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Docket FDA-2022-D-1837

November 8, 2022

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Statement of Identity and Strength – Content and Format of Labeling for Human Nonprescription Drug Products; Draft Guidance; Docket No. FDA-2022-D-1837; FR Vol. 87, No. 174, pp 55438-40, September 9, 2022; Industry Comments

Dear Sir or Madam,

Consumer Healthcare Products Association (CHPA)¹ and the Personal Care Products Council (PCPC)² appreciate this opportunity to provide comments on the U.S. Food and Drug Administration's ("FDA" or "Agency") draft guidance document titled, "Statement of Identity and Strength – Content and Format of Labeling for Human Nonprescription Drug Products".³

CHPA and PCPC members have significant experience and expertise designing the principal display panel (PDP) for over-the-counter (OTC) drug products. Importantly, flexibility in design is key to optimize label comprehension and self-selection by consumers. Many factors contribute to a design that meets consumer and commercial needs, the latter of which are ever-changing. In general, members are very satisfied with the existing regulations for content on the PDP, including statement of identity (SOI), and recommend that no additional guidance on this topic is needed. Ingredient-specific changes or requirements should be managed via the administrative order or NDA process to allow an appropriate dialogue with sponsors. Furthermore, CHPA and PCPC strongly object to FDA using this draft guidance to request labeling changes from sponsors, which we understand has already occurred.

FDA has not provided any evidence to show that the content and format proposals for the SOI meet the stated objective to "aid consumers in comparing different nonprescription drugs and assist consumers in selecting an appropriate product." FDA's draft guidance mentions in the Background section that the purpose of the guidance is to support consistency. The CHPA and PCPC members feel that the Drug Facts Label (DFL) already provides that consistency. In addition, consumers shop by indication and symptoms, not ingredients. Implementation of these proposals would lead to the removal of symptoms on some PDPs due

¹ The Consumer Healthcare Products Association (CHPA) is a national trade association representing manufacturers and distributors of drugs, over-the-counter medications, dietary supplements, and consumer medical devices. Our association is committed to maintaining the highest levels of safety in the manufacture and regulation of consumer self-care products.

² Founded in 1894, the Personal Care Products Council (Council or PCPC) is the voice and advocate for 600 member companies representing the \$450 billion global cosmetics and personal care products industry. Council's members represent approximately 90% of the U.S. beauty industry and are some of the most beloved and trusted brands in beauty and personal care today. As manufacturers, distributors and suppliers of a diverse range of products millions of consumers rely on every day - from sunscreens, toothpaste and shampoo to moisturizer, makeup and fragrance - Council's member companies are global leaders committed to safety, quality and innovation. For more information on cosmetics and personal care products, please visit www.CosmeticsInfo.org.

³ Docket No. FDA-2022-D-1837, 87 Fed. Reg. 55438-40 (Sept. 9, 2022).

to space constraints; this could lead to the inability of consumers to accurately select based on symptoms and cause confusion. Additionally, substantial changes as stated in this guidance in combination with other changes such as the NDC format change from 10-digit to 12-digit will result in significant economic impact due to the need for multiple PDP updates. CHPA and PCPC members are not aware of any data/testing that would support the direction in this guidance. Industry strongly objects to finalizing this guidance until an economic impact analysis is conducted as well as an assessment of the ability of consumers to orient at shelf with PDPs modified with these proposals. The potential for consumer confusion and the negative economic impact outweighs any desired benefit.

CHPA and PCPC comments are organized into general comments followed by specific comments and the appropriate line reference.

General Comments

Guidance Recommendations Expand Beyond Current Labeling Requirements listed in 21 CFR 201.61

The Administrative Procedure Act (“APA”) identifies guidance documents that set forth an agency’s interpretation of a statute or regulation.⁴ This concept is reflected by FDA in the introduction of this guidance, which states that it merely “provides recommendations on the labeling of human nonprescription drug products for the content and format of the required statement of identity and the drug products strength.”⁵ Yet, several of the recommendations in the draft guidance expand well beyond and in some cases conflict with the current labeling requirements for OTC drug products as per 21 CFR 201.61. The Guidance recommends that the sponsor include the ingredient(s) name(s), strength, and route of administration (ROA) which are not required under current regulations. CHPA and PCPC believe the current labeling regulations in 21 CFR 201.61 are clear, serve the consumer and industry well and do not need additional clarification or recommendation via guidance. We do not support modifying or expanding current regulations on labeling via guidance.

This expansion on current regulations is further illustrated by the fact that some labeling recommendations in the guidance reflect previous FDA proposed rulemaking that has not yet been finalized. One example is the proposed Administrative Order titled “Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use”⁶ (“Proposed Sunscreen Order”). This Proposed Sunscreen Order mandates changes to the statement of identity (SOI) requirements including that all active ingredients be listed alphabetically “followed by ‘Sunscreen’ and the product’s dosage form (such as lotion or spray).”⁷ This guidance seems to derive the SOI requirements from the Proposed Sunscreen Order – which was published over a year ago – and inputs them into a guidance that affects all OTC drug products. Consequently, this guidance is arguably an alternative, less participatory, policy vehicle that bypasses the notice and comment rulemaking process under the APA.⁸

It is our members’ experience that consumer comprehension and self-selection studies conducted for approved NDA OTC drug products have already demonstrated that these recommendations for additional information to include ROA, strength, and labeling alignments for the established name are unnecessary on the PDP. Further, member experience is that consumers have well-demonstrated label comprehension and appropriate self-selection without these recommendations for inclusion on the PDP. The recommendations for providing ROA and strength on the PDP as part of the established name is duplicative since the information is already provided in the product’s DFL and net contents statement.

Overall, CHPA and PCPC have concerns that these recommendations, if finalized into guidance, will reflect FDA’s expectation that every approved OTC NDA, ANDA and OTC monograph product be changed to be consistent with this guidance. Such changes to how OTC monograph NDA and ANDA products are labeled must require an economic impact analysis and further regulatory considerations through the rulemaking process rather than a guidance document.

⁴ Pub. L. 89-554, § 553(b), 80 Stat. 383 (1966).

⁵ Docket No. FDA-2022-D-1837, 87 Fed. Reg. 55438-40 (Sept. 9, 2022).

⁶ Proposed Order OTC000008, Docket No. FDA-1978-N-0018; 86 Fed. Reg. 53322 (Sep. 27, 2021).

⁷ *Id.* at 78.

⁸ Pub. L. 89-554, § 553, 80 Stat. 383 (1966).

PDP Space Limitations

The PDP serves as a first point of contact with the consumer. It provides mandatory label information required under 21 CFR 201.61 in addition to product branding and supportive claims that assist the consumer with the selection of the OTC drug product. For example, it is common practice for companies that sell sunscreen products to include the SPF number as a larger callout (for ease of finding the SPF on shelf), product attributes (so a consumer can make an informed choice between products), and graphics associated with a brand's trade dress (to distinguish on shelf) while also accommodating the small packaging sizes common for these types of products. Consequently, OTC drug products currently have limited space to communicate both the regulatory requirements and product attributes to consumers. However, in the guidance, FDA is asking for more information to be placed on an already-crowded PDP, especially for smaller packages.

At the 2021 Nonprescription Drug Facts Label Workshop⁹, FDA received significant feedback on relevant aspects of labeling, including that the PDP needs to be simplified. Consumers look for symptom relief and not chemical names. The retail environment is structured around therapeutic categories that guide consumers for product selection. Multiple presentations discussed the need to have simpler labels on OTC drug products, including the PDP, to help mitigate current consumer confusion and increase their confidence in product decision-making. The additional PDP requirements in the draft guidance are not only inconsistent with the information provided through these FDA workshops, but also 21 CFR 201.15(a)(6) which provides: a "word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 502(c) of the act by reason... of... crowding with other written, printed, or graphic matter."

The additional PDP requirements also seem to contradict a goal of the guidance, which is "to reduce redundancy and consumer confusion."¹⁰ Consumers already know to look for ingredient strength in the DFL, and thus, including that information on the PDP would be redundant. Placement of redundant information on the PDP could also dissuade a consumer from reading the DFL, which already includes the active ingredient strength (or percentage within a formula), as well as other important information such as warnings and directions.

Additionally, it is important that space on the PDP remain available for currently required, or future ingredient-specific information that is deemed critical to safe and effective use, such as for acetaminophen (bold face or highlighting) or claims for sunscreen such as "Broad Spectrum SPF" or "SPF" value statement. PDP space must also remain available for information that may be required in the future.

Overall, we believe that the addition of information to the PDP discussed in the draft guidance will not have the intended effect of increasing consumer understanding of OTC drug products and informing the purchase process. In fact, this guidance may make it more challenging for consumers to understand the information on the PDP and appropriately self-select the product. The implications are not only adding difficulties for certain groups of consumers who need further visual assistance in physical retail stores but may also limit or cause the loss of consumer access to convenience or travel size OTC drug products due to space limitations. Therefore, the prominence and readability of critical information required to appear on the PDP will be compromised due to the lack of PDP space caused by this guidance's additional recommendations.

Appendix 1 provides an example illustration of the potential impact of these recommendations on just one mock SKU.

Specific Comments

Line 83- ROA

CHPA and PCPC disagree with the Agency's recommendation to include the ROA as part of the established

⁹ The Nonprescription Drug Facts Label in a Changing Consumer Marketplace, 2019, June 9, 2021. <https://www.fda.gov/drugs/news-events-human-drugs/nonprescription-drug-facts-label-changing-consumer-marketplace-2021-06092021-06092021>. Accessed October 21, 2022.

¹⁰ Statement of Identity and Strength - Content and Format of Labeling for Human Nonprescription Drug Products; Draft Guidance, Docket No. FDA-2022-D-1837, 87 Fed. Reg. 55438-40 (Sept. 9, 2022), pp. 6.

name. We refer to our general labeling comments on the PDP and note that this recommendation is not consistent with current regulations, is unnecessary and duplicative. We note that Net Contents regulations in 21 CFR 201.62 already require that the dose form be named (e.g., tablets). This information is in a stand-alone portion of the PDP, and it is not necessary as part of the established name. In many cases, the ROA information is self-evident.

Line 100 & Line 172- Strength

FDA recommends that the addition of the strength be included with the established name. CHPA and PCPC disagree with the Agency's recommendation to include the active ingredients strength next to the active ingredient name on the PDP. We refer to our general labeling comments regarding labeling for strength on the PDP. As stated earlier, the information is duplicative and unnecessary since the strength information is already provided in the DFL. Current regulations in 21 CFR 201.61 do not require the strength be included in the established name.

CHPA and PCPC acknowledge that the addition of a strength with the established names may be warranted in rare cases due to known safety concerns. In some cases, such as children's acetaminophen, strength has been added to the PDP to facilitate consumer comparison across products and assure the correct dose calculations and prevent accidental overdose. Therefore, exceptions to require strength on the PDP can be done via the Administrative Order or regulatory process (NDA, ANDA) for specific OTC drug products.

Line 109- SOI placement

FDA recommends that the SOI be placed either directly to the right or directly below the most prominent display of the proprietary name. CHPA and PCPC disagree with the Agency recommendation. The suggested placement of the SOI is too prescriptive, and industry is already challenged to accommodate current labeling requirements based on labeling layout and packaging size. CHPA and PCPC are not aware of any published literature to support the specificity of this recommendation. CHPA and PCPC recommend that the guidance be consistent with current regulations, CFR 201.61, as stated earlier. Use of the phrase "in conjunction" provides sufficient direction and sufficient flexibility to properly place the SOI.

Lines 129, 134, 140, 147 & 151

CHPA and PCPC respectfully request to have "strength and dosage form" be removed from these examples.

Lines 90-92 & 142

FDA recommends that when a product consists of a mixture of active ingredients, all active ingredients should be displayed on the PDP – in alphabetical order – as established name, pharmacological category and strength. This conflicts with regulation 21 CFR 201.61(b), which permits a prominent and conspicuous statement of the general pharmacological action(s) of the mixture or of its principal intended actions(s) in terms that are meaningful to the consumer. This is especially relevant for small packages where space is limited.

We also refer to our general labeling comments on the PDP and note that having the active ingredients listed on the PDP in addition to the DFL is redundant and crowds the PDP, reducing the readability and prominence of required labeling elements. This recommendation is also contrary to the fact that consumers are already accustomed to and familiar with the DFL, including knowing that they will find the active ingredients listed in the very first section of the DFL under the heading "Active Ingredients."

Line 147 & 151- Vertical Alignment

The Agency has provided examples of vertical justification to prevent consumer confusion. CHPA and PCPC are unaware of any published documentation and substantiation that the SOI be vertically aligned in columns to reduce consumer confusion and suggest that such information be generated before recommending this in guidance. Vertically aligned columns present space challenges for many products. CHPA and PCPC members note that the current retail environment is moving to vertical packaging, which conflicts with the recommended layout. It may be either impractical or impossible to achieve these labeling recommendations for products with small count sizes, products that do not use outside cartons, products with window box cartons, tubes or overwraps with blister packages. Alignment depends on type and size of

package; amount of space and guidance must be sufficiently flexible to accommodate the wide variety of packages for OTC products.

Line 168- FDA statement on SOI be at least ½ the size on the most prominent printed matter.

We refer to our general comments on guidance recommendations versus stated regulations and our comments on limited availability of PDP space. Current regulations allow for the use of bold face type and the SOI size to be reasonably related to the most prominent printed matter. In this guidance, FDA recommends that the SOI be “at least half the size”, which is not necessary or reasonable. Layout of the PDP is the sponsor’s responsibility, including ensuring prominence of regulated copy, depending on the package size. As stated earlier, consumers shop for brands and symptom relief or therapeutic category and not statement of identity. CHPA and PCPC members are unaware of any issues of consumer confusion due to prominence of statement of identity that would lead FDA to try to prescribe design elements such as font size.

CHPA and PCPC acknowledge that a specific description of font size for the SOI may be warranted in rare cases due to known safety concerns. An example of this is acetaminophen labeling (21 CFR 326(a)(1)(A)) where a requirement for the SOI to be at least one quarter as large as the most prominent matter on the PDP. These types of specific labeling requirements should be done via the Administrative Order or regulatory process (NDA, ANDA) for specific OTC drug products.

CHPA and PCPC members appreciate the opportunity to provide regulatory input on this draft guidance document. Please feel free to contact us with any questions.

Sincerely,

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SVP, Regulatory & Scientific Affairs
CHPA

Thomas Myers
EVP, Legal & General Counsel
PCPC

APPENDIX I

U Chlorpheniramine maleate / Antihistamine / 4 mg
Chlorpheniramine maleate / Antihistamine / 4 mg
Chlorpheniramine maleate / Antihistamine / 4 mg
Chlorpheniramine maleate / Antihistamine / 4 mg

font size 7.5pt

1/4 to Brand Name



CURRENT PDP

U Chlorpheniramine maleate / Antihistamine /4 mg
Chlorpheniramine maleate / Antihistamine /4 mg

font size 15pt

1/2 to Brand Name



**SOI DOES NOT FIT IN CURRENT
ARCHITECTURE & NO ROOM FOR SYMPTOMS**

· Fever & Body Ache · Cough · Nasal Congestion
· Runny Nose · Sore Throat

“COLUMN” FORMAT DOES NOT WORK

U Chlorpheniramine maleate / Antihistamine / 4 mg
Chlorpheniramine maleate / Antihistamine / 4 mg

font size 10.75pt

1/2 to Brand Name



LOGO SIGNIFICANTLY REDUCED 75%
“COLUMN” FORMAT DOES NOT WORK