

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](mailto:DICE@fda.hhs.gov)

Kind regards,

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



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: Rosa Lopez [mailto:[Rosa.Lopez@btgplc.com](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 number [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)

[REDACTED]

If BLA was selected in item 6, provide Supplement Number

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

[REDACTED]

[REDACTED]

[REDACTED]