

The Nonprescription Drug Facts Label in a Changing Consumer Marketplace 2021

Overview of the Drug Facts Labeling (DFL) Regulatory Requirements

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DFL Scope

- Covers all OTC drug products
- Provides for standardized content and format requirements for the labeling of OTC drug products
- Divided into two main parts: 1) content requirements in paragraph (c) (i.e., headings, subheadings, and the order in which certain information must be listed); and format requirements in paragraph (d)

Where Must the DFL Appear?

- Outside container or wrapper of retail package
- BUT *must* appear on the immediate container if there is no outside container or wrapper

Content Requirements 21 CFR 201.66 (c)



Includes 9 main topical content headings

- Drug Facts Title
- Active ingredient(s)
- Purpose(s)
- Use(s)
- Warnings
- Directions
- Other information
- Inactive ingredients
- Questions or Comments (optional)

WHAT'S ON THE LABEL

ACTIVE INGREDIENT
Therapeutic substance in product; amount of active ingredient per unit

USES
Symptoms or diseases the product will treat or prevent

WARNINGS
When not to use the product; conditions that may require advice from a doctor before taking the product; possible interactions or side effects; when to stop taking the product and when to contact a doctor; if you are pregnant or breastfeeding, seek guidance from a health care professional; keep product out of children's reach

PURPOSE
Product action or category (such as an anti-histamine, antacid, or cough suppressant)

DIRECTIONS
Specific age categories, how much to take, how to take, and how often and how long to take

OTHER INFORMATION
How to store the product properly and required information about certain ingredients (such as the amount of calcium, potassium, or sodium the product contains)

INACTIVE INGREDIENTS
Substances such as colors or flavors

Drug Facts	
Active ingredient (in each tablet) Chlorpheniramine maleate 4 mg	Purpose Antihistamine
Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: sneezing, runny nose, itchy, watery eyes, itchy throat	
Warnings Ask a doctor before use if you have: • Glaucoma • A breathing problem such as emphysema or chronic bronchitis • Trouble swallowing due to an enlarged prostate gland Ask a doctor or pharmacist before use if you are taking benzodiazepines or sedatives. When using this product: • Do not drink alcohol. • Do not take alcohol, sedatives, and tranquilizers as they may increase drowsiness. • Be careful when driving a motor vehicle or operating machinery. • Sedability may occur, especially in children. 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 Adults and children 12 years and over: take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours. Children 6 years to under 12 years: take 1/2 tablet every 4 to 6 hours; not more than 3 tablets in 24 hours. Children under 6 years: ask a doctor.	
Other information Store at 20-25°C (68-77°F). Protect from excessive moisture. Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch	

Drug Facts Title

21 CFR 201.66(c)(1)

- “*Drug Facts*” is the title.
- If the Drug Facts labeling appears on more than one panel or side of the labeling, the title “Drug Facts” must appear at the top of each subsequent content bearing panel.

Active ingredient(s)

21 CFR 201.66(c)(2)



- “***Active ingredient***” or “***Active ingredients***” “(***in each*** [insert the dosage unit stated in the directions for use (e.g., tablet, 5 mL teaspoonful) or in each gram of a topical antimicrobial drug product
- Followed by the established name of each active ingredient
- Quantity of each active ingredient per dosage unit
- Products marketed without discrete dosage units (e.g., topicals) state the proportion (rather than the quantity) of each active ingredient unless otherwise provided in an applicable OTC drug monograph or approved drug application

Purpose(s)

21 CFR 201.66(c)(3)

“Purpose” or ***“Purposes”***, followed by the drug’s

- General pharmacological category(ies) or
- Principal intended action(s)
- Where the drug consists of more than one active ingredient, the general pharmacological categories or the principal intended actions of each active ingredient
- When an OTC drug monograph contains a statement of identity, the pharmacological action described in the statement of identity shall also be stated as the purpose of the active ingredient

Use(s)

21 CFR 201.66(c)(4)

“Use” or ***“Uses”***, followed by the indication(s) for the specific drug product

Warning(s)

21 CFR 201.66(c)(5)

- “**Warning**” or “**Warnings**” heading is followed by one or more warnings, if applicable which may include
- (i) “For external use only” [in bold type] for topical drug products not intended for ingestion, or “For” (select one of the following, as appropriate: “rectal” or “vaginal”) “use only” [in bold type]



Warning(s)

21 CFR 201.66(c)(5)(ii)

(ii) All applicable warnings listed in paragraphs (c)(5)(ii)(A) through (c)(5)(ii)(G) of this section with the appropriate subheadings highlighted in bold type:

- (A) **Reye's syndrome warning for drug products containing salicylates**
- (B) **Allergic reaction and asthma alert warnings**

Warning(s)



21 CFR 201.66(c)(5)(ii) continued

- (C) Flammability warning
- (D) Choking warning
- (E) Liver and stomach bleeding warnings
- (F) Sore throat warning
- (G) Dosage warning on sodium phosphates products
- (H) Sexually transmitted diseases(STDs) warning for vaginal contraceptive and spermicide drug products containing nonoxynol 9

Warning(s)



21 CFR 201.66(c)(5)(iii)

“Do not use”

- Followed by all contraindications for use with the product
- These contraindications are absolute and are intended for situations in which consumers should not use the product unless a prior diagnosis has been established by a doctor or for situations in which certain consumers should not use the product under any circumstances regardless of whether a doctor or health professional is consulted

Warning(s)

21 CFR 201.66(c)(5)(iv)

**“Ask a doctor before use if you have” or
“Ask a doctor before use if the child has”**

- States warnings for people with certain pre-existing conditions (excludes pregnancy) and all warnings for people with certain symptoms
- Warnings under this heading are intended only for situations where consumers should not use the product until a doctor is consulted

Warning(s)

21 CFR 201.66(c)(5)(v)

“Ask a doctor or pharmacist before use if you are”

or

“Ask a doctor or pharmacist before use if the child is

States all major drug-drug and drug-food interaction
warnings



Warning(s)

21 CFR 201.66(c)(5)(vi)

“When using this product”

States side effects consumers may experience, or what to avoid while using the product such as substances (e.g., alcohol) or activities (e.g., operating machinery, driving a car), & warnings about gaseous propellants



Warning(s)

21 CFR 201.66(c)(5)(vii)

“Stop use and ask a doctor if”

Followed by any signs of toxicity or other reactions
that would necessitate immediately discontinuing
use of the product

Warning(s)

21 CFR 201.66(c)(5)(viii)

Any required warnings in an applicable OTC drug monograph, other OTC drug regulations, or approved drug application that do not fit within one of the categories in (c)(5)(i) through (c)(5)(vii), (c)(5)(ix), and (c)(5)(x)

Warning(s)

21 CFR 201.66(c)(5)(ix)

- **If pregnant or breast-feeding** warning in § 201.63
- The additional warning in § 201.63(e) for aspirin or carbaspirin calcium
- The specific Pregnancy and Breast-feeding warning in approved drug applications for ketoprofen, naproxen sodium, and ibuprofen (not intended exclusively for use in children)

Warning(s)

21 CFR 201.66(c)(5)(x)

- **“Keep out of reach of children”** warning
- Accidental overdose or ingestion warnings to get medical help or contact a Poison Control Center right away

Directions

21 CFR 201.66(c)(6)

“Directions”, followed by the directions for use described in an applicable

- OTC drug monograph *or*
- Approved drug application

Other Information

21 CFR 201.66(c)(7)

- “***Other information***”, followed by additional information that is not included under paragraphs (c)(2) through (c)(6), (c)(8), and (c)(9) of this section, but which is required by or is made optional under an applicable OTC drug monograph, other OTC drug regulation, or is included in the labeling of an approved drug application.
- (i) Required information about certain ingredients in OTC drug products (e.g., sodium in §201.64(b), calcium in §201.70(b), magnesium in §201.71(b), and potassium in §201.72(b)).
- (ii) The phenylalanine/aspartame content required by §201.21(b), if applicable
- (iii) Additional information that is authorized to appear under this heading shall appear as the next item(s) of information. There is no required order for this subsequent information.

Inactive Ingredients

21 CFR 201.66(c)(8)

“Inactive ingredients”

- States the established name of each inactive ingredient
- Lists drug product’s inactive ingredients in alphabetical order

Questions? or Questions or Comments?

21 CFR 201.66(c)(9)

- “*Questions?*” or “*Questions or comments?*” is an optional heading
- Gives a telephone number [minimum 6-point bold type] of a source to answer questions about the product
- Recommends including the days of the week and times of the time when a person is available to respond to questions
- A graphic of a telephone or telephone receiver may appear before the heading

Format Requirements

21 CFR 201.66(d)

- Must be legible using any single, clear, easy-to-read type style.
- Addresses type size and style; bold type.
- Aligns using left justification; leading (space between 2 lines of text); other spacing; uppercase & lowercase letters; graphical images.
- Specifies bullets; bar lines and hairlines; hyphens.
- Modified format if small space. Use of more than one labeling panel; modified format is under (d)(10) – allowed if required elements take up more than 60% of total surface area available for labeling.

