

E L E C T R O N I C M A I L M E S S A G E

Date: 22-Oct-2000 02:37pm EDT
 From: Craig Dremann
 dremann@ecoseeds.com
 Dept:
 Tel No:

TO: CHIU (CHIU@A1)
 CC: dremann (dremann@ecoseeds.com)
 Subject: Draft "Guidance for Industry Botanical Drug Products"

Dr. Yuan Yuan Chiu
 FDA, Organization DHHS/FDA/CDER/OPS
 Job title DIRECTOR ONDC
 Building PKLN
 Room 13B31
 Mail stop HFD-800
 Phone 301-827-5918
 Fax 301-594-0746

Dear Dr. Chiu,

Thank you for making time for my wife Sue and I to see you last Friday, and I regret we got tied up in Washington D.C. and couldn't make our meeting, and I hope our cancellation did not cause you a great deal of inconvenience.

We wanted to talk with you about some problem areas regarding the Draft "Guidance for Industry Botanical Drug Products" (later referenced as "Draft GFI-BDP"), and I will outline our major stumbling block below.

Just so you can see what we have been working on, our discoveries of 79 higher plants with antibiotic activities can be seen at <http://www.ecoseeds.com/mrsa.html> We call these new compounds "Botanical Antibiotic", to distinguish them from the traditional chemical and semi-synthetic antibiotics, derived from microorganisms.

In the Draft GFI-BDP: Definitions, Part I. Introductions, second paragraph states "...because of the unique nature of botanicals, FDA finds it appropriate to apply regulatory policies that differ from those applied to synthetic, semisynthetic, or otherwise highly purified or chemically modified drugs (INCLUDING ANTIBIOTICS)." [Emphasis added]

Our firm is developing a new category of drug products, and your draft guide lines apparently did not anticipate that botanical antibiotics would be discovered.

Could the line that I've highlighted above in your definitions be changed, perhaps to read "(including antibiotics derived from microorganisms)" so the old or traditional antibiotics can be considered a

8658
 '00
 OCT 24
 P2:28

00D-1392

ADDS
 C21

separate and non-botanical-drug group; and then our new Botanical Antibiotics could be included within your "Botanical Drug Products: definitions and guidelines?

Let me know what your thoughts are about this issue, and I look forward to hearing from you at your convenience.

Sincerely, Craig Dremann, Ohlone Products (650) 325-7333