Oral comments for FDA Public Meeting
May 1, 2009

Avoiding economic adulteration of dietary supplements:
The need for ingredient supplier qualification guidelines

Andrew Shao, PhD
Vice President, Scientific & Regulatory Affairs
Council for Responsible Nutrition
Washington, DC
ashao@crnusa.org

The Council for Responsible Nutrition (CRN) is a Washington, DC-based trade association representing the dietary supplement industry. Our members include some of the largest and most well known ingredient suppliers, manufacturers, direct sellers and retailers of dietary supplements. We share FDA's concern regarding economic adulteration and applaud the Agency for organizing today's public meeting.

Economic adulteration is a serious and growing concern for all consumer products industries. Whether food, dietary supplement, drugs, devices, or toys, the global supply chain has made the task of sourcing and tracing raw materials exceedingly complex.

It is extremely difficult and costly to follow and trace raw materials throughout the distribution chain. It is equally as challenging to be aware of and develop, disseminate and implement the necessary tools to detect economic adulterants. As the saying goes, "You don't know, what you don't know". Even if it were economically feasible, one could not possibly test all materials at each stage of the distribution chain for all possible adulterants. With the efforts of perpetrators evolving so rapidly, consumer products companies are frequently faced with new, previously unknown adulterants. One cannot test for adulterants that one does not know exist (or have methods for). Finally, one cannot "test quality into products".

The key to avoiding economic adulteration, in the presence or absence of extensive raw material testing, is proper supplier qualification. This is essential to ensure end product quality and is the best and perhaps only way to avoid economic adulteration.

A serious and vigilant approach to ingredient supplier qualification is now needed for all consumer products categories – no product is immune. The lack of awareness of adulterants and absence of proper methods to detect economic adulterants further reinforces this.

Need for ingredient supplier qualification guidelines for dietary supplements?
When it comes to the need for ingredient supplier qualification, dietary supplements are no exception.

- Unlike manufacturers of dietary supplements, which are subject to the dietary supplement Good Manufacturing Practices (GMPs), ingredient suppliers are subject to

food GMPs, a less stringent standard; proper qualification of suppliers to ensure they will help (and not hurt) GMP compliance for the manufacturer is critical.

- In the GMP final rule FDA emphasizes the requirement to qualify ingredient suppliers and verify the information provided on Certificates of Analysis (CofA's) before relying on those CofAs, however, the Agency provides no guidance as to what proper qualification consists of.
- On separate occasions FDA staff have reiterated to CRN the importance of proper ingredient supplier qualification asking "what are your members doing to qualify their suppliers" and listing ingredient supplier qualification as one of their top concerns resulting from a series of initial GMP inspections of large companies.
- Impending food safety legislation is focused on supply chain security and traceability; although the legislation is aimed at conventional foods and not dietary supplements, whatever is passed WILL affect supplements and will likely be a substantial burden on the industry.

To assist with the qualification of ingredient suppliers the dietary supplement industry developed the Standardized Information on Dietary Ingredients (SIDI™) protocol. SIDI assists in the exchange of raw material information between ingredient suppliers and manufacturers. While it is an effective tool, it is insufficient on its own.

CRN urges FDA to work collaboratively with the dietary supplement industry to develop guidelines for ingredient supplier qualification. Such guidelines could serve as the basis of industry best practice or event future regulation.

There are precedents from the excipients and prescription pharmaceutical industries where similar industry-FDA collaborative efforts have been undertaken. We are now looking to the Agency to work with the dietary supplement industry in a similar capacity.

Economic adulteration is a serious and in some instances dangerous issue. At a minimum it undermines consumer confidence and at the extreme costs lives. We appreciate the sense of urgency shown by FDA regarding this issue and we recommend that ingredient supplier qualification be an emphasis Agency-wide going forward. We offer our full support for an industry-FDA collaborative effort to address ingredient supplier qualification for dietary supplements.

Thank you.