

To: Beck, Nancy[Beck.Nancy@epa.gov]
Cc: Jackson, Ryan[jackson.ryan@epa.gov]
From: hutchinsont@gtlaw.com
Sent: Thur 9/7/2017 3:08:11 PM
Subject: RE: EPA regulation of mosquito-related products

Thanks Ryan and thanks Nancy.

Please let us know if we can provide any further information and thanks so much for keeping Tom and his team updated.

Tim

The Honorable Tim Hutchinson
Senior Director (US House 93-97; US Sen. 97-03)
Greenberg Traurig, LLP | 2101 L Street N.W. | Washington, D.C. 20037
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From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Tuesday, September 05, 2017 6:38 PM
To: Hutchinson, Tim (SenDir-DC-GovLP)
Cc: Jackson, Ryan
Subject: RE: EPA regulation of mosquito-related products

Tim,

Ryan forwarded your message to me and asked me to respond.

The guidance is currently still at OMB undergoing their typical interagency review process. As

you likely know, this involves multiple back and forths among the agencies with OMB to work towards resolving all concerns. Once the deliberative dialogue is concluded, FDA will finalize the guidance and then EPA will assume authority. Unfortunately, I can't predict exactly when this will happen, but I do know the agencies are all working together to get to resolution.

As Tom Bostick checks in regularly, once we have some news, I will surely pass it along to him as well as other working with Intrexon. I would be happy to keep you updated as well.

Please let me know if you have any other questions.

Regards,

Nancy

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Begin forwarded message:

From: <hutchinsont@gtlaw.com>

Date: September 5, 2017 at 3:44:54 PM EDT

To: <jackson.ryan@epa.gov>

Cc: <mangasr@gtlaw.com>

Subject: EPA regulation of mosquito-related products

Ryan, I may have missed your response to my inquiry (I have been in and out of the office on vacation). Thanks for any status report you can provide.-- Tim

Ryan—

I hope you are well and have a little time to catch up this month. I know it has been a hectic few months.

I was hoping that you could provide a little information about a jurisdictional issue involving EPA and FDA. I represent Intrexon, which has a subsidiary (Oxitec) that produces a genetically modified mosquito that may become a valuable resource for preventing the spread of the Zika virus and other diseases transmitted by the same type of mosquito (*aedes aegypti*). Back in January, EPA and FDA issued draft guidance for industry on the regulation of mosquito-related products and took public comments. It is my understanding that this guidance is very close to being finalized, and may have already cleared OMB review. I was wondering if you could share any information about when this guidance is expected to be finalized and take effect.

As always, thanks for your assistance.

Tim

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