CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

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October 27, 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 Exploring the Possibility of Proprietary Name Reservation for Drug Products; Establishment of a Public Docket. 79 *Fed. Reg.* 43751-43753 (July 28, 2014). Docket No. FDA-2014-N-1008

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA[1]), appreciates the opportunity to provide comments to the FDA in response to the 28 July 2014 *Federal Register* announcing the opening of a public docket to discuss issues related to reserving proprietary names for drug products (79 Federal Register 43751-43753)[2]. CHPA members applaud the Agency for seeking stakeholder input as it seeks to further the proprietary name review-related performance goals outlined in the Prescription Drug User Fee Act (PDUFA) IV goals letter. The comments below will be restricted to nonprescription drug application (NDA[3]) over-the-counter (OTC[4]) drug products.

In principle, CHPA members support the concept of an early approval program for proposed proprietary drug names (early approval program). However, should FDA decide to implement an early approval program, we expect that FDA would publish a draft Guidance for Industry and we would provide further comment based on the criteria outlined by the Agency. Any such program must be structured in a manner which does not place the sponsor receiving the early approval at a competitive disadvantage (*e.g.,* disclosure of confidential information).

[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] *Federal Register* notice published 28 July 2014 (79 *Federal Register* 43751-43753). Accessed at http://www.gpo.gov/fdsys/pkg/FR-2014-07-28/pdf/2014-17691.pdf on 26 September 2014.
[3] NDA – **N**ew **D**rug **A**pplication
[4] Nonprescription medicines, over-the-counter medicines, and OTCs will be used interchangeably throughout this document.

FDA Request for Comments from Stakeholders

The *Federal Register* notice[2] on the concept of an early approval program for proposed proprietary drug product names lists several issues where stakeholder input is requested. The comments below apply only to nonprescription medicines marketed under an NDA. In response to the question posed by FDA in the *Federal Register* notice regarding drug products marketed under OTC monograph regulations, we submit that any early approval name review process instituted would not be applicable to monograph nonprescription medicines as these products are not subject to premarket approval, including approval of the proprietary drug name.

How a Program (For Reserving Proprietary Names) Would Create Certainty While Balancing the Need to Avoid or Minimize the Risk of Medication Error

The Agency requested stakeholder input regarding an early approval program that would create certainty while balancing the need to avoid or minimize medication errors. An early approval program would allow sponsors to develop their proposed package labeling, principal display panel (PDP), and other product materials with advanced knowledge and increased confidence that the proposed product name would not be rejected following what is often a multi-year research & development (R&D) process. Over-the-counter medicines are typically used without the involvement of health care professionals (HCPs). Therefore, consumer behavior studies[5] may be conducted to ascertain the ability of a consumer to appropriately comprehend the proposed label information, and to properly select and use a nonprescription medicine. Currently, an applicant could invest significant time, research dollars, and personnel resources to test a product name that could subsequently be rejected if another NDA receives approval with the same or a similar name.

Parameters of the Proposed Program

It is unclear if FDA intends to move forward with developing a process whereby a sponsor can "reserve" a proprietary drug product name. If the Agency does so, it is paramount that FDA explore mechanisms to maintain the confidentiality of sponsor trade information while seeking to achieve the identified goals associated with an early approval program. Any early approval program must include safeguards such that the sponsor company would not be placed at a competitive disadvantage if its proposed drug product name receiving early Agency approval was released prior to approval of the sponsor's NDA. Without details of the anticipated goals of an early approval program, it is difficult to provide meaningful suggestions to achieve this balanced approach. However, we could envision for example that the Agency might develop an initial screening process for an applicant's proposed drug product name(s) to identify those it would view as "unacceptable." This initial screening would be based on FDA's own internal database of drug product names that have received Agency approval along with those pending approval under a corresponding NDA. FDA could then communicate its findings (*i.e.,* which name(s) it considered as "unacceptable" only without further explanation) to the applicant, with the applicant making the final decision whether or not to eliminate the specific name(s) from any future testing program. The Agency response to the initial screening would not be considered as binding. If the early approval program permitted FDA full access to approved drug names that may be marketed in the future, and provided subsequent applicants limited

[5] Consumer behavior studies include label comprehension studies, self-selection studies, and actual use studies.

feedback based on approved product names as known to FDA (to ensure confidentiality of the competitor's data), both parties would be able to effectively develop (applicant) and evaluate (FDA) proposed drug names that minimize the risk of a medication error occurring due to the product's proprietary trade name.

An early approval process would be beneficial to both the Agency as well as to applicants if implemented with appropriate criteria and protections. FDA would streamline its review process if, with an appropriately-designed early approval program that provided limited but early input to the applicant, sponsors were able to better develop potential proprietary drug product names for assessment sooner in the testing process. Industry would have increased transparency, predictability, and efficiency as it could receive approval of its preferred drug product name earlier in the application process, and generate necessary data early on for a subsequent naming review should the initial proposal be rejected.

Participation in an early approval program should be at the discretion of the sponsor. However, if an applicant requests and receives early approval for a proposed drug product name, the approval decision should be binding. In the event the proposed name is not approved during the initial review, the sponsor should be allowed to discuss the negative decision (rejection) and/or submit additional data that may have been obtained during the course of the initial review process to further support approval of the proposed drug name. The decision on the proposed rejected drug name (conducted under an early approval program) would not be binding as the discussions and/or subsequent review were being conducted. If a company chooses not to enter the early approval program, any decision (approval or rejection) made regarding the proposed proprietary drug name prior to the approval of an NDA should not be binding.

Once a proposed proprietary drug product name has been granted approval, it should be binding unless and until the sponsor withdraws the approval in writing. Once an approval for a proposed drug product name has been issued, we believe any subsequent applications submitted by other sponsors for a naming review should be rejected if there is sufficient data to demonstrate the likelihood of a medication error to occur due to potential confusion based on the product name.

FDA inquired whether participation in a potential program for reserving proprietary drug product names should be voluntary or mandatory[2]. Without details about how such a program would be administered, CHPA members believe participation should be left to the discretion of the applicant. However, as stated above, a mechanism would need to be established that maintained confidentiality of the drug product name receiving early approval. The system would also need to minimize the likelihood other manufacturers would invest valuable resources (*i.e.,* time, financial, and personnel) to develop a proposed drug product name that is later rejected but which may not have been selected had the sponsor been previously advised the name was unacceptable due to a product name(s) approved for a different sponsor.

Summary

CHPA members appreciate the Agency's effort to increase transparency and predictability during the proprietary name review process. In general, CHPA members support an early approval program for proposed proprietary drug product names. This support is conditional on any early approval program protecting a sponsor's confidential information. However, we will provide additional input to the Agency once FDA has published proposed criteria for an early approval program for stakeholder input. If properly implemented, an early approval program would be beneficial to both FDA and industry. FDA could potentially streamline the review process for proposed proprietary drug names. Industry would have obtained a formal response to its application earlier in its R&D program thus allowing appropriate labeling and product materials to be designed with greater certainty, ensuring nonprescription medicines reach the marketplace to meet the needs of the more than 240 million Americans who use OTC medicines every year[6].

Should questions arise about our comments, please contact me by phone or email. My contact information is listed below.

Sincerely,

Marcia D. Howard, Ph.D.
Senior Director, Regulatory & Scientific Affairs
Email: mhoward@chpa.org
Phone: 202.429.3532

Cc: Kellie Taylor, FDA Center for Drug Evaluation and Research
Stephen Ripley, FDA Center for Biologics Evaluation and Research

[6] The Value of OTC Medicine to the United States (January 2012). Accessed at http://www.yourhealthathand.org/images/uploads/The_Value_of_OTC_Medicine_to_the_United_States_BoozCo.pdf on 7 October 2014.