NATURAL PRODUCTS ASSOCIATION

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James L. Madara, MD, Chief Executive Officer & Executive Vice President
American Medical Association
330 N. Wabash Ave., Suite 39300
Chicago, IL 60611-5885

Dear Dr. Madara,

By way of introduction, the Natural Products Association (NPA) is the leading and largest trade association representing the entire natural products industry. We advocate for our members who supply, manufacture, and sell natural ingredients or finished products for consumers. The Natural Products Association promotes good manufacturing practices as part of the growth and success of the industry. Founded in 1936, NPA represents approximately 1,000 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids. Prior to my current role at NPA, I served as the Associate Director for Research and Strategy at the U.S. Food and Drug Administration's Office of Dietary Supplement Programs. NPA has two high ranking former officials from FDA's Office of Dietary Supplement Programs and is the only trade association with that level of expertise.

Many of your patients are likely to start the new year with goals and resolutions pertaining to their health. For some of them, this means that they will consider whether they should begin taking a dietary supplement to augment their health or to help them to achieve their resolutions. Dietary supplements are regulated by the Food and Drug Administration (FDA), although some operate under the misconception that they are not. In fact, the adverse event reporting system is one of the key ways in which they are regulated.

Adverse events from supplements are extremely low given their widespread usage, and most of these are the result of three factors: accidents, people not consulting with their doctor, or misuse of a product combined with other health factors. Despite the low rate of AERs for dietary supplements, it is important for health care professionals and consumers to report these incidents when they do occur. The laws that regulate supplements require official reporting of adverse events so that the regulators, the health care community and others can review the data and make informed public policy decisions.

Manufacturers of dietary supplements are required to submit all information pertaining to adverse events associated with their products to the FDA. Healthcare professionals and consumers are encouraged to report adverse events to manufacturers or FDA through the

safety report portal. This system, the Center for Food Safety and Applied Nutrition (CFSAN)-Adverse Event Reporting System (or, CAERS) is the same system as MedWatch, which is FDA's reporting program for FDA-regulated products. MedWatch (and CAERS) receives information from the public; when necessary, this information will inform safety alerts.

If you believe that one of your patients has experienced an adverse event related to a dietary supplement, please encourage them to report the event to the FDA through the safety report portal. Alternatively, please consider completing the report for them to ensure that the issue is brought to the Agency's attention.

If you have any questions about this process, the system, or why this is important, please do not hesitate to reach out.

I appreciate your attention to this critical health issue.

Thank you,

Sibyl Swift, Ph.D.
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