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September 15, 2014

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

Re: Comments on FDA Draft Guidance for Industry on Best Practices in Developing Proprietary Names for Drugs. 79 Fed. Reg. 30852-30853 (May 29, 2014). Docket No. FDA-2014-D-0622

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA¹), appreciates the opportunity to provide comments on the FDA's draft guidance for industry entitled "Best Practices in Developing Proprietary Names for Drugs," (draft guidance) released on May 29, 2014 (79 *Federal Register* 30852-30853)^{2,3}. CHPA members hope the Agency will find the suggested revisions outlined in these comments informative as the final version of the guidance is developed.

Separate OTC Drug Guidance Should Be Issued

The current draft guidance addresses best practices for developing proprietary product names for prescription and nonprescription medicines, and biological products. We appreciate the FDA's effort to address differences between prescription and nonprescription medicines in the current version of the draft guidance. However, we believe FDA should draft a separate guidance to address the name review process as it applies specifically to nonprescription (over-the-counter, OTC) medicines for minimization of potential medication errors. CHPA members intend to submit a proposal for Agency consideration which outlines general principles for identifying appropriate proposed proprietary OTC drug names. Our draft proposal will include principles that would apply to OTC products marketed under an abbreviated new drug

¹ CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of over-the-counter medicines and dietary supplements (www.chpa.org).

² FDA Draft Guidance "Best Practices in Developing Proprietary Names for Drugs." Accessed at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM398997.pdf> on 3 September 2014.

³ *Federal Register* notice published 29 May 2014 (79 *Federal Register* 30852-30853). Accessed at <http://www.gpo.gov/fdsys/pkg/FR-2014-05-29/pdf/2014-12348.pdf> on 3 September 2014,

application (ANDA)/new drug application (NDA) and principles that should apply to products marketed under the monograph regulatory paradigm.

Nonprescription drugs and prescription drugs are marketed and sold in distinct and separate ways, and carry with them specific benefits and risks. However, unlike prescription drugs, OTC drugs are typically purchased by a consumer without the involvement of a healthcare professional. For that reason, FDA created Drug Facts to ensure that consumers could readily access important information about an OTC drug such as active ingredients, directions for use and warnings, enabling appropriate self-selection.

FDA has developed guidances which are specific to OTC medicines on other topics of interest to industry⁴. In fact, the second guidance in this series of guidances (entitled “FDA Draft Guidance for Industry Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors”) issued to help sponsors minimize the potential for medication errors does not apply to OTC drugs, only prescription drugs and biologics (see line 39 in the draft guidance⁵). Various factors impacting the name review process that are unique to nonprescription drugs merit separate evaluation and consideration, which is not provided in the current draft guidance document. For example, studies such as label comprehension studies, self-selection studies, and actual use studies, which are unique to OTC medicines, are not acknowledged in the current draft guidance. Manufacturer trade names are a common way to distinguish one OTC medicine from another which may not be true for prescription medicines other than the pioneer product. The ability to have a common proprietary name across a range of OTC medicines that may not share at least one common active ingredient (*i.e.*, “umbrella branding”) is critical, not only to manufacturers’ ability to efficiently market products, but also to consumers’ ability to efficiently recognize and choose appropriate products from a trusted brand. Moreover, the regulatory and marketing framework of OTC medicines contrasted with prescription medicines, in particular the lower risk profiles, specific labeling requirements, self-selection by consumers, and different marketing pathways (*i.e.*, application vs. OTC monograph system) also merit separate, in-depth consideration. Therefore, CHPA believes it would be more effective to address the name review process for nonprescription medicines in a separate document rather than attempting to simply highlight these differences within the current draft guidance.

On July 2, 2014, Health Canada released its final guidance for industry on the process manufacturers should follow and the information to be submitted to regulators for proposed drug names to prevent medication errors⁶. In its final guidance, Health Canada stated that “A *separate* (emphasis added) brand name assessment framework will be developed for nonprescription (over-the-counter) products and natural health products.” We hope that FDA

⁴ List of OTC-specific guidances (final and draft) issues by US FDA. Accessed at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065013.htm> on 3 September 2014.

⁵ FDA Draft Guidance for Industry Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors. Accessed at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf> on 3 September 2013.

⁶ Health Canada Guidance Document for Industry – Review of Drug Brand Names. Accessed at http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/guide/2014-review-examen_drug-medicament_names-marques/index-eng.php on 17 July 2014.

will adopt the same approach as it prepares industry guidance on best practices for developing proprietary drug names by developing a separate guidance focused solely on nonprescription drug products. This separate OTC guidance could also further distinguish appropriate practices for names under FDA review (ANDA/NDA) and those that are not subject to FDA review (monograph and distributor).

CHPA members recognize, however, that the Agency may not agree with our recommendation for a separate guidance for nonprescription medicines. As such, the remainder of this submission addresses concerns CHPA members have identified in the current version of the document in the event our request for a separate OTC guidance document is rejected. Importantly, if the Agency continues to believe that a single guidance for prescription and nonprescription medicines is appropriate, we strongly recommend that the single guidance give clear direction as to which principles do, and do not, apply to nonprescription medicines, as this is not accomplished in the draft document as currently written.

We find the FDA's draft guidance useful to understand the Agency's current thinking on developing proprietary names for OTC drug products. However, we trust FDA will not implement these practices in the interim period between issuance of the draft and final guidance. As stated in our comments below, we do not agree that the methods for evaluation expressed in this draft guidance are appropriate for OTC products, and would like the opportunity to fully engage with FDA prior to implementing certain expectations. Proposed guidances issued in draft allow the Agency to receive valuable stakeholder input that hopefully improves the final content of the guidances. While an individual company may choose to follow the principles set forth in this draft guidance, training for FDA staff should emphasize that manufacturers should not be expected to follow recommendations listed in the draft document. Furthermore, as noted in this draft guidance, guidance is not legally binding for the Agency or the public, and the FDA should always be open to alternative approaches (whether a guidance is draft or final) as long as applicable statutes and regulations have been satisfied.

Draft Guidance Section III: Recommendations for Prescreening Proprietary Name Candidates

Section III of the draft guidance recommends that sponsors screen proposed proprietary names for certain characteristics before proceeding with a full assessment of safety and misbranding concerns. We believe this approach is overly-broad and should be revised with respect to OTC drugs.

Decisions to eliminate a proposed name from further consideration should be data-driven. Even if a proposed name is inconsistent with any of the characteristics set forth in Section III, a sponsor may gain information from testing the name to determine the likelihood of confusion that could result in medication error. Likewise, the Agency should not reject a proposed name based solely on a characteristic set forth in Section III and mere speculation that the name will result in a safety or misbranding issue. The Agency should have a sound rationale to support any name rejection. However, if a sponsor does not provide appropriate data when significant questions exist, it would then be appropriate for the Agency to reject a proposed proprietary drug product name.

We recommend that Section III be revised with respect to OTC drugs to delete the concept of prescreening to eliminate names before testing. Prescreening is another way to describe the risk assessment and mitigation process that is common in product development. FDA should expect OTC drug product manufacturers to be engaged in assessing risks of all aspects of their products prior to launch. If the Agency believes some of the concepts set forth in Section III are appropriate for OTC drugs, manufacturers can consider incorporating these ideas into their general assessment of product risk.

It is important to note that a manufacturer will identify appropriate mitigation of a risk (such as further testing) only in cases where the risk is considered to be frequent and/or severe enough to warrant mitigation. FDA should acknowledge that the need for mitigation is determined on a case-by-case basis. There will be certain scenarios where the risk assessment indicates no further mitigation is necessary, and therefore proprietary names would be submitted for approval, or marketed without, supportive data. FDA should remain flexible on the need for studies and data to support a proposed name. Based on experience and expertise in assessing product risk as part of product development, the sponsor, possibly in consultation with the Agency, would be in the best position to determine what data are needed to substantiate the use of a proposed product name. Manufacturers of OTC medicines have experience in conducting consumer behavior studies⁷ 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.

Comments on some of the characteristics assessed to eliminate proposed names in the prescreening process follow.

Section III.A. Obvious Similarities in Spelling and Pronunciation of Proprietary Names

The Agency states that proprietary names should not be similar in spelling or pronunciation to existing proprietary names, established names, or ingredients. We believe that it is inappropriate to rule out an OTC proprietary name based solely on the fact that it looks like or sounds like an existing name. Sponsors should be able to test these names to assess the likelihood of a safety or misbranding concern. Likewise, the Agency should have a sound rationale showing that the similarity is likely to result in medication error or misbranding before rejecting a proposed proprietary name for sounding or looking like an existing drug name. For OTC medicines in particular, the name is only one factor guiding the selection and use of the product. Other factors germane to the proper selection of OTC medicines include packaging design and color, retail shelf placement, and other visual aids. Any tests needed should be done in the context of a company's risk mitigation plan designed to minimize the occurrence of a medication error.

Section III.F. Same Proprietary Name for Products Containing Different Active Ingredients

The Agency advises against sponsors using the same proprietary name or the same root proprietary name for products that do not contain at least one common active ingredient

⁷ Consumer behavior studies include label comprehension studies, self-selection studies, and actual use studies.

contained in the original marketed product. CHPA members strongly disagree with this position as applied to OTC drugs for a number of reasons.

The proposal that products must share a common active ingredient to share a proprietary 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.

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 of consumer recognition and proper selection of a nonprescription drug. The use of commonly-branded products also provides assurances of quality, consistency and product authenticity.

Secondly, nonprescription medicines may be purchased without involvement of a healthcare professional. OTC products have wide margins of safety where the benefits of product access without involvement of a healthcare professional outweigh the risk. Because OTC medicines are purchased without a learned intermediary, OTC brand names⁸ (brands) are beneficial to inform consumer choice and play a key role in assisting with purchase decisions by identifying the source of different products as known and trusted.

OTC medicine 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. Because of the consistency required by 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), 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 now familiar with where to find critical information on an OTC drug label. Additionally, companies approach the development of umbrella branding through a process that includes risk assessment and risk minimization to further ensure a high level of public safety.

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

Additionally, 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 good will that can enable a company to distinguish its products from those offered by other companies.

It is our position that any policy that limits the ability of a sponsor to utilize umbrella branding and/or brand name line extensions should be based on reliable evidence that the new

⁸ For the purpose of this paper, brand names include umbrella branding and brand name line extensions.

products are, or are likely to be, misleading. It is the responsibility of the 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 regardless of whether or not the brand name line extension product includes at least one active ingredient in common with the product already marketed.

The proposal in the draft guidance to eliminate a proprietary name during the prescreening phase if it does not share a common active ingredient with the existing drug is a significant departure from FDA practice and industry standard in the OTC arena. For years, FDA has acknowledged that OTC drugs are often sold under umbrella brands and do not necessarily share a common active ingredient⁹. Indeed, FDA has approved OTC NDA's utilizing a brand name when another OTC drug exists using the same name but a different active ingredient. The OTC industry has relied on this practice to create established brand names that cover a variety of products with different ingredients.

Unduly restricting a company's ability to use brand names without any evidence of potential harm raises significant constitutional issues. FDA must tailor the guidance's recommendations more directly to the governmental interest at issue so as not to unduly limit sponsor's commercial speech rights.

Section III.G. Reuse of Proprietary Names

The draft guidance advocates eliminating a proposed name during the prescreening phase if the name was previously used for another drug. Again, we believe this approach is unnecessarily limiting. A sponsor should be able to reuse a proprietary name provided that there are no data to suggest a likelihood of confusion that could result in medication error.

Draft Guidance Section IV. Other Naming Attributes That Might Be Considered Misleading or Error Prone

In Section IV of the draft guidance, the Agency lists other attributes for sponsors to consider before proceeding with a full assessment of safety and misbranding concerns. We believe any approach that would rule out proposed proprietary names for OTC drugs without regard to testing is not appropriate.

Comments on the additional attributes set forth in Section IV follow.

Section IV.D. Brand Name Extensions

The draft guidance appropriately notes that brand name extensions would be assessed on a case-by-case basis. As per our previous comments on Section III.F., we recommend Section IV.D. be revised to make clear that brand name extensions for OTC drugs may be appropriate even if the products do not share a common active ingredient.

⁹ Presentation by Gerald Dal Pan, M.D., on 3 May at the 2013 CHPA Regulatory, Scientific & Quality Conference. Presentation title: "Adverse Event Reporting and Medication Safety Considerations: A View from CDER's Office of Surveillance and Epidemiology."

Section IV.F. Proprietary Names of Drug Products Marketed Outside the United States

The draft guidance recommends against using a proprietary drug product name that is identical or nearly identical to a product that is marketed in a foreign country and contains an entirely different active ingredient, even if the proposed product (that would be subject to the naming review) will be marketed only in the US. We disagree with this recommendation as it relates to OTCs. There may be factors, such as different product classification (e.g., OTC in one country while prescription in another), language considerations, and other regulatory requirements, that an applicant has evaluated when developing its proposed drug name for the product that would be sold in the US. Previous or current use of a proprietary drug name for a product marketed globally, while potentially one element in the assessment process, should not be the basis for rejection of a proposed proprietary drug name for a nonprescription medicine to be marketed in the US.

During its webcast entitled “Overview of FDA’s Proprietary Name Review Process” on 15 July 2014, FDA acknowledged that medication errors that have occurred when a proprietary name for a product marketed in the US is identical, or virtually identical in spelling and pronunciation, to a foreign product containing an entirely different active ingredient marketed in a foreign country is not a reason for the name to be found as “unacceptable” in the US¹⁰. CHPA members agree with the Agency’s stated position that foreign medication errors are not a reason to reject a proposed name for a product that will be marketed. We do not agree with the recommendation that manufacturers avoid a proposed proprietary name that is identical or nearly identical to a foreign product that may contain a different active ingredient from the product that would be marketed in the US¹⁰. CHPA members do acknowledge that the Agency may consider global factors in its evaluation process. However, if a product will only be marketed in the US, the decision to approve (or reject) a given proposed drug name should be based mainly on the data relevant to domestic consumers.

Section IV.I. Incorporation of the Sponsor’s Name

The draft guidance recommends against using a sponsor’s name in a proposed proprietary drug product name. This wrongly assumes in the OTC category that consumers always associate a company name with a specific drug. On the contrary, consumers often use OTC brand names to help establish the source of the product, such as private label brands (e.g., CVS brand or Rite Aid brand). OTC brands should be allowed to continue to reference company names in proprietary names in the absence of data establishing a safety or misbranding concern.

¹⁰ CDER Small Business and Industry Assistance (CDER SBIA) Webinar on “Overview of FDA’s Proprietary Name Review Process” – 15 July 2014. Archived webinar and background materials accessed at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm403376.htm> on 17 July 2014. See slide 23 and presentation transcript at 22:14-22:19.

Draft Guidance Section V. Misbranding Review and Methods for Evaluating Safety of Proposed Proprietary Names for Drugs

In Section V, FDA provides guidance on how the Agency evaluates proposed proprietary names beyond the initial screening steps detailed in Sections III and IV.

Section V.A. Misbranding Review (Other Than Medication Error Prevention)

The Agency states that a proprietary name could result in misbranding if it contains a false or misleading representation with respect to safety and efficacy. We recommend that this section be revised to make clear that the Agency will rely on competent data in determining if a name is communicating a false or misleading representation, not mere speculation.

Section V.B. Safety Review

The draft guidance outlines various tests which might be utilized to evaluate the appropriateness of a proprietary drug name. As explained above, CHPA members believe that the guidance does not adequately take into account the specific characteristics of OTC drugs and therefore a separate guidance related to OTC drugs should be issued. Below are comments on the testing approaches set forth in Section V.B.

Section V.B.1. Conduct Name Simulation Studies

The draft guidance describes that the Agency performs simulation studies involving FDA staff to test the response of healthcare professionals to proposed names. The Agency believes that these studies are predictive of errors in actual use. We recommend that the FDA share its rationale for this view, including its process for avoiding potential bias, “testing fatigue,” and other possible confounding issues associated with using FDA staff to test proposed proprietary drug names. In addition, we note that this type of study does not adequately simulate the experience of an average consumer purchasing an OTC product.

Section V.B.1.c. Participants

This section instructs that participants in simulation studies should be actively practicing healthcare professionals. This is not appropriate for OTC drug name testing where the key is consumer self-selection. Later in the draft guidance, the Agency does acknowledge that simulation test should be designed to test the understanding of consumers and healthcare professionals of proposed proprietary drug names (see lines 698-699²).

Section V.B.1.d. Scenarios

The draft guidance states that sponsors should test a minimum of 20 scenarios, representing each possible prescribing condition for the proposed product. Possible test scenarios are listed in Table 1 of the draft guidance. CHPA members do not believe the test considerations as outlined in the draft guidance should be applicable to OTC products. Instead, we recommend modifying the draft guidance to state that manufacturers should design their name simulation study programs based on the scenarios of concern, rather than stating a minimum number of test scenarios which might not be appropriate in all cases.

While the suggested approach outlined in Section V.B.1.d. might be appropriate for prescription drugs, modifications to the scenarios would be necessary for nonprescription drugs. Manufacturers of nonprescription products may conduct consumer behavior studies⁷ during their research and development (R&D) program, which are not part of the routine R&D process for prescription drugs. The current examples outlined in Table 1 are inconsistent with the normal conditions under which OTC medicines are traditionally purchased and/or used (*i.e.*, without requiring involvement of a healthcare professional).

Although the example test scenarios listed in Table 1 are informative, OTC medicine manufacturers would be in the best position to determine the types and number of tests needed to properly evaluate a proposed name for a new nonprescription drug product. As mentioned earlier in these comments, OTC companies, based on their expertise in consumer behavior studies⁷, are uniquely positioned to design testing programs for nonprescription medicines to assess the likelihood of a medication error associated with an OTC medicine. The manufacturer of an OTC medicine should design its study(ies) to reflect the anticipated use conditions in the over-the-counter setting which may or may not involve consultation with a healthcare professional. The study(ies) for nonprescription products adequately test the appropriateness of the proposed product name and label comprehension for the consumers and caregivers who purchase and use these products. Therefore, we anticipate that sponsors may choose to follow an alternate approach to test proposed proprietary drug names based on their internal review and assessment. Individual sponsors would determine if Agency consultation is needed as stated on page 1 of the draft guidance. Furthermore, the Agency should include a separate table outlining example scenarios specifically related to over-the-counter medicines which would be more relevant to the nonprescription medicine use environment than those currently listed in Table 1 of the draft guidance.

Section V.B.2. Obtain Medication Error Data

The draft guidance states that if a sponsor obtains information from ex-US marketing experience on medication errors related to the product's established and proposed proprietary name that may be relevant to the use of the proposed proprietary name in the US, manufacturers should provide this information to the FDA (lines 587-590²). Product classification, naming requirements, and consumer experiences with umbrella brand names vary significantly within the global marketplace. Products marketed in the US and globally may or may not be the same. Additionally, differences in language, culture, and healthcare environment may play a key role in these types of medication errors. For these reasons, CHPA members believe that very little of the data on medication errors that occurred outside of the US would be relevant to the FDA proprietary name review process for a product that would be marketed in the US. This would be especially true for data obtained in non-English speaking countries.

Section V.B.3. Computational Methods 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. It is not clear that POCA is an appropriate assessment tool for OTC drug product names. Aside from that question, the draft guidance indicates this system is available upon request at no charge to sponsors

(manufacturers). However, depending on the manufacturer's available technology, system incompatibility may be experienced. The POCA system should be as user-friendly as possible as not all companies have extensive IT departments that can address any issues of incompatibility experienced while using the current platform. We recommend the Agency's POCA be developed on a platform that is universally accessible to sponsors regardless of the operating system used.

In the current draft guidance, FDA describes how name reviews and approvals will be handled if similar proposed names are submitted around the same time (see footnote 24 in the draft guidance document²). The FDA issued a guidance in February 2010 informing sponsors that they can include up to two proposed proprietary names for Agency review, with the first choice name specified in the complete submission package¹¹. The guidance also states the alternate (secondary) name is reviewed only if the first choice (primary) name is rejected *and* (emphasis added) the sponsor has confirmed in writing to the appropriate review center that it would like the secondary name reviewed. A new PDUFA IV review clock is started upon receipt of the written confirmation from the sponsor to review the alternate proposed proprietary drug name.

CHPA members recommend the Agency allow sponsors to submit up to three proposed drug names when the application is initially filed. Applicants would be responsible for informing FDA of their first and second choice options at the time of initial filing. Should the FDA reject an applicant's first choice proposed drug name, the sponsor would still be required to formally request (in writing) that one of the alternate proposed names be reviewed. Because new information may be identified or obtained during the course of the review process that could alter the sponsor's initial ranking of proposed product names, under our proposal, the sponsor would be allowed to designate which of the two remaining proposed names should be evaluated next, regardless of the priority ranking stated in the original application. No change to the actual naming review process would be required or is suggested.

Section V.B.5. Final Determination of the Acceptability of a Proposed Proprietary Name

The draft guidance states that the Agency will make its final determination on the acceptability of a proposed proprietary name based on its review of all information and analyses described in the guidance along with any information submitted by the applicant. The FDA held a webcast for industry to discuss this draft guidance on 15 July 2014¹⁰. During the question and answer period, a participant asked FDA a question regarding the appeal process if the applicant's first choice option was rejected and whether the agency would accept new data that might be become available since the initial review was conducted. The presenter indicated that the appeal process is outlined in a Manual of Policies and Procedures (MaPP) and that the Agency would accept any new relevant data for review, which should be first submitted to the original reviewing division. We are encouraged to learn new data would be considered by FDA if the preferred name was initially rejected.

¹¹ Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names. Accessed at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf> on 7 July 2014.

CHPA members also believe the process for conveying information to sponsors when a proposed product name is rejected can be improved. FDA should provide the applicant with timely written communication on or before the end of the 90 day review period clearly citing the reason for the rejection. (Telephone communication within the 90 day period is not adequate.) The rejection letter should also state the process to request an appeal of the decision if the applicant disagrees with the Agency's assessment and determination. The appeal process should begin as formal dispute resolution, meaning the first step of Agency reconsideration is at the management level above the person indicated as the decision-maker in the written communication. Whether the sponsor chooses to appeal or not, the FDA should provide the sponsor with the option of selecting the next alternate name to be reviewed at the time of a rejection.

As stated elsewhere in these comments, it is critical that FDA remain open-minded to proposed names and that decisions to reject proposed names be based on sound objective data. Assuming that testing standards can provide a realistic facsimile of the OTC environment, rejections should be informed not only by the existence of an error in a study population, but also by the frequency and the severity of the potential risk of the error. The draft guidance should clearly define standards that the Agency will use to determine the acceptability of a proposed name, or at least provide a detailed explanation of the factors that will define the decision. It is imperative that FDA decisions on proprietary names are practical, predictable, and transparent. We welcome the opportunity stated in Section V.C. of the guidance to meet with FDA early in the name development process to discuss and agree on the acceptance criteria that will apply to names for the products in development.

Section V.C. Name Review for Nonprescription Drug Products

The draft guidance notes that the FDA naming review process for proprietary drug names applies only to OTC products marketed under applications (ANDA, NDA). We agree that it is the responsibility of the sponsor to determine and select proprietary drug names that are appropriate, minimize the chance of consumer confusion, and are not misleading. Additionally, we acknowledge that the test recommendations outlined in this draft guidance may also serve as guidelines for manufacturers of monograph OTC products if they choose to use them when developing data to identify appropriate proprietary product names.

We disagree with the Agency's recommendation that proprietary names of OTC drugs be evaluated using the method described in section V.B. as a "best practice" and request that reference be omitted. As mentioned above, section V.B. does not adequately address the unique nature of OTC drugs. In addition, OTC drug names need to be evaluated on a case-by-case basis, which does not lend itself to a "best practice" or "one-size-fits-all" approach.

Other considerations for testing proposed product names are listed in Section V.C.2. of the draft guidance. Labeling requirements for OTC products¹² stipulate the content and format of information contained in the Drug Facts Label and product labeling. Sponsors must comply with the regulations but are not restricted in what additional information is included in the product labeling as long as it is not false and misleading. It is the applicant's responsibility to ensure that consumers can adequately read and comprehend the proposed Drug Facts

¹² 21 CFR 201 Labeling Requirements for Over-the-Counter Drugs

Labeling. Therefore, data from consumer behavior studies should be one, if not the most, important factor when evaluating an ANDA/NDA for approval. Any review for potential medication error resulting from the proposed proprietary drug name must acknowledge the broader context of data from relevant consumer behavior studies⁷.

Furthermore, nonprescription medicines are marketed directly to consumers at the point of purchase, in packaging that includes identifiable trade dress for individual products. Consumers utilize different features (such as 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) clearly state the labeling requirements for the principal display panel (PDP) for over-the-counter drugs. Sponsors must follow the stated regulations governing the PDP but must not be precluded from, or restricted in, the use of particular colors, fonts, text and other markings on their packaging if the use of such cues is truthful and not *demonstrated* (emphasis added) to be misleading.

Rejection of a proposed product name, and in particular those rejected based on the package label in totality, must be objective¹³. There must be objective facts of record which make the proposed labeling demonstrably false or demonstrably misleading¹⁴. FDA should provide scientific data in support of its decision to reject a proposed trade name, including information regarding the entire package label if these elements contributed to the rejection.

CHPA members encourage FDA to provide clarity about its decision-making process to determine if a proposed proprietary drug product name is acceptable. It would be helpful for FDA to explain any process differences that might exist within the Agency, including within different FDA offices such as the Office of Drug Evaluation IV (ODE IV) and the Office of Generic Drugs (OGD). We ask the FDA to share the standards by which the decision to accept or reject a proposed proprietary drug name is made. Transparency on this matter would be useful to applicants when they evaluate future proposed drug names as they would know what criteria would be used for the assessment process.

Summary

We applaud the Agency for releasing the subject draft guidance. In general, we believe the information contained therein will be useful to sponsors as they design studies to identify appropriate product names which minimize the chance of medication errors. However, CHPA members recommend FDA follow the same approach as Health Canada and develop a separate draft guidance specific to OTC drug products rather than attempting to address best practices for both prescription and nonprescription medicines in the same document. To facilitate this approach, CHPA members intend to submit a proposal for Agency consideration outlining general principles for identifying appropriate proposed proprietary OTC drug names within 6 months of the closing period for the subject draft guidance. However should separate guidances not be possible, we trust the FDA will take the recommendations outlined in this submission under advisement when developing the final version of the document.

¹³ 108 Cong. Rec. 21,066 (1962).

¹⁴ 108 Cong. Rec. 21,066 (1962).

Thank you for your time and attention to this submission. If there are any questions, you may reach me using the contact information provided below.

Sincerely,

A handwritten signature in cursive script that reads "Marcia D. Howard".

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