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**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
(DOCKET NO. 99N-1174)**

**DIETARY SUPPLEMENTS; CENTER FOR FOOD SAFETY AND
APPLIED NUTRITION STRATEGY; PUBLIC MEETING**

STATEMENT OF

**LOS ANGELES GRASSROOTS REGULATORY PARTNERSHIP
DIETARY SUPPLEMENT SUBCOMMITTEE**

Ofelia U. Barretto
Chair Los Angeles Grassroots Regulatory Partnership
Dietary Supplement Subcommittee
Phone 714-870-4471; Fax 714-879-2737
Email: ofeliab@gateway.net

99N-1174

July 20, 1999
Oakland, California

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INTRODUCTION

The Dietary Supplement Subcommittee is part of a larger group called the Los Angeles Grassroots Regulatory Partnership (LAGRP), a partnership between FDA's Los Angeles District and a small group of individuals representing various sectors of FDA-regulated industry in Southern California and Arizona. The partnership was formed in response to a regulatory reinvention initiative launched by President Clinton in 1995, and for the purpose of improving communication and identifying and resolving regulatory concerns.

The Subcommittee was organized in April 1998 by representatives of Southern California's dietary supplement manufacturers, the US Food and Drug Administration - Los Angeles District Office, and the California Department of Health Services - Food and Drug Branch, Southern California Region. This public presentation was prepared collaboratively by Ofelia U. Barretto, Compliant Quality Solutions; Cheryl Cartwright, Westar Nutrition Corp.; Prosy Delacruz, California DHS-FDB, Southern California Region; Florence Nacino, Puretek Corporation and Dulce Passanini, Pharmavite. Comments were solicited from other members of the Subcommittee -- Forouz Ertl, Botanicals International, Christopher Dabner, Shaklee Corporation, and David Navarette, Hunt-Wesson.

The statement will be presented by Ofelia U. Barretto, Chair of the LAGRP Dietary Supplement Subcommittee, and Dietary Supplement Industry Representative to the LAGRP. Ofelia is President of Compliant Quality Solutions, a consulting company to the dietary supplements and food processing industry. She had been the Director of Quality Assurance of Nutrilite Division, Amway Corporation and was with the company for 21 years. She serves on an advisory panel of the United States Pharmacopeia (USP), and had served on various technical committees of the International Pharmaceutical Excipients Council (IPEC), and the Council for Responsible Nutrition (CRN). She was a National Director of the American Society for Quality (ASQ).

STATEMENT

The LAGRP Dietary Supplement Subcommittee would like to thank the Center for Food Safety and Applied Nutrition (CFSAN) for fully implementing the provision of the FDA's Modernization Act to provide a process of soliciting public input in developing a strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act (DSHEA). We respectfully submit the following proposals in response to the seven questions posed by Dr. Joseph Levitt on the CFSAN Dietary Supplement Strategies and Priorities Program.

1) In response to **Question #1**, we propose that an active, strong presence of **regulatory oversight** be provided to the industry, balancing that with removing barriers for growth of healthy, compliant industries. We need a regulatory scheme that is non-duplicative of states' efforts, fair in its application, and promotes less scrutiny of compliant firms and a higher level of scrutiny for those companies operating in disregard of existing laws and regulations.

2) In response to **Questions #2 and #3**, we propose a **risk-based approach** to regulating industry. When considering limited resources, a risk management model in determining responses to public health and safety issues should be adopted.

3) In response to **Question #4**, the ANPR of proposed **GMPs for Dietary Supplements** must be brought to a close. It will provide not only a minimum baseline operating standards for the industry but will clearly set a bar or yardstick by which all firms in the industry can be measured. This yardstick can be equally applied to legitimate, compliant firms and those operations that taint the good reputation of the industry. Also, we believe that the federal government should provide **training** to industry in the areas of new regulations. Clear federal guidance to domestic industries increases their level of compliance and improves their competitiveness.

4) In response to **Question #5**, to better clarify the **boundaries of regulatory definitions** for drugs and dietary supplements, we propose a regulation similar to California's Health and Safety Code Section 110403. This Section lists 40 serious diseases and conditions that make advertising for them a strict liability, such as cancer, prostate gland disorders, tumors, AIDS, heart and vascular diseases tuberculosis, and epilepsy. The California State Legislature intended these serious diseases as conditions for which self-cure is not permissible and needs intervention of medical professionals.

5) In response to **Question #6**, we propose that US FDA, with support from such organizations as the National Institutes of Health (NIH), and the United States Pharmacopeia (USP), set and enforce allowable **authoritative statements and standards of quality** for dietary supplements. The development of identity testing and quantitative methods along with pesticide and microbial safety levels for botanicals are critical for the safety and efficacy of dietary supplements in the marketplace.

6) In response to **Question #7**, we would like to see an enhancement to the **partnerships between federal and state regulatory agencies**. Clear definitions of each agency's roles and responsibilities will support efficient utilization of resources and provide substantive response coordination for industry concerns.

DISCUSSION

1) **Regulatory Presence:** While DSHEA tempered regulatory fervor, we believe that US Congress did not intend for a regulatory absence of oversight from the US FDA for the dietary supplement industry. Consequently there are some products in the market that have harmed consumers. A case in point is ephedra-containing products that have caused over hundreds of reported adverse reactions and about forty deaths among the youthful segment of the population. Even with these reported adverse profiles, this area of concern remains unresolved. Thus, we propose that an active, strong presence of regulatory oversight be provided to the industry, balancing that with removing barriers for growth of healthy, compliant industries. We need a regulatory scheme that is non-duplicative of states' efforts, fair in its application, and promotes less

scrutiny of compliant firms and a higher level of scrutiny for those companies operating in disregard of existing laws and regulations.

2) **Risk-based Approach to Regulating Industry:** As an industry, we would like to see a proactive federal government that anticipates barriers to the growth of industry. However, in the absence of this proactive stance, a response mechanism of prioritizing risks would be appropriate. For example, some states with limited resources are adopting a risk-management model in determining their responses to public health issues. When documented cases of illnesses, deaths or injuries are reported, a 24-hour urgent response is mandated. Where there is a potential for irreversible organ damage or harm, a 30-day significant response is mandated. The rest are relegated to a lesser priority scheme. If we adopt such a program in managing the dietary supplement industry, then, those dietary supplements with documented histories of consumers' adverse events would be addressed and resolved with such expediency. Thus, we propose a risk-based approach be adopted in regulating our industry.

3) **GMPs for Dietary Supplements:** The ANPR of Proposed GMPs for Dietary Supplements must be brought to a close. This proposed GMPs drafted by industry using the Food GMPs as guideline in accordance with DSHEA provides adequate minimum standards without the unnecessary burden of validation and extensive records review as required by Drug GMPs. Such unnecessary requirements increase manufacturing costs that translate to higher costs to consumers, without much value added. This proposed GMPs will provide minimum baseline operating standards for industry and will clearly set a bar or yardstick by which all firms in the industry can be measured. This yardstick can be equally applied to legitimate, compliant firms and those operations that taint the good reputation of the industry.

Training: We also believe that the federal government should provide training to industry. Clear federal guidance to domestic industries increases their level of compliance and improves their competitiveness. The Dietary Supplement Workshop held at the US FDA Los Angeles District Office last October was a good example of FDA's outreach program. The workshop was a project of this Subcommittee and was co-sponsored by the US FDA Los Angeles District and the CA Food and Drug Branch. We need more of these training sessions nationwide.

4) **Regulatory Boundaries:** The boundaries of regulatory definitions for drugs and dietary supplements have not been clearly defined. As a case in point, some industry members raised questions to CFSAN and were sent to CDER, then bounced back to CFSAN. They could not find a federal agency that was willing to take a regulatory stand on what industry can and cannot say. The net result is ambiguity and lack of clarity in what defines a drug or a food supplement. This lack of federal guidance to industry that want to comply and promote truthful disclosure and beneficial effects of supplements on their labels presents problems to industry, and is not to the benefit of consumers. Thus, we propose a regulation similar to California's Health and Safety Code Section 110403. This Section lists 40 serious diseases and conditions that make advertising for them a strict liability, such as cancer, prostate gland disorders, tumors, AIDS, heart and vascular diseases, tuberculosis and epilepsy. The California State Legislature intended these serious diseases as conditions for which self-cure is not permissible and needs intervention of medical professionals. We believe, however, that certain conditions that occur naturally as part of aging, such as benign

hypertrophy of the prostate gland, should not be considered as diseases. Such conditions may warrant **self-care, but not self-cure**, using dietary supplements.

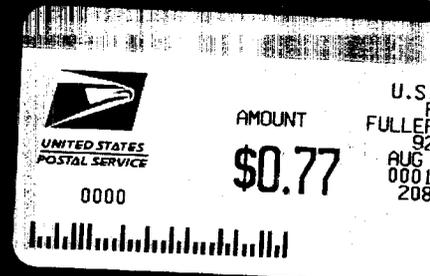
5) **Authoritative Statements and Standards of Quality:** Currently, health claims are allowed if defined by some "authoritative statements." Yet, in practical reality, consensus statements from a body of scientific experts from which health claims may be derived are difficult to achieve. These varying scientific opinions do not provide clear guidance to industry. US FDA has the existing scientific talent and capability to evaluate and collate available scientific information from industry and academic institutions. This information can also be used to establish standard identity markers and pesticide and microbial safety levels for botanicals. Standard identity markers will assure consumers of the desired product, while maximum microbial and pesticide residue standard limits will assure the safety of those products.

6) **Enhanced Partnerships:** President Clinton's Food Safety Initiative contemplated enhanced states' and localities' role in food safety. Currently, we are aware of the partnerships that occur between US FDA and some state regulatory agencies, such as California DHS-FDB. We would like to see enhancements to this partnership by clear definitions of each agency's roles and responsibilities. We see that FDA's role is critical and unambiguous in the need for setting clear standards and baselines for operating practices. We also see that the states' role is critical in providing traceback investigations of known adverse reactions in dietary supplements. As the epidemiological link to local health departments, they are best situated and proximate to the consumers' reports on injuries. When roles are clearly defined, better utilization of resources and substantive responses to industry concerns can be achieved.

CONCLUSION

The LAGRP Dietary Supplement Subcommittee appreciates this opportunity to present their input to the CFSAN 1999 Program Priorities on Dietary Supplements. Our objective is to effect regulations which level the playing field while allowing maximum flexibility to make truthful, non-misleading claims that will allow consumers to make informed decisions about taking safe and effective dietary supplements to maintain and improve their health.

Ofelia U. Barretto
Chair, LAGRP Dietary Supplement Subcommittee
1516 Sunset Lane
Fullerton CA 92833



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852