CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

Submitted electronically via www.regulations.gov

May 17, 2016

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 Food and Drug Administration Review and Action on Over-the-Counter Time and Extent Applications. Docket No. FDA-2016-N-0543[1]

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA[2]) appreciates the opportunity to provide comments on a proposed rule, issued by the U.S. Food and Drug Administration (FDA or Agency), on the Agency's review and action on over-the-counter (OTC) time and extent applications (TEAs). This proposed rule, if finalized as outlined, would supplement the current time and extent application process for OTC drugs by establishing timelines and performance metrics for the Agency's review of non-sunscreen TEAs as set forward in the Sunscreen Innovation Act (SIA). FDA is also taking this opportunity to propose other changes to increase the efficiency of the TEA process.

CHPA members take this opportunity to highlight the need for overall reform to the OTC monograph process. Our position is based on the Agency's estimated timeline of approximately 5-6 years to complete all steps in the review and action process. While the explanation for the estimated timeline for the entire TEA process[3] (see Section V.A.2.a.) is clear, we believe additional improvements to the process for changing an OTC monograph, including those initiated via a TEA, could further streamline the projected TEA schedule. It is important that an improved TEA schedule, which provides a clear and timely path allowing for well-established, safe, and effective active ingredients to enter the monograph system, is a part of an overall reform to the OTC monograph process. A timeline which adds these ingredients in 1-2 years, rather than 5-6 years, would represent significant progress towards accomplishing this goal.

As stated above, based on the Agency's proposed time periods for action for each step, 5-6 years would elapse on a TEA with no unexpected delays before a final rule is issued. The proposed rule notes that the timeline for review of non-sunscreen TEA conditions may vary based on several factors, including the content of the application, complexity of the data, and format of the submission. Additional considerations for the proposed timeframes include FDA public health priorities, available resources to carry out the Agency's public health priorities, and reasonableness.

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[1] *Federal Register* notice published April 4, 2016 (81 *Federal Register* 19069-19086). Accessed at https://www.gpo.gov/fdsys/pkg/FR-2016-04-04/pdf/2016-07612.pdf on April 8, 2016.

[2] The Consumer Healthcare Products Association (CHPA) is the 135-year-old national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products.

[3] For purposes of these comments, unless otherwise stated, the TEA process is assumed to apply only to non-sunscreen OTC ingredients.

These other factors would be expected to lengthen the timeframe for TEA review and actions. Regulatory certainty and efficiency would be diminished if decisions could potentially be delayed for many years.

With respect to format and content of submissions, the *Federal Register* notice[1] of the proposed rule referenced the recently issued draft guidance for industry[4,5] regarding the format and content of data submissions for nonprescription sunscreen active ingredients. CHPA would like to refer FDA to previously submitted comments dated January 19, 2016, related to this draft guidance (see attachment 1). Specifically it is important that FDA also provide guidance on inclusion of the following data/information for non-sunscreen ingredients:

1. Ex-US regulatory experience, including data or other evidence to support a history of safe use and regulatory actions associated with the ingredient;
2. Ex-US adverse event information, including any evaluations by regulators or other authoritative bodies;
3. Safety or efficacy data reviewed and accepted by governmental, scientific, and nonscientific bodies; and
4. Periodic Safety Update Reports filed with ex-US regulators.

The proposed rule's multi-year timeline is illustrative of the fact that, over time, the process to amend OTC Monographs has slowed markedly. Having a system to allow well-established, safe, and effective ingredients to enter the OTC Monograph system remains an important goal. We therefore look forward to the opportunity to engage with FDA on ways to enhance and improve the OTC monograph system, including streamlining or removing steps such as those outlined in the proposed rule on TEAs. We recognize that some potential reforms would require legislative changes and encourage dialogue between FDA and the industry to identify critical aspects.

Thank you for your consideration of our comments. Feel free to contact me should questions arise.

Sincerely,

Marcia D. Howard

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Cc: Kristen Hardin, FDA Center for Drug Evaluation and Research

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[4] Federal Register notice published November 23, 2015 (80 *Federal Register* 72973-73975). Accessed from https://www.gpo.gov/fdsys/pkg/FR-2015-11-23/pdf/2015-29637.pdf on May 10, 2016.

[5] FDA Draft Guidance for Industry: Nonprescription Sunscreen Drug Products – Content and Format of Data Submissions To Support a GRASE Determination Under the Sunscreen Innovation Act. Accessed from http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm473772.pdf on May 10, 2016.

Attachment 1: PCPC/CHPA Comments on Draft Guidance for Industry: Nonprescription Sunscreen Drug Products – Content and Format of Data Submissions To Support a GRASE Determination Under the Sunscreen Innovation Act.

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