A Brief History of the Drug Facts Label for Nonprescription Drugs

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-National Library of Medicine

Before the FDA

Pure Food and Drugs Act of 1906 (the Wiley Act)

False and Misleading Information

1) "Misbranded," as used herein, shall apply to all drugs**,….the package or label** of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which **shall be false or misleading in any particular (False Claims)**

2) If it be an imitation of or offered for sale under the name of another article. **(Counterfeit or "falsified" medicine through labeling)**

3) If the contents of the package as originally put up shall have been removed, in whole or in part, and **other contents shall have been placed in such package** **(Counterfeit of "falsified" medicine through adulteration/tampering)**

4) if the package fail to bear a statement on the label of **the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide**, or any derivative or preparation of any such substances contained therein. **(the product is intoxicating without informing the patient or consumer-material facts are omitted)**

-National Library of Medicine

Elixir Sulfanilimide Disaster

- Famously, Elixir sulfanilimide, which was responsible for at least 100 deaths was recalled and seized due to the presence of diethylene glycol, a solvent which the manufacturer had not tested prior to use.
- The product was misbranded because it contained no alcohol, as required for an “elixir”.
- However, despite the damage done, the company responsible was only required to pay a small fine.
- Even this fine would not have been required had the product been labeled “solution”

The Federal Food Drug and Cosmetic Act of 1938

- This Law added expanded the definitions for Misbranding to include:

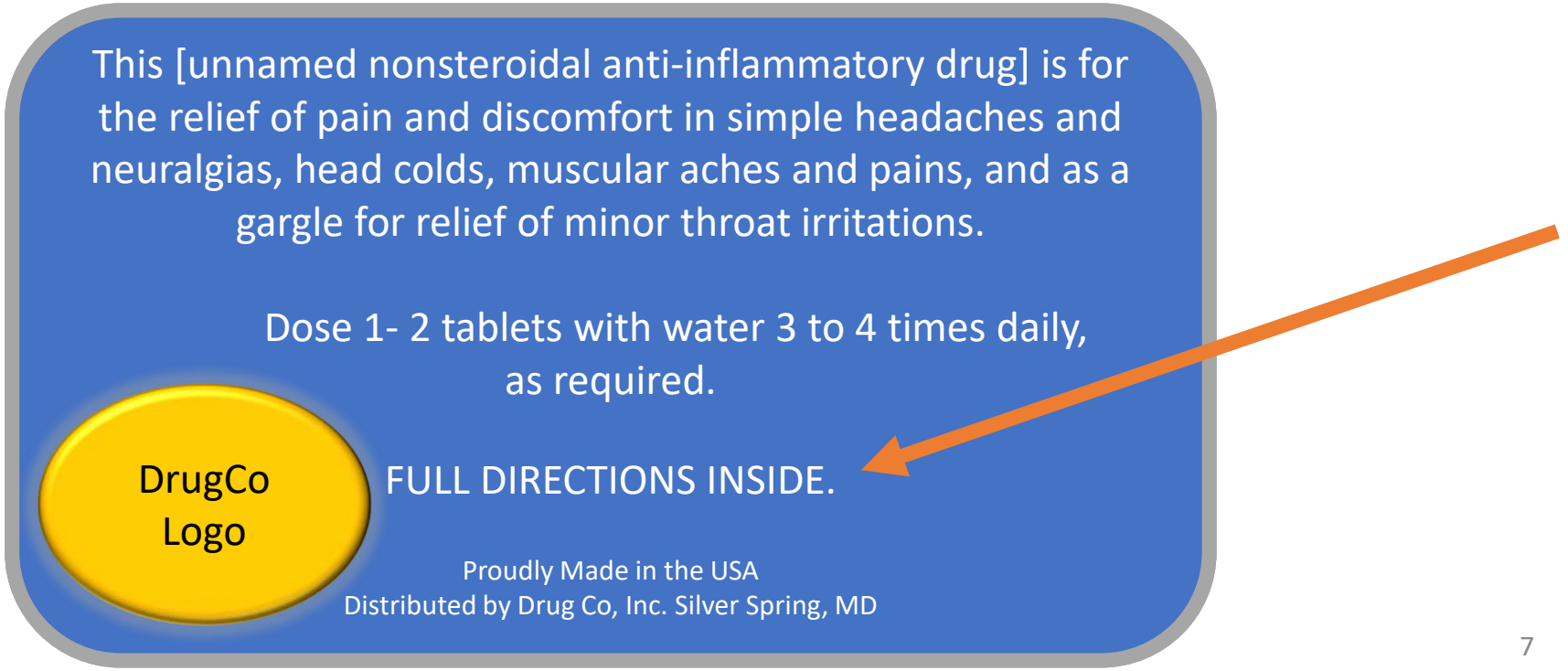
If any word, statement, or other **information required** by or under authority of this chapter to appear on the **label** **or** **labeling** is not prominently **placed** thereon with such **conspicuousness** and in such terms as to render it likely to be read and understood by the ordinary individual **under customary conditions of purchase and use**

If its label does not provide "adequate directions for use **and** such adequate **warnings** against use in those pathological conditions or by children where its use may be **dangerous to health**, or against **unsafe dosage or methods or duration** of administration or application, in such manner and form, as are necessary for the **protection of users"**

"If it is **dangerous to health when used** in the dosage or manner; or with the frequency or duration prescribed, recommended, or **suggested in the labeling** thereof."

1951 Durham-Humphrey Amendments

- Created two classes of drugs. Those Available only with a prescription (Rx Only). And those whose packaging could not suggest the need for prescription (OTC or nonprescription).



Recognizing the Need for Better Way

- 1962 Kefauver Harris Amendments required drugs to demonstrate effectiveness; resulted in the modern NDA system

- Monograph Drugs 1972 and later

- FDA began to propose certain warnings for classes of drug products.

  For example, 21 CFR § 331.30(b)(2) for antacids requires the labeling for certain ingredients to contain a warning "May cause constipation.“

  There was NOT a specific requirement that warnings be visible prior to purchase.

- As a result, labels could still be crowded with promotional material or have information not relevant to safe use of the drug mixed within the directions and warnings.

Recognizing the Need for Better Way

- the Nutrition Labeling and Education Act of 1990 (NLEA)

Dual Columns, Two Forms of the Same Food

Nutrition Facts

12 servings per container

Serving size **1/4 cup dry mix (44g)**

	Per 1/4 cup dry mix		Per baked portion	
Calories	**170**		**300**	
		% DV*		% DV*
Total Fat	1.5g	**2%**	16g	**21%**
Saturated Fat	1g	**5%**	5g	**25%**
Trans Fat	0g		0g	
Cholesterol	0mg	**0%**	60mg	**20%**
Sodium	300mg	**13%**	375mg	**16%**
Total Carb.	36g	**13%**	36g	**13%**
Dietary Fiber	<1g	**2%**	<1g	**2%**
Total Sugars	18g		18g	
Incl. Added Sugars	18g	**36%**	18g	**36%**
Protein	2g		3g	
Vitamin D	0mcg	0%	0mcg	0%
Calcium	100mg	8%	100mg	8%
Iron	1mg	6%	1mg	6%
Potassium	40mg	0%	40mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

-21 CFR 101

Proposals and Discussion

- In the Federal Register of February 27, 1997 (62 FR 9024), FDA proposed to establish a standardized format for the labeling of OTC drug products that included:

  (1) specific headings and subheadings presented in a standardized order

  (2) standardized graphical features such as Helvetica type style and the use of ‘‘bullet points’’ to introduce key information

  (3) minimum standards for type size and spacing.

The Drug Facts Rule

- On March 17, 1999, FDA published a final rule (64 FR 13286) that standardizes format and content requirements for the labeling of OTC drug products. This Drug Facts Rule is codified at (21 CFR §201.66).
- Section 201.66(a) states that the content and format requirements within it apply to the labeling of **ALL** OTC drug products.
- This includes products marketed under a final OTC drug monograph, products marketed under an approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) under [section 505] of the Act, and products for which there is no final OTC drug monograph or approved NDA/ANDA.

Drug Facts

Active Ingredient (in each [insert dosage form]) ***Purpose***

XXXXXXXXXX [XX] g XXXXXXXXXXXXXX

Use(s)

XXXXXXXXXXXXX

Warnings

Do not use

- XXXXXXXXXX

Ask a doctor before use if you have

- XXXXXXXXXX

Ask a doctor or pharmacist before use if you are

- XXXXXXXXXX

When using this product

- XXXXXXXXXX

Stop use and ask a doctor if

- XXXXXXXXXX
- XXXXXXXXXX

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.

Drug Facts (continued)

Directions

- XXXXXXXXXX
- XXXXXXXXXX
- XXXXXXXXXX

Other information

XXXXXXXXXX

Inactive ingredients

XXXXXXXXXX

Questions or Comments?

XXXXXXXXXX

-Thanks to Barbara Ohiaeri

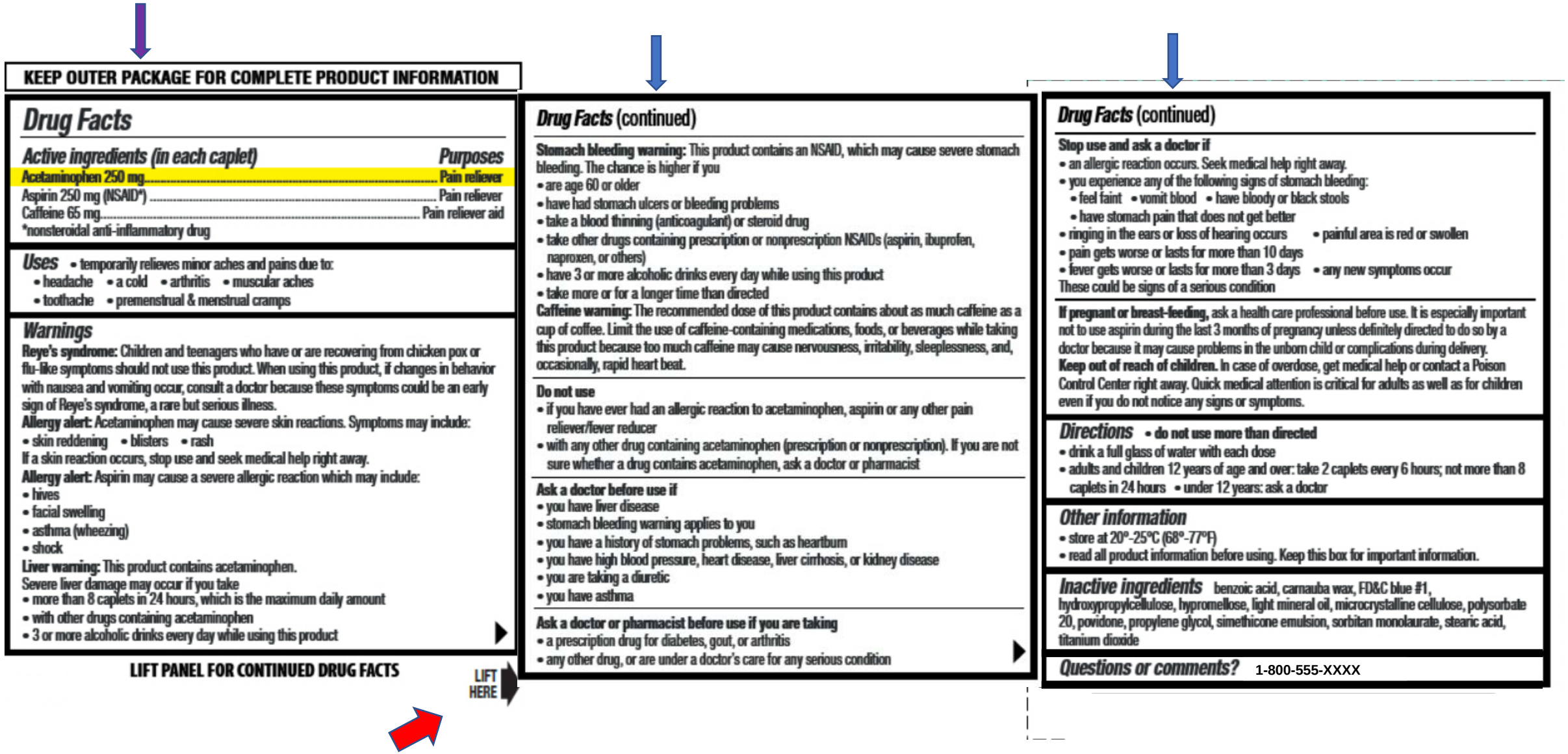
What Has Worked?

- Consumers can make informed purchase choices before taking the product home
- Most serious warnings are presented first and multiple label comprehension studies show this is helpful in conveying the most important safety messages to consumers.
- Many consumers know directly where to look for information relevant to their individual health situation
- Standardization of the format of the drug facts has permitted ease of understanding for physicians and pharmacists advising consumers on their self-treatment choices.

Incremental Changes

- **In 2000, certain changes in formatting were allowed to accommodate stronger warnings (201.66(d)(3))**
- **2000, a Flammability warning was required when appropriate (201.66(c)(5)(ii)(C))**
- **2004, information about cation content (Na+, Ca+, Mg+, K+) were added (201.66(c)(7)(i))**
- **2007, a sexual transmitted disease warning was added (201.66(c)(5)(ii)(H))**
- **2008, an FDA contact number for Adverse Event reporting was added (201.66(c)(5)(vii))**
- **2009, modified warnings for stomach bleeding risk to NSAIDs and liver warnings to acetaminophen products (201.66(c)(5)(ii)(E))**
- **2011 a requirement for Asthma and Allergy alert warnings were added (201.66(c)(5)(ii)(B))**

What Hasn't Worked?



KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredients (in each caplet)	Purposes
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID*)	Pain reliever
Caffeine 65 mg	Pain reliever aid

*nonsteroidal anti-inflammatory drug

Uses • temporarily relieves minor aches and pains due to:
• headache • a cold • arthritis • muscular aches
• toothache • premenstrual & menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
• skin reddening • blisters • rash
If a skin reaction occurs, stop use and seek medical help right away.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:
• hives
• facial swelling
• asthma (wheezing)
• shock

Liver warning: This product contains acetaminophen.
Severe liver damage may occur if you take
• more than 8 caplets in 24 hours, which is the maximum daily amount
• with other drugs containing acetaminophen
• 3 or more alcoholic drinks every day while using this product

LIFT PANEL FOR CONTINUED DRUG FACTS

LIFT HERE

Drug Facts (continued)

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you
• are age 60 or older
• have had stomach ulcers or bleeding problems
• take a blood thinning (anticoagulant) or steroid drug
• take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
• have 3 or more alcoholic drinks every day while using this product
• take more or for a longer time than directed

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

Do not use
• if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

Ask a doctor before use if
• you have liver disease
• stomach bleeding warning applies to you
• you have a history of stomach problems, such as heartburn
• you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
• you are taking a diuretic
• you have asthma

Ask a doctor or pharmacist before use if you are taking
• a prescription drug for diabetes, gout, or arthritis
• any other drug, or are under a doctor's care for any serious condition

Drug Facts (continued)

Stop use and ask a doctor if
• an allergic reaction occurs. Seek medical help right away.
• you experience any of the following signs of stomach bleeding:
• feel faint • vomit blood • have bloody or black stools
• have stomach pain that does not get better
• ringing in the ears or loss of hearing occurs • painful area is red or swollen
• pain gets worse or lasts for more than 10 days
• fever gets worse or lasts for more than 3 days • any new symptoms occur
These could be signs of a serious condition

If pregnant or breast-feeding, ask a health care professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions • **do not use more than directed**
• drink a full glass of water with each dose
• adults and children 12 years of age and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours • under 12 years: ask a doctor

Other information
• store at 20°-25°C (68°-77°F)
• read all product information before using. Keep this box for important information.

Inactive ingredients benzoic acid, carnauba wax, FD&C blue #1, hydroxypropylcellulose, hypromellose, light mineral oil, microcrystalline cellulose, polysorbate 20, povidone, propylene glycol, simethicone emulsion, sorbitan monolaurate, stearic acid, titanium dioxide

Questions or comments? 1-800-555-XXXX

Other things to Consider?

All DFL's are currently in print format

Use of New Media, including:

-E-commerce sites where the product is sold without providing consumer access to the DFL

-New technologies (smart phones, social media, etc.) provide new ways of obtaining information and education

The Future

-This Workshop is the beginning of the future of the DFL

Thank You!