From: OC GCP Questions
To: [redacted]
Subject: Research with a dietary supplement
Date: Tuesday, March 13, 2018 12:16:00 PM

Good afternoon –

This office cannot determine whether you need an IND. You will need to contact the Center for Drugs (CDER) at druginfo@fda.hhs.gov Also please see FDA dietary supplement webpage.

Dietary Supplements

Kind regards,

The OGCP group.

From: [redacted]
Sent: Monday, March 12, 2018 5:06 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Research with a dietary supplement

Hello,

I have an investigator who was contacted by a health supplement company to test the impact of a dietary supplement on daily stress. The company will use the results of the study to show the effects (no matter the outcome) that have been investigated in a placebo controlled trial. They will also be able to state that the supplement has been researched in a particular population. This product is available to the public and the research will involve questionnaires, blood pressure measurements, cortisol levels through saliva samples, and heart rate.

This type of research is new for me and I was asked to determine if this was a clinical trial and if so, is it an FDA regulated clinical trial. I believe that this would be considered a clinical trial but not an FDA clinical trial since guidance indicates that dietary supplements are not considered drugs.

I have been doing some research and noticed that we need to determine if an IND is required for this research. From my understanding, an IND is not required when a lawfully marketed dietary supplement is studied for its effect on the structure or function of the body or its mechanism of action. I believe this research falls under this description.

I was hoping to get some additional guidance and clarification on this type of work. Does the researcher need to obtain an official determination from the FDA regarding the need for an IND? Would you consider this a clinical trial?

I am happy to provide additional information or have a phone discussion.

Thank you for your time and assistance with this matter.

[redacted]