

APPROVED

By Jean Gildner at 3:40 pm, Dec 07, 2016

From: Gildner, Jean
To: "[Margarita Aguilera](#)"
Subject: RE: BLA 125603 MACI - Late Cycle Meeting and Amendments
Date: Friday, September 09, 2016 1:32:00 PM

Hi Margarita,

In regards to question 1. You can submit the Training Materials as a response to Information Request, under the new section 1.15 Promotional Materials.

In regards to question 2. Providing the "Categorical Exclusion of Environmental Assessment" statement and withdrawing the previous EA will be fine.

In regards to question 3. Meeting package will be sent September 16, 2016 our Late Cycle Meeting is scheduled for September 30 th.

Have a great weekend, Jean

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From: Margarita Aguilera [mailto:maguilera@vcel.com]
Sent: Wednesday, September 07, 2016 11:58 AM
To: Gildner, Jean
Subject: BLA 125603 MACI - Late Cycle Meeting and Amendments

Dear Jean,

Welcome back! Hope you had a nice relaxing and enjoyable vacation.

I wanted to follow up and get your advice on a couple of things:

1. We are preparing to submit the final draft HCP training material before September 20. My plan is to submit under 1.15.1.7 Response to information request, can you confirm that this is acceptable.
2. We are also preparing to submit an amendment to request a Categorical Exclusion of Environmental Assessment as agreed with the Agency, on the basis that the to be marketed product, MACI, (b) (4) and therefore there will be no increase in the existing levels of use or change in the intended uses of the product (§ 25.30(k)). The guidance requires a statement indicating “no extraordinary circumstances exist that require submission of an EA”, however, we have already submitted one with the BLA. Do we simply provide the statement to withdraw the previously submitted EA?
3. Finally, can you advise if you will be providing a background package for the **late-cycle meeting**, with the discipline review letters issued to date, and a brief summary of any substantive application issues. I would also appreciate if you can provide the time of the T-con at your earliest convenience.

Looking forward to your responses.

Best Regards,
Margarita

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