

Docket No. 1995N-0304

BEFORE THE
UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PETITION FOR RECONSIDERATION
AND
PETITION FOR STAY OF ACTION

BY THE
CHINESE HERBAL PRODUCTS COMMITTEE
OF THE
AMERICAN HERBAL PRODUCTS ASSOCIATION

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**Final Rule Declaring Dietary Supplements Containing Ephedrine
Alkaloids Adulterated**

March 12, 2004

95N-0304

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Pursuant to 21 C.F.R. § 10.33 ("Administrative reconsideration of action") and 21 C.F.R. § 10.35 ("Administrative stay of action"), the undersigned Chinese Herbal Products Committee of the American Herbal Products Association ("AHPA") submits this petition to request a stay and reconsideration of the provisions of 21 C.F.R. § 119.1 declaring dietary supplements containing ephedrine alkaloids to be adulterated which was made final in a Federal Register notice published February 11, 2004 (69 Fed. Reg. 6787). The relief requested is that the Food and Drug Administration ("agency") stay the April 12, 2004 effective date of this regulation only insofar as it pertains to traditional herbal formulas that are marketed to licensed health care practitioners for dispensing to their patients and that the agency reconsider the regulation in light of a serious and substantial factual error in the agency's underlying rationale. In addition, it is requested that the agency stay the final rule with respect to its application to the use of pinellia (*Pinellia ternata*) and heart-leaf sida (*Sida cordifolia*) in dietary supplements that are formulated as traditional herbal formulas. Neither of these botanicals were previously mentioned in the agency's Federal Register notices in this rulemaking and neither were referred to in the various publications, clinical studies or case reports upon which the agency relied to make its decision in this matter.

AHPA is the national trade association and voice of the herbal products industry, which is comprised of domestic and foreign companies doing business as importers, growers, manufacturers, and distributors of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of

products which contain herbs and which are used to enhance health and quality of life. The Chinese Herbal Products Committee is a committee of AHPA, which was chartered to promote and protect responsible commerce of those herbs and herbal products that are included in and/or based on traditional use of Chinese herbs.

AHPA Chinese Herbal Products Committee members manufacture and sell dietary supplements that are traditional Chinese herbal formulas containing botanicals, including botanicals in which ephedrine alkaloids are naturally occurring. Many of these products are marketed solely to licensed health care practitioners, e.g., acupuncturists or naturopaths, who dispense such products to their patients. Members of the AHPA Chinese Herbal Products Committee estimate that the dietary supplements that they manufacture and market to licensed health care practitioners and that are traditional Asian formulas include at least 300 products that contain ephedra herb and at least 900 products that contain *pinellia*.

A. Decision Involved

In the Federal Register of February 11, 2004, 69 Fed. Reg. 6787, the agency published a final rule declaring dietary supplements containing ephedrine alkaloids to be adulterated. The effective date of that final rule is April 12, 2004. The agency has previously announced, through the Commissioner of Food and Drugs, that it will take prompt regulatory action with respect to products that remain on the market after that date.

B. Action Requested

AHPA requests that FDA reconsider the final rule to recognize that dietary supplements that contain ephedrine alkaloids do not present an unreasonable risk of illness or injury under conditions of use that include formulation as a traditional Asian herbal formula or as a traditional Ayurvedic herbal formula, and that are for dispensing by a licensed health care practitioner within the practitioners scope of practice and in a manner consistent with traditional practice.

AHPA also requests that the final rule be stayed only insofar as it pertains to traditional herbal formulas as described above until the agency has reconsidered the action based on readily available information regarding how traditional Asian or Ayurvedic herbal formulas are labeled and marketed as dietary supplements in this country, and after it has provided for notice and opportunity for comment on its decision to include *Sida cordifolia* and *Pinellia ternata* within the reach of the final rule.

C. Statement of Grounds

1. The Final Rule, Insofar as it Applies to Traditional Herbal Formulas, Incorrectly Describes These Products as Not Labeled and Marketed as Dietary Supplements.

In the preamble to the final rule, the agency has stated that:

“several Ephedra species (including those known as ma huang) have a long history of use in traditional Asian medicine. **These products** are beyond the scope of this rule because they **are not marketed as dietary supplements**. The use of ephedrine alkaloids in traditional Asian medicine is discussed in more detail in section V.B.5 of this document. As we describe there, **this rule does not change how these products are regulated under the act.**” [69 Fed. Reg. 6793 – 94.]

Unfortunately, this highlighted language is simply incorrect. It is the practice of manufacturers and distributors of traditional Asian formulas to market their products as dietary supplements. The final rule completely changes how these products are regulated under the Federal Food, Drug, and Cosmetic Act because these products are presently marketed as dietary supplements.

Further in the preamble to the final rule, FDA stated, again erroneously, that “this rule applies only to products regulated as dietary supplements (See 62 FR 30678 at 30691). Traditional Asian medicine practitioners do not typically use products marketed as dietary supplements.” 69 Fed. Reg. at 6914.

At a meeting of AHPA’s Chinese Herbal Products Committee on March 5, 2004, members surveyed reported that they label their traditional herbal formulas as dietary or herbal supplements and have done so consistently since the agency promulgated regulations for the labeling of dietary supplements. Many of these members also reported that their primary, or in some case only, market for these products is to practitioners of traditional Asian medicine. These members do not understand how the agency could have reached the erroneous conclusions that these products are not marketed as dietary supplements.

The Committee is concerned that while the agency has recognized the importance of traditional herbal formulas to the licensed practitioners who dispense and prescribe them, and appeared in the preamble to intend to allow continued access by practitioners to traditional herbal formulas that contain ephedrine alkaloids, the agency has failed to address the issue in a manner that is factually based. The Chinese Herbal Products Committee of AHPA therefore

requests that the agency reconsider its rule in light of the information provided herein. In addition, AHPA and its Committee urge the agency to communicate with this important traditional community so that any amended regulation takes into account all of the facts and circumstances regarding traditional herbal formulas and their use in traditional Asian medicine by licensed practitioners.

2. There Was No Opportunity for Comment Provided With Respect to the Inclusion of *Sida cordifolia* or *Pinellia ternata* in the Final Rule.

The Chinese Herbal Products Committee has diligently searched the agency's various Federal Register notices regarding dietary supplements containing ephedrine alkaloids and finds no mention of *Sida cordifolia* or *Pinellia ternata* until their mention in the preamble to the final rule. This is a serious breach of the requirements of the Administrative Procedure Act and the agency's implementing regulations. If the agency intends to ban these botanicals from dietary supplements, it must correct this procedural failing by issuing a new notice of proposed rulemaking and allowing opportunity for comment. That notice must, at a minimum, address the issue of whether these botanicals, *Sida cordifolia* and *Pinellia ternata*, present an unreasonable risk of illness or injury.

3. The Agency Failed to Make a Proper Analysis as Required by the Regulatory Flexibility Act.

The Regulatory Flexibility Act ("RFA") (5 U.S.C. § 601-612), requires an agency to consider the impact of its rulemaking on small businesses and to consider less burdensome alternatives. Under the RFA, agencies must prepare both an initial and final regulatory flexibility analysis for rules that may have a significant economic impact on a substantial number of small entities. In

practice, this requires agencies to prepare an analysis whenever a rule's impact on small entities cannot be described as *de minimis*. This regulatory flexibility analysis must be undertaken, unless an agency head provides a "certification," which is a finding of no significant impact on a substantial number of small entities.

Because FDA erroneously concluded that traditional herbal formulas are not marketed as dietary supplements, the regulatory flexibility analysis undertaken by the agency is flawed. The analysis does not address this segment of the market at all.

Under the final rule, it is wholly lawful to market ephedrine-containing traditional herbal formulas so long as they are not labeled as dietary supplements. But the premise of this conclusion, that such products are not now marketed as dietary supplements, was flawed from the outset. Accordingly, the impact of the final rule on those who manufacture and distribute traditional herbal formula dietary supplements containing ephedrine alkaloid-containing botanicals was not considered at all. The agency has recognized that most of the manufacturers and distributors of dietary supplements meet the definition of small businesses. 60 Fed. Reg. At 67211 (Dec. 28, 1995).

It is the position of the Chinese Herbal Products Committee and AHPA that the agency must consider the collateral as well as the direct effects of the final rule before it may be implemented. This has not been done at all with respect to dietary supplement manufacturers and marketers of traditional herbal

formulas. Because most of these are small businesses, this analysis is important and should be done.

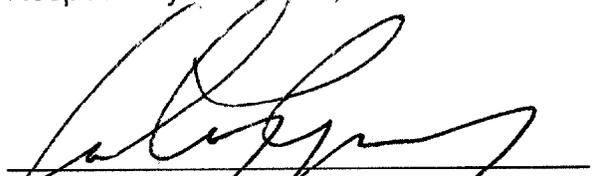
D. CONCLUSION

The Chinese Herbal Products Committee of AHPA requests that FDA reconsider the final rule regarding ephedrine alkaloid containing dietary supplements that are traditional herbal formulas and that they are dispensed by a licensed health care practitioner within the practitioner's scope of practice and in a manner consistent with traditional practice. In addition, the Committee and AHPA request a stay of the final rule only insofar as it pertains to traditional herbal formulas that are marketed as dietary supplements and that contain ephedrine alkaloids, until the agency has had the opportunity to confer with AHPA regarding the collateral effect of the rule on the availability of traditional herbal formulas to acupuncturists and the other healthcare professionals who dispense them. A stay of the regulation would not adversely effect the public interest because the agency has concluded these products may be marketed as traditional Asian medicines for dispensing by practitioners for purposes other than weight loss or energy.

The action requested here is not novel nor is it unique. In acting last year to ban ephedrine alkaloid containing dietary supplements, California specifically provided for the continued sale and dispensing of such products through licensed practitioners and not for weight loss or energy. This is an option that AHPA urges the agency to consider, recognizing that it is an uncharted area with respect to dietary supplements. Indeed, the unique character of traditional

herbal formulas and the way they are dispensed to patients is an area that can best be addressed through direct communication between the affected community and the agency.

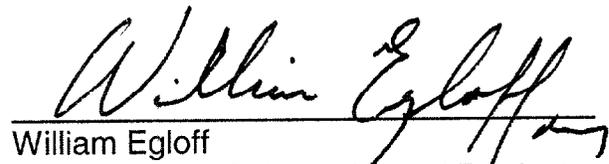
Respectfully submitted,



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