

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

Date: 23-Oct-2000 10:59<sup>pm</sup> EDT  
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TO: Yuan-Yuan Chiu 301-827-5918 FAX 301 ( CHIU@A1 )  
CC: dremann ( dremann@ecoseeds.com )  
Subject: Draft "Guidance for Industry Botanical Drug Products"

Dear Dr.

Thank you for your reply. Is it possible that you forward my emails so they could be offically added to your docket as comments on the Draft GFI-BDP?

The other two problems I see in the Draft are as follows:

1. There's a lot of information requested, especially about the growers and suppliers, that most companies would consider trade secrets; and there is no language in the Draft on what information would be held confidential by FDA and not disclosed to our commercial competition. Part of my competitive edge as a commercial concern is the sources of supply that I have developed; and in some cases like seeds or botanicals, that can be the only edge you have.
2. The requirement that the growers or wild-crafters certify the Botanicals, or that they supply a voucher specimen is the ideal situation from a regulatory position; but having been in the seed trade for almost 30 years, there's no possibility of that ever happening. I think if you talk to the industry about this requirement, they will tell you about the impossibility of this ever happening.

And what form would this proposed "certification" take? A sworn statement? Most wildcrafters, and even growers of botanicals are not botanists, so they would lack the direct knowledge to make any certification reliable. Wildcrafted materials will be the biggest stumbling block, because all the harvesters want to keep everything secret any way.

Finally, am I correct in my question in my last email, that FDA in proposing the Draft GFI-BDP did not anticipate the discovery of Botanical Antibiotics; and as the Draft currently stands, our products are not covered until that Definition section is amended to redefine and separate the old microorganism-derived antibiotics from our new Botanical Antibiotics?

I look forward to your reply, and remain,

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