From: OC GCP Questions
To: [redacted]
Subject: Please help us find the best path to FDA approval of our anti-cancer agent
Date: Wednesday, July 23, 2014 1:13:39 PM

Good afternoon --

You will need to contact the Center for Drugs (CDER) directly to see if you need an investigational new drug (IND) application with FDA. Please see their contact information below.

IND Contacts:

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

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.

-----Original Message-----
From: [redacted]
Sent: Wednesday, July 23, 2014 1:04 PM
To: OC GCP Questions
Cc: [redacted]
Subject: Please help us find the best path to FDA approval of our anti-cancer agent

Dear Sir / Madam

We are a nascent biotechnology company comprised of basic scientists from the [redacted] . We have a unique "lead compound" that has proven efficacious as an anti-cancer agent in a series of preclinical studies. With the understanding that substantial, additional, preclinical work will be required, we are optimistic that this agent may be useful in treating a variety of metastatic cancers in humans. Please provide any available information that may help guide future work along a path to Clinical Trials, and FDA approval. Although we have many decades of R&D experience, both in academia, and in the biotechnology industry among the principals of our new company, we have little to no experience with the FDA.

Thanks you very much for your assistance in this matter.
[redacted]