

From: [Erdman, Heather](#)
To: [CBER Ethics](#); [Kresge, Phillip](#)
Cc: [FDA Ethics Advice](#)
Subject: RE: [EXTERNAL] Re: Requesting Assistance Complying with Post-Employment Restrictions
Date: Monday, May 15, 2023 11:05:25 AM
Attachments: [image002.png](#)
[image008.png](#)
[image014.png](#)

Hi Cherie,

1.

(b) (4)

 - a. Doran Fink was NOT on the review team for
 - b. Nor does it appear that he was routed an individual amendment for a consult review.
 - c. I cannot attest as to whether he was involved in a supervisory or team lead review role for staff reviewing this submission
2. We have two INDs in our system, from “

(b) (4)

 ” (nothing under “

(b) (4)

 ” alone): IND

(b) (4)

 and IND

(b) (4)

 - a. Doran Fink was not on the review team for IND

(b) (4)
 - b. Nor does it appear that he was routed an amendment for a consult review, IND

(b) (4)
 - c. I cannot attest as to whether he was involved in a supervisory or team lead review role for staff reviewing this submission

Please feel free to reach out if you have any questions.

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

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



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From: CBER Ethics <CBEREthics@fda.hhs.gov>

Sent: Monday, May 15, 2023 10:43 AM

To: Kresge, Phillip <Phillip.Kresge@fda.hhs.gov>; CBER Ethics <CBEREthics@fda.hhs.gov>

Cc: FDA Ethics_Advice <FDAEthics_Advice@fda.hhs.gov>; Erdman, Heather <Heather.Erdman@fda.hhs.gov>

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

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



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



From: Kresge, Phillip

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

To: CBER Ethics <CBEREthics@fda.hhs.gov>

Cc: FDA Ethics_Advice <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



From: FDA Ethics_Advice <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>

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



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

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

To: FDA Ethics_Advice <FDAEthics_Advice@fda.hhs.gov>

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

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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



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

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

To: fdaethics_advice@fda.hhs.gov <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



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From: Erdman, Heather <Heather.Erdman@fda.hhs.gov>

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

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

Cc: OTP RPMS <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 (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

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

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

To: OTP RPMS <OTPRPMS@fda.hhs.gov>

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

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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

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(408) 326-0303 | Ext. 226

Darkhorseconsultinggroup.com



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