

Message

From: Matthews, Keith [KMatthews@wileyrein.com]
Sent: 8/11/2017 3:55:36 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
CC: Bostick, Thomas [TBostick@intrexon.com]
Subject: RE: mosquitos

Good morning Nancy,

Thanks for getting back to me. I hope that you've had a good trip to California for the crop tours.

First, I'd like to emphasize that we really do appreciate the time that OPP has put into to reviewing our draft application package. We know that they have plenty of PRIA work keeping them busy, so for staff to take time to look at our package is greatly appreciated.

Just to clarify, the package that we submitted presents currently available data and evidence that demonstrate that release of OX513A will not have adverse effects to humans or the environment, including any endangered species. In that sense, it is a complete package because all endpoints and exposure scenarios required for a Section 3 registration are addressed.

BPPD has indicated previously that confirmatory data on proteodynamics of the active ingredient (tTAV) and inert (DsRed2) would be helpful to conclude conclusively that no adverse effects will occur. Those data are being generated and should be available this Fall. Therefore, our package, and the subsequent formal application, will meet the requirements for a Section 3(c)(7)(C) conditional registration, which would be conditioned on submission of the confirmatory protein data.

If you'd like to discuss further, I'm available at any time at the number below.

Best,

Keith

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From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Friday, August 11, 2017 10:55 AM
To: Matthews, Keith <KMatthews@wileyrein.com>
Subject: mosquitos

Keith,

I've been in California all week doing crop tours and finally had a moment to check voice messages today. I know OPP has been thoroughly reviewing the package and does have some thoughts/suggestions. I will get an update when I'm back in the office on Monday and perhaps we can chat after that. Also, can you clarify for me if the package is a complete section 3 or if you are looking for a conditional section 3 approval because there is still some data that are in the works? Perhaps this is semantics and I'm not understanding the terminologies completely yet, but I thought that

there was some further data that would be coming later, thus when you say complete section 3, do you mean a conditional section 3 (pending development of data that is forthcoming)?

Thanks,
Nancy

Nancy B. Beck, Ph.D., DABT
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