Daniel G. Gottlieb

From: Leah Kendall
Sent: Monday, May 14, 2012 12:07 PM
To: Nguyen, Thinh (FDA\OC); Love, Patricia; Weiner, John
Cc: Bradley Merrill Thompson; Leah Kendall
Subject: CPC - Clinical trial Q&A
Attachments: CPC - Clin trial QA matrix response to OCP 11May12 FINAL.pdf

Dear Thinh, Patricia, and Barr,

Attached are the revised questions relating to clinical trials, in follow up to the teleconference on January 11, 2012, and your email of February 15, 2012. We appreciate your patience while our members worked on creating a new draft that incorporated OCP's feedback on the call, as well as your written comments on the list of questions. As you will see, we revised our draft list of questions substantially based on your feedback. The major revisions include:

- Adding explanations of CPC's understanding of current requirements, examples illustrating the question we are asking, and, as applicable, narrative comments on the reasons we believe a particular question is important.
- Focusing the questions on drug delivery combination products.
- Narrowing the list into just eight (8) key questions, which represent the areas of most concern to CPC.

As you read through the draft, you will see that the questions that CPC would like clarification on are based on industry experiences where there has been disparate information provided from different divisions, or specific requirements that were provided in a response to an application that seems to pertain to drug delivery devices in general and not to a specific product reviewed. Due to the applicability of the information to a type of drug delivery, we support FDA addressing these industry questions in a guidance document or other public communication.

After you have had an opportunity to review, please let us know your availability for a meeting to discuss the revised draft and appropriate next steps, including as you mentioned below, working with the appropriate staff in the Centers and OCC to begin drafting the responses to your questions and publish them either in a guidance document or some other form of transparent communication

We truly appreciate the continued dialogue on these issues and look forward to future discussions.

Thank you,

Leah and Brad

LEAH KENDALL | BIO
(317) 569-9131 (DIRECT) | (317) 569-9520 (FAX)
LKENDALL@EBGLAW.COM

EPSTEIN BECKER GREEN
9001 WESLEYAN ROAD, SUITE 212 | INDIANAPOLIS, IN 46268
(317) 454-8985 (MAIN) | WWW.EBGLAW.COM

From: Nguyen, Thinh (FDA\OC) [mailto:Thinh.Nguyen@fda.hhs.gov]
Sent: Wednesday, February 15, 2012 3:03 PM