

Subject: RE: US REgulatory Process - Next Steps

From: "O'Hare, Jeanette R - APHIS" <Jeanette.R.OHare@aphis.usda.gov>

Date: 4/14/2017 10:43 AM

To: Royden Saah <royden.saah@islandconservation.org>, David Threadgill <dwthreadgill@tamu.edu>, "Ruell, Emily W - APHIS" <Emily.W.Ruell@aphis.usda.gov>, "Eisemann, John D - APHIS" <John.D.Eisemann@aphis.usda.gov>, Tennille K Lamon <tennillek@tamu.edu>, "Bridges, David R" <david.bridges@tamu.edu>

CC: "jrgodwinnc@gmail.com" <godwin@ncsu.edu>, Karl Campbell <karl.campbell@islandconservation.org>, "Fred Gould (fred_gould@ncsu.edu)" <fred_gould@ncsu.edu>, Gregg Howald <gregg.howald@islandconservation.org>, "Piaggio, Antoinette J - APHIS" <Toni.J.Piaggio@aphis.usda.gov>

Hi Royden,

I'm available on all the dates and times you proposed below for both calls.

Jeanette R. O'Hare
Registration Manager
USDA APHIS WS National Wildlife Research Center
4101 LaPorte Avenue
Fort Collins, CO 80521-2154
970-266-6156 FAX: 970-266-6157

From: Royden Saah [mailto:royden.saah@islandconservation.org]

Sent: Friday, April 14, 2017 7:43 AM

To: O'Hare, Jeanette R - APHIS <Jeanette.R.OHare@aphis.usda.gov>; David Threadgill <dwthreadgill@tamu.edu>; Ruell, Emily W - APHIS <Emily.W.Ruell@aphis.usda.gov>; Eisemann, John D - APHIS <John.D.Eisemann@aphis.usda.gov>; Tennille K Lamon <tennillek@tamu.edu>; Bridges, David R <david.bridges@tamu.edu>

Cc: jrgodwinnc@gmail.com <godwin@ncsu.edu>; Karl Campbell <karl.campbell@islandconservation.org>; Fred Gould (fred_gould@ncsu.edu) <fred_gould@ncsu.edu>; Gregg Howald <gregg.howald@islandconservation.org>; Piaggio, Antoinette J - APHIS <Toni.J.Piaggio@aphis.usda.gov>

Subject: US REgulatory Process - Next Steps

Importance: High

Good Morning All, This is important and pertaining to a joint meeting with FDA, EPA and USDA-APHIS regulators.

Gregg and I had another meeting with FDA yesterday. This one was more impromptu and a follow-up to the April 3rd meeting. We again spoke to Sarah Bembe – the FDA point of contact for GBIRD. Sarah wanted to ask us to hold off the submission of an INAD contrary to our first meeting. Sarah requested a larger meeting with GBIRD partners.

If you are in the 'To:' line, PLEASE LET ME KNOW OUR AVAILABILITY for the below dates/times that Sarah gave as available for her FDA/EPA/USDA colleagues are:

April 28, 2017 from 2-3pm EDT

May 3, 2017 from 2-3pm EDT

We (Gregg and I) are setting up a pre-meeting this coming Tuesday for planning purposes. Gregg is in HI, so times are

tight. PLEASE LET ME KNOW YOUR AVAILABILITY FOR THE FOLLOWING PRE-MEETING TIMES:

April 18, Tuesday
11:30 EDT
12:00 EDT
12:30 EDT

Again, this is important. Thanks for your attention to this matter.
-Royden

J. Royden Saah
Coordinator
Genetic Biocontrol of Invasive Rodents Program

From: Royden Saah
Sent: Thursday, March 09, 2017 7:34 PM
To: 'O'Hare, Jeanette R - APHIS' <Jeanette.R.OHare@aphis.usda.gov>; David Threadgill <dwthreadgill@tamu.edu>;
Ruell, Emily W - APHIS <Emily.W.Ruell@aphis.usda.gov>; Eisemann, John D - APHIS
<John.D.Eisemann@aphis.usda.gov>; Gregg Howald <Gregg.Howald@islandconservation.org>
Cc: jrgodwinnc@gmail.com <godwin@ncsu.edu>; Tennille K Lamon <tennillek@tamu.edu>; Bridges, David R
<david.bridges@tamu.edu>; Karl Campbell (<Karl.Campbell@islandconservation.org>
<Karl.Campbell@islandconservation.org>; Fred Gould (<fred_gould@ncsu.edu> <fred_gould@ncsu.edu>; Piaggio,
Antoinette J - APHIS <Toni.J.Piaggio@aphis.usda.gov>
Subject: US REgulatory Process

Hi All,

Heather called me today for some basic information. There will be no meeting tomorrow. Heather informed me that Sara Bembe will be our project. She said it does look like we will need to do an Investigational New Animal Drug soon. Sara will email a set of questions for us to fill out. After that, we will have a more formal meeting about the process.

There will be a formal meeting. The earliest a meeting will be done is 30 days after information is received. I informed her about the DARPA process and asked if she was the FDA lead for DARPA Safe Genes – answer was no, but she new that DARPA Safe Genes was ongoing.

So... This is the group that will be involved with answering the questionnaire from FDA and be involved with the upcoming meeting to answer our original questions.

Of note: I emphasized that we are a non-profit. Heather said there may be processes, depending on how things unfold, that do not have fees – e.g. Minor Animal Amendment.

Will keep this group posted.

From: O'Hare, Jeanette R - APHIS [<mailto:Jeanette.R.OHare@aphis.usda.gov>]
Sent: Thursday, March 09, 2017 5:32 PM
To: David Threadgill <dwthreadgill@tamu.edu>; Ruell, Emily W - APHIS <Emily.W.Ruell@aphis.usda.gov>; Eisemann, John D - APHIS <John.D.Eisemann@aphis.usda.gov>
Cc: Royden Saah <royden.saah@islandconservation.org>; Gregg Howald <gregg.howald@islandconservation.org>;

jrgodwinn@gmail.com <godwin@ncsu.edu>; Tennille K Lamon <tennillek@tamu.edu>; Bridges, David R <david.bridges@tamu.edu>

Subject: RE: Genetic Biocontrol of Invasive Rodents (GBIRd) Program

David,

Having the TAMU regulatory staff available is excellent. Thank you!

Jeanette R. O'Hare
Registration Manager
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Fort Collins, CO 80521-2154
970-266-6156 FAX: 970-266-6157

From: David Threadgill [<mailto:dwthreadgill@tamu.edu>]

Sent: Thursday, March 09, 2017 3:25 PM

To: Ruell, Emily W - APHIS <Emily.W.Ruell@aphis.usda.gov>; Eisemann, John D - APHIS <John.D.Eisemann@aphis.usda.gov>

Cc: Royden Saah <royden.saah@islandconservation.org>; O'Hare, Jeanette R - APHIS <Jeanette.R.OHare@aphis.usda.gov>; Gregg Howald <gregg.howald@islandconservation.org>; John Godwin <godwin@ncsu.edu>; Tennille K Lamon <tennillek@tamu.edu>; Bridges, David R <david.bridges@tamu.edu>

Subject: Re: Genetic Biocontrol of Invasive Rodents (GBIRd) Program

Hi Emily, John et al, I'm bring in Tennille Lamon and David Bridges at TAMU who are our regulatory leads with FDA to connect with APHIS and this effort.

david

On Mar 9, 2017, at 10:05 AM, Ruell, Emily W - APHIS <Emily.W.Ruell@aphis.usda.gov> wrote:

Hi Royden,

My availability on Friday is the same as John's.

Thanks,

Emily

From: Eisemann, John D - APHIS

Sent: Thursday, March 09, 2017 9:04 AM

To: Royden Saah <royden.saah@islandconservation.org>; David Threadgill <dwthreadgill@tamu.edu>; O'Hare, Jeanette R - APHIS <Jeanette.R.OHare@aphis.usda.gov>; Ruell, Emily W - APHIS <Emily.W.Ruell@aphis.usda.gov>

Cc: Gregg Howald <gregg.howald@islandconservation.org>; jrgodwinn@gmail.com <godwin@ncsu.edu>

Subject: RE: Genetic Biocontrol of Invasive Rodents (GBIRd) Program

I am available anytime EXCEPT 11:30 am to 12:30 pm MST

John D. Eisemann

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From: Royden Saah [<mailto:royden.saah@islandconservation.org>]
Sent: Thursday, March 09, 2017 9:02 AM
To: David Threadgill <dwthreadgill@tamu.edu>; Eisemann, John D - APHIS <John.D.Eisemann@aphis.usda.gov>; O'Hare, Jeanette R - APHIS <Jeanette.R.OHare@aphis.usda.gov>; Ruell, Emily W - APHIS <Emily.W.Ruell@aphis.usda.gov>
Cc: Gregg Howald <gregg.howald@islandconservation.org>; jrgodwinnc@gmail.com <godwin@ncsu.edu>
Subject: FW: Genetic Biocontrol of Invasive Rodents (GBIRd) Program

Hi All, I am going to reach out to Heather for Friday Afternoon. How does this look to your calendars? David especially, does this work for you? Is one time better than others?

From: Lombardi, Heather [<mailto:Heather.Lombardi@fda.hhs.gov>]
Sent: Wednesday, March 08, 2017 9:47 AM
To: Royden Saah <royden.saah@islandconservation.org>
Cc: Epstein, Laura <Laura.Epstein@fda.hhs.gov>; Bembe, Sarah <Sarah.Bembe@fda.hhs.gov>
Subject: RE: Genetic Biocontrol of Invasive Rodents (GBIRd) Program

Hi Royden,

Your email was forwarded to me by Laura Epstein. I'd like to learn more about your project so I can better answer your questions. Would you have time for a quick call sometime this week?

Best,

Heather

Heather A. Lombardi, Ph.D.
Acting Leader
Emerging Technologies Team (HFV-106)
Office of New Animal Drug Evaluation
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7500 Standish Place
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Tel: 240-402-0685
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From: Royden Saah [<mailto:royden.saah@islandconservation.org>]
Sent: Monday, March 06, 2017 12:52 PM
To: Epstein, Laura
Cc: jrgodwinnc@gmail.com; Gregg Howald
Subject: Genetic Biocontrol of Invasive Rodents (GBIRd) Program

Hi Laura,

You may not remember me, but I coordinate the non-profit group that is attempting to develop and assess genetic tools (gene drives) for sex reversal in mice. We met by phone when Gregg Howald and I visited FDA in Rockville last year and in person, as I recall, at the NCSU meeting in October.

Our group is currently negotiating with DARPA for an award that will require aggressive development of constructed gene drives in mice. NCSU (John Godwin-copied) is leading the DARPA effort. I would like to have a meeting with you and the leads of the development & assessment teams to explore the following:

- 1) In the process of developing a single sex, gene driven mouse, when would the regulatory process start?
- 2) What are the responsibilities of the sponsor?

If you could point me to the person who coordinates the FDA calendars, I could work with her/him to find a time that works for key people in FDA and the GBIRd partnership. I can provide video link, or phone link if necessary.

Many Thanks
Royden

J. Royden Saah
Coordinator
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