From: OC GCP Questions
To: [redacted]
Subject: RE: Questions Regarding FDA Form 3674
Date: Wednesday, March 18, 2015 8:22:00 AM

Good morning,

FDA has two documents which you may wish to refer to regarding your questions. First, you may wish to review the instructions for completing Form FDA 3674, available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM354618.pdf , in particular, I would note the instruction for completing item 9 Box B.

FDA also has a guidance document related to Form FDA 3674 available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM164819.pdf which discusses the submission of a certification for NDA supplements.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

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, March 17, 2015 9:35 AM
To: OC GCP Questions
Subject: Questions Regarding FDA Form 3674

To Whom It May Concern:

- Is a sponsor required to submit FDA Form 3674 for Phase I study if we are reporting the trial on clinicaltrials.gov?
- Is a sponsor required to update the FDA From 3674 for supplement application (e.g NDA) that is changing the route of administration and dosage and changing the protocol significant?

Thank you for your assistance.

[redacted]