From: OC GCP Questions
To: [redacted]
Subject: RE: Questions regarding clinical trial
Date: Thursday, July 16, 2015 3:33:00 PM

Good afternoon,

Please be aware that the determination of whether a trial is an "applicable clinical trial" must be made by the responsible party associated with that trial and familiar with all aspects of the clinical trial. FDA cannot make that determination for any party. As your question appears to be related to whether the trial you describe involves a clinical investigation of a drug, you may wish to discuss this issue with your legal counsel.

The NIH website does contain the Elaboration of Definitions which can be referred to in making the determination of whether a trial is an applicable clinical trial and required to register and submit results to ClinicalTrials.gov. Discussion of "applicable drug clinical trial" begins on page 7 of the document.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

From: [redacted]
Sent: Tuesday, July 14, 2015 9:42 AM
To: OC GCP Questions
Subject: Questions regarding clinical trial

We are a company that manufactures a [redacted]. Though we had previously been inspected by the FDA, our most recent inspector said he was turning the inspections over to the state as we deemed our product to be a food.

We are interested in running a trial of our patent pending process to determine if ingestion of these [redacted] at specific time intervals improves fatigue in hemodialysis patients. Up to 97% of patients on hemodialysis experience some degree of fatigue upon completion of the dialysis session, commonly referred to post-dialysis fatigue or washout.

We cannot determine if such a trial would be subject to the FDAAA regulations, as such a trial would be using a food (not a drug nor a device) to improve fatigue (not a disease state), but would be conducted on humans.

Furthermore, would such a trial need to be registered with ClinicalTrials.gov?

Please provide guidance so that we may comply with all applicable laws and regulations. We would like to proceed as soon as possible, so a timely response would be appreciated.

Sincerely,

[redacted]