From: Jim Rock[redacted]
Sent: Tuesday, November 11, 2008 12:43 PM
To: Jennifer Goodrum; 'L.D. King'; Tara McCarthy; Sarah Dodge
Subject: Re: FDA joint letter

Sorry for coming into this late, but here are two suggestions for additions that I spoke to LD about a few minutes ago. I think they are two important issues that need to be addressed. My additions are underlined, and are both below and attached.

In response to the significant concerns expressed by pharmacy organizations and the public, FDA subsequently acknowledged that the CPG should be revised. We believe that receiving input from healthcare organizations and the public is critical to achieving an optimal FDA policy for ensuring the patients receive the medications they need. We ask that this be undertaken before initiating an enforcement action against a pharmacy that is dispensing estriol pursuant to a valid prescription.

Furthermore, CPGs by their very nature do not have the force of law. As stated in its preamble, it is only the "current thinking" of the agency and "does not operate to bind FDA or the public." We are concerned that the agency is treating this CPG as law when in fact this is not the case.

One of the barriers for prescribers with the IND process is the institutional review board (IRB) approval and review process. The process is prohibitively costly and burdensome for treating individual patients in a clinical setting. This requirement, alone, in effect eliminates estriol as a treatment option. Furthermore, new information we have been provided by doctors investigating the IND process has revealed that IRB's may not be able to accept protocols and studies that include existing patients. If this is true, it would mean that INDs patients currently taking estiol could not be part of any IND that is supposed to be set up for this very purpose.

Further, we understand that at least one application by a physician who followed the Agency's instructions and guidance on completing INDs for estriol has been denied. We also understand that information from this

application was used in enforcement actions against the pharmacies identified by this doctor as providing estriol for the treatment of her patients.

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