CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

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http://www.regulations.gov, Docket No. FDA-2018-D-2074

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Re: Letter of Support for The Healthcare Distribution Alliance (HDA) Position on the Draft Guidance for Industry: Initiation of Voluntary Recalls

Dear Dr. Jung and Mr. Fox,

The Consumer Healthcare Products Association (CHPA) appreciates this opportunity to provide comments to the Food and Drug Administration (FDA) regarding the Draft Guidance for Industry: Initiation of Voluntary Recalls, Docket No. FDA-2018-D-2074, 84 Fed. Reg. 17112 (April 24, 2019) (Recall Draft Guidance).

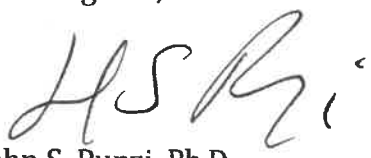
The Consumer Healthcare Products Association (CHPA) is the 138-year-old trade association representing the nation's leading over-the-counter (OTC) medicine and nutritional supplement manufacturers. We strongly support the Healthcare Distribution Alliance's (HDA) position on the Draft Guidance for the initiation of voluntary recalls and request that those product categories, including OTC medicines, which are exempt from carrying a unique identifier, be clearly acknowledged, including a citation to any relevant exemptions and/or exceptions.

The Draft Guidance is particularly concerning because it includes the phrase, "whether required or not, firms should use sufficient coding..." to assure "positive lot identification and to facilitate the effective recall of all violative lots." We believe this guidance may be taken literally as required practice by state inspectors who regulate the wholesalers/distributors who in turn, potentially could ask for additional product coding on OTC products. Our members believe that given appropriate quality agreements with wholesaler distributors, inventory and distribution practices and procedures, along with current recordkeeping practices for

distribution, it is unnecessary to include any additional coding or recordkeeping requirements in the Recall Draft Guidance. Current recall processes and procedures have worked well in the past and remain effective today. Recalls of OTC products are rare, and little benefit would be seen with an added burden of additional coding.

I am happy to speak with you about this issue at greater length and detail. Feel free to contact me directly at your convenience.

Best Regards,



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