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15 September 2014

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

Re: Comment on FDA Draft Guidance for Industry on Best Practices in Developing Proprietary Names for Drugs. 79 Fed.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:

Concentrics Research (Concentrics)[1] appreciates the opportunity to provide comments on the FDA's draft guidance for industry entitled "Best Practices in Developing Proprietary Names for Drugs," (draft guidance) released on May 29, 2014 (79 *Federal Register* 30852-30853). We have also participated in the task force that worked with the Consumer Healthcare Products Association (CHPA) to provide comments on this guidance and we support CHPA's position.

Concentrics is a consumer healthcare research company. We work with most of the manufacturers of over-the-counter (OTC) drugs, devices and supplements. Our work is largely devoted to research such as label comprehension, self-selection and actual use studies as well as a wide range of customized consumer use and human factors testing. We have also conducted REMS programs involving comprehension of the medication guide. Our company also develops labeling, patient package inserts, patient leaflets and instructions for consumer products. Throughout this work, we have interacted with thousands of consumers and conducted in excess of two million consumer interviews. We ardently believe in clear communications and consumer safety. We support the

[1] Concentrics Research LLC, Indianapolis, IN and Parsippany, NJ; www.concentricsresearch.com

concept of assuring the consumers understand the purpose (indication) of OTC drugs and the associated directions and warnings. Further, we strongly support efforts to assure that the product name and/or labeling not cause consumer confusion.

We appreciate FDA's efforts to assure that proprietary names do not cause confusion and we support a "systematic, standardized and transparent approach to proprietary name evaluation." However, we do not believe that the draft guidance is aligned with how consumers search for or make decisions about OTC medications. Consumers use brand names and trade dress as guideposts to assist them in finding the medications they need. Brands represent trust and reliability for a product and consumers tend to select the same brands repeatedly because they are effective and proven. In addition, consumers are accustomed to a brand representing multiple products or line extensions. This is a familiar process for nearly all consumer products. Further, the majority of consumers understand that a brand family may be comprised of products that may have different indications, ingredients, instructions or warnings. The products are labeled and tested to assure that these characteristics are comprehended by a general population of consumers.

In addition to our comments above, we provide the following specific comments:

SECTION III: RECOMMENDATIONS FOR PRESCREENING PROPRIETARY NAME CANDIDATES		
Line Number	**Comment and Rationale**	**Proposed Change (if applicable)**
107-116	FDA objects to proprietary names having similar spelling or pronunciation, yet, as stated above, the familiarity of the brand name and trade dress are important as a reference point to consumers. Many OTC products have similar names and some have different indications or ingredients, but the labeling can be tested and improved to assure that consumers are not confused by differences in any product attributes.	Build on the established Label Comprehension Guidance for Nonprescription Drug Products[2] by testing comprehension and the ability of consumers to discern the differences among products in a brand family. Similar names should be permitted if they do not cause confusion.
140-155	FDA objects to the incorporation of USAN stems in the name. This unilateral objection should be based on objective data, not a hypothetical concern.	Testing can be conducted with consumers to learn if the name is confusing and if so, iterative changes can be made in the qualitative testing to improve the labeling and the name.

[2] Guidance for Industry Label Comprehension Studies in Nonprescription Drug Product, August 2010.

SECTION III: RECOMMENDATIONS FOR PRESCREENING PROPRIETARY NAME CANDIDATES (continued)		
Line Number	**Comment and Rationale**	**Proposed Change (if applicable)**
157-167	FDA objects to the use of the same root proprietary name of products that do not contain at least one common active ingredient contained in the original marketed product. For all the reasons stated above, there should not be a unilateral decision to prevent names with the same root. The commonality of the name across a brand family allows consumers to find the brand that they trust. Once they find the brand family, they can then scan the products for the differences and identify the product that best meets their needs.	Testing can be conducted with consumers to learn if the name is confusing and if so, iterative changes can be made in the qualitative testing to improve the labeling and the name
339-361	FDA objects to brand name line extensions (BNLEs) having the same root proprietary name for multiple products. They cite errors that have resulted from BLNEs for a different indication, the administration of an unnecessary active ingredient and the use of a product in the wrong patient population; however, these issues have been limited. No one solution will assure 0% errors or confusion; however, objective iterative testing can optimize the label and name to reduce the possibility of any confusion.	Testing can be conducted with consumers to learn if the name is confusing and if so, iterative changes can be made in the qualitative testing to improve the labeling and the name.

SECTION V: MISBRANDING REVIEW AND METHODS FOR EVALUATING SAFETY OF PROPOSED PROPRIETARY NAMES FOR DRUGS		
Line Number	**Comment and Rationale**	**Proposed Change (if applicable)**
466-472	FDA conducts simulation studies among FDA staff to “test the response of healthcare professionals to proposed names.” Since OTCs are evaluated and selected by consumers vs. healthcare providers, this process does not provide a valid testing method to predict any consumer confusion.	Simulation studies with FDA staff should not be conducted for OTC products. Consumers should be tested directly to determine if there is any confusion.

SECTION V: MISBRANDING REVIEW AND METHODS FOR EVALUATING SAFETY OF PROPOSED PROPRIETARY NAMES FOR DRUGS		
Line Number	**Comment and Rationale**	**Proposed Change (if applicable)**
474-490	FDA suggests "real-world" simulation studies be conducted to reflect the full range and variety of tasks involved in the prescribing, transcribing, dispensing and administration of drugs as well as tasks involved in consumer selection of OTC drugs. The real-world tasks involved in an OTC environment include the consumer seeking out a new OTC medication, evaluating the labeling, making a selection decision and then a purchase decision. The consumer makes these decisions, not the healthcare provider, so the testing processes should be reflective of *consumer evaluation and selection tasks.*	This can be done in a label comprehension and/or self-selection study. Further a discernment study can be conducted to learn if the consumer can distinguish key differences between a new product and several others in the brand family.
533-575	FDA suggests that testing be conducted to assure "a minimum of 20 scenarios, reflective of "each prescribing condition." The arbitrary requirement for 20 scenarios is not useful; any scenario testing should be a function of the tasks that need to be evaluated or tested. Also, the testing of prescribing scenarios is not consistent with the OTC environment.	The number of scenarios should be a function of the information that needs to be tested. The testing should be comprised of scenarios that evaluate decision-making by consumers.
607-656	FDA recommends the use of their Phonetic and Orthographic Computer Analysis (POCA) system for evaluating look-alike, sound alike names. Testing to evaluate look-alike, sound-alike names is not useful in an OTC environment in which may products are within brand families with similar names.	Testing can be conducted with consumers to learn if the name is confusing and if so, iterative changes can be made in the qualitative testing to improve the labeling and the name.
668-683	FDA recommends that proprietary name testing be conducted by both consumers and healthcare providers; however, healthcare providers do not routinely prescribe or recommend a specific OTC medication; they may suggest a medication class and give examples of product names.	Testing should be with consumers who make the product evaluation, selection, purchase and use decisions, not with a healthcare provider.

SECTION V: MISBRANDING REVIEW AND METHODS FOR EVALUATING SAFETY OF PROPOSED PROPRIETARY NAMES FOR DRUGS		
Line Number	**Comment and Rationale**	**Proposed Change (if applicable)**
685-695	FDA recommends that consumers demonstrate their ability to identify an appropriate product at the point of purchase based on the product name and other information on the principal display panel as defined in 21 CRF 201.60.	Consumer discernment studies are designed to evaluate if consumers can identify how the product is different from other products in the product brand family. While no manufacturer should be expected to test all the products in a brand family, it is advisable to test at least 2 other products, each with a different indication or ingredient than the base product.

Thank you for the opportunity to present this feedback on the draft guidance. We believe that the adjustments described above for the evaluation of proprietary names for OTC drugs will provide a solid path forward for the testing and evaluation processes.

Sincerely,

Julie L. Aker
President & CEO
Concentrics Research LLC