

From: Hooban, Christopher
Sent: Monday, September 28, 2015 8:58 AM
To: Krammer, Marlene
Cc: Rangetiner, Barbara; Ammons, Stanley
Subject: RE: BLA 125587/0; Form 3455

Thank you for the response.

From: Krammer, Marlene [mailto:marlene.krammer@octapharma.com]
Sent: Monday, September 28, 2015 7:20 AM
To: Hooban, Christopher
Cc: Rangetiner, Barbara; Ammons, Stanley
Subject: RE: BLA 125587/0; Form 3455

Dear Mr. Hooban:

I refer to your Email to Mr. Ammons dated September 25, 2015 in regards to BLA 125587/0, Form 3455.

As none of the investigators of our clinical studies NGAM-01, NGAM-02 and NGAM-05 had disclosable financial interests, Form 3455, Disclosure Statement, is not submitted within the BLA. Instead, Form 3454, Certification is included in Module 1.3.4 "Financial-certification-disclosure". The list of investigators is attached to this single Form 3454.

Kind regards, Marlene Krammer

Marlene Krammer
Manager
International Regulatory Affairs Department

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From: Hooban, Christopher [mailto:Christopher.Hooban@fda.hhs.gov]
Sent: Friday, September 25, 2015 1:19 PM
To: Ammons, Stanley
Subject: BLA 125587/0; Form 3455

Mr. Ammons,

Good afternoon. One of the reviewers is having trouble finding Form 3455. Would you be able to point out where it can be found in the submission?

Chris Hooban

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