Message

From: Matthews, Keith [KMatthews@wileyrein.com]
Sent: 6/7/2017 7:40:53 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
CC: Milhouse, Gloria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a424462e03c4a82ba83121d59d8b34d-Gmilhous]
Subject: RE: Meeting w/ Keith A. Matthews (Wiley Rein LLP

Nancy,

Thank you for scheduling the meeting. Tom Bostick will be out of town at the time of the meeting, but would like to call in. Would it be possible to have a call-in number for the meeting?

Also, Jack Bobo, Intrexon's Chief Communications Officer will be attending in person.

Thanks,

Keith

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-----Original Appointment-----
From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Tuesday, June 6, 2017 1:19 PM
To: Beck, Nancy; Keigwin, Richard; McNally, Robert; Jakob, Avivah; Matthews, Keith
Cc: Brown, Byron
Subject: Meeting w/ Keith A. Matthews (Wiley Rein LLP
When: Friday, June 9, 2017 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomEast3156/DC-EPA-EAST-OCSPP

From: Matthews, Keith [mailto:KMatthews@wileyrein.com]
Sent: Friday, May 19, 2017 7:10 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Cc: Brown, Byron <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 Ex. 6 at any time that is convenient for you.

Again, many thanks for your attention to this matter.

Best,

Keith

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From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Thursday, May 18, 2017 3:58 PM
To: tbostick@intrexon.com; rbailey@gdcillc.com; Matthews, Keith <KMatthews@wileyrein.com>
Cc: Brown, Byron <brown.byron@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Dravis, Samantha <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
****
Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator

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