

October 25, 2000

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

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**CITIZEN PETITION**

The American Herbal Products Association, The Consumer Healthcare Products Association, The National Nutritional Foods Association and The Utah Natural Products Alliance (“trade associations”) submit this petition under 21 C.F.R. §§ 10.25 and 10.30 to request that the Commissioner of Food and Drugs withdraw the remaining portions of its June 4, 1997 proposed rule, Dietary Supplements Containing Ephedrine Alkaloids (Docket No. 95N-0304), 62 Fed. Reg. 30678, and adopt and implement in its place a standard for the labeling and marketing of dietary supplement products containing ephedrine alkaloids, as set forth below. These trade associations, which represent the vast majority of the manufacturers and distributors of ephedra products, have uniformly adopted a voluntary program that includes all of the elements provided below, and several states have considered and enacted these or similar provisions as state law. As such, the elements of the voluntary program and the several state laws represent a standard (hereafter referred to as “the standard” or “the current standard”) that is applied nationally by all the major companies marketing ephedra-containing dietary supplements.

Recent analyses of the safety of ephedra, presented at the Department of Health and Human Services public meeting on August 8-9 (HHS public meeting) and submitted to FDA as comments, confirm that ephedra products are safe when marketed and consumed according to the current standard. Further, new data presented at the HHS public meeting confirmed the significant public health benefits that ephedra products provide in the area of weight loss. The consensus of the HHS meeting, as stated in the

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HHS' Office on Women's Health Report on the meeting, was that industry and government should work together to educate consumers about ephedra products and to conduct further research into the safety and benefits of these products. This will also ensure that the standard continues to be evaluated and reevaluated.

Therefore, by withdrawing the remaining portions of the 1997 proposed rule and adopting the standard contained in this petition, FDA will assure continued access to safe and useful products and will open the door to cooperative efforts with industry and other government agencies to allow public education and to produce additional data.

#### A. ACTION REQUESTED

The trade associations request that the Commissioner of Food and Drugs withdraw the remaining portions of FDA's proposed rule, Dietary Supplements Containing Ephedrine Alkaloids (Docket No. 95N-0304), 62 Fed. Reg. 30678 (June 4, 1997), and adopt the current standard for the formulation, labeling and marketing of dietary supplement products containing ephedrine alkaloids as set forth below:

#### ***Labeling***

1. The label of the goods should bear an adequate cautionary statement, which shall at a minimum include the following language, or comparable language:

*WARNING: Not intended for use by anyone under the age of 18. Do not use this product if you are pregnant or nursing. Consult a health care professional before using this product if you have heart disease, thyroid disease, diabetes, high blood pressure, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, if you are using a monoamine oxidase inhibitor (MAOI) or any other prescription drug, or you are using an over-the-counter drug containing ephedrine, pseudoephedrine or phenylpropanolamine (ingredients found*

*in certain allergy, asthma, cough/cold and weight control products).*

*Exceeding recommended serving will not improve results and may cause serious adverse health effects.*

*Discontinue use and call a health care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath, or other similar symptoms.*

2. The product label shall list the amount of ephedrine alkaloids and caffeine alkaloids, if present, per serving.

### ***Serving Limits***

Products are not to contain in excess of 25mg of total ephedrine alkaloids per serving; usage instructions should limit daily consumption to 100mg of total ephedrine alkaloids.

### ***Herbs of Commerce Conformity***

Label identification must be in conformity with the standard common name listed in *Herbs of Commerce*.

### ***Synthetic Ingredients***

Neither finished consumer goods nor raw materials used in their manufacture are to contain any synthetically derived ephedrine alkaloids or their salts (e.g., ephedrine sulfate; pseudoephedrine hydrochloride; phenylpropanolamine hydrochloride).

### ***Marketing***

No claims shall be made that the product may be useful to achieve an altered state of consciousness, euphoria, or as a “legal” alternative for an illicit drug.

## **B. STATEMENT OF GROUNDS**

Industry has effectively implemented a voluntary program for ephedra products. This voluntary industry program began more than four years ago. Virtually all major manufacturers and distributors of ephedra products, who are members of the undersigned

trade associations, have adopted the program. Further, these or similar standards have been incorporated into state law in Ohio, Washington, Hawaii and Michigan.<sup>1</sup> The elements of the voluntary program and several state laws represent the current standard adopted by all the major firms marketing ephedra-containing products.

The standard is based on and supported by an ever-increasing amount of data relevant to the safety and benefits of ephedra products, including:

- The long history of safe use of ephedra and similar FDA-regulated products;
- Clinical data on ephedrine/caffeine combination products, and on ephedra alone and combined with caffeine, showing the safety and benefits of these products for weight loss;<sup>2</sup>
- Consumption data showing that sales of ephedra products have increased exponentially over the last five years while the number of reports of adverse events have decreased;<sup>3</sup>
- Comparisons of estimates of the incidence of strokes, heart attacks and seizures in the general population to the incidence of the same events in ephedra consumers, showing that there is no increased in risk from the consumption of ephedra;<sup>4</sup>

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<sup>1</sup> See Haw. Rev. Stat. Ann. § 329-64(a)(5); Mich. Stat. Ann. § 7220(1)(c)(ii); Ohio Rev. Code Ann. § 3719.44(K)(2)(a); Wash. Admin. Code § 248-883-030(3).

<sup>2</sup> These data were presented at the IIHS meeting and have been submitted by various parties to FDA in response to FDA's requests for comments. Existing data are summarized in a comprehensive literature review submitted to FDA on October 2, 2000 with the Ephedra Education Council Expert Panel comments (EEC Expert Panel Comments), and in other comments submitted to FDA. Important new clinical studies have been completed that are consistent with the current standards and with existing data showing benefits. These studies are expected to be published in the near future.

<sup>3</sup> See American Herbal Products Association Comments to FDA filed October 2, 2000; EEC Expert Panel Comments.

<sup>4</sup> See EEC Expert Panel Comments.

- Comprehensive analyses of all adverse event reports submitted to FDA showing that there is no association between the reported serious adverse events and the consumption of ephedra products according to the current standard;<sup>5</sup> and
- Thorough reviews of the published literature, including all published case reports, showing that the published literature supports the safety of ephedra products when consumed according to the current standard.<sup>6</sup>

The action requested would make it possible for consumers to have continued access to products that, based on existing and new data on their safety and usefulness in weight loss, are gaining acceptance by prominent experts in obesity. The potential importance of these products to help with weight loss, and therefore with one of the most serious public health threats to the American public, was made clear at the recent Health and Human Services public meeting on August 8-9, 2000. Formal FDA adoption of the current standard and withdrawal of the remaining portions of FDA's existing proposal would permit the continued availability of ephedra while additional research is pursued to further optimize our understanding of ephedra's safety and benefits.

### C. ENVIRONMENTAL IMPACT

Neither an environmental assessment nor an environmental impact statement is required for the action requested of the agency because the requested agency action is categorically excluded pursuant to 21 C.F.R. § 25.30(h) in that it is concerned with issuance of procedural or administrative regulations and guidelines.

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<sup>5</sup> See EEC Expert Panel Comments.

<sup>6</sup> See EEC Expert Panel Comments and other comments submitted to FDA.

D. ECONOMIC IMPACT

According to 21 C.F.R. § 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of the petition.

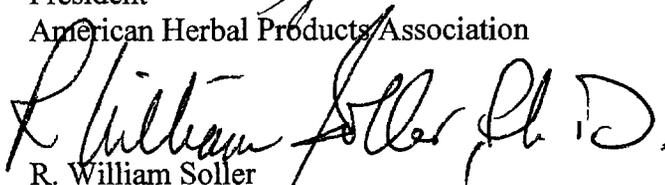
E. CERTIFICATION

The trade associations certify, that to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners, which are unfavorable to the petition.

Respectfully submitted,



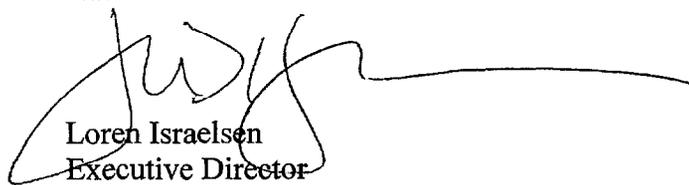
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