

Reminder: AOL will never ask you to send us your password or credit card number in an email. This message has been scanned for known viruses.

From: ldking@ [redacted]  
To: [redacted]@aol.com  
Subject: FDA  
Date: Mon, 6 Nov 2006 11:43 AM

Scott:

My initial comments:

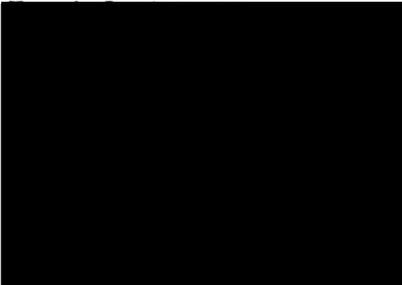
- A. We must attack the premise that compounded drugs fall under the FDCA; they do not.
- The CPGs are unenforceable and flawed. FDA has agreed to reissue; they haven't (we can document this if necessary).
- B. components of FDA approved products as a CPG factor is inappropriate and more restrictive than former Congressional law. FDA can't be more restrictive than Congress.
- Anticipatory compounding language as described in the CPG is more restrictive than former Congressional law and therefore inappropriate.
- Section C can not be violations of FDCA if they are not violations of state law, and if your pharmacy meets the criteria of the exemption (i.e. ordinary practice selling at retail).
- The entire GMP discussion (C.5) is irrelevant.

There is good congressional committee report language around what "copy of commercially available product" means (we can provide this if necessary). The committee wished to give deference to the prescriber on what a "significant difference" was. We hold that the presence of a prescription is documentation of medical need. The prescriber determines if a medication that is significantly different is needed.

Depending how your counsel wants to respond, we can provide detailed comments on why the CPG factors in both CPGs are inappropriate.

Let me know if I can help further. Terry's contact info follows.

LD



*IACAP  
response*

\*\*\*\*\*

L.D. King  
Executive Director / Executive Vice President

International Academy of Compounding Pharmacists

