Statement of Identity and Strength — Content and Format of Labeling for Human Nonprescription Drug Products

Guidance for Industry

DRAFT GUIDANCE

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

September 2022
Labeling

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Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353; Email: druginfo@fda.hhs.gov
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TABLE OF CONTENTS

I. INTRODUCTION 1

II. BACKGROUND 2

III. CONTENT AND FORMAT OF THE STATEMENT OF IDENTITY AND STRENGTH 2

A. Content of the Statement of Identity 2

1. Established Name 3
2. Pharmacological Category 4

B. Strength 4

C. Formatting and Placement of the Statement of Identity and Strength 4

1. Direct Conjunction of the Proprietary Name and Statement of Identity 4
2. Configuration of the Statement of Identity and Strength 5
3. Prominence 7

APPENDIX: CONFIGURATION OF THE STATEMENT OF IDENTITY AND STRENGTH 8

Statement of Identity and Strength — Content and Format of Labeling for Human Nonprescription Drug Products Guidance for Industry[1]

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I. INTRODUCTION

This guidance provides recommendations on the labeling of human nonprescription drug products for the content and format of the required statement of identity[2] and the drug product's strength.[3] The recommendations in this guidance are intended to help manufacturers[4] ensure consistent content and format of the statement of identity and strength for all nonprescription drug products.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Office of Nonprescription Drugs in the Center for Drug Evaluation and Research at the Food and Drug Administration.

[2] See 21 CFR 201.61.

[3] For purposes of this guidance, we interpret the term *nonprescription drug products* to cover over-the-counter (OTC) drug products marketed under a new drug application, abbreviated new drug application, or as an OTC monograph drug under section 505G of the Federal Food, Drug, and Cosmetic Act. This guidance does not apply to human prescription drugs or biologic products or human nonprescription biological products.

[4] Manufacturers, packers, distributors, applicants, relabelers, and sponsors are henceforth referred to as *manufacturers*.

II. BACKGROUND

Labeling for nonprescription drug products is intended to enable consumers to self-select appropriately and use the nonprescription drug product safely and effectively without the supervision of a health care practitioner. Nonprescription drug products must comply with applicable labeling requirements under 21 CFR part 201, including, but not limited to, the statement of identity under section 201.61. The statement of identity is one of the principal features on nonprescription drug product labeling and consists of the established name for the nonprescription drug product, if one exists, followed by an accurate statement of the general pharmacological category(ies) or the principal intended action(s) of the drug product.[5] The labeling of all nonprescription drug products must display the statement of identity on the drug product's principal display panel (PDP).[6, 7] Consistent content and format of the statement of identity and strength[8, 9] on the PDP may aid consumers in comparing nonprescription drug products and assist consumers in appropriate self-selection.

III. CONTENT AND FORMAT OF THE STATEMENT OF IDENTITY AND STRENGTH

A. Content of the Statement of Identity

The statement of identity must consist of the established name for the nonprescription drug product, if one exists, followed by an accurate statement of the general pharmacological category(ies) or the principal intended action(s) of the drug product.[10] For over-the-counter (OTC) monograph drug products, if the applicable OTC monograph contains a statement of identity, the drug product must use the statement of identity in the applicable monograph.[11] However, to the extent they are not consistent, FDA does not intend to take action against the marketing of an OTC monograph drug product that follows the content guidelines for the

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[5] See 21 CFR 201.61(a) and (b).

[6] The term *principal display panel* (PDP), as it applies to over-the-counter drugs in package form, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The PDP "shall be large enough to accommodate all the mandatory label information required to be placed thereon by [21 CFR part 201] with clarity and conspicuousness and without obscuring designs, vignettes, or crowding" (21 CFR 201.60).

[7] See 21 CFR 201.61(a).

[8] See the guidance for industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022). We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[9] See the guidance for industry *Safety Considerations for Product Design to Minimize Medication Errors* (April 2016).

[10] See 21 CFR 201.61(b).

[11] See section 505G(a) of the Federal Food, Drug, and Cosmetic Act; 21 CFR 330.1(c)(1).

statement of identity as described in this guidance rather than the applicable OTC drug monograph, as long as the drug product is marketed in compliance with all other applicable statutes, regulations, and requirements (including other applicable requirements set forth in a corresponding OTC drug monograph).

1. Established Name

The term *established name* is defined in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as an official name designated pursuant to section 508 of the FD&C Act. If no such official name has been designated, and the drug or ingredient is an article recognized in an official compendium (such as the United States Pharmacopeia (USP)), then the established name is the official title described in such compendium.[12] If neither of the two options above applies, then the established name is the common or usual name of the drug. FDA does not routinely designate official names under section 508 of the FD&C Act.[13, 14] Therefore, the established name of a drug product will ordinarily be the USP drug product monograph title for that drug product.

The USP General Chapter <1121> *Nomenclature* and USP Nomenclature Guidelines describe the general format for a drug product monograph title as "[DRUG] [ROUTE OF ADMINISTRATION] [DOSAGE FORM]." For some dosage forms, the route of administration (ROA) is omitted.[15] Consistent with these principles, if there is no USP drug *product* monograph for a nonprescription drug product with a single active ingredient, FDA recommends that the nonprescription drug product use the USP drug *substance* monograph title "[DRUG]," which should be followed by the "[ROA] [DOSAGE FORM]," as the established name of the drug product.[16]

For a nonprescription drug product that consists of a mixture of two or more active ingredients and that does not have a USP drug *product* monograph, FDA recommends that the

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[12] In general, manufacturers of OTC drug products should refer to 21 CFR 299.4(e) on established names for drugs, as well as USP General Chapter <1121> *Nomenclature* available at http://www.usp.org and the USP Nomenclature Guidelines available at https://www.usp.org/health-quality-safety/compendial-nomenclature.

[13] See 21 CFR 299.4(e); see also the final rule, "Designated Names: Revocation of List of Official Names of Drugs," published September 25, 1984 (49 FR 37574).

[14] The terminology "common or usual name of the drug" refers to a historical concept that with time has fallen out of use. See the final rule, "Designated Names: Revocation of List of Official Names of Drugs," published September 25, 1984 (49 FR 37574) (explaining that "common or usual name" was used to refer to names for drug products adopted in *USAN (U.S. Adopted Names) and the USP Dictionary of Drug Name*s). Therefore, we recommend following the more typically used USP drug product monograph compendial name.

[15] The ROA is omitted from dosage form titles for which the ROA is understood. Some examples include "oral" for orally administered capsules, tablets, and lozenges and "topical" for products such as topically applied creams, ointments, and lotions. See the USP Nomenclature Guidelines for more detailed information on this topic.

[16] When the drug substance is a salt, see the guidance for industry *Naming of Drug Products Containing Salt Drug Substances* (Salt guidance) (June 2015). While the Salt guidance addresses prescription drug products approved under the FD&C Act, FDA applies the principles in the Salt guidance for naming nonprescription drug products to align with USP General Chapter <1121> and the USP Nomenclature Guidelines.

nonprescription drug product use the applicable USP drug *substance* monograph title[17] for each active ingredient in the drug product, which should be followed by the "[ROA] [DOSAGE FORM]," as the established name of the drug product.[18] Further, in general, FDA recommends that each drug substance monograph title for each active ingredient in such a drug product be listed in alphabetical order.[19]

2. Pharmacological Category

The pharmacological category is based on the principal intended action(s) of the nonprescription drug product. For OTC monograph drug products, the pharmacological category is specified in the applicable OTC drug monograph.[20]

B. Strength

FDA recommends that the strength of the drug product's active ingredient(s)[21] immediately follows the statement of identity on the PDP.

C. Formatting and Placement of the Statement of Identity and Strength

1. Direct Conjunction of the Proprietary Name and Statement of Identity

FDA recommends that the statement of identity be placed either directly to the right of or directly below the most prominent display of the proprietary name in the PDP. The statement of identity must be placed in direct conjunction with the most prominent display of the proprietary

[17] When the drug substance is a salt, see the Salt guidance.

[18] For some dosage forms, the ROA is omitted. The ROA is omitted from dosage form titles for which the ROA is understood. Some examples include *oral* for orally administered capsules, tablets, and lozenges and *topical* for products such as topically applied creams, ointments, and lotions. See the USP Nomenclature Guidelines for more detailed information on this topic.

[19] There may be cases when FDA has determined or recommended a listing configuration other than alphabetical order for active ingredient names in the statement of identity. A possible example could be that of a prescription to OTC switch, where the consumer or health care practitioner may already be familiar with a particular listed order based on historical practice, and a change in order might negatively affect how the health care practitioner recommends the drug product or how the consumer uses the drug product. These cases should be further discussed with FDA.

[20] See 21 CFR 330.1(c)(1); FD&C Act section 505G(a).

[21] When the drug substance is a salt, see the Salt guidance.

name,[22] if one is present.[23, 24] This implies that the proprietary name and the statement of identity should not be separated by any intervening matter, such as a logo, tagline, descriptor, or any other graphic, which may detract, obfuscate, or de-emphasize the statement of identity. FDA does not consider trademark symbols associated with proprietary names on the PDP (e.g., registered trademark symbols (®), unregistered trademark symbols (^{TM})) to be intervening matter. The statement of identity must be in lines generally parallel to the base on which the package rests as it is designed to be displayed.[25]

2. Configuration of the Statement of Identity and Strength

FDA recommends the following configurations for the statement of identity and strength in labeling for nonprescription drug products:

- Recommendation 1: for a nonprescription drug product with a single active ingredient, the statement of identity and strength should be consistent with any of the following configurations:[26]

  [**Established Name**] [**Pharmacological Category**] [**Strength**]

  OR

  [**Established Name**] [**Pharmacological Category**]
  [**Strength**]

  OR

  [**Established Name**]
  [**Pharmacological Category**]
  [**Strength**]

- Recommendation 2: for a nonprescription drug product that consists of a mixture of active ingredients, the established name should be followed by the pharmacological

[22] The proprietary name of a drug product is its brand name (sometimes referred to as the product's *trade name*).

[23] See 21 CFR 201.61(b).

[24] Drug products marketed without a proprietary name may use the statement of identity and strength as the *product title* of the nonprescription drug product (see the second example in the Appendix). Alternatively, the established name of the drug product may be used as the *product title* followed by the statement of identity and strength (see the last example in the Appendix).

[25] See 21 CFR 201.61(c).

[26] Consistent with the recommendation in section III.A.1., Established Name, of this guidance, if there is no USP drug *product* monograph for a nonprescription drug product with a single active ingredient, FDA recommends that the established name be presented as the USP drug *substance* monograph title "[DRUG]," followed by the "[ROA] [DOSAGE FORM]."

category and the strength of each active ingredient.[27] To reduce redundancy and consumer confusion, the statement of identity should appear vertically aligned in columns consistent with the following configuration:

[**Drug A**]	[**Pharmacological Category A**]	[**Strength A**]
[**Drug B**]	[**Pharmacological Category B**]	[**Strength B**]
[**Drug C**]	[**Pharmacological Category C**]	[**Strength C**]
[**ROA**] [**Dosage Form**]		

- Recommendation 3: in cases in which the ROA is omitted, the statement of identity and strength should appear consistent with the following configuration:

[**Drug A**]	[**Pharmacological Category A**]	[**Strength A**]
[**Drug B**]	[**Pharmacological Category B**]	[**Strength B**]
[**Drug C**]	[**Pharmacological Category C**]	[**Strength C**]
[**Dosage Form**]		

Though the configurations in Recommendations 1, 2, and 3 have left-aligned text, in general, text for the statement of identity and strength can be presented in other alignment types (e.g., center aligned, right aligned, justified).

An OTC monograph drug product must follow the applicable requirements specified in its OTC monograph, including requirements for the statement of identity.[28] However, to the extent they are not consistent, FDA does not intend to take action against the marketing of an OTC monograph drug product that follows the content and formatting guidelines for the statement of identity and strength as described in this guidance rather than the applicable OTC monograph, as long as the drug product is marketed in compliance with all other applicable statutes, regulations, and requirements (including other applicable requirements set forth in a corresponding OTC drug monograph).

[27] Consistent with the recommendation in section III.A.1, Established Name, of this guidance, for a nonprescription drug product that consists of a mixture of two or more active ingredients and that does not have a USP drug *product* monograph, FDA recommends that the established name be presented as the applicable USP drug *substance* monograph title for each active ingredient in the drug product (in alphabetical order), followed by the "[ROA] [DOSAGE FORM]."

[28] Section 505G of the FD&C Act. Nonprescription drug products marketed under the OTC drug review are referred to as OTC monograph drugs. An OTC monograph drug can be marketed without an approved drug application described in section 505 of the FD&C Act if it meets the requirements of section 505G of the FD&C Act (known as the OTC drug review), as well as other applicable requirements.

166 *3. Prominence*
167
168 The statement of identity must be presented in bold face type.[29, 30] FDA recommends the
169 statement of identity be at least half the size of the most prominent printed matter on the PDP.[31,
170 32] Furthermore, the statement of identity should be prominent on the PDP considering all
171 pertinent factors, including typography, layout, contrast, and other printing features on the PDP.
172 FDA recommends that the strength, following the statement of identity on the PDP, also be
173 presented in bold face type.
174

[29] See 21 CFR 201.61(c).

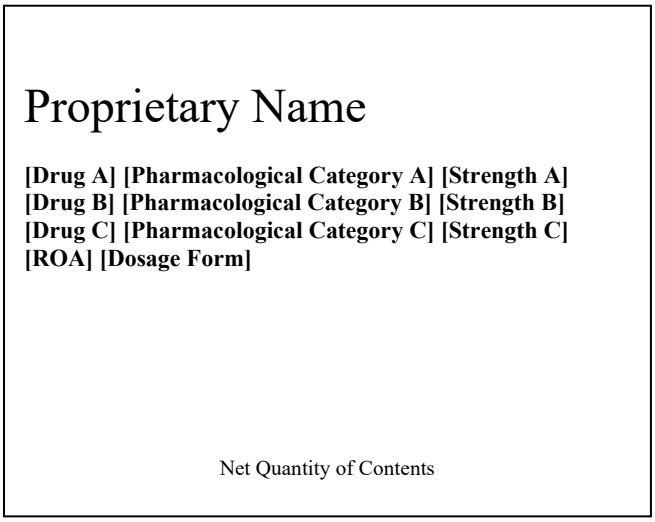
[30] In certain instances, there may be additional formatting requirements for the statement of identity. For example, see 21 CFR 201.326(a)(1)(i).

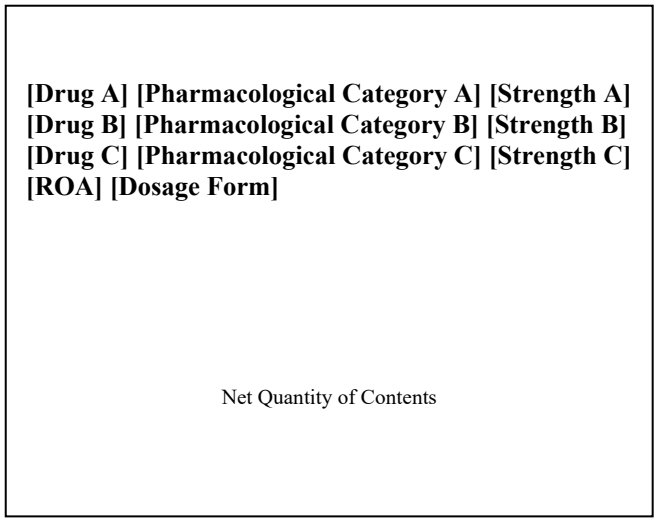
[31] At times, there may be additional size requirements for the statement of identity. For example, see 21 CFR 201.326(a)(1)(i)(A) and (B).

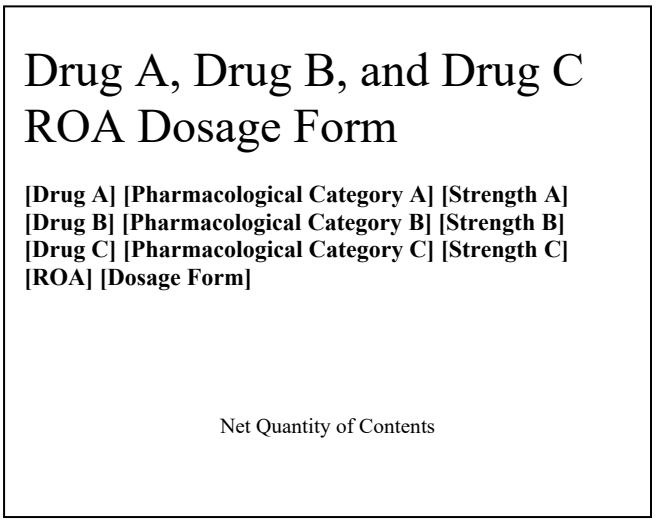
[32] See 21 CFR 201.15.

APPENDIX:
CONFIGURATION OF THE STATEMENT OF IDENTITY AND STRENGTH

The following principal display panels are examples of appropriate configuration for the statement of identity and strength in labeling for a nonprescription drug product with multiple active ingredients.[1]







[1] ROA = route of administration. The ROA is omitted from dosage form titles for which the ROA is understood. Some examples include *oral* for orally administered capsules, tablets, and lozenges and *topical* for products such as topically applied creams, ointments, and lotions. See the USP Nomenclature Guidelines for more detailed information on this topic.