

**From:** [CBER Ethics](#)  
**To:** [Kresge, Phillip](#); [CBER Ethics](#)  
**Cc:** [FDA Ethics Advice](#); [Erdman, Heather](#)  
**Subject:** RE: [EXTERNAL] Re: Requesting Assistance Complying with Post-Employment Restrictions  
**Date:** Monday, May 15, 2023 10:42:33 AM  
**Attachments:** [image010.png](#)  
[image016.png](#)  
[image022.png](#)

---

Hi Heather,

Doran Fink reached out to us in reference to his past duties, are you able to see if he worked on the assignments below?

He asked:

1. Was I the assigned CMC reviewer for BB-IND (b) (4) ?
2. Was I the assigned CMC reviewer for any IND submissions sponsored by (b) (4) ?

Regards,

**Cherie Jones**

*Ethics Program Specialist*

Center for Biologics Evaluation and Research (CBER)  
Office of Management (OM)  
Division of Program Services  
U.S. Food and Drug Administration  
W-301-796-8886  
C- (b) (6)  
[Cherie.Jones@fda.hhs.gov](mailto:Cherie.Jones@fda.hhs.gov)



**Ethics Website:**

<https://fda.sharepoint.com/sites/CBER-OneOM/SitePages/CBER-Ethics.aspx>

---

**From:** Kresge, Phillip <Phillip.Kresge@fda.hhs.gov>  
**Sent:** Monday, May 15, 2023 10:21 AM  
**To:** CBER Ethics <CBERethics@fda.hhs.gov>  
**Cc:** FDA Ethics\_Advice <FDAethics\_Advice@fda.hhs.gov>  
**Subject:** RE: [EXTERNAL] Re: Requesting Assistance Complying with Post-Employment Restrictions

Hi CBER Ethics,

Just following up on this inquiry. Would we be able to find this information for him, please?

Thank you,

**Phillip Kresge**

*Ethics Specialist*

Office of Operations

Office of Ethics and Integrity

U.S. Food and Drug Administration

Tel: 301-796-2754

Email: [Phillip.Kresge@fda.hhs.gov](mailto:Phillip.Kresge@fda.hhs.gov)



---

**From:** Kresge, Phillip

**Sent:** Tuesday, May 9, 2023 8:41 AM

**To:** CBER Ethics <[CBEREthics@fda.hhs.gov](mailto:CBEREthics@fda.hhs.gov)>

**Cc:** FDA Ethics\_Advice <[FDAEthics\\_Advice@fda.hhs.gov](mailto:FDAEthics_Advice@fda.hhs.gov)>

**Subject:** FW: [EXTERNAL] Re: Requesting Assistance Complying with Post-Employment Restrictions

Hi CBER Ethics,

Do you have any way of looking up whether Doran Fink ("Don") was involved in the following two particular matters, please?

He asked:

1. Was I the assigned CMC reviewer for BB-IND (b) (4) ?
2. Was I the assigned CMC reviewer for any IND submissions sponsored by (b) (4) ?

Thank you,

**Phillip Kresge**

*Ethics Specialist*

Office of Operations

Office of Ethics and Integrity

U.S. Food and Drug Administration

Tel: 301-796-2754

Email: [Phillip.Kresge@fda.hhs.gov](mailto:Phillip.Kresge@fda.hhs.gov)



---

**From:** FDA Ethics\_Advice <[FDAEthics\\_Advice@fda.hhs.gov](mailto:FDAEthics_Advice@fda.hhs.gov)>

**Sent:** Tuesday, May 9, 2023 8:39 AM

**To:** Don Fink <(b) (6)@darkhorseconsultinggroup.com>

**Cc:** FDA Ethics\_Advice <[FDAEthics\\_Advice@fda.hhs.gov](mailto:FDAEthics_Advice@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] Re: Requesting Assistance Complying with Post-Employment Restrictions

Hi Don,

We do not have access to this information, but I will reach out to CBER Ethics to see what they can find.

Kindest regards,

**Phillip Kresge**

*Ethics Specialist*

**Office of Operations**

**Office of Ethics and Integrity**

**U.S. Food and Drug Administration**

Tel: 301-796-2754

Email: [Phillip.Kresge@fda.hhs.gov](mailto:Phillip.Kresge@fda.hhs.gov)



---

**From:** Don Fink <(b) (6)@darkhorseconsultinggroup.com>

**Sent:** Monday, May 8, 2023 11:06 PM

**To:** FDA Ethics\_Advice <[FDAEthics\\_Advice@fda.hhs.gov](mailto:FDAEthics_Advice@fda.hhs.gov)>

**Subject:** [EXTERNAL] Re: Requesting Assistance Complying with Post-Employment Restrictions

**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.

Dear FDA Ethics Official,

Just a quick note as a follow-up to my original email sent 02May2023. In the absence of any specific instructions, I am presuming that I am not conflict restricted with respect to the request from the named party, (b) (4), to provide representational participation before the Agency at a Formal Meeting at their bequest and on their behalf.

Respectfully,

*Don Fink*

**Don Fink, PhD** (*he/him/his*)

Master Practice Expert, Regulatory

**Dark Horse Consulting Group**

(408) 326-0303 | Ext. 226



The contents of this e-mail, including any attachments, are for the sole use of the intended recipient(s) and may contain confidential or privileged information. If you are not the intended recipient, any use, disclosure, or distribution of this e-mail or its attachments is prohibited. If you are not the intended recipient, please notify the sender by reply e-mail and destroy all copies of this e-mail and any attachments.

---

**From:** Don Fink <(b) (6)@darkhorseconsultinggroup.com>

**Date:** Tuesday, May 2, 2023 at 1:31 PM

**To:** [fdaethics\\_advice@fda.hhs.gov](mailto:fdaethics_advice@fda.hhs.gov) <[fdaethics\\_advice@fda.hhs.gov](mailto:fdaethics_advice@fda.hhs.gov)>

**Subject:** FW: Requesting Assistance Complying with Post-Employment Restrictions

Dear FDA Ethics Official,

I am forwarding you this short e-mail chain per the recommendation of Regulatory Project Management staff in the FDA Center for Biologics Evaluation and Research, Office of Therapeutic Products.

I am contacting the agency as a matter of due diligence with respect to compliance with post-employment restrictions. As a former FDA/CBER/OTAT/DCGT/CTB employee now working in the private sector for the past 2.5-years as a CMC consultant, I am aware of and familiar with the restrictions outlined in the Summary of Post-Employment Restrictions (January 2022). I am seeking specific counsel from the agency to ensure that I remain in compliance with the following two restrictions that are applicable to All Employees (I was not a "Senior Employee" at any time during my FDA career):

**18 US Code 207(a)(1) Permanent Ban on "Switching Sides."** Former employees are subject to a lifetime ban on communicating to or appearing before the Government on behalf of their new employer or anyone else regarding specific party matters in which they participated personally and substantially during their entire government service.

**18 US Code 207(a)(2) Two-Year Official Responsibility Provision.** For two years after leaving federal employment, former employees cannot make representational communications to or appearances before the Government regarding specific party matters that were pending under their official responsibility during their last year of government service.

I am respectfully requesting agency assistance with respect to the following:

1. Was I the assigned CMC reviewer for BB-IND (b) (4) ?
2. Was I the assigned CMC reviewer for any IND submissions sponsored by (b) (4) ?

Project management staff in FDA/CBER/OTP has indicated I contact the Office of Ethics Integrity with respect to this request.

Thank you in advance for your assistance addressing this matter.

Respectfully,

*Don Fink*

**Don Fink, PhD** (*he/him/his*)  
Master Practice Expert, Regulatory

**Dark Horse Consulting Group**  
(408) 326-0303 | Ext. 226

[Darkhorseconsultinggroup.com](https://Darkhorseconsultinggroup.com)



The contents of this e-mail, including any attachments, are for the sole use of the intended recipient(s) and may contain confidential or privileged information. If you are not the intended recipient, any use, disclosure, or distribution of this e-mail or its attachments is prohibited. If you are not the intended recipient, please notify the sender by reply e-mail and destroy all copies of this e-mail and any attachments.

---

**From:** Erdman, Heather <[Heather.Erdman@fda.hhs.gov](mailto:Heather.Erdman@fda.hhs.gov)>

**Date:** Tuesday, May 2, 2023 at 12:21 PM

**To:** Don Fink <(b) (6) [@darkhorseconsultinggroup.com](mailto:@darkhorseconsultinggroup.com)>

**Cc:** OTP RPMS <[OTPRPMS@fda.hhs.gov](mailto:OTPRPMS@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] Requesting Your Assistance Complying with Post-Employment Restrictions

Dear Dr. Fink:

Thank you for reaching out to us. It may be more appropriate for you to contact [fdaethics\\_advice@fda.hhs.gov](mailto:fdaethics_advice@fda.hhs.gov) (or via ph# 240-402-1111), in order to comply with the Summary of Post-Employment Restrictions (January 2022). They can contact us about past file involvement. I hope this helps.

Best regards,

*Heather*

**Heather Erdman, MCPM, RAC (US,EU), CQPA (she/her/hers)**

Chief, Regulatory Review Branch 1

Division Review Management & Regulatory Review 1 (DRMRR1)

Office of Review Management & Regulatory Review (**ORMRR**)

Office of Therapeutic Products (OTP)

Center for Biologics Evaluation and Research | U.S. Food and Drug Administration

Tel: 240.402.8055 (Office) | Tel: (b) (6) (Mobile) | [Heather.Erdman@fda.hhs.gov](mailto:Heather.Erdman@fda.hhs.gov)

**ORMRR's Mission:** To support the growing needs of our nation to enhance biological products in a safe and ethical manner within a dynamic environment. We provide regulatory and scientific expertise through our exceptional customer-service to OTP and external stakeholders protecting public health and advancing innovation in therapeutic products



"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone."

---

**From:** Don Fink <(b) (6)@darkhorseconsultinggroup.com>

**Sent:** Monday, May 1, 2023 11:36 PM

**To:** OTP RPMS <[OTPRPMS@fda.hhs.gov](mailto:OTPRPMS@fda.hhs.gov)>

**Subject:** [EXTERNAL] Requesting Your Assistance Complying with Post-Employment Restrictions

**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.

Greetings!

As a former FDA/CBER/OTAT/DCGT/CTB employee now working in the private sector as a CMC consultant, I am seeking your assistance verifying that I am not conflicted with respect to representing a Client before the Agency (FDA/CBER) as outlined in the Summary of Post-Employment Restrictions (January 2022).

I am respectfully requesting your assistance with respect to the following:

1. Was I the assigned CMC reviewer for BB-IND (b) (4) ?
2. Was I the assigned CMC reviewer for any IND submissions sponsored by (b) (4) ?

Thank you in advance for your assistance addressing this matter of Ethics Integrity.

Best,

*Don Fink*

**Don Fink, PhD** (*he/him/his*)  
Master Practice Expert, Regulatory

**Dark Horse Consulting Group**  
(408) 326-0303 | Ext. 226

[Darkhorseconsultinggroup.com](http://Darkhorseconsultinggroup.com)



The contents of this e-mail, including any attachments, are for the sole use of the intended recipient(s) and may contain confidential or privileged information. If you are not the intended recipient, any use, disclosure, or distribution of this e-mail or its attachments is prohibited. If you are not the intended recipient, please notify the sender by reply e-mail and destroy all copies of this e-mail and any attachments.