From: OC GCP Questions
To: [redacted]
Subject: RE: FDA Form 3674 needed for original BLA submission?
Date: Monday, December 17, 2018 8:44:00 AM
Attachments: [redacted]

Good morning,

An original biologic license application (BLA) would require the submission of Form FDA 3674. Submission of Form FDA 3674 to a marketing application is independent of whether a form was previously submitted to an investigational new drug application (IND). As noted in FDA's guidance on submission of this form (see link below), the submission of a BLA represents the initiation of the regulatory review process to supporting the approval of a previously unapproved product and provides a means to satisfy the statutory certification requirement.

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM562439.pdf

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

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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 14, 2018 7:43 PM

To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA Form 3674 needed for original BLA submission?

Hello,

Do we need to provide a Form 3674 in an original BLA if the 3674 forms have already been provided in the relevant IND? We have submitted 3674 forms for all covered studies in the BLA at the time the original protocols were submitted to the IND.

Thank you for your time,
[redacted]

[redacted]