Appointment

From: Wozniak, Chris [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8287E326F7A148FB9870D5D79333DEBC-CHRIS WOZNIAK]
Sent: 2/1/2017 10:24:42 PM
To: Wozniak, Chris [wozniak.chris@epa.gov]; Kough, John [Kough.John@epa.gov]; Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; McNally, Robert [Mcnally.Robert@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Wakefield, Benjamin J. [wakefield.benjamin@epa.gov]; Kaczmarek, Chris [Kaczmarek.Chris@epa.gov]; Suarez, Mark [Suarez.Mark@epa.gov]; Wyatt, TJ [Wyatt.Tj@epa.gov]; laura.epstein@fda.hhs.gov; Brinda.Dass@fda.hhs.gov; Reynolds, Alan [Reynolds.Alan@epa.gov]; Tapken, Wiebke [Tapken.Wiebke@epa.gov]; Maignan, Tawanda [Maignan.Tawanda@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Saunders, Jennifer [Saunders.Jennifer@epa.gov]; Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]; Ciarlo, Timothy [Ciarlo.Timothy@epa.gov]
CC: Kausch, Jeannine [Kausch.Jeannine@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]
BCC: DCRoomPYS8100/Potomac-Yard-One [DCRoomPYS8100@epa.gov]

Subject: OPP / Oxitec / FDA meeting
Location: DCRoomPYS8100/Potomac-Yard-One

Start: 2/9/2017 8:00:00 PM
End: 2/9/2017 9:30:00 PM
Show Time As: Busy

Adding in Alan, Wiebke, and Tawanda:

Jack Bobo (Intrexon) and Camilla Beech (consultant for Oxitec) will be coming in to discuss the possibilities for regulatory oversight of their Aedes aegypti OX513A sterile male mosquitoes. As you know, a major portion of the discussion will center around the transition from FDA-CVM for oversight by OPP, as well as exploring requirements / timing for an EUP or Section 18 action.

Likely the Intrexon contingent will grow and I will forward names and an agenda as they become available. FDA-CVM personnel to attend include Laura Epstein and Brinda Dass.

I am adding in Mark Suarez from RD for his perspective on mosquito control and TJ Wyatt and Tawanda Maignan for any questions which may arise from talk of a Section 18 action. Intrexon has indicated that this is one area they would like to explore.

FDA's site has information and links to Draft Guidance document #236 on oversight of GE mosquitoes as well as links to the EA and FONSI produced for the OX513A product.
http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm446529.htm

Chris

Ex. 6 - Personal Privacy