consumer's ability to use safely and appropriately (without a health care provider)
- Types of Studies:
  - Label comprehension studies
  - Self-selection studies
  - Human factors studies
  - Actual use studies

OTC Drug Review ("The Monograph")

- 1962: law that required drugs to demonstrate effectiveness; resulted in the NDA system
- Big problem: over 100,000 OTC drug products
- Couldn't take them all off the market, and couldn't possibly review 100,000 NDAs
- 1972: set up expert panels to review OTC drug ingredients, by therapeutic category

Examples of OTC Drug Categories

- Antacids
- Antidiarrheal products
- Antiemetics
- Antiperspirants
- Cough and cold products
- Wart removers
- Sleep aids
- Ophthalmic products
- Hemorrhoidal products
- Dandruff products
- Anticaries products
- Otic products
- Analgesics

What is an OTC Drug Monograph?

- A sort of “recipe book” for marketing requirements for an OTC drug
- A list and explanation of GRASE conditions

  GRASE = Generally Recognized As Safe and Effective
- If a sponsor follows the “recipe book” exactly, it can market a monograph drug without coming to FDA for approval every time
- The expert panels finished some monographs, but not all
- Final monographs are published in the

  Code of Federal Regulations: 21 CFR parts 331-358
- Drug products that don’t meet the conditions of the monograph can apply for approval under the NDA system

Public "Notice-and-Comment" Rulemaking Process: 3 Steps

Each step is published in the Federal Register

Comment

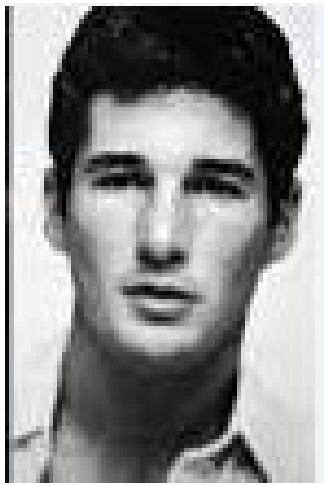
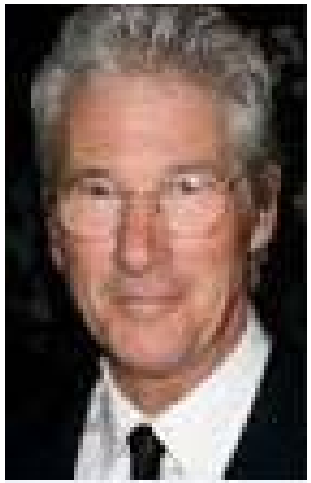
Comment

1. Advance Notice of Proposed Rulemaking

2. Tentative Final Monograph

3. Final Monograph

Rulemaking takes time

OTC Drug Regulatory Pathways

New Drug Application

- Product specific (including formulation)
- Confidential filing
- Clinical development required
- Application submitted for approval
- Application fees (PDUFA)
- Adverse event reporting requirements
- Comply with good manufacturing practices

Monograph Process

- Ingredient and category specific regulations (CFR 330-358)
- Public process - No data confidentiality
- Clinical development not required
- May rely on existing data
- No user fees
- Limited reporting requirements (serious adverse events only)
- Comply with good manufacturing practices

Pathways to Market OTC Drugs

NDA or Monograph?

NDA or Monograph?

Pathways to Market OTC Drugs

New Drug Application (NDA)

OTC Drug Monograph

Little-Known Fact?

The Federal Trade Commission (not the FDA) regulates OTC drug advertising.

FDA regulates prescription drug advertising.

The Future of OTC Drugs?

- More Rx-to-OTC switches, some for new therapeutic areas
- Harnessing technology to allow more drugs to be available over-the-counter?:
  The Nonprescription Safe Use Regulatory Expansion (NSURE)
- Reform of the monograph regulatory system?

OTC Drug Contact Information

General Information:

Division of Drug Information

druginfo@fda.hhs.gov

855-543-3784

Report Adverse Events:

MedWatch

http://www.fda.gov/Safety/MedWatch/