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July 27, 2022

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rom 1061
Rockville, MD 20852

Re: Premarket applications, postmarketing reports and recordkeeping, and labeling for Nonprescription Drug Product With an Additional Condition for Nonprescription Use; Information Collection under the Paperwork Reduction Act of 1995; 87 *Fed. Reg*. 38313. Docket No. FDA–2021-N-0862.

Dear Sir or Madam:

The Consumer Healthcare Products Association[1] ("CHPA") submits these comments on the information collection incorporated into the proposed rule on Nonprescription Drug Product With an Additional Condition for Nonprescription Use ("FDA" or the "Agency")" published on June 28, 2022 ("Proposed Rule").[2,3,4] The Agency invited stakeholders to provide input on "premarket applications, postmarketing reports and recordkeeping, and labeling for nonprescription drug products with an additional condition for nonprescription use." For more than 141 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of OTC medical products. CHPA members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases.

[1] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.

[2] FDA, Nonprescription Drug Product With an Additional Condition for Nonprescription Use; Proposed Rule, 87 *Fed. Reg*. 38313 (June 28, 2022). Accessed from https://www.govinfo.gov/content/pkg/FR-2022-06-28/pdf/2022-13309.pdf on July 7, 2022.

3 FDA Nonprescription Drug Product with an Additional Condition for Nonprescription Use (Proposed Rule) Regulatory Impact Analysis (June 22, 2022). Accessed from https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/nonprescription-drug-product-additional-condition-nonprescription-use-proposed-rule-regulatory on July 7, 2022.

[4] Proposed Collection, "Premarket applications, postmarketing reports and recordkeeping, and labeling for Nonprescription Drug Products With an Additional Condition for Nonprescription Use.'

The FDA is soliciting comments on the alternative reporting mechanism requiring the applicant to submit a single, consolidated report for all consumers affected by the same failure in implementation of an additional condition for nonprescription use (ACNU) rather than a report for each individual impacted by the same failure. CHPA believes the questions posed in the information collection notice (ICN) are closely tied to other regulatory elements within the proposed rule. CHPA will include substantive comments regarding the postmarketing reporting for ACNU failures addressed in the ICN with our full comments on the proposed rule.

We believe that summary periodic reporting of what the proposed rule terms "additional conditions of nonprescription use failure" is the most effective method to track and report relevant concerns to the Agency without being overly burdensome. It will be important to define the types of information to be reported in summary data so that it is also consistent with existing adverse event requirements and tracking systems currently in place for OTC medicines marketed under an approved application. While we agree that reporting of adverse events associated with potential failures due to an ACNU may be necessary, CHPA members believe the definition of a "failure" as outlined in the proposed rule is too broad and poses challenges with collecting relevant data from consumers. Our comments on the proposed rule will include revisions to how failures should be defined, captured, and reported to the Agency.

CHPA appreciates the opportunity to provide suggestions to the Agency on "Premarket applications, postmarketing reports and recordkeeping, and labeling for Nonprescription Drug Product With an Additional Condition for Nonprescription Use." We ask FDA to refer to our comments on the proposed rule once submitted to the docket as CHPA's detailed response to the questions posed in the ICN. We are also happy to email a copy to your attention.

Thank you for your time and attention. Please do not hesitate to contact me if you have any questions.

Respectfully Submitted,

Brigid Zeller Digitally signed by Brigid Zeller Date: 2022.07.27 12:10:46 -04'00'

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