

# SDA

## STATE DRUG ADMINISTRATION

DEPARTMENT OF INTERNATIONAL COOPERATION  
A 38, Beilishilu  
Beijing 100810  
China

Phone: 86 - 10 - 68315647  
86 - 10 - 68311986  
Fax: 86 - 10 - 68315648

Ms. Jennie Butler  
Dockets Management Branch  
FDA

November 7, 2000

Dear Ms. Jennie Butler,

I am sending to you, on behalf of our Administration, our comments on the Guidance of Botanic Products. We are very interested in your work of establishing the guidance and hope to further strengthen the cooperation between our two agencies. The comments are as following:

Page 5:

D. Applicability of Combination Drug Registration revised as follows:  
Botanical drug products that are derived from a single parts or multiple parts of a plant(....), or parts from different plant species (not more than 4 plant species).....are not considered to be fixed-combination.

IX page 24:

A paragraph is added following the first paragraph:  
If a botanical products is legally marked in the foreign countries as well as the United State, and its efficacy and safety are confirmed by phase I and II that are conducted in foreign countries based on GCP standards, the product can apply directly for phase III( expanded clinical trial) study. In addition, the preclinical toxicological assessment of the products, especially those products that have been used extensively for a long time without significant adverse reaction being reported, may be required as less as possible.

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page 30:

"C" Batch to batch consistency

The last sentence in this paragraph is revised as follows: " Relevant chemical constituent, as many as possible, present in the drug substance batches should be qualitatively or quantitatively comparable based on spectroscopic and /or chromatographic fingerprinting.

We hope our suggestions will be helpful to your work and will be grateful to you if you could keep us informed about the progress of your guidance.

Best regards.

Yours sincerely,



Lili Zhao  
Deputy Director  
Department of International Cooperation  
State Drug Administration  
People's Republic of China