Appointment

From: Wozniak, Chris [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8287E326F7A148FB9870D5D79333DEBC-CHRIS WOZNIAK]
Sent: 2/23/2017 7:21:11 PM
To: Fuentes, Clara [Fuentes.Clara@epa.gov]; Martinez, Jeannette [Martinez.Jeannette@epa.gov]

Subject: Oxitec data requirements
Location: DCRoomPYS8771/Potomac-Yard-One

Start: 2/28/2017 7:00:00 PM
End: 2/28/2017 8:00:00 PM
Show Time As: Tentative

Required Attendees: Pease, Anita; Tapken, Wiebke; Milewski, Elizabeth; John Kough; Nesci, Kimberly; Leahy, John; Borges, Shannon; Wyatt, TJ; Mendelsohn, Mike; Fuentes, Clara; Martinez, Jeannette
Optional Attendees: Odenkirchen, Edward

Hold for discussion of data needs re: OX513A

We hope to meet March 6 or 7 with Oxitec to discuss data requirements and a path forward (EUP or Section 18), so hopefully we can pull together a list of what information we feel we need from Oxitec above and beyond what they have provided in the EA as reviewed by FDA, CDC and BPPD. We will need to also think ahead as to what information beyond efficacy data will be important for them to collect in any US field trials. My hope is that we will have list to pass through management by Friday, March 3.

One outstanding question is, will we allow for consideration of efficacy or other data obtained during field trails in the Cayman Islands to this EUP or Section 18 approval?

Thanks

Chris

https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm446529.htm links to FDA's EA and FONSI for OX513A