

**Comments to the Federal Food and Drug Administration  
Docket #99N-1174**

**Prepared by**

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**on behalf of the  
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**Introduction to the American Herbalists Guild**

The American Herbalists Guild (AHG) is a non-profit educational organization of professional herbalists specializing in the medicinal use of plants. It is the only organization whose professional membership must submit to a admissions review committee before acceptance as a professional member is awarded. This process is designed to assure a high degree of education, experience, and competency has been attained by the member. AHG members are designated by the term Herbalist (AHG) after their name. AHG professional membership includes herbalists, pharmacists, naturopathic physicians (NDs), medical doctors (MDs), and nurses.

The primary goal of the AHG in legislative matters is to provide a voice for herbalists who are among the most well trained and experienced of all the health disciplines who utilize herbs for healing. This voice is often not represented in such debates. We appreciate the opportunity to be able to present our comments and concerns regarding the questions posed by the Agency.

We commend the Agency for addressing issues regarding consumer safety, labeling regulation for health related products, and streamlining the process by which such issues are addressed and resolved. The AHG welcomes the opportunity to work with the Agency in developing rational guidelines for the regulation of herbal products. Following are our comments to the questions posed by the Agency.

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1. Are there any safety issues, labeling, or marketplace issues that the agency should address quickly through enforcement efforts in order to ensure that products on the market are safe and not misleadingly labeled?

As a product category, it is clear that the majority of herbal products represent a minimal risk to consumers while the benefit is potentially great. The reason this large measure of safety exists is not because herbs are benign as represented by some, but rather due to the fact that many of the relatively toxic botanicals that were used in the past, many of which formed the basis of many modern drugs, were eliminated from common use due to their relative toxicity. Those herbal products which have remained on the market for the past 100+ years have done so because people have been able to use them with a relatively high degree of safety and efficacy.

Still, there are a number of safety issues that remain with botanicals. This occurs most often in situations of adulteration when a relatively benign herb is substituted with a more toxic botanical. There are numerous examples of which the Agency is aware. Based on our experience in the herb community, use of adulterants, in the overwhelming majority of cases, is due to innocent mistakes rather than criminal negligence, with few exceptions. These adulterations most often occur in the herbal industry, though health practitioners are also subject to adulterations in the marketplace. The herbal industry, is very young and as the Agency knows, for many manufacturers, adequate quality control procedures are lacking. I believe the Agency also knows that this is changing quickly as increased interest in herbal products is stimulating increased levels of responsibility for assuring the products that are delivered are both safe and efficacious whether sold as dietary supplements or dispensed as medicines.

We believe the primary reason for such mistakes in identity is due to a lack of easily accessible information. This is especially true for many of the newly formed herbal companies that are relatively late to the market. The core herbal industry has more than 30 years of quality control experience that is lacking in the plethora of new companies of recent years. This will likely lead to increased reporting of adverse events and possibly increased incidence of adulterations or sub-standard products.

Of the specific areas requiring addressing, the widespread use of ephedra in herbal energy and weight loss products ranks high on the list of many herbal practitioners. The majority of herbalists, this is especially true of the traditional Chinese herbal community from which we learn about ephedra, acknowledge the value and importance of ephedra as part of the botanical materia medica. However, the majority of herbalists also feel that use of ephedra in weight loss and energy supplements is a misuse of the plant. These products are subject to abuse by those who are misguided into believing it is a safe alternative to other fad weight management programs and especially by the young. We do not however, support the Agency's position in trying to completely restrict the trade of ephedra to only prescription (Rx) or over the counter (OTC) use. Herbalists, traditional Chinese medical practitioners and naturopathic physicians are highly trained or highly skilled health professionals who are knowledgeable about the proper use of ephedra. Rather, we support the efforts of the Agency's own advisory committee and the American Herbal Products Association in developing appropriate dosage limits, temporal limits, and warnings. In this way, consumers may still receive the benefit the herb has to offer while maintaining a relatively high degree of safety.

Specific adulteration problems continue to persist. The herbalist community knows of these adulterations better than most. Works are underway to identify these adulterants and make them known to the industry.

Regarding safety issues in general. We feel the current MedWatch adverse reporting system of FDA is inadequate for generating meaningful data that can be used to increase the level of safety of dietary supplements by consumers. MedWatch is a passive system with no critical review of the data that are submitted. This we believe is its greatest flaw and has led to findings being misrepresented in the media. In order to be a meaningful reporting system, raw data must be critically reviewed to determine whether the adverse event reported is in fact associated with the botanical(s). We understand the enormity and difficulties of such a task but believe it is achievable by employing a multi-disciplinary committee of health professionals consisting at least of: herbalist, physician, pharmacist, pharmacologist and an industry representative. The data and findings generated from such a committee would provide a significant service to the industry, the Agency, and to consumers.

2. What type or area of research on dietary supplements should FDA direct its resources.

There are a number of different areas we feel are important for the Agency to invest in. First and foremost is education of manufacturers in quality control issues, especially among the smaller and relatively new companies. FDA has made strides in this area through the sponsorship of botanical microscopy workshops which have been well received. Additional classes and workshops in botanical identification, raw material sourcing, macroscopic, microscopic, and chemical fingerprinting, record keeping, good manufacturing practices, etc. are needed and would go a long way in improving the quality control of the industry. This would require the Agency take a proactive participatory rather than a regulatory and adversarial role as has been the case historically.

Other areas to focus on would be the review, development, and/or acceptance of validated analytical methods used for the qualitative and quantitative evaluation of raw botanicals and botanical products. Works are underway by other organizations such as United States Pharmacopoeia, American Herbal Pharmacopoeia, and the Institute for Nutraceutical Advancement. Efforts should be made to work cooperatively avoiding the duplication of efforts.

Lastly, we believe it is important for FDA to take a proactive role in investigating the potential benefit of botanical supplements. It is not a mistake that botanicals have remained the oldest form of medicine known to humans. It is for good reason, many of which defy normal pharmacological investigation, but which none-the-less has value. The Agency is always taking the stance of being reactive rather than proactive. Perhaps this is inherent in the Agency's mandate. We would like to suggest that it does not have to be this way. If the political will was there, FDA could assume a leadership role in investigating the potential benefits of dietary supplements rather than always taking an antagonistic stance toward them.

3. In light of limited resources, how can FDA leverage more resources to implement its strategies

Based on the goals as stated above, partnering with industry on specific initiatives such as an improved adverse reporting system, good manufacturing practices (GMPs), identification of known adulterants, etc. would be the most efficient means for improving the quality control of dietary supplements for consumers.

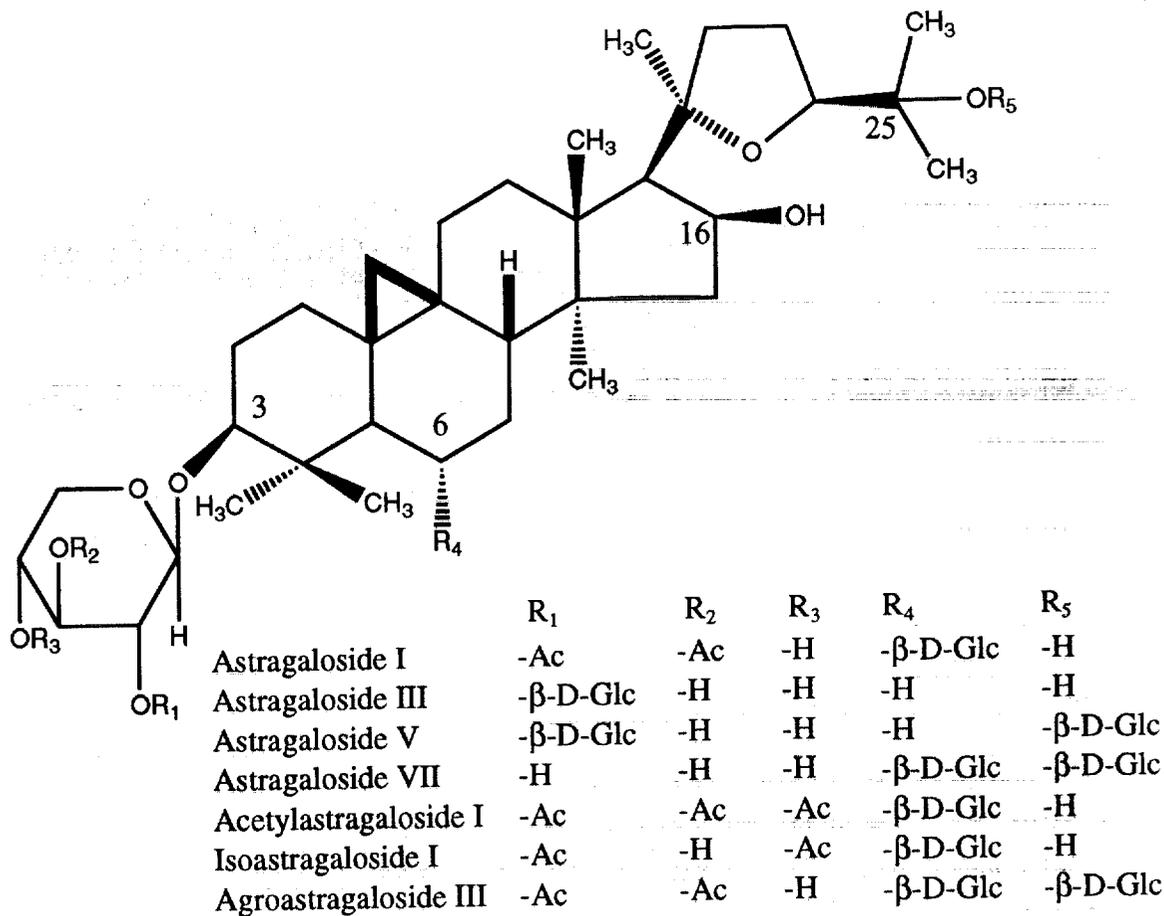
4. What tasks should be included under each separate program area listed in the priorities document?

5. What factors, such as regulations and guidances, should FDA consider as it determines how to best implement each program area?

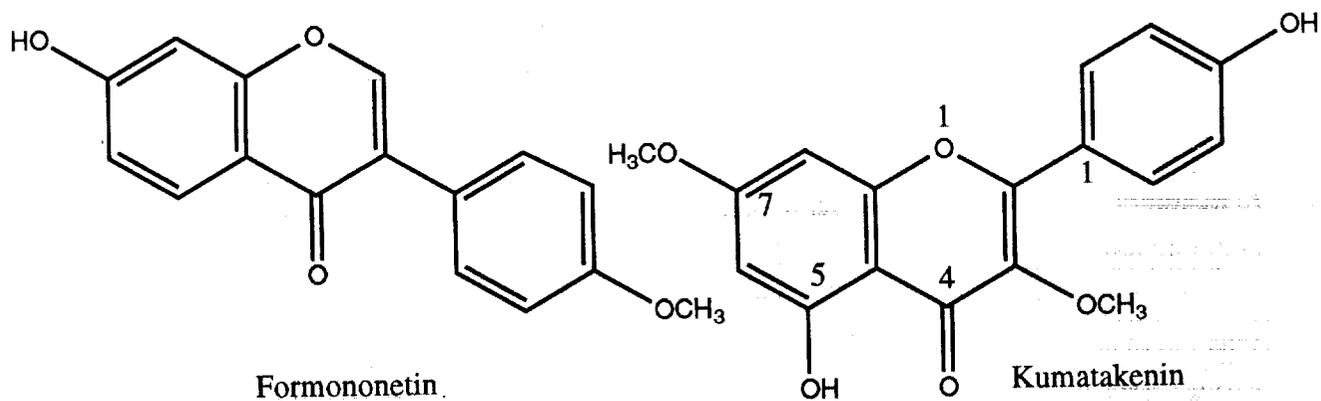
We do not believe FDA has tapped into the expertise necessary for making an informed decision about how botanicals should be regulated. Too many times such policy statements are made by MDs or PhDs who know little or nothing about the practical use of herbs. While able to provide valuable input regarding botanicals these typically relied upon botanical experts lack the skill and experience needed to make informed decisions about herb safety policy. We oppose the Agency's attempt to impose regulations that we feel it lacks the expertise to address adequately. We encourage the Agency to actively seek cooperation from members of the industry and the professional herbal medicine community in addressing these various issues. Regarding adverse reporting systems, many herb companies currently have such systems in place. Similarly, pharmacovigilance programs are available worldwide. This information need only be collected and reviewed to provide a good basis of knowledge from which to work from. We also believe an annual assessment, based on sales volume, is appropriate for funding such a system.

6. In addition to ensuring consumer access to safe dietary supplements that are truthful and not misleadingly labeled, what other objectives should the overall strategy include?

Ways to assist consumers in understanding the benefits of dietary supplements. The Agency appears to continue to operate from the mind set that dietary supplements are of questionable safety and benefit and it is time this attitude be changed to embrace that fact that an ever increasing body of scientific knowledge and consumer satisfaction demonstrates a significant value in the use of dietary supplements.



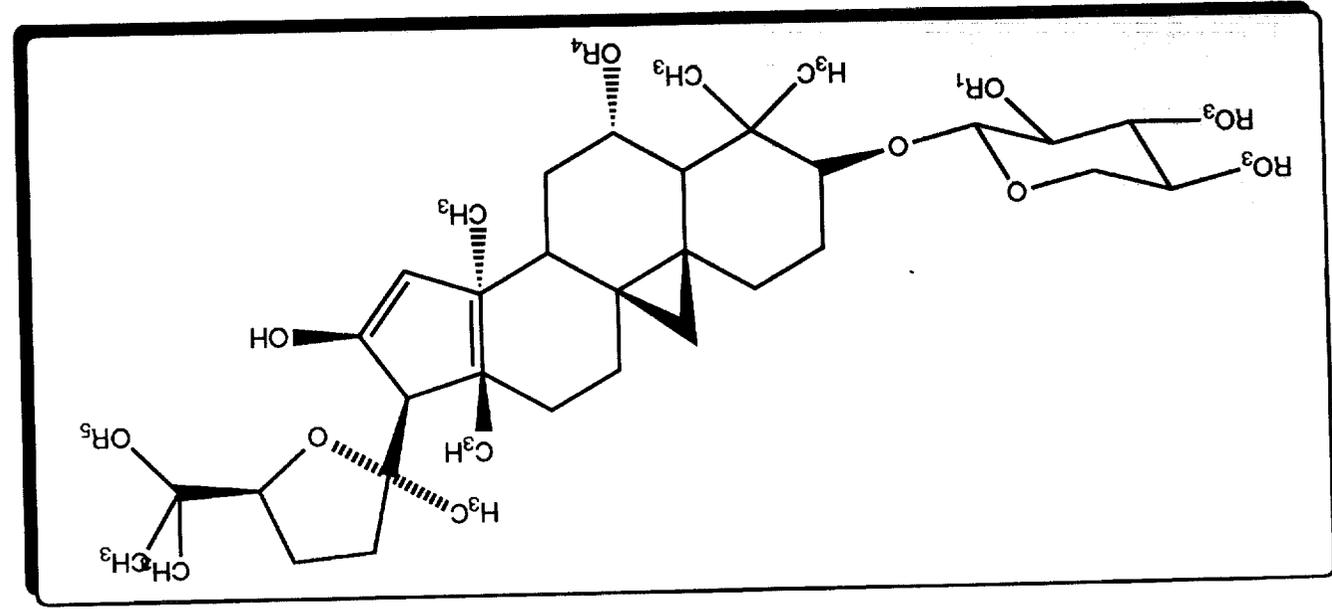
**Figure 6** Triterpenoids of *Astragalus membranaceus*



**Figure 7** Flavonoid and isoflavonoid components of *Astragalus membranaceus*

7. Are the criteria for prioritizing each task appropriate? Which tasks should the agency undertake first?

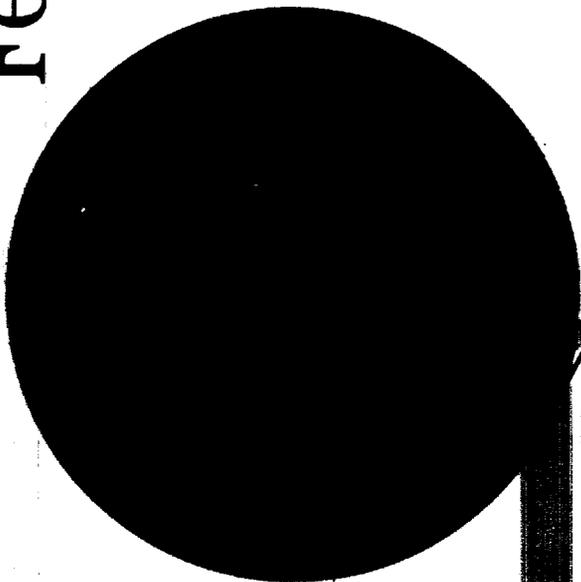
This concludes our comments. We appreciate the Agency accepting these comments and the AHG will support all rational efforts to develop appropriate guidelines that assure botanical products, whether used as supplements or medicines, are used with the highest degree of safety and efficacy.



	R <sub>1</sub>	R <sub>2</sub>	R <sub>3</sub>	R <sub>4</sub>	R <sub>5</sub>
Astragaloside I			H—	β-D-Glc	H—
Astragaloside II		H—	H—	β-D-Glc	H—
Astragaloside III	β-D-Glc	H—	H—	H—	H—
Astragaloside IV	H—	H—	H—	β-D-Glc	H—
Astragaloside V	β-D-Glc	H—	H—	H—	β-D-Glc
Astragaloside VI	β-D-Glc	H—	H—	β-D-Glc	H—
Astragaloside VII	H—	H—	H—	β-D-Glc	β-D-Glc
Acetyl astragaloside I				β-D-Glc	H—
Isoastragaloside I		H—		β-D-Glc	H—
Isoastragaloside II	H—		H—	β-D-Glc	H—

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