



DRAFT #3

UNPA STATEMENT ON EPHEDRA

On April 29, 2005, members of the Utah Natural Products Alliance (UNPA) unanimously voted to make “NO SALES” of ephedra products a condition of UNPA membership. Since FDA’s final regulation prohibiting the sale of ephedra, no UNPA member company has sold ephedra.

A recent court decision held that FDA did not have adequate scientific evidence to find that a daily dose of 10 mg or less of ephedrine alkaloids presented a significant or unreasonable risk of illness or injury. The court remanded the case back to FDA for further rule-making. This decision has prompted renewed criticism of the Dietary Supplement Health and Education Act (DSHEA) and reopens the prospect of future sales of ephedra dietary supplement products in the U.S.

DSHEA created a statutory framework for dietary supplements, including a safety standard which is now under further review as a result of this case. UNPA’s members believe it is advisable to maintain an ephedra-free market until the judicial and regulatory processes are complete. Ephedra has a long history of use as an ingredient in traditional Chinese medicine. Its utility within that tradition is well respected and can provide important insights with respect to the safe use of botanicals via their history of traditional use.

UNPA believes that DSHEA needs to be fully implemented and enforced by FDA as soon as possible, including prompt publication of Good Manufacturing Practices (GMPs). We also support legislation to create an adverse event reporting system for dietary supplements. We will also continue to actively support efforts to provide FDA the increased funding needed to fully implement and enforce DSHEA.

UNPA is hopeful that ephedra will not derail more than ten years of efforts to implement DSHEA and believe an ephedra-free market to be an key step toward those ends.

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