

## Electronic Mail Message

Date: 9/30/00 8:57:27 AM  
From: zhao lili ( nicpbpi@public.bta.net.cn )  
Subject: =?gb2312?B?u9i4tDogu9i4tDogVGhhbmsgW91?=  
8623 .00 OCT 16 P1:59

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Dear Dr. Qiu,

I refer to the CDER's Guidance of Botanic Products", our Directors have arranged meetings to learn and discuss your guidance. Now we would like to provide some comments on it for your consideration. As I work as an liaison officer, so please forward our comments to your related office because I do not know how to send our comments to the office. Please forgive me to put you into such trouble. But you know our people eagerly want to exchange scientific views with you on this issue. You may know, in June our Director Mr. Zheng met Dr. Henny and expressed his willingness to further strengthen the cooperation between our two agencies and put the botanic products on priorities. The following are our official comments. Because today is the last day for public comments I have to be in hurry to send it to you. In case you are not in your office today and it would be late to take our comments into consideration when you get this mail, please help me to explain to your people the reason that I do not know how directly send our comments to your related office. Tomorrow is our national day and we will have 7 days off but I still can be reached by e-mail.

Our 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.

page 30:

"C" Batch to batch consistency

00D-1392

C 18

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 will be grateful to hear your comments on ours and would like to be informed with the development of your guidance.

Best regards.

Lili Zhao

p.s. Let me know wether you have received this message.

---Original Message---

发件人: Yuan-Yuan Chiu 301-827-5918 FAX 301-594-0746 <CHIU@cder.fda.gov>  
收件人: zhao lili <nicpbpi@public.bta.net.cn>  
日期: 2000年8月14日 6:29  
主题: Re: »Ø,': Thank You

>Lili;

>

>"NDA day" continues to be practiced in Biopharm area as an internal meeting,  
>but not other areas because of short review timeline under PDUFA and because  
>there are multiple internal multiple disciplinary NDA review progress  
>meetings.

>

>A piece of good news, the FDA Draft Guidance for Industry on Botanical Drug  
>Products was published for public comment for 60 days on 8/10/00. You can  
find  
>it at [www.fda.gov/cder/guidance/1221dft.pdf](http://www.fda.gov/cder/guidance/1221dft.pdf). I'll welcome your comments  
which  
>should be sent to FDA docket so that they can be evaluated officially.

>

>Yuan-yuan

>

>



# Office of New Drug Chemistry FAX Transmittal Sheet

*Office of New Drug Chemistry  
FAX Transmittal Sheet*

Food & Drug Administration  
Center for Drug Evaluation  
and Research  
Rockville, MD 20857  
5600 Fishers Lane  
HFD-800, Room 13B31  
Office: 301-827-5918  
Fax: 301-594-0746

DATE: 10-16-00.

TO: Dockets Management Branch

FROM:

FAX #: 7-6870

Pages excluding cover:

COMMENT(S):

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