



POSITION STATEMENT

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FDA Ban on Ephedra

FDA announced on December 30 that it would soon finalize a regulation banning ephedra in dietary supplements on the grounds that it poses an “unreasonable risk.” The Council for Responsible Nutrition (CRN), one of the industry’s leading trade associations, has the following observations.

1. CRN has been encouraging FDA to take decisive action on ephedra. While we do not believe the ban was the only step the agency could have taken, we commend FDA for taking action under the provisions of The Dietary Supplement Health and Education Act (DSHEA), demonstrating that the law works when implemented.
2. CRN would not object to a ban if FDA’s rationale is scientifically and legally sound. The rationale will be included in the preamble to the final regulation, when it is published in a few weeks, but was not made available in the materials FDA released this week. Clinical studies and scientific reviews have concluded that ephedra can be used safely for weight loss within a certain dosage range, provided consumers observe certain contraindications included in an extensive label warning. If FDA were to conclude that the usage restrictions are not being properly observed by the general public, that could provide a basis for considering the product to present an “unreasonable risk.” However, in making this risk/benefit judgment, it will be important for FDA to accurately assess both parts of the equation.
3. DSHEA is an appropriate, workable law for the dietary supplement industry, provided it is implemented and enforced. FDA Commissioner Mark McClellan has recently taken strong actions to implement DSHEA. There is no need for Congress to reinvent the wheel by making sweeping changes to DSHEA. Congress and FDA just need to make sure the wheel is still turning, as it appears to be under Dr. McClellan’s leadership.
4. Some legislators believe that there is a need for mandatory reporting of **serious adverse events** associated with dietary supplements. CRN could support such a requirement, even though such reporting is not required for other categories of food or for monographed over-the-counter drug products.
5. Some legislators have argued that dietary supplements should be subject to **premarket approval**, in the same way that drugs are regulated. It is important to note that dietary supplements have always been regulated in this country as a category of food, not drugs. Premarket approval is no guarantee of safety, as demonstrated by the fact that numerous prescription drugs have been recalled for safety reasons after receiving FDA approval. Also, premarket approval is a very expensive process that would make it difficult, if not impossible, for consumers to have access to a wide variety of beneficial dietary supplement products at a reasonable cost.
6. Ephedra is only one of the multitude of dietary supplements on the market and is an anomaly in terms of the safety concerns it has triggered. DSHEA covers not only ephedra, but also vitamins, minerals, botanicals, specialty supplements, sports nutrition products, and weight management supplements.
7. More than 150 million American adults consume dietary supplements, and CRN believes they have a right of access to a wide variety of safe and beneficial products. Dietary supplements are an important part of a healthy lifestyle, and the science shows these products play a positive role in contributing to health promotion and disease prevention.