From: Kezer, Doreen M
To: [redacted]
Subject: IND question
Date: Thursday, June 14, 2018 11:02:00 AM
Attachments: [redacted]

Hi [redacted] –

I would recommend starting with the Center for Drugs (CDER). Their email is druginfo@fda.hhs.gov and by phone 855-543-3784 or 301-796-3400. This office will determine if you need an IND. I have also included FDA's SFSAN website. You will see their contact information at the bottom right of the page.

Foods

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

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From: Less, Joanne
Sent: Thursday, June 14, 2018 10:48 AM
To: [redacted]
Cc: [redacted]
Subject: RE: IND question

Hi, [redacted],

It looks like you've already consulted FDA's guidance on determining when an IND is needed (https://www.fda.gov/downloads/drugs/guidances/ucm229175.pdf), so your question would be best addressed by the experts in CFSAN. I've copied Doreen on this as she handles the majority of the questions we receive in our OGCP Inbox and/or makes sure they get to the right FDA office for response.

Kind regards,

Joanne

From: [redacted]
Sent: Wednesday, June 13, 2018 4:49 PM
To: Less, Joanne <Joanne.Less@fda.hhs.gov>
Cc: [redacted]
Subject: IND question

Hi Joanne

I have a question about whether an IND might be needed for a protocol. This is the classic "when is a food a drug" scenario.

In brief, the intervention is to provide children at high risk for growth anemia and lead poisoning with either usual care, a micronutrient supplement or a daily eggs for a year and follow growth, incidence of anemia and lead levels. I have copied attached a pdf of the IRB application as it currently stands, which describes the study hypothesis, aims and intervention.

On the one hand, it would seem that this would require an IND as the supplement and eggs are being used to prevent anemia and lead poisoning. On the other hand, the IND exemption guidance states the following: ""For purposes of the dietary supplement labeling requirements, a "'disease' is damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition" (21 CFR 101.93(g)(1)). 18 21 U.S.C. 321(g)(1)(B)."

One might consider the diseases as resulting from an essential nutrient deficiency, and that the egg and micronutrient supplementation are addressing that.

Thoughts? Or can you refer me to the best person to answer this?

Thanks

[redacted]

[redacted]

[redacted]