



POSITION STATEMENT

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Full Enforcement of GMPs, NOT Country of Origin Labeling, Is Strongest Way to Ensure Safety and Quality of Imported Dietary Supplement Ingredients

Current Good Manufacturing Practices (GMPs) for Dietary Supplements Ensure Quality and Safety Measures; Prevent Adulteration and Misbranding

- GMPs for dietary supplements, which were issued last year, are specific rules for the manufacturing processes of vitamins, minerals, herbs and botanicals, amino acids and other specialty supplements like fish oils and glucosamine and chondroitin. These rigorous practices impose higher standards on supplements than food GMPs apply to traditional foods.
- Dietary Supplement GMPs include thorough requirements for identity testing for *all* ingredients as they arrive at the manufacturer's site. Manufacturers must qualify their suppliers before receiving goods; incoming ingredients must be quarantined until their identity is confirmed using scientifically valid methods of analysis; and all components of dietary supplements must meet specifications established by the manufacturer – regardless of whether the ingredient came from across town or across the world.
- Manufacturers are accountable to the public and FDA for the ingredients that go into their products and FDA has access to all manufacturers' records during inspection, including access to the country of origin of all supplement ingredients. The existing bioterrorism law already requires all parties in the production and distribution of dietary ingredients to keep records "one up and one down" that permit the agency to trace the pedigree of ingredients back to their original source.
- More than 150 million Americans use dietary supplements each year. These products help prevent disease and promote good health as a part of an overall healthy lifestyle. Reasonable regulations, like GMPs, the bioterrorism law, and existing labeling requirements for dietary supplements, help companies better meet the needs and expectations of consumers interested in improving their health. Imposing additional COOL requirements on dietary supplement labeling adds costs without benefiting consumers.

Country of Origin Labeling (COOL): Unworkable and Ineffective for Consumers

- Mandatory country of origin labeling (COOL) for all manufacturers of conventional foods, including dietary supplements, would not impact import safety or the quality of products.
- Consumers want and deserve appropriate regulations that ensure the supplements they depend on for good health and wellness are made with quality ingredients accurately detailed on the label that are prepared, produced and stored in a manner that assures the identity, purity and strength of the product. COOL does not provide that assurance and merely informs a consumer where an ingredient is sourced. Knowing the source of the ingredient is not an indicator of safety and is less relevant and beneficial to the consumer than knowing the manufacturer has imposed high standards at every step of production.

POSITION STATEMENT, continued:

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- The reality of today's global economy is that ingredients are sourced from multiple suppliers all around the world. Compound that with the fact that many supplements contain a variety of ingredients. For example, to list all the countries of origin for all ingredients in a multivitamin (containing 25 or more essential nutrients) on one product label, or to maintain current sources on a company's website, would be impractical, if not impossible and likely confusing for consumers.
- In addition, single batches of products may include raw materials from multiple sources even during a single "run" of the manufacturing line, which could be difficult to present on a website.
- The increased labeling complexity from adding COOL would distract and divert consumers from other important label information. Manufacturers value the relationships they have with their consumers. Consumers' questions and concerns regarding any product can, and should be, addressed by contacting the listed manufacturer whose contact information is required to be provided on the label. By contrast, the substantial costs and difficulties for FDA to enforce COOL would further burden an already resource-strapped agency.

CRN Opposes COOL and Supports Greater Enforcement of GMPs Specific to Dietary Supplements