USANA
HEALTH SCIENCES

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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 96N-0417
Good Manufacturing Practices for Dietary Supplements

USANA Health Sciences, Inc. respectfully submits comments regarding the proposed Good Manufacturing Practice (GMP) for Dietary Supplements published in the Federal Registered on March 13, 2003. Our comments mirror many of the points raised by other trade associations regarding this matter such as the Council for Responsible Nutrition, the National Nutritional Foods Association and the American Herbal Products Association. In particular, as a member of the Utah Natural Products Alliance (UNPA), we endorse and fully support those comments submitted by the Executive Director, Mr. Loren Israelsen.

As a company, USANA has provided dietary supplements for its domestic and international customers for over ten years. We are well aware of the history, issues, controversies, and regulations promulgated under the Dietary Supplement Health and Education Act (DSHEA). We fully support the legislative intent regarding DSHEA, including the development and enforcement of GMP regulations. The agency is well aware of industry's desire for dietary supplement GMP regulations as mandated by Congress. We welcome the long overdue proposed rule. However, we believe that the proposed rule for GMP as currently published exceeds legislative intent and presents a larger economical burden to those within this industry than rationalized by the agency.

Within the preamble of the proposed rule, the agency requested comments on various points and rationale regarding the agency's proposal, including additional elements to enhance the proposal. Although, comments are merited on many of the specific points, we feel many of the issues are inter-related. Therefore, our comments are grouped into major topics.

Legal Authority

The agency requested comments regarding its legal authority to issue GMP regulation. Section 403(g)(2) of DSHEA states that GMP regulations "shall be modeled after current good manufacturing practice regulations for foods...". Again USANA fully endorses the need for adequate dietary supplement GMP that serves both the industry and its consumers. However, we believe that the agency exceeded it legal authority and legislative mandate under the following:

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(A) The agency has established an extremely broad definition for the term modeled. The preamble noted the meaning as "a preliminary pattern." The agency furthered established a new working definition by creating a composite regulatory category that combines regulations from both food and drug. The agency's rationale was based upon "characteristics and hazards" of dietary supplements.

We believe this is a new concept and definition that is further distorted by the inclusion of dietary ingredients with dietary supplements. The agency contends that legislative intent authorized FDA to establish regulations in this rule that exceeds parallel provisions under food GMP. However, other general definitions for the word "model" or "modeled" use terms such as copy, facsimile, and representation. To establish a "preliminary pattern" and greatly surpass that pattern is a very narrow interpretation of the word "modeled." The agency did not establish that their interpretation was aligned with congressional mandate and establishes a legal challenge that could further delay GMP establishments.

(B) The agency expressed concern with respect to the safety of dietary supplements. The preamble clearly states that a principal feature of the proposed rule is detection and avoidance of adulteration. This position is new for the agency under its history of GMP proposals. Neither the foods, medical devices nor drug GMP models position products as adulterated until proven otherwise. We contend that such a position is also outside the GMP food model and is contrary to congressional mandate.

(C) The agency also included dietary ingredients under this proposed rule. Many ingredients are common to both dietary supplement and conventional foods. For example, vitamin A and D are used to fortify milk, bread, and cereals. This extends DSHEA to dietary ingredient suppliers that may only supply conventional foods and not dietary supplement producers. This places a new economical burden on dietary ingredient suppliers that do not wish to supply dietary supplement producers. We further contend that the agency does not have legal authority to make such an extension from DSHEA.

In summary, USANA does not believe that the agency has the legal authority to issue a final regulation for dietary supplement GMP that include in material or significant ways provisions from drug, medical device or other GMP models. The agency's authority to issue this regulation must follow the pattern and intent of food GMP to the exclusion of any other GMP type or model that FDA has or may issue. Nowhere in congressional records do statement of DSHEA sponsors such as Senators Hatch and Harkin harmonize with the broad

interpretations by FDA. To do so exceeds legislative intent under DSHEA and is an abuse of power.

Economic Impact

Again we endorse the comments by UNPA regarding the financial impact to this industry. We are actively working with UNPA on collecting additional economic data to assess, more accurately, costs associated with raw material and finished product testing. We request the opportunity to present additional data within 30 days after the comment period closes. Nevertheless, we contend that the agency has grossly under-calculated the impact of the proposed rule to industry. We cite the following examples:

(A) Using the proposed raw material testing requirements we asked two contract laboratories to give a price for testing USP grade Calcium Citrate. The USP monograph requires 10 separate tests to verify USP specifications. The laboratories bid approximately $1,400 to $1,500. The average test cost was $140 to $150 per test. The cost per test is 2.5 times greater than the average cost assumed from the agency's economic data. This represents a significant burden for our company and the industry.

(B) Shared cost burdens are a key element towards minimizing operating expenses. A domestic company supplies the USP grade Calcium Citrate cited above to our facility. This same supplier also provides the Calcium Citrate to the pharmaceutical industry. The company and ingredient are part of a master drug file. Under the drug GMP model, the pharmaceutical company can accept the supplier's Certificate of Analysis (CofA) provided the supplier has undergone an extensive evaluation by the client. Only the monograph identification tests are required. Because the supplier is testing the end product and providing a document to certify their action, the pharmaceutical company that receives the document can minimize their cost of testing. The result is a cost-effective method that does not compromise consumer safety.

Nevertheless, under the proposed ruled the CofA and supplier are regarded as frivolous. The receiving company would be required to duplicate all tests. The number of duplicate test is multiplied when the same batch of raw material is shipped to multiple location. Not only do the individual company costs increase, but so does the industry as a whole. Instead of allowing suppliers to be part of our quality system, the proposed rule has isolated them from dietary supplements producers and mandated repeat testing.

(C) Internal data suggests that consumers of this industry are price sensitive by a 1:1 ratio. Our internal estimate for the cost of compliance to the proposed rule raises product costs of goods by approximately 9.5%. If the cost is passed onto consumers, our sales are estimated to decline by 11%. This is a significant

decrease to the economic viability of our company. We would be forced to take dramatic measures such as labor reductions or move to foreign soil to adjust.

(D) In the preamble, the agency acknowledged that a small percentage of companies would be negatively impacted by the proposed rule. The impact would include going out-of-business, relocation to foreign soil, etc. The impact was based upon certain assumptions derived from the economic data. However, if the impact is undervalued, then the number of companies negatively impacted is also undervalued.

In summary, USANA believes that the agency has miscalculated the cost of compliance with the proposed rule. The agency noted in the preamble that the proposed rule lacked adequate data to accurately calculate costs associated with compliance for small business. It is our position that the data is flawed and unreliable. Further accurate analysis is needed before the rule could be finalized.

GMP Perspective

We are concerned with the Agency's perspective regarding GMP for dietary supplements. The proposed rules are a great departure from the ANPR framework published six years ago. The agency's position has shifted from developing a good GMP structure to adulteration avoidance. The agency had abandoned the prior ANPR backdrop and now uses the guise of public health concerns based on several examples of adulterated, misbranded or mislabeled dietary supplements. We wish to comment on that perspective.

(A) The preamble cites *D. Lanata* as an example and rationale for the proposed GMP structure. However, even under the proposed rule, *D. Lanata* could still occur. We use again USP Calcium Citrate as an example. The ingredient has a 97.5 to 100.5% range in purity per the monograph. Even after performing all monograph tests, you can accept a 2.5% level of impurity. The impurities tested include heavy metal, organic volatile impurities, acid insoluble substances, arsenic, and fluoride. Therefore, *D. Lanata,* which is not one of the required monograph contamination tests, could still be present and undetected. The extreme testing requirements under the proposed rule do not necessarily enhance public safety. They do, however, increase the cost burdens to consumers looking for Calcium supplements.

(B) The agency is well aware of the vast and diverse nature of the dietary supplement industry. The product range is broad and extensive. The agency's approach was to propose a "one glove fits all." This approach, however, is flawed. It does not account for the various methods used, available technology, or sound quality principles that can both enhance public safety and minimize the burden of compliance.

For example, vitamin-mineral and probiotic tablets represent two distinct and unique areas. Technology, equipment, and methods are different. Therefore, GMP should reflect common elements. The areas of uniqueness should be placed in sub-categories of GMP. The agency has an established precedent using the food GMP model. Infant feeding formula, low acid canned foods, etc., are sub-categorized under food GMP. Additional requirements or variations to food GMP reflect the unique nature of the product category. We strongly recommend using this approach.

(C) Under the current food model, raw ingredients are visually inspected and accepted based on the supplier's Certificate of Analysis. Under the proposed rule, face value acceptance is not possible. USANA believes that strong vendor management programs provide assurances towards conformance with suppliers CofA's. The program should include auditing, technical agreements, random testing, etc., to maintain a good working partnership with suppliers. Such a program does not diminish public safety. Supplier-manufacturing partnerships provide collaborative efforts towards increased quality and cost reductions. The end consumer benefits from better quality products and lower prices. This approach would combine GMP best practices, and sound quality principles.

(D) The agency requested comment on whether this proposed rule should apply to foreign manufacturers. We are puzzled why such a comment is warranted. The agency is well aware that FDA lacks jurisdiction over many foreign manufacturers. However, we would stress that supplier certification mentioned earlier could equally apply here as well. This puts the burden on the dietary supplement producers

(E) Throughout this preamble, the agency repeatedly used the term identity, purity, quality, strength, and composition. However, in the proposed rule no definition for each of these terms was provided. We strongly recommend that such terms be defined if they are the foundation for the proposed rule. For example, unless clearly defined the term "purity" can be misinterpreted. Is the agency going to accept USP Calcium Citrate with a 97.5 to 100.5% range in purity? Or is this range too broad and not "pure" enough? The lack of clarification makes comments on the proposed rule difficult.

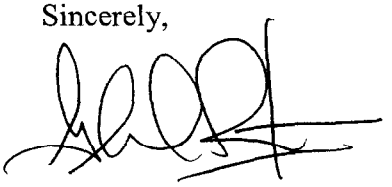
(F) One tried and true quality principle taught by Dr. W. Edward Deming regards finished product testing as a flawed method. "You design quality into a product not test it." Because the agency has adopted the adulteration detection

philosophy, dietary supplements are destined towards poorer quality and increased consumer risk. By designing GMP (quality system) that fosters improvements in raw materials, training, production techniques, etc., product quality and consumer safety is always enhanced. Such features can be modeled after food GMP. We believe this philosophical approach provides the agency with the consumer safety they desire, and the industry with cost effective methods for operations.

Summary

In summary, USANA supports the need to publish and enforce reasonable Good Manufacturing Practice regulations provided they mirror economic realities within the limits established by Congress. We appreciate the opportunity to provide comments on this regulation. We offer our continued support and cooperation to develop final regulations.

Sincerely,



Glen S. Putnam
Director, Quality Assurance & Regulatory Affairs
USANA Health Sciences, Inc.