From: OC GCP Questions
To: [redacted]
Subject: Question regarding FDA 3674 form
Date: Friday, January 27, 2017 11:27:00 AM
Attachments: [redacted]

Good morning –

Please see the link below to instructions on how to complete the form, specifically #7.

http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM354618.pdf

If I have not adequately answered your question, please contact the Center for Devices (CDRH) directly at DICE@fda.hhs.gov

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Rosa Lopez [mailto:Rosa.Lopez@btgplc.com]
Sent: Friday, January 27, 2017 10:41 AM
To: OC GCP Questions
Subject: Question regarding FDA 3674 form

Hi,

I wanted to ensure we are filling out form FDA 3674 correctly. Our company has been issued a modular PMA numbe[redacted]. We are submitting the last module and would like to know if field #7 below should be left blank or should the modular number be indicated?

Thank you in advance for your help.

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☒ PMA ☐ HDE ☐ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*	If BLA was selected in item 6, provide Supplement Number
[redacted]	

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

[redacted]

[redacted]