From: OC GCP Questions
To: [redacted]
Subject: Clinical Trials involving dietary supplements
Date: Wednesday, June 03, 2015 11:05:22 AM

Good morning –

The 45 CFR 46 regulations are governed by the Office of Human Research Protections (OHRP). You can contact them directly.

Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Toll-Free Telephone within the United States: (866) 447-4777
Telephone: (240) 453-6900
Fax: (240) 453-6909
E-mail: OHRP@hhs.gov

Contact OHRP | HHS.gov

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Tuesday, June 02, 2015 2:52 PM
To: OC GCP Questions
Subject: Clinical Trials involving dietary supplements

Office of good clinical practice,

I am wondering about the application of 45 CFR 46 to clinical trials sponsored by a nutritional supplement company. If the clinical trial is only to look at the structure/function claims of the product and not to apply for a new drug, and the study is being paid for only by the private company does 45 CFR 46 apply?

Thank you,

[redacted]