From: OC GCP Questions
To: [redacted]
Subject: RE: [redacted] FDA form 3674 certificate of compliance
Date: Wednesday, January 03, 2018 11:06:00 AM
Attachments: Form FDA 3674.pdf
FDA-3674_instr supplmnt_508(2.13).pdf
[redacted]

Good morning [redacted],

It appears that you are having difficult filling out and submitting Form FDA 3674. Attached is a copy of the form and the instructions that go along with it. This form is electronically fillable and may be submitted along with an application to FDA. If you are having problems with the process for the electronic submission of your application, I would suggest you contact the regulatory project manager within the product review division you are working with. They would be the most appropriate resource for how to submit your application.

I hope this information is helpful.

Patrick J. McNeilly, Ph.D.
Senior Health Policy Analyst

Office of Good Clinical Practice
U.S. 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: Friday, December 29, 2017 11:24 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: [redacted] FDA form 3674 certificate of compliance

Hi,

Your stupid form 3674 requires a fax number, but faxing is obsolete technology from the 1980's. People haven't used faxes for decades. Please remove this crazy bureaucratic barrier to entry immediately.
I have no idea how this obnoxious form works, either. What is with that, anyway? You only want to hear from people "in the know"? What good is a computer form that cannot be filled in and submitted electronically? If the form is submitted automatically, PLEASE SAY SO SOMEWHERE ON THE FORM, or provide proper instructions. Or is embarrassing everyone new to this system of absurdities somehow amusing to you people?

You asked for a six or eight digit number from the ClinicalTrials.gov people who seem to be willfully incompetent. They don't seem to care that almost 100 people a day die from opioid addiction. The $10 billion a week lost also appears to be lost on them. The pheromone is the grease on a man's face.

I've found [redacted] which causes opioid addiction. Giving just a few milligrams cures opioid addiction outright. The [redacted] is a product produced by the intact human skin and under current law, it is not subject to regulation. I cannot understand why submitting this form is so difficult and frustrating.

[redacted], Senior Scientist in Charge