Message

From: Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]
Sent: 1/4/2017 10:07:41 PM
To: Nalubola, Ritu [Ritu.Nalubola@fda.hhs.gov]
CC: McNally, Robert [Mcnally.Robert@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
Subject: RE: Help with EOP question re: Oxitec
Attachments: for FDA how EPA would regulate insects 01 04 2016 .docx

Hi, Ritu. I am sending a file with our suggested response. It is a bit long, so let me know if you need something else – like something less detailed.

From: Nalubola, Ritu [mailto:Ritu.Nalubola@fda.hhs.gov]
Sent: Wednesday, January 04, 2017 9:52 AM
To: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Subject: Re: Help with EOP question re: Oxitec

We have other comments, too, that we are working on. But, essentially, yes, we won't get clearance until we finish the review process. Our plan is to send responses back today. Is that doable?
Thanks very much, Elizabeth!

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Milewski, Elizabeth
Sent: Wednesday, January 4, 2017 9:43 AM
To: Nalubola, Ritu
Subject: RE: Help with EOP question re: Oxitec

Hi, Ritu. I will work on an answer today, and try to get internal clearance ASAP. What is your deadline? Are they holding up issuance of your guidance documents until this is answered?

From: Nalubola, Ritu [mailto:Ritu.Nalubola@fda.hhs.gov]
Sent: Wednesday, January 04, 2017 9:02 AM
To: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Cc: Epstein, Laura <Laura.Epstein@fda.hhs.gov>; Zborowsky, Ashley <Ashley.Zborowsky@fda.hhs.gov>; Flamm, Eric <Eric.Flamm@fda.hhs.gov>
Subject: Help with EOP question re: Oxitec
Importance: High

Hi Mike, Elizabeth – Our guidance documents are going through inter-agency review, and below is a question we received from EOP on the mosquito draft guidance. Could you please help with a response to this question? I added a brief clarifying note but will defer to you on the substantive response re: EPA review. Please let me know if we should discuss.
Thanks!
Ritu

Given that the draft mosquito guidance will now mean that applications such as Oxitec GE mosquitos will now be under EPA regulatory regime instead of FDA's new animal drug, what is EPA's regulatory regime? Can FDA or EPA provide a short description of what regulation of GE mosquitos for pesticide purposes look like?

FDA response: We are issuing the mosquito guidance in draft form and will finalize it after public comment. The Oxitec GE mosquito that is currently with FDA will be transitioned over to EPA when we finalize the guidance. Please see EPA's response regarding their regulatory process.

EPA response:

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