

From: Sarah Ryan Dodge [REDACTED]
Sent: Monday, December 29, 2008 2:33 PM
To: L.D. King
Cc: 'Jennifer Goodrum'; 'Tara McCarthy - Work'
Subject: RE: FDA Warning Letters Update

L.D.,

When the idea was posed to me, I thought of it with a much more broad-based response. I would never think IACP should get into the business of writing sample responses to the FDA, as each and every case is different, with a different set of circumstances.

I was thinking more of a "Do's and Don'ts" check off sheet(with some detail) for them when confronted by the FDA. Since this is happening with increasing frequency, it may be beneficial to put something out there, of course with the disclaimer, that ALL actions should be vetted with your attorney to ensure compliance with local and state laws. If nothing else, I would think this would empower some people, as many feel that they are simply completely ill-equipped to deal with the big, bad FDA, when many resources are out there, but have to be put to use by them.

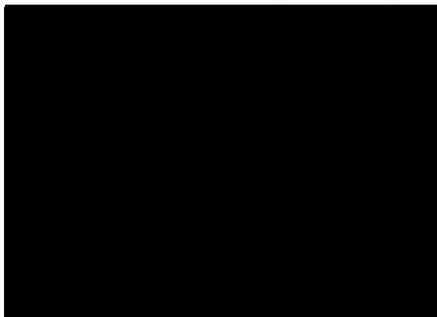
I could even have some of my husband's former FDA partners review something for us (as a favor) so we can get some kind of tool out there for our members...just some food for thought, below.

Rather, what I thought might be helpful and within our abilities (and with limited - if any - legal costs) would be to make the following recommendations or provide commentary on:

- 1) What should you do if the FDA send you a letter?
 - Consult your attorney
 - Consult an FDA attorney?
 - Respond within a certain window of time?
 - Buy time?
- 2) What if the FDA visits your pharmacy, the following are your rights?
 - To see a search warrant or other document?
 - To request your attorney's presence during any search or review of your records?
 - Request that such such search or other visit take place at an alternative time/day when your customers are not present
 - What do you have to provide/are not required to provide?
 - Discuss with your attorney such search before it takes place and possible legal recourse if search goes beyond stated purpose?
- 3) Document your dealings (all dealing, whether large or small) and keep good notes on dates and times of conversations. subject of conversations and with whom, out of which FDA office?
- 4)What legal authority if is the FDA operating under, according to them?

5) Other items...

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