Appointment

From: Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]
Sent: 9/1/2021 1:42:34 PM
To: Herrick, Jacquelyn [Herrick.Jacquelyn@epa.gov]; Shuler, Jamey [Shuler.Jamey@epa.gov]; Britton, Cathryn [Britton.Cathryn@epa.gov]; Biscoe, Melanie [Biscoe.Melanie@epa.gov]; Fletcher, Rachel [fletcher.rachel@epa.gov]; Miller, David [Miller.DavidJ@epa.gov]; Niman, Aaron [niman.aaron@epa.gov]; Recore, Shanna [Recore.Shanna@epa.gov]; Rossmeisl, Colleen [Rossmeisl.Colleen@epa.gov]; Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]; Backus, Byron [Backus.Byron@epa.gov]; Andrews, Elizabeth [Andrews.Elizabeth@epa.gov]; Saunders, Jennifer [Saunders.Jennifer@epa.gov]; Leifer, Kerry [Leifer.Kerry@epa.gov]; Hospital, Jocelyn [Hospital.Jocelyn@epa.gov]; Walls, Cassi [Walls.Cassi@epa.gov]; Spatz, Dana [Spatz.Dana@epa.gov]; VanAlstine, Julie [VanAlstine.Julie@epa.gov]; Hart, Ellen [Ellen.Hart@fda.hhs.gov]; Hugunin, Kelly [Kelly.Hugunin@fda.hhs.gov]; Clarke, Angela [Angela.Clarke@fda.hhs.gov]; Echeverria, Marietta [Echeverria.Marietta@epa.gov]; Matuszko, Jan [Matuszko.Jan@epa.gov]; Vogel, Dana [Vogel.Dana@epa.gov]; Aubee, Catherine [Aubee.Catherine@epa.gov]; Reaves, Elissa [Reaves.Elissa@epa.gov]; Di Salvo, Paul [DiSalvo.Paul@epa.gov]; Colby, Deanna [colby.deanna@epa.gov]
CC: Suarez, Mark [Suarez.Mark@epa.gov]; Waterworth, Rebeccah [Waterworth.Rebeccah@epa.gov]; Hawkins, Caleb [Hawkins.Caleb@epa.gov]; Kaul, Monisha [Kaul.Monisha@epa.gov]; Johnson, Marion [Johnson.Marion@epa.gov]; Mallampalli, Nikhil [Mallampalli.Nikhil@epa.gov]; Dutch, Veronica [Dutch.Veronica@epa.gov]; Jennings, Susan [Jennings.Susan@epa.gov]

Subject: Welcoming FDA - Seresto Review
Attachments: Elanco- Seresto 6a2 letter_signed.pdf
Location: Microsoft Teams Meeting

Start: 9/16/2021 5:00:00 PM
End: 9/16/2021 6:00:00 PM
Show Time As: Busy

Required Attendees: Herrick, Jacquelyn; Shuler, Jamey; Britton, Cathryn; Biscoe, Melanie; Fletcher, Rachel; Miller, David; Niman, Aaron; Recore, Shanna; Rossmeisl, Colleen; Breeden-Alemi, Julie; Backus, Byron; Andrews, Elizabeth; Saunders, Jennifer; Leifer, Kerry; Hospital, Jocelyn; Walls, Cassi; Spatz, Dana; VanAlstine, Julie; Hart, Ellen; Hugunin, Kelly; Clarke, Angela; Echeverria, Marietta; Matuszko, Jan; Vogel, Dana; Aubee, Catherine; Reaves, Elissa; Colby, Deanna; Di Salvo, Paul
Optional Attendees: Suarez, Mark; Waterworth, Rebeccah; Hawkins, Caleb; Kaul, Monisha; Johnson, Marion; Mallampalli, Nikhil; Dutch, Veronica; Jennings, Susan

9/9 Update: Add the agenda and attach the enhanced 6a2 letter EPA sent to Elanco.

AGENDA:

Meeting Goal: Introduce FDA to EPA review of Seresto, discuss FDA's role and begin to organize the collaborative review.

1) Welcome and introductions, including individual areas of expertise *(Jamey, Jackie, Colleen)*
2) Background on Seresto *(Jackie)*
    a. Brief history
    b. Incidents & 2021 news articles
    c. CBD Petition *(Rachel)*
3) Purpose of the review/Scope *(Jackie)*
    a. Goal of the review
    b. Data that were requested (6a2 letter)
    c. Overview of data that were submitted by Elanco *(Colleen/Aaron)*
4) Recent analyses and current status of EPA review *(Colleen/Aaron/James)*
5) General overall approach moving forward *(Colleen)*
    a. FDA's anticipated role – discussion *(all - FDA/EPA)*

6) Next steps *(Colleen, Jackie)*
    a. Recurring meetings with technical team
    b. Recurring full team meetings

Hi all,

This will be our first meeting with our FDA colleagues. I hope we can welcome (& thank) them, give an overview of the review, and start discussion on what specific areas of the review we most need their help.

BEAD, we'll keep you looped in, but feel free to skip for now!

Let me know if you have any questions ahead of this meeting.

Jackie

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