From: OC GCP Questions
To: [redacted]
Subject: Seeking confirmation that a specific dietary supplement will not require an IND
Date: Tuesday, June 16, 2015 11:55:25 AM

Good afternoon –

In order to determine whether an IND is needed you will need to contact the Center for Drugs (CDER). Please see their contact information below.

Questions about drug products (other than gcp questions)
301-796-3400
Druginfo@fda.hhs.gov
Questions about whether a product is subject to IND regulations: call 301-796-3400

Kind regards,

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

From: [redacted]
Sent: Tuesday, June 16, 2015 10:54 AM
To: OC GCP Questions
Subject: Seeking confirmation that a specific dietary supplement will not require an IND

Dear Office of Good Clinical Practice,

We would like to conduct a pilot study in 20 humans on the effects of purified [redacted] as a dietary supplement to improve generalized intestinal health through improving microbiome composition. [Redacted] is a natural component of human milk and many other animal based foods, and has been made in purified form for medical device use for over 25 years.

Our pre-clinical data shows beneficial microbiome shifting in mice, as well as protection from intestinal bacterial infections in mice fed hyaluronan of a specific size range around 35kDA.

According to the "Guidance for Clinical Investigators, Sponsors and IRBs" (Sept 2013), p12, section 1, and conversations with the regulatory specialists at the [redacted], it appears that we do not require and IND.

We have applied to the NIH for dietary supplement funding, and it appears that our project received some enthusiasm for proceeding. I now have to provide FDA correspondence that our supposition is correct.

I have called numerous telephone numbers at the FDA, and I am still no closer to figuring out how to obtain a definitive way to go about getting an official informal, or formal, statement as to whether a [redacted] dietary supplement is exempt or requires an IND. I would be incredibly grateful if you could provide clear guidance on how to proceed.

With best wishes,

[redacted]