From: OC GCP Questions
To: [redacted]
Subject: RE: Question on FDA Form 3674
Date: Wednesday, July 09, 2014 2:22:00 PM

Good morning,

In our guidance document related to the Form FDA 3674 (found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM164819.pdf), FDA has indicated that an efficacy supplement to a BLA would require the submission of a 3674. Your message indicates that you will be submitting a new sBLA and it appears that you will be submitting information which would not have been included in the previous sBLA. You would need certify that you have complied with the requirements of Section 402(j) of the Public Health Service Act for the information being provided at this time and would therefore need to submit a new Form FDA 3674 with your application.

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, July 08, 2014 8:42 PM
To: OC GCP Questions
Subject: Fwd: Question on FDA Form 3674

Hello,

[REDACTED] is writing to seek guidance on how to interpret requirements for FDA Form 3674 in an event in which Form 3674 certification was previously submitted.

Specifically, Form FDA 3674 (to confirm compliance with 42 USC 282(j), Section 402(j) of PHSA) was filed to support a sBLA in 2012. At the time of the 2012 sBLA, updates were reported which included the results for the primary outcome. In planning for an upcoming 2014 sBLA, in which the same clinical trial will be submitted in support of a new sBLA, [REDACTED] is seeking guidance on the need to submit a new form FDA 3674. Based on [REDACTED] understanding, a cross-reference to the 2012 Form 3674 that certified compliance with posting of results for the primary endpoint, is sufficient.

Could you please confirm if it is necessary for us to submit a new Form 3674 for our upcoming sBLA

application or could we simply just refer to the previous Form 3674 submitted in the 2012 sBLS?

Thank you in advance for your guidance.

Regards,
[REDACTED]