Message

From: Nalubola, Ritu [Ritu.Nalubola@fda.hhs.gov]
Sent: 2/16/2017 8:16:37 PM
To: McNally, Robert [Mcnally.Robert@epa.gov]
Subject: RE: Oxitec -- next steps

And hope you have a nice extra-long weekend!
Ritu

From: Nalubola, Ritu
Sent: Thursday, February 16, 2017 3:10 PM
To: 'McNally, Robert'
Cc: Mendelsohn, Mike; Hartman, Mark; Leahy, John; Zborowsky, Ashley; Epstein, Laura; Flamm, Eric
Subject: RE: Oxitec -- next steps

Bob – That sounds great! And I'm sharing this with FDA colleagues.

For FDA, Ashley plans to call Deepti Kulkarni. Our messages will be:

1) EPA has shared with us EPA's decision about EUP path possibility. We will defer to EPA on any EPA-specific questions

2) Convey advice we received from CEQ re: INAD waiver but also note that the waiver considerations are now somewhat moot given EPA's decision on EUP possibility which provides an immediate path for firm

Plus items 3, 4, and 5 same as yours below.

If Mike could please let Ashley know once he has determined a time for the call with Keith, that would be great so Ashley can plan for calling Deepti soon after.

Thanks!
Ritu

From: McNally, Robert [mailto:Mcnally.Robert@epa.gov]
Sent: Thursday, February 16, 2017 2:57 PM
To: Nalubola, Ritu
Cc: Mendelsohn, Mike; Hartman, Mark; Leahy, John
Subject: Oxitec -- next steps
Importance: High

Ritu,

We are fine with delivering this short message below for the call on Friday.

Convey to Keith Matthews:

1) EUP/Sec 5 and relevant conditions, incl. that it is a path the firm can immediately proceed with and that EPA can issue the EUP before 236 is final;

(2) Intrexon can immediately submit a Section 18 and EPA can begin review, but that 236 would have to be final before EPA grants the Section 18; and

(3) EPA and FDA are ready to have a joint meeting with firm as soon as the firm is available (as early as next week) to discuss additional details.

(4) We have collaborated with FDA extensively, but we defer to FDA, who will contact Intrexon later this morning to discuss FDA issues separately.

(5) Suggest that we should discuss EPA-FDA intersects at the joint meeting.

How does this sound?

Mike M will call Keith early in AM, since I am on leave. He may have Elizabeth M join him.

Thanks

Bob