Guidance for Industry

Labeling OTC Human Drug Products Using a Column Format

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

December 2000
OTC

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I. INTRODUCTION

This guidance is intended to assist manufacturers, packers, and distributors who wish to present labeling information for their over-the-counter (OTC) human drug products using a column format.

II. BACKGROUND

In the *Federal Register* of March 17, 1999 (64 FR 13254), the Food and Drug Administration (FDA) published a final regulation establishing standardized content and format requirements for the labeling of OTC human drug products. Standardized labeling for OTC drug products is intended to make it easier for consumers to read and understand OTC drug product labeling and use OTC drug products safely and effectively.

The new Drug Facts labeling regulation in 21 CFR 201.66 covers all OTC drug and drug-cosmetic products, whether marketed under a new drug marketing application (NDA), abbreviated new drug application (ANDA), or OTC drug monograph (or product not yet the subject of a final OTC drug monograph).

Section 201.66(d)(5) of the labeling regulation provides that the Drug Facts labeling information may appear on more than one panel on the outside container of the retail package, or on the immediate container label if there is no outside container or wrapper. When continuing the required content and format information onto multiple panels, the required order and flow of

[1] This guidance has been prepared by the Division of Over-the-Counter (OTC) Drug Products in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA).

headings, subheadings, and information must be maintained as well. The regulation also requires the use of a visual graphic (e.g., an arrow) to signal the continuation of the Drug Facts labeling to the next adjacent panel.

The Agency received a number of inquiries as to whether the required labeling information may be presented using a column format. One question is whether the required headings, subheadings, and text can be divided into columns *within* a single, defined Drug Facts box or similar enclosure (hereafter referred to together as the *Drug Facts box*), or whether such an approach would be inconsistent with the final rule. The final format for the Drug Facts box generally favors a vertical, linear presentation, to enhance readability and facilitate product comparisons. Except for the presentation of active ingredient and purpose information (see § 201.66(d)(6)) and the use of a table to present complex dosing information (see § 201.66(d)(9)), the final format does not allow required information to be separated into columns *within* a given Drug Facts box. However, the rule does allow for the use of an alternative column format that can help to maximize available labeling space and, in some instances, improve readability. Specifically, this guidance describes how more than one Drug Facts box can appear on each side of a package or a container to allow for the use of columns.

III. USING COLUMNS AS PART OF THE STANDARD LABELING FORMAT

The format established by the regulation requires most headings, subheadings, and text to be left justified (see § 201.66(d) and (d)(4)). The regulation also requires the use of horizontal barlines and hairlines — extending to each side of the Drug Facts box — to provide separation between headings and subheadings (see § 201.66(d)(8)). These requirements contribute to the overall organization of the information, provide the user with easy and consistent access to required information, and help maximize the amount of open space *within* the Drug Facts box. More open space (i.e., space not occupied by text) generally contributes to greater readability.

The regulation, however, can accommodate the use of more than one Drug Facts box on each side of a package container (see Fig. 1), or the use of side-by-side Drug Facts boxes on a wraparound label (e.g., the label of a bottle of cough syrup). Such a presentation generally is consistent with the rule, provided it is done in a manner that allows for the clear and legible presentation of all required labeling information. In the case of elongated packages (such as toothpaste and topical ointment packages), the column format may noticeably improve readability.

The following recommendations should be helpful if you are considering the use of columns in OTC drug product labeling.

A. Vertical Barline/Hairline

If you are using two or more Drug Facts boxes on the same side of a package, the right side of the first column and the left side of the second column can share a common vertical barline extending to each end of the Drug Facts box (see Fig. 1). This also applies to the right side of the second column and the left side of the third column, if a third column is used.

B. Number of Boxes Per Side

- Different sides of a package do not have to contain the same number of Drug Facts boxes.
- Two or more Drug Facts boxes can appear on one or more sides of a package, and a single Drug Facts box can appear on one or more sides of a package.
- If you are using two or more Drug Facts boxes on the same side of a package, the first Drug Facts box or column should be to the left of each successive box (see Fig. 1).

C. Box or Column Size

When multiple Drug Fact boxes appear on the same side of a package, the boxes, enclosures, or columns should be approximately the same size (see Figs. 1 and 2).

D. Titles[2]

- The first Drug Facts box must bear the title *Drug Facts* (see Figs. 1 and 2)
- Subsequent boxes on the same side of the package must bear the title *Drug Facts (continued)* at the top of the box (see Figs. 1 and 2).
- If the Drug Facts information appears on more than one side of the package, each box on each subsequent side of the package must bear the title *Drug Facts (continued)* (see Fig. 3).

E. Visual Graphics

If Drug Facts information appears in two or more columns on one side of a package (see Figs. 1 and 2) or on more than one side of a package (see Fig. 3), a visual graphic (e.g., an arrow) should be used at the bottom of the first column and/or side of the package (and at the bottom of subsequent columns and/or sides of the package, where needed) to signal continuation of the Drug Facts labeling to the next appropriate Drug Facts box on the package.

F. Order and Flow of Information

The continuation of the required labeling onto multiple Drug Facts boxes or columns must be done in a manner that retains the order and flow of headings, subheadings, and information, meeting all the requirements of § 201.66.

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[2] These title formats are required in 21 CFR 201.66(c)(1) and (d)(5).

G. Active Ingredients/Purpose Information

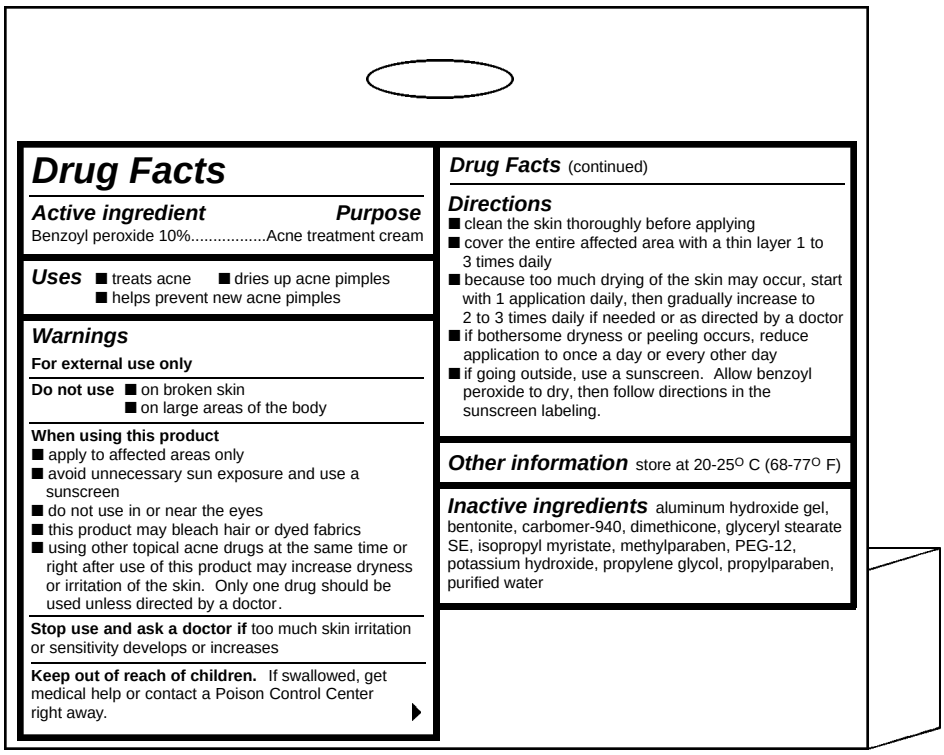
- Section 201.66(d)(6) requires ***Active Ingredients*** information to be left justified and the corresponding ***Purpose*** information to be right justified. The regulation requires that this information be presented in a manner that readily associates each active ingredient with its purpose.
- When multiple Drug Facts boxes are used, it is important that the boxes be wide enough to allow the ***Active Ingredients*** and ***Purpose*** information to appear on the same horizontal line.
- Where the Drug Facts box is too narrow to accommodate the ***Active Ingredient(s) (in each dosage unit)*** and ***Purpose*** headings on the same line, the dosage unit information *(in each dosage unit)* required under § 201.66(c)(2) may appear on the same line as the heading ***Active Ingredient(s)*** or immediately under the heading ***Active Ingredient(s)*** on the next line using left justification (see Fig. 3).

IV. COLUMNS UNDER THE MODIFIED LABELING FORMAT

When the Drug Facts labeling requires more than 60 percent of the total surface area available to bear labeling, the regulation provides that the box required in § 201.66(d)(8) may be omitted if the Drug Facts labeling is set off from the rest of the labeling by use of color contrast (§ 201.66(d)(10)(v)). In such a case, if more than one Drug Facts box or column is used on the same side of a package, or side-by-side on a wrap-around label, the columns should be separated by adequate vertical common space of a contrasting color (see Fig. 2). Horizontal barlines and hairlines should begin and end where the text begins and ends and should not extend into the common space between the columns.

Figure 1. Drug Facts in Columns
Two Drug Facts Boxes on One Side of a Package

Standard Labeling Format
Package with Carton Riser



Drug Facts

Active ingredient ***Purpose***
Benzoyl peroxide 10%.....Acne treatment cream

Uses ■ treats acne ■ dries up acne pimples
■ helps prevent new acne pimples

Warnings

For external use only

Do not use ■ on broken skin
■ on large areas of the body

When using this product
■ apply to affected areas only
■ avoid unnecessary sun exposure and use a sunscreen
■ do not use in or near the eyes
■ this product may bleach hair or dyed fabrics
■ using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. Only one drug should be used unless directed by a doctor.

Stop use and ask a doctor if too much skin irritation or sensitivity develops or increases

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions
■ clean the skin thoroughly before applying
■ cover the entire affected area with a thin layer 1 to 3 times daily
■ because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 to 3 times daily if needed or as directed by a doctor
■ if bothersome dryness or peeling occurs, reduce application to once a day or every other day
■ if going outside, use a sunscreen. Allow benzoyl peroxide to dry, then follow directions in the sunscreen labeling.

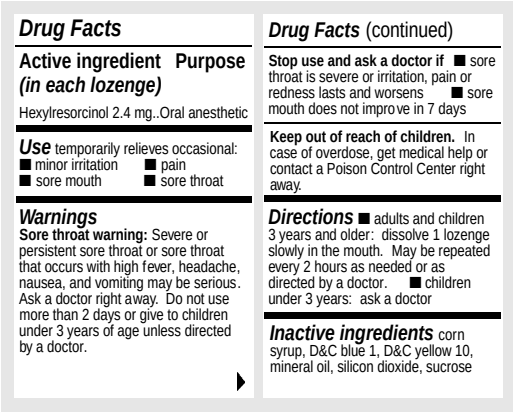
Other information store at 20-25^{O} C (68-77^{O} F)

Inactive ingredients aluminum hydroxide gel, bentonite, carbomer-940, dimethicone, glyceryl stearate SE, isopropyl myristate, methylparaben, PEG-12, potassium hydroxide, propylene glycol, propylparaben, purified water

* Note: 14 point Helvetica Bold Italic Title
8 point Helvetica Bold Italic Headings
6 point Helvetica Bold Subheadings
6 point Helvetica Regular Text
7 point Leading

Figure 2. Drug Facts in Columns
Two Drug Facts Boxes on One Side of a Package

Modified Labeling Format



Drug Facts

Active ingredient **Purpose**
(in each lozenge)

Hexylresorcinol 2.4 mg..Oral anesthetic

Use temporarily relieves occasional:
■ minor irritation ■ pain
■ sore mouth ■ sore throat

Warnings
Sore throat warning: Severe or persistent sore throat or sore throat that occurs with high fever, headache, nausea, and vomiting may be serious. Ask a doctor right away. Do not use more than 2 days or give to children under 3 years of age unless directed by a doctor.

Drug Facts (continued)

Stop use and ask a doctor if ■ sore throat is severe or irritation, pain or redness lasts and worsens ■ sore mouth does not improve in 7 days

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 3 years and older: dissolve 1 lozenge slowly in the mouth. May be repeated every 2 hours as needed or as directed by a doctor. ■ children under 3 years: ask a doctor

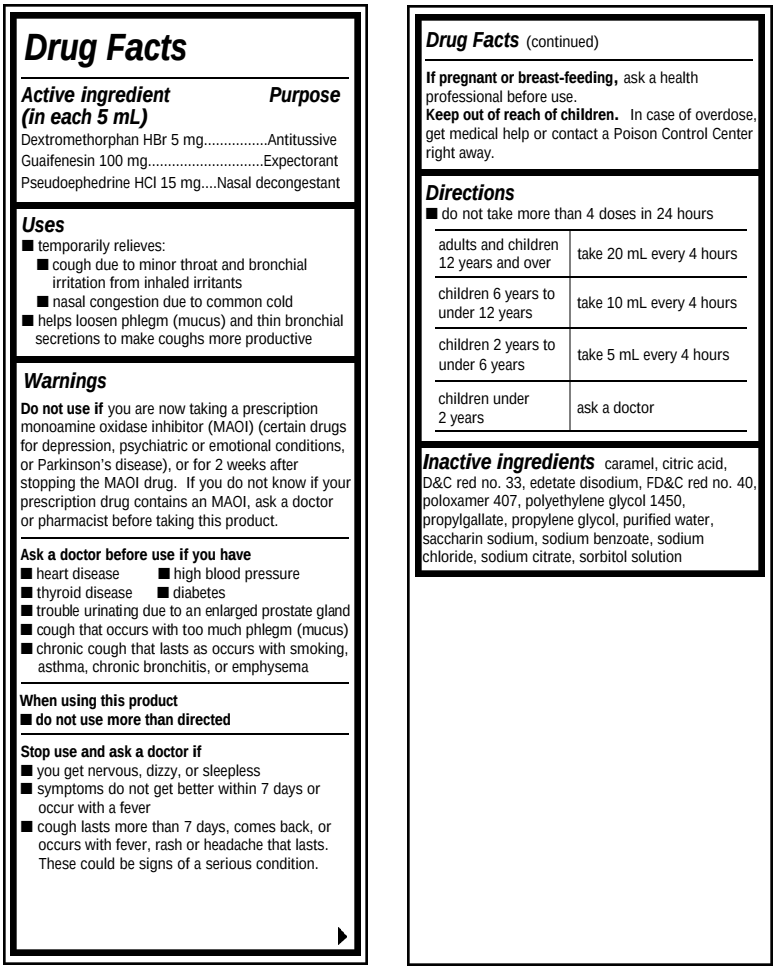
Inactive ingredients corn syrup, D&C blue 1, D&C yellow 10, mineral oil, silicon dioxide, sucrose

* Note: 9 point Helvetica Narrow Bold Italic Title
8 point Helvetica Narrow Bold Italic Headings
6 point Helvetica Narrow Bold Subheadings
6 point Helvetica Narrow Text
6 point Leading

Box barline omitted; color contrast used to highlight Drug Facts information

Figure 3. Drug Facts with Active Ingredients Information on Two Lines (For Single or Multiple Drug Facts Boxes)

Standard Labeling Format
Outer Carton



Drug Facts

Active ingredient (in each 5 mL)	***Purpose***
Dextromethorphan HBr 5 mg	Antitussive
Guaifenesin 100 mg	Expectorant
Pseudoephedrine HCl 15 mg	Nasal decongestant

Uses

- temporarily relieves:
  - cough due to minor throat and bronchial irritation from inhaled irritants
  - nasal congestion due to common cold
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- chronic cough that lasts as occurs with smoking, asthma, chronic bronchitis, or emphysema

When using this product

- **do not use more than directed**

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days or occur with a fever
- cough lasts more than 7 days, comes back, or occurs with fever, rash or headache that lasts. These could be signs of a serious condition.

Drug Facts (continued)

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

- do not take more than 4 doses in 24 hours

adults and children 12 years and over	take 20 mL every 4 hours
children 6 years to under 12 years	take 10 mL every 4 hours
children 2 years to under 6 years	take 5 mL every 4 hours
children under 2 years	ask a doctor

Inactive ingredients caramel, citric acid, D&C red no. 33, edetate disodium, FD&C red no. 40, poloxamer 407, polyethylene glycol 1450, propylgallate, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution

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6 point Helvetica Narrow Bold Subheadings
6 point Helvetica Narrow Text
7 point Leading