From: OC GCP Questions
To: [redacted]
Subject: RE: acess FORM fda 3674
Date: Monday, May 07, 2018 8:19:00 AM
Attachments: Form FDA 3674.pdf
ACT_Checklist.pdf
[redacted]

Good morning,

I'm sorry you are having issues obtaining a copy of Form FDA 3674. A copy of the form is attached to this message.

Regarding your question related to trials conducted to support an abbreviated new drug application (ANDA), certain trials involving bioavailability or bioequivalence may be subject to the requirements for registration and results submission to ClinicalTrials.gov and, if so, an NCT number would need to be included in section 10 of Form FDA 3674. Attached is a copy of the National Institutes of Health "Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT)." You may wish to review this document, particularly the discussion of Phase 1 trials beginning on page 8, when determining whether a trial is required to be registered with ClinicalTrials.gov.

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.
Senior Health Policy Analyst

Office of Good Clinical Practice
U.S. Food and Drug Administration

[redacted]

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: Monday, May 07, 2018 5:34 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: acess FORM fda 3674
Importance: High

To whom it may concern,

We are a pharmaceutical company LOCATED in [redacted],and we would like to know how to get **FORM FDA 3674**,we were only able to access to instructions for completion, we couldn't access to the FORM itself. Moreover ,for **section 10** regarding **National Clinical Trials numbers**, we guess this section is not applicable for **ANDA**.

Could you please help us with that.

Best regards.

[redacted]