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June 14, 2021

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on Draft Guidance for Industry; Best Practices in Developing Proprietary Names for Human Nonprescription Drugs, Availability. 85 *Fed. Reg.* 79187-79189 (December 9, 2020). Docket No. FDA-2020-D-0770[1]

Dear Sir/Madam:

The Consumer Healthcare Products Association (CHPA[2]) appreciates the opportunity to provide additional comments on the FDA's draft guidance for industry titled "Best Practices in Developing Proprietary Names for Human Nonprescription Drugs," (draft guidance) released on December 9, 2020 (85 *Federal Register* 79187-79189)[1,3]. In February 2021, CHPA members submitted general principles for identifying appropriate proprietary drug product names for over-the-counter (OTC) medicines based on industry best practices. CHPA members have carefully reviewed the draft guidance and have incorporated additional recommended changes into the Agency's draft guidance for consideration. Our goal is simply to align this guidance with the OTC environment and the processes that consumers use to differentiate OTC drugs. In keeping with the mission of the FDA Center for Drug Evaluation and Research's (CDER) Office of Surveillance and Epidemiology (OSE) Division of Medication Error and Prevention Analysis (DMEPA), CHPA member feedback is designed to minimize the risk of medication errors due to consumer confusion attributed to an OTC drug product name.[4]

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[1] Published in December 9, 2020 *Federal Register*. Accessed at https://www.govinfo.gov/content/pkg/FR-2020-12-09/pdf/2020-27057.pdf on January 8, 2021.

[2] The Consumer Healthcare Products Association (CHPA) is the 140-year-old national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines, consumer medical devices (Class I/certain Class II medical devices) and dietary supplements. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products. (www.chpa.org)

[3] FDA Draft Guidance "Best Practices in Developing Proprietary Names for Human Nonprescription Drugs." Issued December 2020. Accessed from https://www.fda.gov/media/144257/download on February 17, 2021.

[4] FDA Website: Medication Errors Related to CDER-Regulated Drug Products. Access from https://www.fda.gov/drugs/drug-safety-and-availability/medication-errors-related-cder-regulated-drug-products on June 4, 2021.

The OTC environment is significantly different than the prescription (Rx) environment; therefore, the methods for proprietary name assessment must reflect the real-world consumer environment, not the process of prescribing and filling prescriptions. Most importantly, the consumer relies on much more than the drug name to make a product selection. The exterior OTC labeling has a Principal Display Panel (PDP) with key information about the ingredients and indication while the Drug Facts Label (DFL) also has information on warnings and directions. Furthermore, consumers make the final product selection decisions, not healthcare providers. FDA regulations (see 21 CFR 201.60 and 21 CFR 201.66) as well as guidances for nonprescription label comprehension and self-selection all cite that testing should be done to reflect the "conditions of customary use…."

CHPA members have invested over two years writing, re-writing, and researching best practices for OTC proprietary name testing. It was very disappointing to see that none of the approaches and key principles proposed by the OTC industry (in response to the 2014 draft guidance on naming principles for both Rx and OTC drugs[5]) was incorporated into the current draft guidance after waiting several years for the Agency to review stakeholder comments. As issued in December 2020, the draft guidance maintains nearly all of the principles in the final guidance titled "Best Practices in Developing Proprietary Names for Human Prescription Drug Products; Guidance for Industry"[6] and in fact, refers readers of the nonprescription guidance to the Rx guidance in select instances. CHPA members have again convened over the past 6 months to review and re-write sections to align the FDA's draft guidance with the OTC environment. Where they are compatible with OTC drug selection conditions, the principles outlined in the Agency's draft guidance have been maintained. We are compelled to clarify and correct sections (in the current draft guidance) to reflect an OTC environment in these four main areas:

- Purchase decisions for OTC medicines are ultimately made by consumers.
  - Less than 0.01% of OTCs are prescribed by HCPs and the consumer still makes the final product selection decision even when HCPs are involved or consulted.[7]
- Consumers use the PDP when making OTC product selections.
  - Consumers use the information on the PDP to make a product decision, not just the product name.
- Look-alike, sound-alike testing is inappropriate for OTC drugs.
  - Look-alike, sound-alike (LASA) methods are not appropriate for evaluating proprietary names for OTC products since most OTCs are

[5] FDA Draft Guidance: Best Practices in Developing Proprietary Names for Human Drug Products (issued May 2014) is provided as a separate attachment.
6 FDA Final Guidance: Best Practices in Developing Proprietary Names for Human Prescription Drug Products; Guidance for Industry (December 2020). Accessed from https://www.fda.gov/media/88496/download on June 4, 2021.
[7] Source: NPA Audit from January 2015 to December 2020, Prescriptions written for OTC drugs, IQVIA.

designed to look alike and sound alike due to umbrella branding practices.

- New terminology for umbrella branding is unnecessary.
  - The umbrella branding definition is returned to what has historically been used by FDA, the OTC industry, and in fact is used by the entire consumer products industry. The introduction of new definitions (*i.e.*, "Family trade name") in the FDA draft guidance is problematic and confusing.

Consumers are the Ultimate End Users of OTC Drug Products

The current FDA (or Agency) draft guidance has broadly defined end users to include not only consumers, but also patients, patient caregivers, prescribing physicians, nurses, pharmacists, technicians, and other individuals who are involved in routine selection, purchase, procurement, stocking, storage, prescribing, dispensing, and administration of nonprescription drug products (*e.g.*, medication technicians) (see lines 468-472 of draft guidance).[8] However, an OTC medicine is "…a drug product marketed for use by the *consumer* (emphasis added) without the intervention of a health care professional in order to obtain the product."[9] OTC medicines are purchased off-the shelf and do not require a doctor's prescription[10], or they may be purchased through e-commerce.

In the draft guidance, the Agency noted that sponsors should consider how nonprescription medicines will be used by consumers, patients, caregivers, physicians, and other health care professionals (see lines 62-64). However, we think it bears emphasizing that the final purchase decision is made by the true end user, the consumer, regardless of whether or not the product has been recommended or prescribed by a health care professional (HCP). Based on data from IQVIA evaluating the number of prescriptions written for OTC drugs between January 2015 and December 2020, HCPs prescribed OTC drug products 0.01% compared to those selected by consumers (*i.e.,* 237,000 OTCs prescribed by HCPs vs. 2,900,000,000 OTCs selected by consumers).[7] Furthermore, when a HCP prescribes an OTC drug to a patient, the patient goes to the retail site and, as with any OTC consumer, selects the product from the store shelf or retail website Therefore, routine screening or testing to determine the ability to discern between different OTC drug products should be

[8] Unless noted otherwise, line numbers correspond to the line numbers in the FDA draft guidance issued in December 2020.

9 FDA Webpage: Small Business Assistance: Frequently Asked Questions on the Regulatory Process of Over-the-Counter (OTC) Drugs. Accessed from https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-regulatory-process-over-counter-otc-drugs on May 25, 2021.

[10] FDA Website: Prescription Drugs and Over-the-Counter (OTC) Drugs: Questions and Answers. Accessed from https://www.fda.gov/drugs/questions-answers/prescription-drugs-and-over-counter-otc-drugs-questions-and-answers on May 25, 2021.

focused on the consumer. Testing of potential drug product names for OTC medicines that focuses on HCPs should not be standard or best practice.

Selection of OTC Product Is Based On Information on the PDP Not Just the Name

The introduction section of the draft guidance indicates the document "…describes best practices to help minimize proprietary name-related medication errors…" (see lines 16-17). CHPA members believe it is critical to have a proprietary name that facilitates accurate identification, as well as safe and effective use, of an OTC drug product by the end users (which in the case of OTC medicines are predominantly consumers). We understand the reason for focusing on ONLY the name for a prescription product because the name is the primary source of information on the box or bottle by which to distinguish the drugs.

The nonprescription labeling is significantly different than the prescription labeling of a drug. The nonprescription labeling provides not only the name, but important and distinguishing information (*e.g.*, indication, symptoms, ingredients) on the PDP and a comprehensive Drug Facts Label (DFL) to inform the consumer about the uses, warnings, and directions. Best practices for selecting a proprietary OTC drug product name should be done with the totality of the information commonly used by consumers to properly select and use these medicines (*i.e.,* product name, PDP, trade dress, DFL) and not the name alone in isolation. Further support for the position that consumers rely on more than just the product name on the PDP for selecting OTC products is reflected in FDA's 2019 proposed rule for OTC sunscreen products. In the rule, the Agency commented that the proposed statement of identity "…would supplement other important elements of the PDP to provide a succinct summary of the product's key characteristics on the front of the package or container, *permitting consumers to more readily compare products and either select or avoid a given product accordingly* (emphasis added)."[11]

OTC medicines are marketed directly to consumers at the point of purchase (*i.e.,* in retail stores and e-commerce platforms), in packaging that includes identifiable trade dress for individual products. Consumers use different features (*e.g.*, package shape, color, font, and other visual cues) in addition to the product name to distinguish one OTC medicine from another during product selection. Current regulations (21 CFR 201.60) establish the labeling requirements for the principal display panel (PDP) for OTC drugs. Sponsors use product packaging and labeling elements to facilitate appropriate product selection by the end users by communicating important information about the product.

[11] FDA Proposed Rule for Sunscreen Drug Products for Human Use. on February 26, 2019. 85 *Fed. Reg.* FR 6204 – 6275 (February 26, 2019). Docket No. FDA-1978-N-0018. Access from https://www.govinfo.gov/content/pkg/FR-2019-02-26/pdf/2019-03019.pdf on June 4, 2021.

Look-Alike, Sounds-Alike (LASA) Approaches to Proprietary Names are Not Appropriate for Nonprescription Products

While it is understandable that LASA methods are appropriate for prescription products that have similar looking or sounding names, these methods are generally NOT appropriate for nonprescription products. Nonprescription products are placed on the retail shelf or in an e-commerce view by an identifiable brand name and trade dress within a therapeutic category and indication within a related therapeutic category. The brand name signals a brand that a consumer may trust and the trade dress offers visual cues, including color and graphics, to communicate information to the consumer.[12]

Because of umbrella branding, nonprescription products *do* look-alike and sound-alike. Therefore, sections of the Agency draft guidance related to FDA label simulation testing, POCA testing, and other LASA methods are not reflective of the OTC environment in which all of the information on the PDP, and not the name alone, are pivotal in product selection decisions. OTC medicines also have other distinguishing features (*i.e.,* design, use of colors, graphics, logos) to ensure that consumers can differentiate one product in an umbrella brand from another. In addition, results from risk assessment and/or discernment testing conducted in name simulation studies for nonprescription products help minimize consumer confusion.

Section III. B. of the draft guidance outlines what FDA considers as potential sources of error, including phonetic, spelling, and orthographic similarities. Sponsors are encouraged to conduct each of the types of assessments described in the draft guidance, more specifically name simulation studies and computational methods to identify names with potential orthographic, spelling, and phonetic similarities. We do not agree that the methods for evaluation expressed in this draft guidance are appropriate for OTC products. Furthermore, CHPA members disagree that these types of tests should be routinely performed during the development of proprietary drug product names for OTC medicines for the reasons outlined below.

Manufacturers of OTC medicines have experience in conducting consumer behavior studies[13] that are not performed for prescription drugs, and therefore have developed a unique expertise in designing appropriate testing programs to assess the likelihood of potential medication errors resulting from the use of an OTC medication. CHPA members have made edits to the FDA draft guidance (provided as a separate document) that reflect testing considerations focused on consumer discernment that can be applied when evaluating an appropriate proprietary name for an OTC drug product.

[12] CHPA White Paper: Consumer Navigation and Selection Behaviors for OTC Products in a Retail Setting (September 23, 2014).
[13] Consumer behavior studies include label comprehension studies, self-selection studies, actual use studies, and human factor studies.

Preliminary Name Simulation Studies with FDA Staff

The draft guidance describes how the Agency performs simulation studies involving FDA staff to test the response of healthcare professionals to proposed names. The Agency believes that "…when an error is observed in a small study, this suggests that there will be errors in actual use (see lines 267-268)."[3] CHPA members agree that small-scale studies are useful to inform subsequent studies but only if the methods are similar. We suggest that the small scale preliminary name simulation evaluation reflect the real-world consumer environment and be conducted with consumers, not with FDA staff. Name simulation studies as being conducted by the Agency on FDA personnel are not appropriate for OTC drug name testing where the focus is on consumers who make self-selection decisions when purchasing nonprescription medicines. CHPA members do not believe these types of studies adequately simulate the experience of an average consumer purchasing an OTC product in the real-world setting.

Computational Method to Identify Names With Potential Orthographic, Spelling and Phonetic Similarities

The Agency suggests that sponsors utilize its Phonetic and Orthographic Computer Analysis (POCA) system to screen proposed product names (see lines 294-296). This is based on the look-alike and sound-alike approach that, for the reasons cited above, CHPA members do not feel is appropriate for determining if OTC products can be differentiated within an umbrella brand.

Recommendations Pertaining to the Use of a Proprietary Name Already Associated with Marketed Product(s) as Defined by Umbrella Branding

In Section IV of the draft guidance and the accompanying glossary, FDA defines the terms "brand name extension" and "family trade name" (see pages 10-11, 14-15). The proposal that products must share a common active ingredient to share a proprietary name (which the Agency is now defining as family branding or family trade name) assumes that consumers purchasing OTC drugs equate the brand name to a specific active ingredient, and therefore confusion would result if brand names were used for products with different active ingredients. This assumption ignores the realities of today's OTC marketplace and the value of brand names. CHPA members strongly disagree with this position as applied to OTC drugs for a number of reasons.

The current version of the draft guidance has revised the Agency's definition of brand name extension (compared to the definition cited in the May 2014 original version of the joint Rx/OTC draft guidance which is provided as a separate attachment) without providing any explanation or rationale for the change. The OTC industry defines umbrella branding as the practice of selling either different products or different

versions of the same product under the same brand name but the use of umbrella branding is not unique to nonprescription drug products. This practice is commonplace within the consumer products landscape. For example, Apple™ is the umbrella brand name under which the iPhone™, iPad™, and MacBook™ computer, are sold as individual products. FDA should revert to the original definition for brand name extension as noted in the May 2014 FDA guidance on best practices in developing proprietary names for drugs.

Brand names for OTC products serve multiple important purposes for consumers. First, unlike prescription drugs, brand names, umbrella branding, and brand name line extensions can be used as an initial step in consumer recognition and proper selection of OTC medicines. The use of umbrella-branded products also provides assurances of quality, consistency, and product authenticity to end users. Secondly, these medicines may be purchased without involvement of an HCP. OTC medicines have safety profiles where the benefits of product access without involvement of an HCP outweigh the risk. Because OTC medicines are purchased without a learned intermediary, OTC brand names[14] (brands) are beneficial to inform consumer choice and play a key role in assisting consumers with purchase decisions by identifying the source of different products as known and trusted.

OTC drug product labels are required to contain all of the information necessary for the product's safe and effective use by consumers without consultation with a healthcare professional. The regulations for the principal display panel (PDP) as outlined by 21 CFR 201.60, and the Drug Facts label (see 21 CFR 201.66) ensure consistency required of the information available to consumers during the process of selecting the appropriate product. Therefore, there is limited reason to believe that consumers are likely to be misled by OTC umbrella branding or line extensions, resulting in adverse health consequences. Consumers are familiar with where to find critical information on an OTC drug label. Furthermore, companies approach the development of umbrella branding through a process of risk assessment and risk minimization to further ensure a high level of public safety, whether or not the products in question share a common ingredient.

Umbrella branding and brand name line extensions can provide many other benefits to consumers which may not initially be obvious. Consumers can use brand names as the first step in appropriately selecting an OTC drug product, allowing them to choose the product that most appropriately addresses their needs. Umbrella branding may include products with different active ingredients or combination of ingredients which provide similar therapeutic benefits, thus allowing consumers to identify products treating their symptom(s) within a particular product category.

[14] For the purpose of this paper, brand names include umbrella branding and brand name line extensions.

Lastly, OTC brands make it easier to identify products, and provide an increased incentive for the brand owner to invest in improvements among the products carrying the common brand name to maintain consumer loyalty. OTC brand names are of significant value to the brand name owner. Brand names are the principle repository of goodwill that can enable a company to distinguish its products from those offered by other companies.

It is the responsibility of each sponsor to identify and implement a plan to minimize the risk of consumer confusion when utilizing a brand name line extension or introducing a new umbrella brand. This should be the case whether or not the brand name line extension product has at least one active ingredient in common with the previously marketed product. CHPA members have revised the guidance to make clear that brand name extensions for OTC drugs may be appropriate even if the products do not share a common active ingredient.

Existing regulatory requirements for reporting adverse events believed to be associated with an OTC drug allow both the FDA and the sponsor to surveil for a potential safety signal based on consumer confusion due to the drug product name that led to an adverse event.[15] Sponsors have formal processes in place to investigate reported adverse event data to determine causality and to assess for potential trends.

Summary

CHPA members strongly encourage FDA to consider the comments provided and reissue a new version of the draft guidance that specifically addresses best practices for identifying proprietary names for OTC drug products. FDA should remain flexible on the need for relevant studies as well as the data to support a proposed name for nonprescription medicines. Industry has proposed best practices it believes are most appropriate for identifying potential proprietary OTC drug names. CHPA member recommendations have been integrated into our edited version of the Agency guidance that accompanies this cover letter.

CHPA members hope FDA finds these recommendations useful and applies them to an updated version of the guidance. We are happy to respond to any questions that arise during the review process. My contact information is provided below.

[15] See 21 CFR 329.100 Nonprescription Human Drug Product Subject to Section 760 of the Federal Food, Drug, and Cosmetic Act.

Thank you for your time and attention to this submission. The Agency's thoughtful consideration of our feedback is appreciated.

Sincerely,

Marcia D. Howard
Digitally signed by Marcia D. Howard
Date: 2021.06.14 12:55:55 -04'00'

Marcia D. Howard, Ph.D., CAE
Vice President, Regulatory & Scientific Affairs
Email: mhoward@chpa.org
Phone: 202 429 3532 (office) | 202 494 6856 (cell)

Cc: Danielle Harris, Lubna Merchant, Gerald Dal Pan, (FDA CDER OSE)
Theresa Michele, Karen Murry, Amanda Pike-McCrudden (FDA CDER Office of Nonprescription Drugs)

Supporting Documents Submitted to the Docket as Separate Attachments:

1. FDA Draft Guidance: Best Practices in Developing Proprietary Names for Human Drug Products (Issued May 2014)
2. CHPA's edited version of FDA Draft Guidance: Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products (Issued December 2020) (with track changes)
3. CHPA's edited version of the FDA Guidance: Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products (Issued December 2020) (with track changes accepted)
4. CHPA White Paper: Consumer Navigation and Selection Behaviors for OTC Products in a Retail Setting (September 23, 2014)