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Jeffery Shuren, M.D.
Assistant Commissioner for Policy
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Draft Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act; Availability [Docket No. 2007D-0388]

Dear Assistant Commissioner Shuren:

The Natural Products Association, formerly the National Nutritional Foods Association (NNFA), is submitting this letter as a formal comment, concerning the draft guidance Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109-462, 120 Stat. 3469), appearing in the Federal Register on October 15, 2007 (Volume 72, Number 198). The Natural Products Association was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products. The Natural Products Association is a non-profit 501 (c) (6) association whose mission is to unite a diverse membership, from the smallest health food store to the largest natural products supplier. We champion consumers' freedom of choice in our marketplace. We strengthen and safeguard retailers and suppliers. We build strong markets to fuel industry growth. We act together with uncompromising integrity, and we encourage all to reach ever higher standards of quality. We are the largest trade association in the Natural Products industry by sheer numbers representing over 10,000 members. Thank you very much for the opportunity to comment.

First and foremost we recognize that FDA, specifically the Center for Food Safety and Applied Nutrition (CFSAN) has numerous challenges to address, so it can better protect the public health, and we enthusiastically support the use of Serious Adverse Event Reporting as well as other efforts to address those challenges. FDA has demonstrated in other industries where the agency has regulatory oversight that mandatory reporting

of serious adverse events enables the agency to identify risks, should they exist, both quickly and accurately. For this reason amongst others, the Natural Products Association has been a proponent of Serious Adverse Event Reporting (SAER) for Dietary Supplements, we believe they are a critical component for maintaining the level of consumer confidence that some 190 Million Americans that take a supplement as a part of a healthy lifestyle currently enjoy. We would like to commend CFSAN for offering guidance on Serious Adverse Event Reporting on what has proven to be both a very busy and a very productive year for CFSAN. With that in mind, we also want to ensure that the agency understands the challenges the industry faces in complying with the agency's regulations, and how guidance may be enhanced to improve compliance through clarification, but also address issues central to the new regulatory requirements.

With respect to the guidance we believe the following areas need greater clarification to eliminate confusion:

- 1) Guidance question # 9 "Are retailers required to submit serious adverse event reports for dietary supplements to FDA? A retailer whose name appears on the label of a dietary supplement as its distributor may, by agreement, authorize the manufacturer or packer of the dietary supplement to submit the required adverse event reports for such dietary supplement to the FDA so long as the retailer directs to the manufacturer or packer all adverse events associated with such dietary supplement that are reported to the retailer through the address or telephone number on the label of the dietary supplement." With respect to the contact information that must be present on the label we believe that 21 CFR § 101.5 and § 343(e) (1) should be referenced here to eliminate any confusion associated with the new law. Dietary supplement manufacturing firms, and/or said "responsible parties" as put forth in the law; in compliance with the U.S. code sections listed in the previous sentence are not and should not be required to make any labeling changes in reference to contact information. And, we note that the new law explicitly did not require any label changes. Clearly, the drafters of the legislation would have statutorily mandated additional label changes if any such label changes were desired or needed to provide consumers with additional contact information.
- 2) Guidance question #23 "Does FDA have an on-line option at FDA's MedWatch website for submitting serious adverse events reports for dietary supplements electronically? No. We do not have this option available for dietary supplement adverse event reporting at this time. Serious adverse event reports for dietary supplements must be submitted by filling out MedWatch Form 3500A and mailing it to FDA along with the product label and any other attachments." The serious adverse event reporting requirements as put forth in the law for OTC pharmaceuticals was written in parallel with dietary supplements. However per the respective guidance for dietary supplements and OTCs there appears to be one major difference. That difference being the agency's refusal to accept

electronic filings for dietary supplements. While we support the agency's decision in not offering an electronic option at this time, we understand that such a system (both electronic submission and record keeping) would have to be 21 CFR Part 11 compliant. Considering the small number of adverse events the agency currently receives (and anticipates receiving) on dietary supplements, coupled with the small business concern that makes up a great deal of the dietary supplement industry, this would not be feasible economically for either the agency or the industry at this time. However, there are factors that may rapidly shift the need for an electronically viable system for both the agency and industry. Specifically, the use of third-party services to submit adverse event reports, firms that produce pharmaceuticals as well as dietary supplements thus currently submit reports electronically, and international firms who may not be able to meet the 15-day window due to geography and postal systems, are just a few examples where electronic submission may be favorable. For the reason that the law was written in parallel between dietary supplements and OTCs, we believe more discussion is needed in the guidance on what the future holds for electronic submission as well as the referencing of 21 CFR Part 11 at a minimum for those dietary supplement firms who intend to store records electronically.

We would welcome the opportunity to participate in any forum where future guidance on SAERs and issues surrounding SAERs for dietary supplements may be discussed further.

Very truly yours,

A handwritten signature in blue ink that reads "Daniel Fabricant". The signature is written in a cursive, flowing style.

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