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**From:** Matthews, Keith [KMatthews@wileyrein.com]  
**Sent:** 6/6/2017 1:24:50 PM  
**To:** Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]  
**CC:** Brown, Byron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9242d85c7df343d287659f840d730e65-Brown, Byro]  
**Subject:** RE: Sec 3 Registration for Mosquitos

Good morning Nancy,

That would be great. I'm available any time 8:00 to 5:00 on Friday.

Thank you,

Keith

Keith A. Matthews | Attorney at Law  
Wiley Rein LLP  
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**From:** Beck, Nancy [mailto:Beck.Nancy@epa.gov]  
**Sent:** Tuesday, June 6, 2017 8:19 AM  
**To:** Matthews, Keith <KMatthews@wileyrein.com>  
**Cc:** Brown, Byron <brown.byron@epa.gov>  
**Subject:** RE: Sec 3 Registration for Mosquitos

Keith, I will ask our scheduler, Gloria, to find an hour for Friday.  
Stay tuned.

Nancy

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Nancy B. Beck, Ph.D., DABT  
Deputy Assistant Administrator, OCSP  
P: 202-564-1273

**Ex. 6**

[beck.nancy@epa.gov](mailto:beck.nancy@epa.gov)

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**From:** Matthews, Keith [mailto:KMatthews@wileyrein.com]  
**Sent:** Monday, June 5, 2017 6:09 PM  
**To:** Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>  
**Cc:** Brown, Byron <[brown.byron@epa.gov](mailto:brown.byron@epa.gov)>  
**Subject:** RE: Sec 3 Registration for Mosquitos

Nancy,

Thanks for getting back to me. Sorry about my number, I actually do have my office phone forwarded to my cell phone, which I had turned off to re-boot, apparently right before you called. Your call did come through, however, after I restarted it.

I can meet anytime this week that is convenient for you and your team, and would be grateful for the opportunity to meet with you.

Please let me know day and time will work best.

Best,

Keith

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**From:** Beck, Nancy [<mailto:Beck.Nancy@epa.gov>]  
**Sent:** Monday, June 5, 2017 5:52 PM  
**To:** Matthews, Keith <[KMatthews@wileyrein.com](mailto:KMatthews@wileyrein.com)>  
**Cc:** Brown, Byron <[brown.byron@epa.gov](mailto:brown.byron@epa.gov)>  
**Subject:** RE: Sec 3 Registration for Mosquitos

Keith,  
Got your message and tried to return the call. However, your voice mail doesn't seem to be working--it forwards to another number.  
Perhaps would be best to have you come in and meet with me and my team so that we are all hearing the same thing. Shall we set this up? Byron let me know if you would like to join.

Regards,  
Nancy

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Nancy B. Beck, Ph.D., DABT  
Deputy Assistant Administrator, OCSPP  
P: 202-564-1273

**Ex. 6**

[beck.nancy@epa.gov](mailto:beck.nancy@epa.gov)

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**From:** Matthews, Keith [<mailto:KMatthews@wileyrein.com>]  
**Sent:** Friday, May 26, 2017 12:19 PM  
**To:** Brown, Byron <[brown.byron@epa.gov](mailto:brown.byron@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>  
**Cc:** Bostick, Thomas <[TBostick@intrexon.com](mailto:TBostick@intrexon.com)>  
**Subject:** RE: Sec 3 Registration for Mosquitos

Byron,

Not a problem. I appreciate your getting back to me so quickly.

Tuesday, 2:00 to 3:00 will work for Tom and me. Tom will be out of the country, but would like to call in. Should he use your office number?

Best,

Keith

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**From:** Brown, Byron [<mailto:brown.byron@epa.gov>]  
**Sent:** Friday, May 26, 2017 11:50 AM  
**To:** Matthews, Keith <[KMatthews@wileyrein.com](mailto:KMatthews@wileyrein.com)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>  
**Cc:** Bostick, Thomas <[TBostick@intrexon.com](mailto:TBostick@intrexon.com)>  
**Subject:** RE: Sec 3 Registration for Mosquitos

Hi Keith – sorry for the delay. I am currently without support staff and having to do my own scheduling ... looks like Nancy and I have availability for a call or meeting on Tuesday between 12 noon and 3 pm. Let me know some time during that window will work. - Byron

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**From:** Matthews, Keith [<mailto:KMatthews@wileyrein.com>]  
**Sent:** Wednesday, May 24, 2017 9:58 AM  
**To:** Brown, Byron <[brown.byron@epa.gov](mailto:brown.byron@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>  
**Cc:** Bostick, Thomas <[TBostick@intrexon.com](mailto:TBostick@intrexon.com)>  
**Subject:** RE: Sec 3 Registration for Mosquitos

Byron,

Many thanks for your message. We appreciate the opportunity to meet with you and Nancy to follow up on last week's meetings.

Best,

Keith

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**From:** Brown, Byron [<mailto:brown.byron@epa.gov>]  
**Sent:** Wednesday, May 24, 2017 9:44 AM  
**To:** Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Matthews, Keith <[KMatthews@wileyrein.com](mailto:KMatthews@wileyrein.com)>  
**Subject:** RE: Sec 3 Registration for Mosquitos

Keith – I received your voicemail and we'll try to find a time in the next couple of days to discuss in person. – Byron

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**From:** Beck, Nancy  
**Sent:** Monday, May 22, 2017 7:59 PM

**To:** Matthews, Keith <[KMatthews@wileyrein.com](mailto:KMatthews@wileyrein.com)>

**Cc:** Brown, Byron <[brown.byron@epa.gov](mailto:brown.byron@epa.gov)>

**Subject:** RE: Sec 3 Registration for Mosquitos

Keith,

A few response to your comments:

Regarding the FDA transfer, we working to find out if there is anything that might keep FDA from transferring authority sooner, rather than waiting until after the mosquito season.

Regarding the registration process, based on what I thought you said last week, and the slides you provided, my understanding is that a Section 3 review generally takes 13 months. However, I recall you mentioning that with a conditional approval it could be done in about 7 months. I have not had a chance to speak with OPP about the timeline.

Neither the timelines for review, nor the data needs for the Section 3 conditional approval were discussed in any depth on Thursday. I hope this is helpful.

Regards,

Nancy

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Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

**Ex. 6**

[beck.nancy@epa.gov](mailto:beck.nancy@epa.gov)

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**From:** Matthews, Keith [<mailto:KMatthews@wileyrein.com>]

**Sent:** Friday, May 19, 2017 7:10 PM

**To:** Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>

**Cc:** Brown, Byron <[brown.byron@epa.gov](mailto:brown.byron@epa.gov)>

**Subject:** RE: Sec 3 Registration for Mosquitos

Nancy,

Many thanks for your time this week, and for the time that you put into coming up to speed on this very complex matter.

We are very pleased to hear that OPP has confirmed that we can submit a Section 3 application before the transfer of jurisdiction, and we have started ramping up the resources to complete our Section 3 application as soon as possible.

As we discussed the other day, this process has become quite complicated, with a number of different aspects of it with different agencies, and a number of possible regulatory outcomes. Before we focus all of our efforts on the Section 3 application, I'd like to confirm a couple of key points that are crucial to ensure that we are able to release OX513A males in the summer of 2017. First, that FDA will finalize the guidance to transfer jurisdiction to EPA as soon as possible. As I believe I mentioned on Thursday, OGC has taken the position that EPA cannot issue a Section 3 registration until jurisdiction has formally transferred from FDA (which, as a legal matter, I believe is correct). Therefore, that transfer should take place as soon as possible. FDA has essentially been waiting on Dr. Gottlieb to be confirmed before moving on this action. It is my understanding that once the FDA staff has his concurrence the transfer can be effected almost immediately. Second, that OPP is prepared not only to accept a Section 3 application, but will diligently proceed to evaluate it expeditiously and be in a position to render a decision in time to enable 2017 releases. As we discussed, there is a substantial body of data available

that demonstrates the safety and efficacy of OX513A, and I fully believe that these data are sufficient for purposes of a registration. We have previously been told by BPPD that new toxicity data must be submitted to qualify for a registration. As I noted, I have been reviewing, defending, and issuing pesticide registrations since the 1990s, I do not believe that the new data are necessary for the registration – given the substantial existing database on the safety and efficacy of OX513A. We are developing these data, and we would be pleased to submit them post approval, i.e., we would be pleased to accept a conditional registration with the understanding that the data will be submitted within any reasonable time frame that EPA sets. The new data are not necessary, however, to meet the FIFRA standard and register OX513A now.

It is my understanding that this is where Thursday's meeting came out. Before we reach out to Rick and BPPD, however, to discuss the details of developing and submitting the Section 3, I wanted to confirm this understanding.

Please feel free to contact me at the number below, or on my cell phone at 240 483 7786 at any time that is convenient for you.

Again, many thanks for your attention to this matter.

Best,

Keith

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[www.wileyrein.com](http://www.wileyrein.com) | [LinkedIn](#) | [Twitter](#)

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**From:** Beck, Nancy [<mailto:Beck.Nancy@epa.gov>]  
**Sent:** Thursday, May 18, 2017 3:58 PM  
**To:** [tboostick@intrexon.com](mailto:tboostick@intrexon.com); [rbailey@gdcillc.com](mailto:rbailey@gdcillc.com); Matthews, Keith <[KMatthews@wileyrein.com](mailto:KMatthews@wileyrein.com)>  
**Cc:** Brown, Byron <[brown.byron@epa.gov](mailto:brown.byron@epa.gov)>; Keigwin, Richard <[Keigwin.Richard@epa.gov](mailto:Keigwin.Richard@epa.gov)>; Dravis, Samantha <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)>  
**Subject:** Sec 3 Registration for Mosquitos

Tom, Roy, and Keith,

It was a pleasure to meet you all today (and yesterday). The work you are doing is fascinating to me, not to mention the large potential public health significance.

I've checked with Rick Keigwin, the Acting Director of our Pesticides office, and he has confirmed that you can indeed submit the registration request, and begin the process, before the authority is transferred from FDA to EPA. Rick is cc'd above if you have any specific questions about how to make this happen. I'm sure his staff can provide assistance.

Regards,

Nancy

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**Ex. 6**

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