**From:** Yang, Sixun
**To:** Fink, Doran; Hulse, Andrea
**Subject:** RE: (b) (4) (b) (4) Q Fever (b) (4)
**Date:** Thursday, January 5, 2017 3:39:41 PM

---

Yea, I saw that. Let's see...

**From:** Fink, Doran
**Sent:** Thursday, January 05, 2017 3:36 PM
**To:** Yang, Sixun; Hulse, Andrea
**Subject:** RE: (b) (4) (b) (4) Q Fever (b) (4)

Sounds like (b) (4)

---

Doran L. Fink, MD, PhD
Team Leader, CRB-2
FDA/CBER/OVRR/DVRPA
White Oak Bldg 71, Rm 3311
(301) 796-2640

**From:** Yang, Sixun
**Sent:** Thursday, January 05, 2017 3:33 PM
**To:** Hulse, Andrea
**Cc:** Fink, Doran
**Subject:** RE: (b) (4) (b) (4) Q Fever (b) (4)

Sounds like a plan. thanks

**From:** Hulse, Andrea
**Sent:** Thursday, January 05, 2017 3:28 PM
**To:** Yang, Sixun
**Cc:** Fink, Doran
**Subject:** RE: (b) (4) (b) (4) Q Fever (b) (4)

(b) (4), (b) (5)

Andrea

**From:** Yang, Sixun
**Sent:** Thursday, January 05, 2017 3:10 PM
**To:** Hulse, Andrea
**Cc:** Fink, Doran
**Subject:** RE: (b) (4) (b) (4) Q Fever (b) (4)

Ok. (b) (4)

(b) (4)

(b) (4)

Thanks.
Sixun

**From:** Hulse, Andrea
**Sent:** Thursday, January 05, 2017 3:03 PM
**To:** Yang, Sixun
**Cc:** Fink, Doran
**Subject:** RE: (b) (4)

(b) (4) Q Fever (b) (4)

Hi Sixun,

As discussed last week, (b) (4) Q-fever (b) (4)

Andrea

---

**From:** Henchal, Laraine
**Sent:** Wednesday, December 28, 2016 6:06 PM
**To:** Daugherty, Jon; Steele, Matthew; Sutkowski, Elizabeth M.; Collazo, Carmen; Roberts, Jeff; Hulse, Andrea; Norris, Scott; Slater, Jay; Burns, Drusilla L.; LeBlanc, Ralph; Fiore, Cara; Austin-Hansberry, Lori; Proestel, Scott
**Cc:** Sun, Wellington; McVittie, Loris; Pandey, Rakesh; Nelle, Timothy; Walker, Carol A. (CBER); Senn, Kevin; Henchal, Erik; Ramanathan, Roshan; Lee, Lucia; Ferris, Meghan; Fink, Doran
**Subject:** (b) (4) (b) (4) Q Fever (b) (4)
**Importance:** High

Hi all,

(b) (4), (b) (5)

(b) (4), (b) (5) Q Fever (Coxiella burnetii, (b) (4), (b) (5)

(b) (4), (b) (5)

Thanks, L

(b) (4), (b) (5)

Laraine S. Henchal
Branch Chief, Review Management Support Branch
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
Division of Vaccines & Related Product Applications
10903 New Hampshire Avenue
WO71, G112 (for regulatory submissions)
Silver Spring, MD 20993-0002
Phone: 301-796-2640
Fax: 301-595-1244

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**From:** Chattopadhyay, Rana
**To:** Yang, Sixun; Cowley, Siobhan; Harman, Christine
**Cc:** Fink, Doran; Trout, Deborah; Norris, Scott; Daugherty, Jon
**Subject:** (b) (4) Q-Fever (b) (4)
**Date:** Wednesday, January 11, 2017 11:08:05 AM
**Attachments:** image001.png
image002.jpg
image003.jpg
image004.jpg
image005.jpg
image006.jpg
**Importance:** High

---

Dear (b) (4)

Although (b) (4), (b) (5)
(b) (4), (b) (5)

Thanks.

Rana

**LINK TO** (b) (4), (b) (5)
(b) (4), (b) (5)

**Rana Chattopadhyay, PhD**
*Biologist [Regulatory]*

**Division of Vaccines and Related Product Applications**
**Center for Biologics Evaluation and Research**
**Office of Vaccines Research and Review**
**U.S. Food and Drug Administration**
Tel: 301-796-2640, Fax: 301-595-1244
rana.chattopadhyay@fda.hhs.gov

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| | |
|---|---|
| **From:** | Chattopadhyay, Rana |
| **To:** | Yang, Sixun; Cowley, Siobhan; Harman, Christine; Rohan, Patricia; Cheung, Charles (Yinkiu) |
| **Cc:** | Fink, Doran; Dreher-Lesnick, Sheila; Trout, Deborah; Austin-Hansberry, Lori; Yan, Lihan |
| **Subject:** | Request for (b) (4) Q fever (b) (4) |
| **Date:** | Monday, February 27, 2017 3:05:30 PM |
| **Attachments:** | image001.png<br>image002.jpg<br>image003.jpg<br>image004.jpg<br>image005.jpg<br>image006.jpg |
| **Importance:** | High |

---

Dear (b) (4)

Please (b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Thanks.
Rana

**Rana Chattopadhyay, PhD**
*Biologist [Regulatory]*

**Division of Vaccines and Related Product Applications**
**Center for Biologics Evaluation and Research**
**Office of Vaccines Research and Review**
**U.S. Food and Drug Administration**
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rana.chattopadhyay@fda.hhs.gov

**********

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**From:** Fink, Doran
**To:** Yang, Sixun
**Subject:** RE: Excel tracker action request: Pre-IND 3183
**Date:** Thursday, March 2, 2017 10:03:16 AM

---

I'm in it now.

---

Doran L. Fink, MD, PhD
Team Leader, CRB-2
FDA/CBER/OVRR/DVRPA
White Oak Bldg 71, Rm 3311
(301) 796-2640

---

**From:** Yang, Sixun
**Sent:** Thursday, March 02, 2017 10:03 AM
**To:** Fink, Doran
**Subject:** RE: Excel tracker action request: Pre-IND 3183

Sounds good! Thanks.

(b) (4) Q fever (b) (4)

---

**From:** Fink, Doran
**Sent:** Thursday, March 02, 2017 10:00 AM
**To:** Yang, Sixun
**Subject:** RE: Excel tracker action request: Pre-IND 3183

Let's give her until COB tomorrow.

---

Doran L. Fink, MD, PhD
Team Leader, CRB-2
FDA/CBER/OVRR/DVRPA
White Oak Bldg 71, Rm 3311
(301) 796-2640

---

**From:** Yang, Sixun
**Sent:** Thursday, March 02, 2017 9:59 AM
**To:** Fink, Doran
**Subject:** RE: Excel tracker action request: Pre-IND 3183

Do I need to wait for Andrea's input before I send them to JP?

Thanks.

---

**From:** Fink, Doran
**Sent:** Thursday, March 02, 2017 9:54 AM
**To:** Yang, Sixun
**Subject:** RE: Excel tracker action request: Pre-IND 3183

I made a few more edits, but I think it's in good shape for the meeting.

---

Doran L. Fink, MD, PhD
Team Leader, CRB-2
FDA/CBER/OVRR/DVRPA
White Oak Bldg 71, Rm 3311
(301) 796-2640

---

**From:** Yang, Sixun
**Sent:** Tuesday, February 28, 2017 5:37 PM
**To:** Fink, Doran
**Subject:** Excel tracker action request: Pre-IND 3183

File: Pre-IND 3183 (Live-attenuated CHIKV vaccine (VLA1553); Valneva)

Team Leader/Co-rapporteur input has been requested regarding:
Doran, the draft review for your inputs. Thanks. -Sixun

Link to Excel file: (b) (5)
(b) (5)

**From:** Chattopadhyay, Rana

**To:** Yang, Sixun; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Burns, Drusilla L.; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa

**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna

**Subject:** INTERNAL Discusion on (b) (4) Q-Fever (b) (4) (b) (4)

**Attachments:** (b) (4)

---

Dear (b) (4)

Please (b) (4)

(b) (4), (b) (5)

e-link to (b) (4), (b) (5)

---
Teleconference information
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Local: 1-301-796-7777
toll free: 1-855-828-1770
2. Follow the instructions that you hear on the phone.
Cisco Unified MeetingPlace meeting ID: (b) (6)

**From:** Fink, Doran
**To:** Burns, Drusilla L.
**Subject:** RE: (b) (4) Q-fever (b) (4)
**Date:** Monday, March 6, 2017 3:15:14 PM

---

Thanks – (b) (4), (b) (5)
(b) (4), (b) (5)

Doran L. Fink, MD, PhD

Team Leader, CRB-2

FDA/CBER/OVRR/DVRPA

White Oak Bldg 71, Rm 3311

(301) 796-2640

---

**From:** Burns, Drusilla L.
**Sent:** Monday, March 06, 2017 3:01 PM
**To:** Fink, Doran
**Subject:** (b) (4) Q-fever (b) (4)

Doran,

I talked with Freyja and she is (b) (4), (b) (5)
(b) (4), (b) (5)
(b) (4), (b) (5)

Drusilla

**From:** Sun, Wellington
**To:** Chattopadhyay, Rana; Burns, Drusilla L.; Fink, Doran; Cowley, Siobhan; Yang, Sixun; Rohan, Patricia; Cheung, Charles (Yinkiu); Harman, Christine
**Cc:** Hulse, Andrea; Williams, Freyja; Dreher-Lesnick, Sheila; Stibitz, Earle S.; Finn, Theresa; Pratt, Douglas R.
**Subject:** RE: (b) (4) Q fever (b) (4)
**Date:** Wednesday, March 8, 2017 2:23:51 PM

---

FYI there is no (b) (4), (b) (5)
(b) (4), (b) (5)

---

**From:** Chattopadhyay, Rana
**Sent:** Tuesday, March 07, 2017 1:10 PM
**To:** Burns, Drusilla L.; Fink, Doran; Cowley, Siobhan; Yang, Sixun; Rohan, Patricia; Cheung, Charles (Yinkiu); Harman, Christine
**Cc:** Sun, Wellington; Hulse, Andrea; Williams, Freyja; Dreher-Lesnick, Sheila; Stibitz, Earle S.; Finn, Theresa; Pratt, Douglas R.
**Subject:** RE: (b) (4) Q fever (b) (4)

Drusilla:

The (b) (4)
(b) (4) But I

Rana

---

**From:** Burns, Drusilla L.
**Sent:** Tuesday, March 07, 2017 1:01 PM
**To:** Chattopadhyay, Rana; Fink, Doran
**Cc:** Sun, Wellington; Hulse, Andrea; Williams, Freyja; Dreher-Lesnick, Sheila
**Subject:** (b) (4) Q fever (b) (4)

I have asked Freyja (b) (4), (b) (5)
(b) (4), (b) (5)

Rana, (b) (4), (b) (5)

Drusilla

| | |
|---|---|
| **From:** | Burns, Drusilla L. |
| **To:** | Fink, Doran; Yang, Sixun; Chattopadhyay, Rana; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Williams, Freyja |
| **Subject:** | RE: INTERNAL Discussion on (b) (4) Q-Fever (b) (4) (b) (4) |
| **Date:** | Thursday, March 9, 2017 12:51:32 PM |

I like that approach.

Drusilla

---

**From:** Fink, Doran
**Sent:** Thursday, March 09, 2017 12:50 PM
**To:** Burns, Drusilla L.; Yang, Sixun; Chattopadhyay, Rana; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Williams, Freyja
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4)Q-Fever (b) (4)

The (b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Doran L. Fink, MD, PhD

Team Leader, CRB-2

FDA/CBER/OVRR/DVRPA

White Oak Bldg 71, Rm 3311

(301) 796-2640

---

**From:** Burns, Drusilla L.
**Sent:** Thursday, March 09, 2017 12:45 PM
**To:** Fink, Doran; Yang, Sixun; Chattopadhyay, Rana; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Williams, Freyja
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4)Q-Fever (b) (4)

Good point. (b) (4)

With that said, (b) (4), (b) (5)
(b) (4), (b) (5)

From a (b) (4), (b) (5)
(b) (4), (b) (5)

Drusilla

---

**From:** Fink, Doran
**Sent:** Thursday, March 09, 2017 12:36 PM
**To:** Burns, Drusilla L.; Yang, Sixun; Chattopadhyay, Rana; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Williams, Freyja
**Subject:** RE: INTERNAL Discussion on (b) (4)
(b) (4)Q-Fever (b) (4)

Remind me, (b) (4), (b) (5)

(b) (4), (b) (5)

<< OLE Object: Picture (Device Independent Bitmap) >>

Doran L. Fink, MD, PhD

Team Leader, CRB-2

FDA/CBER/OVRR/DVRPA

White Oak Bldg 71, Rm 3311

(301) 796-2640

---

**From:** Burns, Drusilla L.
**Sent:** Thursday, March 09, 2017 12:23 PM
**To:** Yang, Sixun; Fink, Doran; Chattopadhyay, Rana; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Williams, Freyja
**Subject:** RE: INTERNAL Discussion on (b) (4)
(b) (4)Q-Fever (b) (4)

There is some (b) (4), (b) (5)
Q fever (b) (4), (b) (5)
(b) (4), (b) (5)
(b) (4), (b) (5) Q fever (b) (4), (b) (5)
(b) (4), (b) (5)

I would (b) (4), (b) (5)
(b) (4), (b) (5)

I think that it would (b) (4), (b) (5)
(b) (4), (b) (5)
(b) (4), (b) (5)

(b) (4)
(b) (4)

Drusilla

---

**From:** Yang, Sixun
**Sent:** Thursday, March 09, 2017 11:31 AM
**To:** Fink, Doran; Burns, Drusilla L.; Chattopadhyay, Rana; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington
**Cc:** Williams, Freyja
**Subject:** RE: INTERNAL Discussion on (b) (4)
(b) (4)Q-Fever (b) (4)

I have no idea. That is what I wanted to know.

(b) (4), (b) (5)
(b) (4), (b) (5) Q fever (b) (4), (b) (5)
(b) (4), (b) (5)

**From:** Fink, Doran
**Sent:** Thursday, March 09, 2017 10:58 AM
**To:** Yang, Sixun; Burns, Drusilla L.; Chattopadhyay, Rana; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington
**Cc:** Williams, Freyja
**Subject:** RE: INTERNAL Discussion on (b) (4) Q-Fever (b) (4)

Sixun, (b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

That being said, (b) (4), (b) (5)

(b) (4), (b) (5)

Doran

Doran L. Fink, MD, PhD

Team Leader, CRB-2

FDA/CBER/OVRR/DVRPA

White Oak Bldg 71, Rm 3311

(301) 796-2640

**From:** Yang, Sixun
**Sent:** Thursday, March 09, 2017 10:41 AM
**To:** Burns, Drusilla L.; Chattopadhyay, Rana; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna

**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4) Q-Fever (b) (4)

Drusilla and Freyja,

Thanks for (b) (4), (b) (5) (b) (4), (b) (5) Q fever. (b) (4) (b) (4)

(b) (4) Q fever (b) (4) (b) (4) *Coxiella burnetii* (b) (4) (b) (4) (b) (4) Q fever (b) (4) (b) (4)

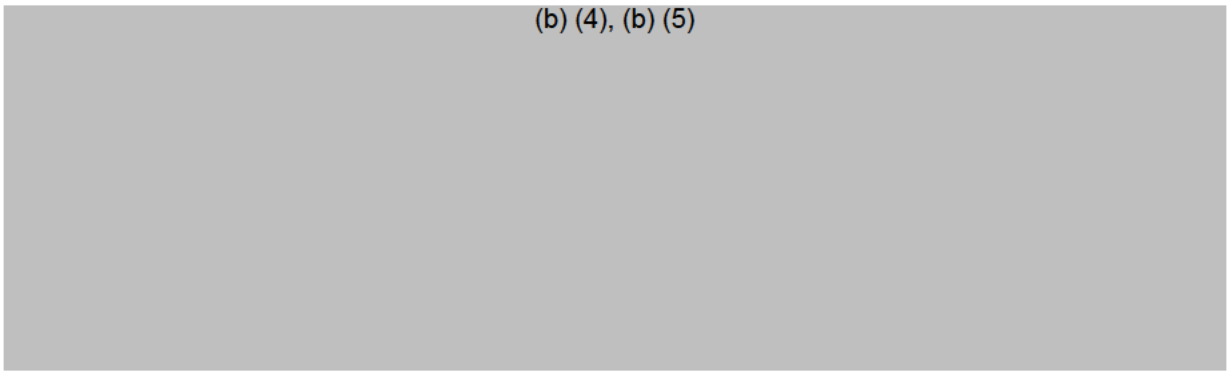
(b) (4) Q fever (b) (4)

(b) (4) (b) (4) *Coxiella burnatii* (b) (4) Q fever (b) (4) (b) (4) (b) (4) Q fever.

---

**From:** Burns, Drusilla L.
**Sent:** Thursday, March 09, 2017 10:12 AM
**To:** Chattopadhyay, Rana; Yang, Sixun; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4) Q-Fever (b) (4)

At our meeting last Monday concerning (b) (4), (b) (5) Q-fever (b) (4), (b) (5) (b) (4), (b) (5)



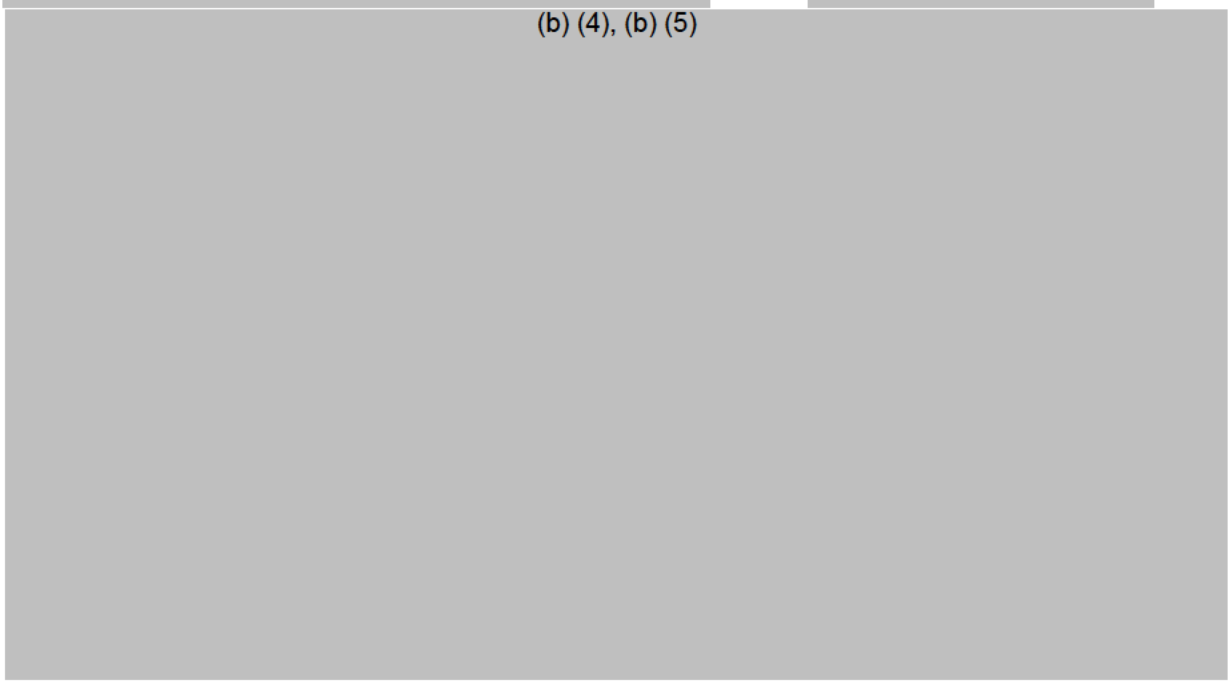

Drusilla




(b) (4), (b) (5)

Q fever

(b) (4), (b) (5)



Q fever (b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5) Q fever.

-----Original Appointment-----
**From:** Chattopadhyay, Rana
**Sent:** Wednesday, January 18, 2017 1:58 PM
**To:** Chattopadhyay, Rana; Yang, Sixun; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Burns, Drusilla L.; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** INTERNAL Discusion on (b) (4) Q-Fever (b) (4)
**When:** Monday, March 06, 2017 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** WO, Bldg. 71, Room 3244

Dear (b) (4)

Please (b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

e-link to (b) (4), (b) (5)

(b) (4)

---

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   Local: 1-301-796-7777

   toll free: 1-855-828-1770

2. Follow the instructions that you hear on the phone.

   Cisco Unified MeetingPlace meeting ID: (b) (6)

**From:** Williams, Freyja
**To:** Pratt, Douglas R.
**Cc:** Yang, Sixun; Yan, Lihan; Fink, Doran; Hulse, Andrea; Burns, Drusilla L.
**Subject:** RE: INTERNAL Discussion on (b) (4) Q-Fever (b) (4)
**Date:** Thursday, March 9, 2017 3:06:25 PM

Everyone (b) (4), (b) (5)
But you are correct (b) (4), (b) (5)
(b) (4), (b) (5)
(b) (4), (b) (5) Q fever (b) (4), (b) (5)
(b) (4), (b) (5) C. burnetii (b) (4), (b) (5)

Ultimately (b) (4), (b) (5)

**Freyja Williams**
*Biologist*

**CBER**
**DBPAP**
**U.S. Food and Drug Administration**
Tel: 540-362-3239
freyja.williams@fda.hhs.gov

---

**From:** Pratt, Douglas R.
**Sent:** Thursday, March 09, 2017 2:57 PM
**To:** Williams, Freyja
**Cc:** Yang, Sixun; Yan, Lihan; Fink, Doran; Hulse, Andrea
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4) Q-Fever (b) (4)

(b) (4), (b) (5)

My main point is that (b) (4), (b) (5)
(b) (4), (b) (5)

---

**From:** Williams, Freyja
**Sent:** Thursday, March 09, 2017 2:20 PM
**To:** Yan, Lihan; Pratt, Douglas R.; Yang, Sixun; Chattopadhyay, Rana; Burns, Drusilla L.; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa

**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4) Q-Fever (b) (4)

(b) (4), (b) (5)

**Freyja Williams**
*Biologist*

**CBER**
**DBPAP**
**U.S. Food and Drug Administration**
Tel: 540-362-3239
freyja.williams@fda.hhs.gov

<< OLE Object: Picture (Device Independent Bitmap) >>

<< OLE Object: Picture (Device Independent Bitmap) >> << OLE Object: Picture (Device Independent Bitmap) >> << OLE Object: Picture (Device Independent Bitmap) >> << OLE Object: Picture (Device Independent Bitmap) >> << OLE Object: Picture (Device Independent Bitmap) >>

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**From:** Yan, Lihan
**Sent:** Thursday, March 09, 2017 2:15 PM
**To:** Pratt, Douglas R.; Yang, Sixun; Williams, Freyja; Chattopadhyay, Rana; Burns, Drusilla L.; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4) Q-Fever (b) (4)

Agree with Douglas. (b) (4), (b) (5)

Lihan

---

**From:** Pratt, Douglas R.
**Sent:** Thursday, March 09, 2017 2:02 PM
**To:** Yang, Sixun; Williams, Freyja; Chattopadhyay, Rana; Burns, Drusilla L.; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna

**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4) Q-Fever (b) (4)

I don't (b) (4), (b) (5)
(b) (4), (b) (5)

Douglas

---

**From:** Yang, Sixun
**Sent:** Thursday, March 09, 2017 12:50 PM
**To:** Williams, Freyja; Chattopadhyay, Rana; Burns, Drusilla L.; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4) Q-Fever (b) (4)

(b) (4), (b) (5)

---

**From:** Williams, Freyja
**Sent:** Thursday, March 09, 2017 12:35 PM
**To:** Yang, Sixun; Chattopadhyay, Rana; Burns, Drusilla L.; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4) Q-Fever (b) (4)

The (b) (4)

(b) (4) (b) (4), (b) (5)

(b) (4), (b) (5)

**Freyja Williams**
*Biologist*

**CBER**
**DBPAP**
**U.S. Food and Drug Administration**
Tel: 540-362-3239
freyja.williams@fda.hhs.gov

<< OLE Object: Picture (Device Independent Bitmap) >>

<< OLE Object: Picture (Device Independent Bitmap) >> << OLE Object: Picture (Device Independent Bitmap) >> << OLE Object: Picture (Device Independent Bitmap) >> << OLE Object: Picture (Device Independent Bitmap) >> << OLE Object: Picture (Device Independent Bitmap) >>

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**From:** Yang, Sixun
**Sent:** Thursday, March 09, 2017 12:14 PM
**To:** Chattopadhyay, Rana; Burns, Drusilla L.; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa; Williams, Freyja
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4) Q-Fever

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5) Q fever, (b) (4), (b) (5)

(b) (4), (b) (5)

**From:** Chattopadhyay, Rana
**Sent:** Thursday, March 09, 2017 11:48 AM
**To:** Burns, Drusilla L.; Yang, Sixun; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa; Williams, Freyja
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4) Q-Fever (b) (4)

Doran, Jon and I think, we should (b) (4), (b) (5)
(b) (4), (b) (5)

(b) (4), (b) (5)

Thanks.

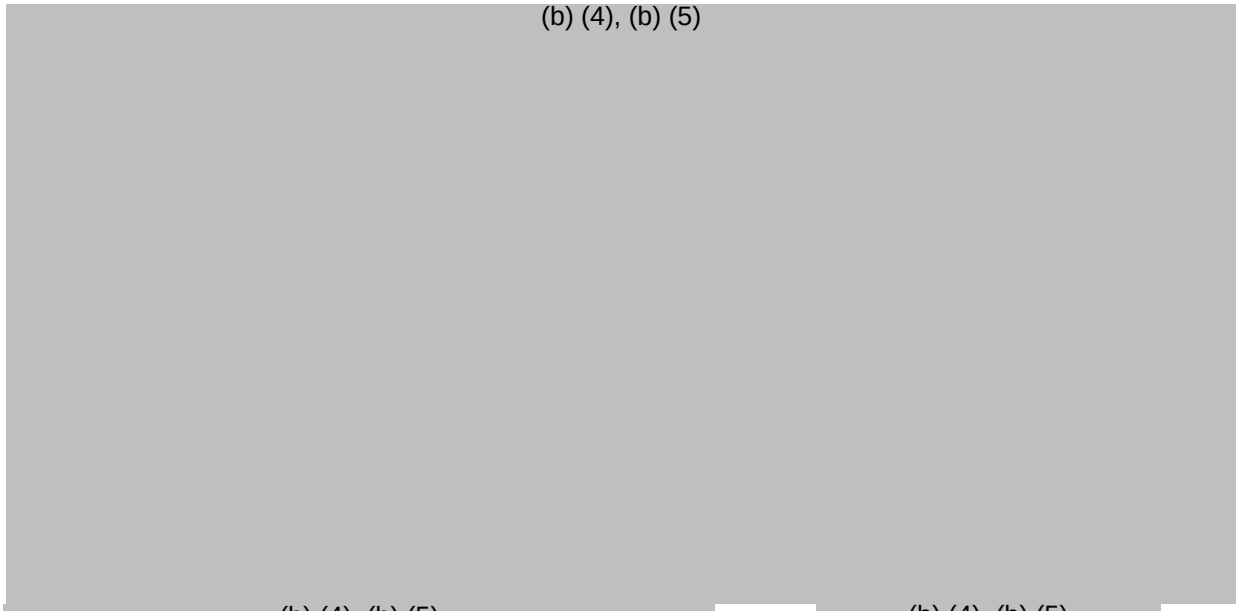
Rana

---

**From:** Burns, Drusilla L.
**Sent:** Thursday, March 09, 2017 10:12 AM
**To:** Chattopadhyay, Rana; Yang, Sixun; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4) Q-Fever (b) (4)

At our meeting last Monday concerning (b) (4), (b) (5) Q-fever (b) (4), (b) (5)
(b) (4), (b) (5)

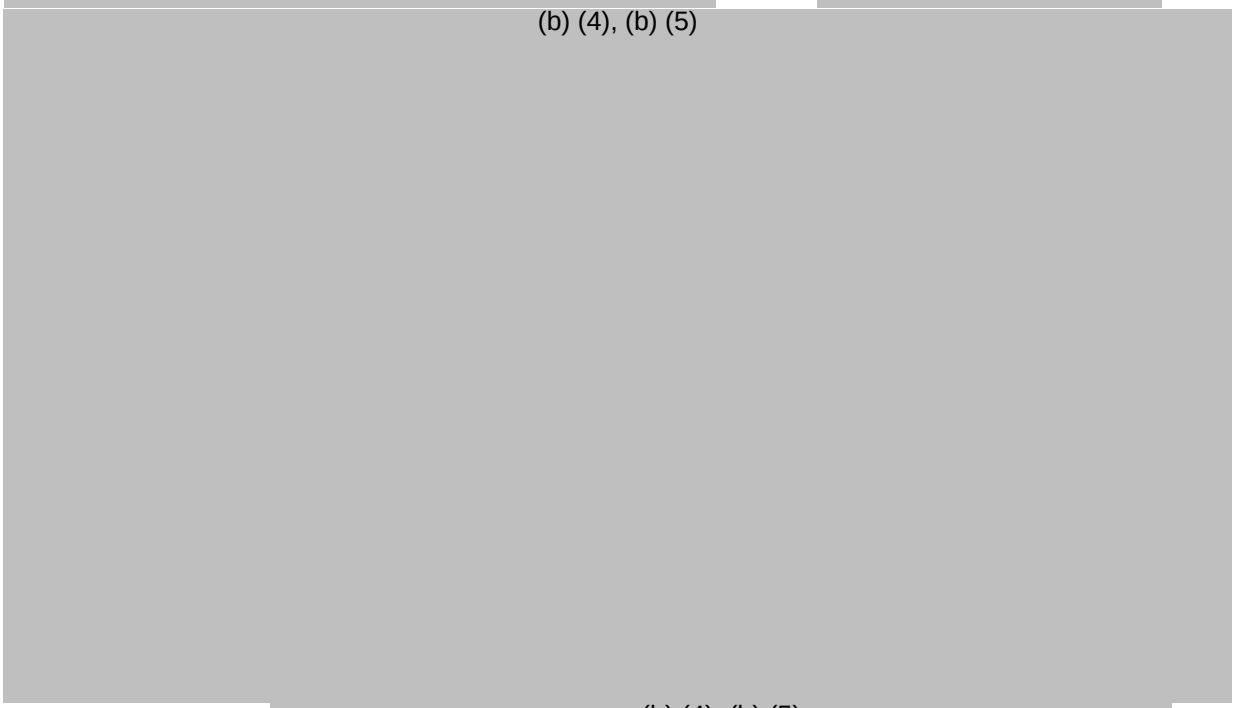
Drusilla




(b) (4), (b) (5)

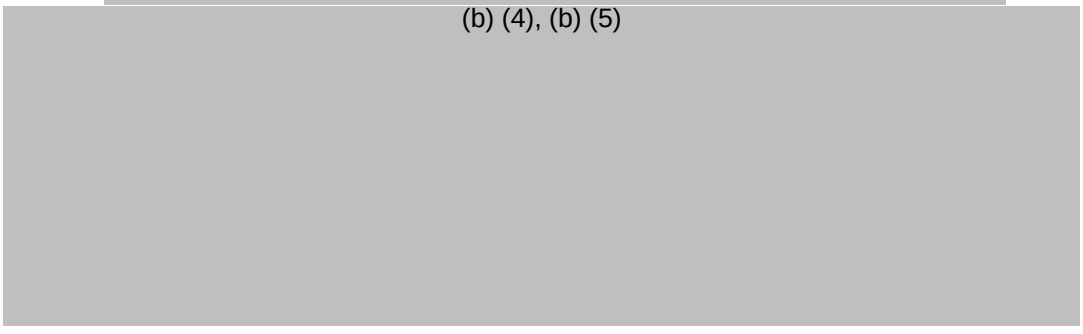
Q fever

(b) (4), (b) (5)

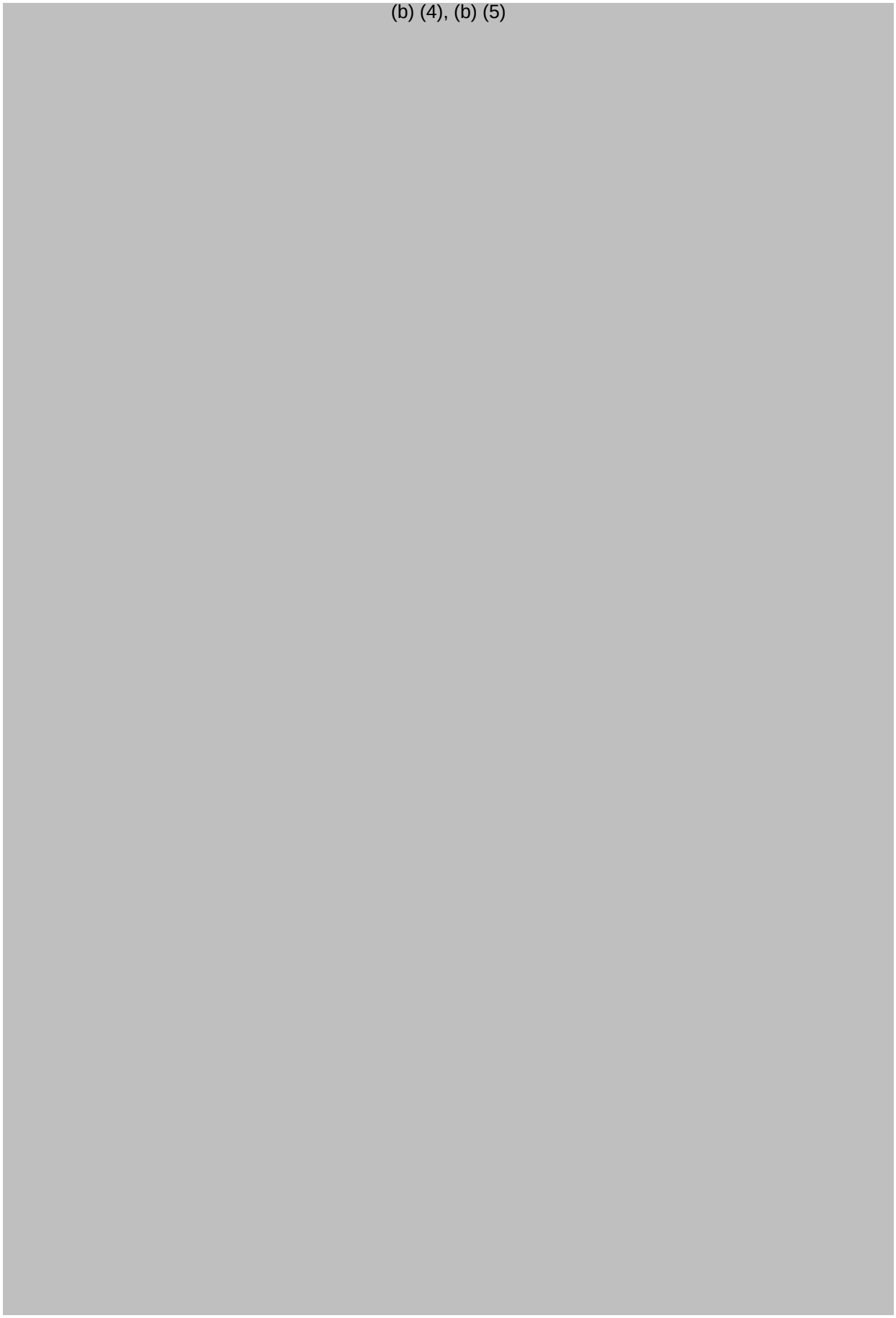



Q fever

(b) (4), (b) (5)



(b) (4), (b) (5)



(b) (4), (b) (5)

(b) (4), (b) (5) Q fever.

-----Original Appointment-----
**From:** Chattopadhyay, Rana
**Sent:** Wednesday, January 18, 2017 1:58 PM
**To:** Chattopadhyay, Rana; Yang, Sixun; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Burns, Drusilla L.; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** INTERNAL Discusion on (b) (4) Q-Fever (b) (4)
**When:** Monday, March 06, 2017 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** WO, Bldg. 71, Room 3244

Dear (b) (4)

Please (b) (4), (b) (5)
(b) (4), (b) (5)

(b) (4), (b) (5)

e-link to (b) (4), (b) (5)

(b) (4)

---

Teleconference information

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1. Provide your number when you join the meeting to receive a call back. Alternatively, you can call one of the following numbers:

   Local: 1-301-796-7777

   toll free: 1-855-828-1770

2. Follow the instructions that you hear on the phone.

   Cisco Unified MeetingPlace meeting ID: (b) (6)

| | |
|---|---|
| **From:** | Slater, Jay |
| **To:** | Burns, Drusilla L.; Williams, Freyja; Yang, Sixun; Pratt, Douglas R.; Fink, Doran; Daugherty, Jon; Chattopadhyay, Rana; Yan, Lihan |
| **Subject:** | FW: DHMH Clinician Letter: Q Fever |
| **Date:** | Friday, March 10, 2017 3:34:31 PM |
| **Attachments:** | Q Fever clinician letter 3-10-2017 F.pdf<br>image001.png<br>image002.jpg<br>image003.jpg<br>image004.jpg<br>image005.jpg<br>image006.jpg |

---

FYI

**Jay E. Slater, MD**
*Director, Division of Bacterial, Parasitic and Allergenic Products*

**Center for Biologics Evaluation and Research**
**Office of Vaccines Research and Review**
**U.S. Food and Drug Administration**
Tel: 240-402-7396
jay.slater@fda.hhs.gov

cid:image001.png@01D1C57E.DFA022A0

**From:** Maryland Department of Health and Mental Hygiene [mailto:7ca34f02-0005-3000-80c0-fceb55463ffe@notify.mir3.com]
**Sent:** Friday, March 10, 2017 3:30 PM
**To:** Slater, Jay
**Subject:** DHMH Clinician Letter: Q Fever

Dear Maryland Health Care Provider:

Attached to this message you will find a DHMH Clinician letter containing an important update on Q Fever (infection caused by *Coxiella burnetii*). Information on its Natural History and Transmission, Clinical Signs and Symptoms, how to Diagnose and Treat, and Public Health Response.

Sincerely,

The Office of the Secretary

Department of Health and Mental Hygiene

201 W. Preston Street

Baltimore, MD 21201

* Please do not respond directly to this e-mail. The originating e-mail account is not monitored.

Thank you,
Maryland Department of Health and Mental Hygiene

STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
*Larry Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Dennis R. Schrader, Secretary*

March 10, 2017

Dear Colleagues,

We would like to remind Maryland providers that Q fever can occur in Maryland. Q fever (infection caused by *Coxiella burnetii*) has recently been detected in animals in the National Capital and Baltimore Metropolitan regions in Maryland. *Coxiella burnetii* is known to naturally occur in Maryland, and sporadic human and animal cases have been reported in past years. At this time, the Maryland Department of Health and Mental Hygiene (DHMH) is not aware of any human illness caused by *C. burnetii*; however, DHMH would like to alert clinicians to include Q fever in the differential diagnosis of patients with appropriate symptoms and exposure to goats, sheep and cattle.

**Natural History and Transmission**

Cattle, sheep, and goats are the primary reservoirs of *C. burnetii*, and organisms are excreted in milk, urine, and feces of infected animals with the highest numbers shed during birthing in the amniotic fluids and the placenta. Exposure usually occurs by inhalation of air that is contaminated by excreta of infected animals; consumption of unpasteurized dairy products can also result in infection.

**Clinical Signs and Symptoms**

Q fever can cause acute or chronic illness; acute symptoms usually develop within 2-3 weeks of exposure. As many as half of infected persons are asymptomatic. Q fever can cause mild or severe symptoms, which may include high fever; chills or sweats; fatigue or general malaise; severe headache; myalgia; nausea, vomiting, or diarrhea; chest pain, abdominal pain; or non-productive cough.

Most persons with acute Q fever infection recover completely, however, some may experience serious illness with pneumonia, granulomatous hepatitis, myocarditis, or central nervous system complications. Chronic Q fever with endocarditis is more likely to occur in those with valvular heart disease, arterial aneurysms, vascular grafts, or immunosuppression.

Women who are infected during pregnancy may be at risk for miscarriage, stillbirth, pre-term delivery, or low infant birth weight.

**Diagnosis**

Diagnosing Q fever can be challenging. Symptoms vary from patient to patient and can be difficult to distinguish from other diseases. Serologic assays will frequently be negative in the first 7-15 days of illness. Detection of *C. burnetii* DNA by PCR within the first 2 weeks of illness (and prior to initiation of antibiotics) can rapidly confirm an acute Q fever infection. For definitive diagnosis in the early

stages of illness it is recommended to use serologic tests in combination with PCR of whole blood or serum.

Patient history**.** Providers should ask about potential exposure to infected livestock or employment in high risk occupations such as animal health or farming. Providers should screen for risk factors for chronic Q fever (valvular heart disease, arterial aneurysms, vascular grafts, or immunosuppression) so that patients with acute Q fever can be monitored using serology for two years to ensure rapid diagnosis and treatment of chronic Q fever.

Other clinical evidence**.** Prolonged fever with low platelet count, normal leukocyte count, and elevated liver enzymes are suggestive of acute Q fever infection, but may not be present in all patients. Laboratory diagnosis includes paired serology, PCR and culture isolation via specialized methods. Serology and PCR are generally available at commercial laboratories.

**Treatment**

Healthcare providers must treat patients based on clinical suspicion alone and not wait for the return of confirmatory tests.

Doxycycline is the recommended first-line treatment for non-pregnant adults with Q fever and is most effective at preventing severe complications if it is started within the first 3 days of symptoms. Treatment must be based on clinical suspicion and should always begin before laboratory results return. If the patient is treated within the first 3 days of the disease, fever generally subsides within 72 hours, although in severely ill patients, fever may persist for longer periods despite treatment.

Treatment is generally not recommended for patients who are asymptomatic or who have already recovered from their illness, but might be considered for those at high risk of developing chronic Q fever. There is no role for prophylactic antimicrobial agents in preventing Q fever after a known exposure and prior to symptom onset; attempts at prophylaxis will likely extend the incubation period by several days but will not prevent infection from occurring.

The CDC and the Q Fever Working Group have published guidance with additional detail about the disease, its diagnosis and its treatment, entitled, “Diagnosis and Management of Q Fever – United States, 2013”. The guidance is available at:
https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6203a1.htm

**Public Health Response**

Contact your local health department if you suspect Q fever in a patient:
http://phpa.dhmh.maryland.gov/IDEHASharedDocuments/ReportableDisease_HCP.pdf

As always, thank you for your attention to this and other important public health information.

Sincerely,



Lucy E. Wilson, MD, ScM
Chief, Center for Surveillance, Infection Prevention and Outbreak Response

**From:** Fink, Doran
**To:** Yang, Sixun; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington (Wellington.Sun@fda.hhs.gov)
**Subject:** RE: (b) (5) Q fever
**Date:** Friday, March 10, 2017 3:41:00 PM

---

This article describes a "small study" to be conducted in children 10-15 years of age that may pave the way for a larger study – however, unclear whether the larger study would evaluate efficacy in a controlled and formal manner or whether it would be an immunobridging and safety study to extend licensure to younger ages, (b) (5)
(b) (5)
(b) (5)

Doran L. Fink, MD PhD
Medical Officer (Team Leader)
CRB2/DVRPA/OVRR/CBER/FDA
(301) 796-2640

---

**From:** Yang, Sixun
**Sent:** Friday, March 10, 2017 1:56 PM
**To:** Fink, Doran; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington
**Subject:** (b) (5) for Q fever

You may find the link interesting. It appears that Australia is going to test Q-VAX in children <15 years of age. (b) (5)
(b) (5)

http://www.abc.net.au/news/2017-02-20/farmers-push-for-q-fever-vaccination-to-include-children/8286348

**From:** (b) (6)
**To:** (b) (6) (b) (6) Fink, Doran; (b) (6) (b) (6) (b) (6)
**Subject:** FW: DHMH Clinician Letter: Q Fever
**Date:** Tuesday, March 14, 2017 11:24:50 AM
**Attachments:** Q Fever clinician letter 3-10-2017 F.pdf
ATT00001.htm

---

I have been looking for a case for about 20 years now, but it might be just around the corner – see attached for nice summary – reminding clinicians that coxiella has been found in in animals in National Capital and Baltimore Metropolitan regions in Maryland….
(b) (6)

---

**From:** (b) (6) [mailto (b) (6) @peninsula.org]
**Sent:** Monday, March 13, 2017 2:47 PM
**Subject:** DHMH Clinician Letter: Q Fever

Dear Maryland Health Care Provider:

Attached to this message you will find a DHMH Clinician letter containing an important update on Q Fever (infection caused by *Coxiella burnetii*). Information on its Natural History and Transmission, Clinical Signs and Symptoms, how to Diagnose and Treat, and Public Health Response.

Sincerely,

The Office of the Secretary

Department of Health and Mental Hygiene

201 W. Preston Street

Baltimore, MD 21201

* Please do not respond directly to this e-mail. The originating e-mail account is not monitored.

Thank you,
Maryland Department of Health and Mental Hygiene

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Peninsula Regional Medical Center has implemented a secure email policy. You may be the recipient of a Cisco Registered Envelope secured message. First-time recipients will be asked to create and confirm a password before given access to the Cisco Registered Envelope Service. If you need assistance in accessing your Secure Message, contact our Service Desk at support@peninsula.org or 410-543-7777.

---

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STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
*Larry Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Dennis R. Schrader, Secretary*

March 10, 2017

Dear Colleagues,

We would like to remind Maryland providers that Q fever can occur in Maryland. Q fever (infection caused by *Coxiella burnetii*) has recently been detected in animals in the National Capital and Baltimore Metropolitan regions in Maryland. *Coxiella burnetii* is known to naturally occur in Maryland, and sporadic human and animal cases have been reported in past years. At this time, the Maryland Department of Health and Mental Hygiene (DHMH) is not aware of any human illness caused by *C. burnetii*; however, DHMH would like to alert clinicians to include Q fever in the differential diagnosis of patients with appropriate symptoms and exposure to goats, sheep and cattle.

**Natural History and Transmission**

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**Clinical Signs and Symptoms**

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Most persons with acute Q fever infection recover completely, however, some may experience serious illness with pneumonia, granulomatous hepatitis, myocarditis, or central nervous system complications. Chronic Q fever with endocarditis is more likely to occur in those with valvular heart disease, arterial aneurysms, vascular grafts, or immunosuppression.

Women who are infected during pregnancy may be at risk for miscarriage, stillbirth, pre-term delivery, or low infant birth weight.

**Diagnosis**

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stages of illness it is recommended to use serologic tests in combination with PCR of whole blood or serum.

Patient history**.** Providers should ask about potential exposure to infected livestock or employment in high risk occupations such as animal health or farming. Providers should screen for risk factors for chronic Q fever (valvular heart disease, arterial aneurysms, vascular grafts, or immunosuppression) so that patients with acute Q fever can be monitored using serology for two years to ensure rapid diagnosis and treatment of chronic Q fever.

Other clinical evidence**.** Prolonged fever with low platelet count, normal leukocyte count, and elevated liver enzymes are suggestive of acute Q fever infection, but may not be present in all patients. Laboratory diagnosis includes paired serology, PCR and culture isolation via specialized methods. Serology and PCR are generally available at commercial laboratories.

**Treatment**

Healthcare providers must treat patients based on clinical suspicion alone and not wait for the return of confirmatory tests.

Doxycycline is the recommended first-line treatment for non-pregnant adults with Q fever and is most effective at preventing severe complications if it is started within the first 3 days of symptoms. Treatment must be based on clinical suspicion and should always begin before laboratory results return. If the patient is treated within the first 3 days of the disease, fever generally subsides within 72 hours, although in severely ill patients, fever may persist for longer periods despite treatment.

Treatment is generally not recommended for patients who are asymptomatic or who have already recovered from their illness, but might be considered for those at high risk of developing chronic Q fever. There is no role for prophylactic antimicrobial agents in preventing Q fever after a known exposure and prior to symptom onset; attempts at prophylaxis will likely extend the incubation period by several days but will not prevent infection from occurring.

The CDC and the Q Fever Working Group have published guidance with additional detail about the disease, its diagnosis and its treatment, entitled, “Diagnosis and Management of Q Fever – United States, 2013”. The guidance is available at:
https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6203a1.htm

**Public Health Response**

Contact your local health department if you suspect Q fever in a patient:
http://phpa.dhmh.maryland.gov/IDEHASharedDocuments/ReportableDisease_HCP.pdf

As always, thank you for your attention to this and other important public health information.

Sincerely,



Lucy E. Wilson, MD, ScM
Chief, Center for Surveillance, Infection Prevention and Outbreak Response

**From:** Yang, Sixun
**To:** Fink, Doran
**Subject:** (b) (4)
**Date:** Wednesday, March 15, 2017 1:52:11 PM

---

Thanks. I will (b) (4), (b) (5)

**From:** Fink, Doran
**Sent:** Wednesday, March 15, 2017 1:50 PM
**To:** Yang, Sixun
**Subject:** RE: (b) (4)
(b) (4), (b) (5)

---

Doran L. Fink, MD, PhD
Team Leader, CRB-2
FDA/CBER/OVRR/DVRPA
White Oak Bldg 71, Rm 3311
(301) 796-2640

**From:** Yang, Sixun
**Sent:** Wednesday, March 15, 2017 1:47 PM
**To:** Fink, Doran
**Subject:** RE: (b) (4)

Doran,

It looks fine with me.

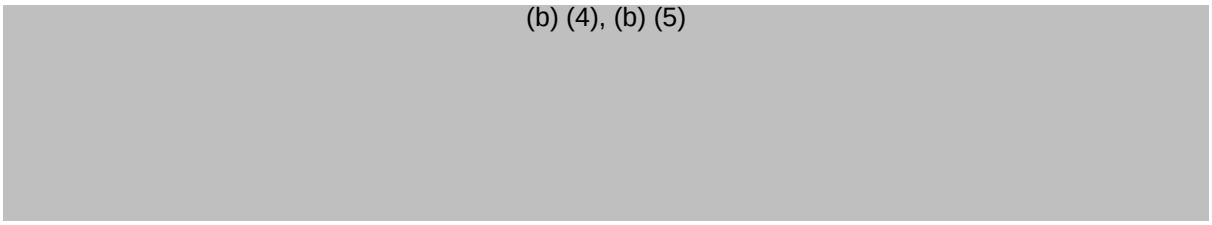
(b) (4)
(b) (4) Q fever (b) (4)
(b) (4)
(b) (4) Q fever cases (b) (4)
(b) (4) Q fever (b) (4)
(b) (4)
*C. burnetii* (b) (4)
(b) (4) *C. burnetii* (b) (4)
(b) (4)

Thanks.

Sixun

**From:** Fink, Doran
**Sent:** Wednesday, March 15, 2017 8:03 AM
**To:** Hulse, Andrea
**Cc:** Yang, Sixun
**Subject:** (b) (4)

(b) (4), (b) (5)


(b) (4), (b) (5)

| | |
|---|---|
| **From:** | Chattopadhyay, Rana |
| **To:** | Finn, Theresa; Burns, Drusilla L.; Yang, Sixun; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Williams, Freyja |
| **Cc:** | Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna |
| **Subject:** | RE: INTERNAL Discussion on (b) (4) Q-Fever (b) (4) (b) (4) |
| **Date:** | Thursday, March 16, 2017 9:39:57 AM |

Thank you, Theresa. I'll include this in our (b) (4)

Rana

---

**From:** Finn, Theresa
**Sent:** Thursday, March 16, 2017 9:39 AM
**To:** Chattopadhyay, Rana; Burns, Drusilla L.; Yang, Sixun; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Williams, Freyja
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4)Q-Fever (b) (4)

Rana – with regard to (b) (4), (b) (5)
(b) (4), (b) (5)

Theresa

---

**From:** Chattopadhyay, Rana
**Sent:** Thursday, March 09, 2017 11:48 AM
**To:** Burns, Drusilla L.; Yang, Sixun; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa; Williams, Freyja
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4)Q-Fever (b) (4)

Doran, Jon and I (b) (4), (b) (5)
(b) (4), (b) (5)

If this (b) (4), (b) (5)
(b) (4), (b) (5)

Thanks.

Rana

---

**From:** Burns, Drusilla L.
**Sent:** Thursday, March 09, 2017 10:12 AM
**To:** Chattopadhyay, Rana; Yang, Sixun; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** RE: INTERNAL Discussion on (b) (4) (b) (4) Q-Fever (b) (4)

At our meeting last Monday concerning (b) (4), (b) (5) Q-fever (b) (4), (b) (5)
(b) (4), (b) (5)

Drusilla

(b) (4), (b) (5)

(b) (4), (b) (5)

Q fever

(b) (4), (b) (5)

(b) (4), (b) (5)

Q fever

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5) Q fever.

-----Original Appointment-----
**From:** Chattopadhyay, Rana
**Sent:** Wednesday, January 18, 2017 1:58 PM
**To:** Chattopadhyay, Rana; Yang, Sixun; Cowley, Siobhan; Harman, Christine; Fink, Doran; Trout, Deborah; Daugherty, Jon; Hulse, Andrea; Pratt, Douglas R.; Sun, Wellington; Burns, Drusilla L.; Slater, Jay; Rohan, Patricia; Austin-Hansberry, Lori; Bridgewater, Jennifer; Yan, Lihan; Cheung, Charles (Yinkiu); Renshaw, Carolyn; McVittie, Loris; Finn, Theresa
**Cc:** Dreher-Lesnick, Sheila; Stibitz, Earle S.; Alimchandani, Meghna
**Subject:** INTERNAL Discusion on (b) (4) Q-Fever (b) (4)
**When:** Monday, March 06, 2017 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
**Where:** WO, Bldg. 71, Room 3244

Dear (b) (4)

Please (b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

e-link to (b) (4), (b) (5)

(b) (4)

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Teleconference information

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1. Provide your number when you join the meeting to receive a call back. Alternatively, you can call one of the following numbers:

   Local: 1-301-796-7777

   toll free: 1-855-828-1770

2. Follow the instructions that you hear on the phone.

   Cisco Unified MeetingPlace meeting ID: (b) (6)

**From:** Fink, Doran
**To:** Chattopadhyay, Rana; Yang, Sixun
**Cc:** Hulse, Andrea
**Subject:** RE: Q (b) (4)
**Date:** Thursday, March 23, 2017 9:21:00 AM
**Attachments:** (b) (4)

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(b) (4), (b) (5)

Doran L. Fink, MD PhD
Medical Officer (Team Leader)
CRB2/DVRPA/OVRR/CBER/FDA
(301) 796-2640

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**From:** Chattopadhyay, Rana
**Sent:** Thursday, March 23, 2017 8:18 AM
**To:** Yang, Sixun; Fink, Doran
**Cc:** Hulse, Andrea
**Subject:** FW: Q (b) (4)
**Importance:** High

Sixun and Doran
Yesterday afternoon (b) (4)
(b) (4)

Thanks.

Rana

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**From:** Hulse, Andrea
**Sent:** Wednesday, March 22, 2017 4:04 PM
**To:** Chattopadhyay, Rana
**Subject:** RE: Q (b) (4)

I didn't forget. (b) (4)

Thanks,

Andrea

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**From:** Chattopadhyay, Rana
**Sent:** Wednesday, March 22, 2017 3:47 PM
**To:** Hulse, Andrea
**Subject:** Q (b) (4)

Andrea
(b) (4)

Thanks.

Rana

7 pages have been determined to be not releasable: (b)(4)

| | |
|---|---|
| **From:** | MCM presentation distribution list on behalf of Hinton, Kesha |
| **To:** | FDA-MCM-PRESENTATIONS@LIST.NIH.GOV |
| **Subject:** | August 29, 2019 - Join us for an MCMi lecture: Marmosets, melioidosis and co-trimoxazole |
| **Date:** | Thursday, August 15, 2019 7:43:50 AM |

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**August 29, 2019, Time - 1:30 p.m. - 2:30 p.m.**

**WO Building 1, room 4101/4103/4105 (combined)**

**Marmosets, melioidosis and co-trimoxazole**

This lecture will be an overview of the diverse clinical presentation of melioidosis and how Dstl has used the small nonhuman primate, the common marmoset, to elucidate aspects of the disease pathogenesis.

**Speaker bio sketch:**

Dr. Michelle Nelson started working at Dstl in 1995 and works within the Microbiology and Biological Detection group of the CBR Division. During her career she has focused on a technical role and additionally has actively supported national and international operations. Initially she studied the survival of various aerosolised, high containment pathogens under different environmental conditions. She then went on to complete an MSc in Medical Microbiology and a PhD identifying potential polysaccharide vaccine candidates for two containment level 3 (CL-3) pathogens, Burkholderia pseudomallei and Burkholderia mallei. The primary focus of her research from that point onwards has been to develop animal models of pathogens such as the bacterial agents, Francisella tularensis, Bacillus anthracis, Coxiella burnetii and the Burkholderia species, as well as viral agents such as the MERS-CoV and the filoviruses. The models used to assess medical countermeasures include small animal models, mice, hamsters, rats and guinea pigs. However, over the last 10 years she has lead and developed the marmoset infectious disease model capability at Dstl, for which she was shortlisted for the Women in Defence Award in 2018.

**To register for this training session in person (and to receive a calendar appointment)**

https://lms.learning.hhs.gov/Saba/Web/Main/goto/RegisterCatalog?offeringId=class000000000147371&oneClickLearningON=true

Remote Access Instructions Webcast Registration (pre-registration is required): To register for the webcast, please click the link below and then follow the instructions on the registration page. After you register you will receive a link via email to access the live webinar. You must log in with your username and password which you create when you register. Please pre-register at least one day before the event to ensure you receive the access link email and outlook invitation for the session.

**LINK TO REGISTER for ADOBE WEBCAST:**

https://collaboration.fda.gov/aug292019/event/registration.html

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http://list.nih.gov/cgi-bin/wa.exe?SUBED1=FDA-MCM-PRESENTATIONS&A=1

**From:** (b) (6)
**To:** world@worldtribune.com
**Subject:** [EXTERNAL] Fwd: Questions for FDA - SV40 and CBER
**Date:** Monday, June 27, 2022 5:25:39 PM
**Importance:** High

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Members of the VRBPAC,

I reviewed your statements on June 14 and June 15 with great interest. Janet Woodcock connected me with Paul Richards at the FDA when I discovered the monkey virus (SV40) hidden in the Polio vaccine. This same monkey virus was allegedly used in gain of function research in New Orleans in the 1960's. The attempt was to weaponize SV40 to create a rapid growth cancer causing agent.

The FDA has assured me, with little to no evidence to support this assurance, that SV40 is not responsible for the increase in cancers since the polio vaccine was rolled out across the United States.

Now we sit on the cusp of your decision to green light never-ending updates to the COVID-19 vaccines on an unsuspecting population. The national security implications of this are astounding.

How many of you have researched the racial specificity of the spike protein? Are you even aware that some races of human have no ACE2 receptors, making them immune to the spike protein?

How many of you are immune to this spike protein?

Trust has been given to you to regulate pharmaceutical companies and maintain public faith in the practice of medicine. Once lost, trust is difficult if not impossible to regain.

If you feel threatened or coerced to vote a certain, please contact me and become a whistleblower or confidential informant.

The following questions have been submitted to CBER's Paul Richards. Perhaps you will find them illuminating.

John Davidson

PS. Why aren't we testing for Coxiella Burnetii?

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Paul,

Thank you for your patience in waiting for me to formulate these questions. In the interest of understanding I want

to let you know that I in recent months I have been operating a website / documentary series called “Broken Truth” (BrokenTruth.com). I have traveled and interviewed families who were vaccine injured or lost loved ones to the vaccines.

After watching the two FDA CBER Vaccine and Biologicals committee votes last week and hearing the concern members had regarding the messaging and lack of efficacy in the vaccines after the second dose, it is apparent that the problems the FDA faces are:

1. The COVID-19 warning messaging was far too effective and has resulted in a mass delusion of fear by parents across the country.
2. The CDC ignored the FDA committee members concerns about properly presenting the benefits of the vaccine and the actual risks covid presents to their children.
3. The FDA committee members have voted to continue trials in children despite the lack of emergency risk or demonstration of vaccine efficacy.

Due to my unique understanding of previous FDA situations like this regarding SV40, it appears we are repeating mistakes. Without proper checks and balances this will likely only get worse for the FDA and the biomedical industry. This is why I have created a campaign to encourage the injured or at risk citizens of the US to file medical license board complaints against people involved in misrepresentation of fact like Rochelle Walensky.

The FDA, CDC, NIH et all need to correct the risk messaging that has been mangled by the CDC and public news media, which means you need people like me to continue this work.

**If at some point in the future the FDA wishes to discuss funding opportunities to aid my efforts, you have my contact information.**

**SV40 and additional questions**

1. Did the FDA or any other government entity track batches / shipments of Polio vaccines?

2. Did the FDA maintain documentation of which Americans received which tainted batches of Polio vaccines?

3. What methodology did the FDA utilize to ascertain that SV40 did not cause cancer?

4. According to the FDA / Pfizer documentation, the only test on pregnant animals for the Covid vaccine occurred on lab mice. The FDA considered this adequate for Covid vaccine approval for pregnant women. With the Polio vaccine, lab rodents were exposed to SV40 which resulted in tumor production, yet the FDA interprets the SV40 lab animal data as lacking.
**Which is it? Are animal tests adequate for identifying risks or are they not?**

5. How does the FDA prevent conflicts of interest - or the appearance of conflicts of interest - when members of the Vaccine and Biological advisory board are linked to multiple pharmaceutical companies and aren’t required to list royalties as part of their financial disclosures?

6. Was the FDA or its members like Albert Monto involved in the weaponized SV40 gain of function research in the early 1960’s as described in the book ‘Dr. Mary’s Monkey?

7. Is the FDA aware of any efforts to harvest tumors from children killed by cancer after Polio vaccine innoculation?

**COVID Questions**

8. According to a contract with the US Army, Pfizer states they will reply to any information requests regarding the COVID vaccine. Do you, Paul, work for Pfizer or the FDA?

9. If the FDA can review all EMR’s for all patients, why do you rely on VEAERS data for adverse event reporting?

10. What types of punishment do doctors, hospitals and healthcare workers face for failure to report data to VAERS?

11. Why does the FDA allow publications and press releases to call the Pfizer vaccine 'Fully' approved when it is still only available via EUA?

12. Why are FDA officials allowed to signal to each other their voting opinions without punishment prior to voting?

13. The NIH and FBI as well as other agencies have disclosed upwards of 1000 different investigations of Chinese influence into clinical trials and medical research. How can the FDA and other entities ensure that COVID-19 was not part of an ongoing biological attack on the citizens of the United States?

14. Who is responsible for enforcement of ethical and criminal actions by FDA officials who fail to enforce civil or criminal penalties like the one in this article you are referenced in here?
https://www.raps.org/news-and-articles/news-articles/2020/3/fda-closes-zolgensma-data-manipulation-case-withou

15. The diagnosis for Covid and many other ailments is simple and can be done by assumption (presumed positive) in many incidents. The FDA diagnosis criteria for vaccine injury limits the diagnosis to two weeks after the second shot only. Why?

16. According to the CDC Website, the FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. Many victims claim their doctors are not reporting adverse events to VAERS. Can the FDA provide data on which providers are NOT reporting any events?

17. Would the FDA support efforts to add COVID-19 vaccine injured deaths to the FEMA Covid Burial Assistance program?

Thank you for your time.