

From: Fain, Kevin (NIH/NLM/NCBI) [E]
Sent: Fri, 3 May 2019 14:23:19 +0000
To: Berger, Adam (NIH/OD) [E];Plank-Bazinet, Jennifer (NIH/OD) [E];Tonsing-Carter, Alyssa (NIH/OD) [E];Paltoo, Dina (NIH/NLM) [E]
Cc: Williams, Rebecca (NIH/NLM/NCBI) [E];Fine, Anna (NIH/NLM/NCBI) [E]
Subject: NLM Slides for Bi-Monthly Discussion with OSP
Attachments: OSP Bimonthly Project Briefing (3 May 2019) Final.pptx

Dear all – Becky, Anna, and I just wanted to provide our slides that we will walk through and discuss with you at today’s bi-monthly meeting. We are looking forward to speaking with you. Thanks again.

Best, Kevin

Kevin M. Fain, JD, MPH, DrPH
Senior Advisor for Policy and Research, ClinicalTrials.gov
National Library of Medicine
National Institutes of Health
301-435-3142
kevin.fain@nih.gov

NLM Proposal for Implementing Notices of Violations

Page 003 of 220 to Page 009 of 220

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

From: Fain, Kevin (NIH/NLM/NCBI) [E]
Sent: Thu, 9 May 2019 22:17:17 +0000
To: Plank-Bazinet, Jennifer (NIH/OD) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]; Fine, Anna (NIH/NLM/NCBI) [E]
Cc: Sheehan, Jerry (NIH/NLM) [E]; Paltoo, Dina (NIH/NLM) [E]; Berger, Adam (NIH/OD) [E]
Subject: RE: FDA Letter Templates for Formal Review and Clearance
Attachments: Pre-Notice Template-Registration-OCC reviewed clean_KMF2 RJW.docx, Pre-Notice Template-Results-OCC reviewed clean_KMF2.docx, Notice Template-Registration_OCC reviewed clean_KMF2.docx, Notice Template-Results_OCC reviewed clean_KMF2.docx, FDA_Templates_Info_to_NLM_5_9_2019.docx



Hi Jennifer – thanks for your understanding about the timing. I wanted to let you know that we have completed our review of the FDA template letters and have incorporated comments and some suggested edits in the Pre-Notice and Notice of Noncompliance letters for the failure to register and submit results, which I have attached. (b)(5)

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We also wanted to note just a few additional points:

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Please let me know if I can help with any questions or follow-up on anything. We're happy to discuss further. Thanks again for your help.

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From: Plank-Bazinet, Jennifer (NIH/OD) [E]
Sent: Wednesday, May 08, 2019 5:37 PM
To: Fain, Kevin (NIH/NLM/NCBI) [E] <kevin.fain@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>
Cc: Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Paltoo, Dina (NIH/NLM) [E] <dina.paltoo@nih.gov>; Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Subject: RE: FDA Letter Templates for Formal Review and Clearance

Hi Kevin,

Proposed Template for FDA to Provide Information to NLM for Notice of Violations (5-1-2019)

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Proposed Template for FDA to Provide Information to NLM for Notice of Violations (5-1-2019)

(b)(5)

(b)(5)

From: Berger, Adam (NIH/OD) [E]
Sent: Mon, 13 May 2019 16:33:38 +0000
To: McNeilly, Patrick; Foltz, Bridget A (FDA/OC); Norton, Marci (FDA/OC); Katz, Donna (FDA/OC); Brown, Sheila (OGCP) (FDA/OC); Flamberg, Gemma (FDA/OC); Paltoo, Dina (NIH/NLM) [E]; Fain, Kevin (NIH/NLM/NCBI) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]; Fine, Anna (NIH/NLM/NCBI) [E]; Dean, Diane (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Hammond, Christopher (NIH/OD) [E]
Cc: Less, Joanne (FDA/OC); McInerney, Julia (NIH/OD) [E]; Plank-Bazinet, Jennifer (NIH/OD) [E]; Tonsing-Carter, Alyssa (NIH/OD) [E]
Subject: RE: ClinicalTrials.gov Letter Sharing
Attachments: NLM_Violations_Proposal_Presentation_13 May 2019 .pptx

Hi Pat,

Attached is a PPT presentation that NLM would like to walk through for today's call.

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



-----Original Appointment-----

From: McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>
Sent: Wednesday, April 24, 2019 11:23 AM
To: McNeilly, Patrick; Foltz, Bridget A (FDA/OC); Norton, Marci (FDA/OC); Katz, Donna (FDA/OC); Brown, Sheila (OGCP) (FDA/OC); Flamberg, Gemma (FDA/OC); Paltoo, Dina (NIH/NLM) [E]; Fain, Kevin (NIH/NLM/NCBI) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]; Fine, Anna (NIH/NLM/NCBI) [E]; Dean, Diane (NIH/OD) [E]; Berger, Adam (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Hammond, Christopher (NIH/OD) [E]
Cc: Less, Joanne (FDA/OC); McInerney, Julia (NIH/OD) [E]; Plank-Bazinet, Jennifer (NIH/OD) [E]; Tonsing-Carter, Alyssa (NIH/OD) [E]
Subject: ClinicalTrials.gov Letter Sharing
When: Monday, May 13, 2019 3:00 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: WO32, Room 4242 or Via Webex

Updating with Agenda:

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NIH – please let us know if there is anything else you wish to add.

Follow-up meeting on sharing FDA Notices of Noncompliance with NIH.

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Meeting password:

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IMPORTANT NOTICE: Please note that this Webex service allows audio and other information sent during the session to be recorded, which may be discoverable in a legal matter. By joining this session, you automatically consent to such recordings. If you do not consent to being recorded, discuss your concerns with the host or do not join the session.

NLM Proposal for Implementing Notices of Violations

May 13, 2019

Page 016 of 220 to Page 036 of 220

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of the Freedom of Information and Privacy Act

From: Plank-Bazinet, Jennifer (NIH/OD) [E]
Sent: Thu, 23 May 2019 20:18:50 +0000
To: Berger, Adam (NIH/OD) [E]
Cc: Plude, Denise (NIH/OD) [E]
Subject: FW: FOR YOUR APPROVAL: FW: FDA Letter Templates for Formal Review and Clearance
Attachments: Pre-Notice Template-Registration-OCC reviewed clean_KMF2 RJW_JPB.docx, Pre-Notice Template-Results-OCC reviewed clean_KMF2_JPB.docx, FDA_Templates_Info_to_NLM_5_9_2019.docx, Notice Template-Results_OCC reviewed clean_KMF2_JPB.docx, Notice Template-Registration_OCC reviewed clean_KMF2_JPB.docx

As I mentioned in our meeting.

From: Plank-Bazinet, Jennifer (NIH/OD) [E]
Sent: Sunday, May 12, 2019 7:16 PM
To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Subject: FOR YOUR APPROVAL: FW: FDA Letter Templates for Formal Review and Clearance

Hi Adam,

I reviewed the information sent over by NLM. Many of their comments are carried through on all of the documents. Therefore, start with the file "Pre-Notice Template-Registration-OCC reviewed clean_KMF2 RJW_JPB.docx". I did not carry all of my comments through all of the other documents.

(b)(5) "FDA_Templates_Info_to_NLM_5_9_2019".

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You and I have our one on one tomorrow, so we could discuss these then, if time permits.

Thanks,

Jennifer

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Sent: Thursday, May 09, 2019 6:17 PM
To: Plank-Bazinet, Jennifer (NIH/OD) [E] <jennifer.bazinet@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>
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We also wanted to note just a few additional points:

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Please let me know if I can help with any questions or follow-up on anything. We're happy to discuss further. Thanks again for your help.

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Cc: Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Paltoo, Dina (NIH/NLM) [E] <dina.paltoo@nih.gov>; Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
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Cc: Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Paltoo, Dina (NIH/NLM) [E]

<dina.paltoo@nih.gov>; Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>

Subject: RE: FDA Letter Templates for Formal Review and Clearance

Hi Jennifer – Becky and I wanted to let you know that we will need just a bit more time to provide you with our comments on the FDA letter templates. We will plan to provide you our comments as soon as possible tomorrow if that's ok? Sorry for the delay and thanks again for your help.

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To: Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Fain, Kevin (NIH/NLM/NCBI) [E] <kevin.fain@nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>

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Subject: FW: FDA Letter Templates for Formal Review and Clearance

Hi Becky, Kevin, and Anna,

(b)(5)

Thanks!

Jennifer

From: McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>

Sent: Friday, April 12, 2019 2:16 PM

To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Ampey, Bryan (NIH/OD) [E] <bryan.ampey@nih.gov>; Fain, Kevin (NIH/NLM/NCBI) [E] <kevin.fain@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Paltoo, Dina (NIH/NLM) [E] <dina.paltoo@nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Elliott, Kristina (NIH/NLM/NCBI) [C] <kristina.elliott@nih.gov>

Cc: Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>

Subject: FDA Letter Templates for Formal Review and Clearance

Good afternoon NIH,

(b)(5)

- Pre-Notice Template - Failure to Register
- Pre-Notice Template - Failure to Submit Results
- Pre-Notice Template - Failure to Certify
- Notice of Noncompliance Template - Failure to Register
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Best.

Pat McNeilly

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Proposed Template for FDA to Provide Information to NLM for Notice of Violations (5-1-2019)

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Sent: Tue, 11 Jun 2019 21:29:45 +0000
To: Plank-Bazinet, Jennifer (NIH/OD) [E]
Cc: Plude, Denise (NIH/OD) [E]
Subject: RE: FOR YOUR APPROVAL: FW: FDA Letter Templates for Formal Review and Clearance
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Really late but I've reviewed. I stopped carrying my comments through but trust you will capture when you carry yours over as well. Let me know if you want to discuss anything.

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



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Sent: Thursday, May 23, 2019 4:19 PM
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Pat McNeilly

Patrick J. McNeilly, Ph.D.

Captain, USPHS

Senior Health Policy Analyst

Office of the Commissioner
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Tel: 301-796-2941

patrick.mcneilly@fda.hhs.gov



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Sent: Fri, 14 Jun 2019 20:39:14 +0000
To: McNeilly, Patrick (FDA/OC)
Cc: Berger, Adam (NIH/OD) [E];Jorgenson, Lyric (NIH/OD) [E];Ampey, Bryan (NIH/OD) [E];Fain, Kevin (NIH/NLM/NCBI) [E];Williams, Rebecca (NIH/NLM/NCBI) [E];Tonsing-Carter, Alyssa (NIH/OD) [E];Sheehan, Jerry (NIH/NLM) [E];Paltoo, Dina (NIH/NLM) [E];Fine, Anna (NIH/NLM/NCBI) [E];Elliott, Kristina (NIH/NLM/NCBI) [C];Foltz, Bridget A (FDA/OC);Brown, Sheila (OGCP) (FDA/OC);Katz, Donna (FDA/OC);Norton, Marci (FDA/OC);Hammond, Christopher (NIH/OD) [E];Merlis, Maura (NIH/OD) [E];Flamberg, Gemma (FDA/OC)
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Hi Pat,

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Please let us know if you have any questions on concerns. Have a great weekend!

Jennifer

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(NIH/NLM/NCBI) [C] <kristina.elliott@nih.gov>

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Pat McNeilly

Patrick J. McNeilly, Ph.D.

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Tel: 301-796-2941
patrick.mcneilly@fda.hhs.gov



Proposed Template for FDA to Provide Information to NLM for Notice of Violations (5-1-2019)

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Proposed Template for FDA to Provide Information to NLM for Notice of Violations (5-1-2019)

(b)(5)

(b)(5)

From: Fine, Anna (NIH/NLM/NCBI) [E]
Sent: Fri, 14 Aug 2020 16:59:34 +0000
To: Berger, Adam (NIH/OD) [E]
Cc: Culp, Michelle (NIH/OD) [E];Tonsing-Carter, Alyssa (NIH/OD) [E];Williams, Rebecca (NIH/NLM/NCBI) [E]
Subject: RE: Review of Transfer of Notices of Noncompliance
Attachments: Transfer of Notices of Noncompliance_02-04-2020 (004) - OGC 2.24.20 NLM3 OSP.docx, Violation-Notices (24 Sept 2019)_For_FDA - FDA Comments_NLM_Response_27 Nov 2019 - OGC 2.24.20 NLM2AF7.30.pptx

Hi Adam,
We made edits to the mock-ups to now include the non-compliance statement and also to the process document to reflect our discussion from July 24.
Let us know if you need anything before sending back to FDA.

Thank you,
Anna

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Sent: Monday, July 27, 2020 5:08 PM
To: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; McNeilly, Patrick (FDA/OC) <Patrick.Mcneilly@fda.hhs.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerny, Julia (NIH/OD) [E] <julia.mcinerny@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>
Cc: Hardesty, Rebecca (NIH/OD) [E] <rebecca.hardesty@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>; Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi all,

Just want to thank everyone for the great call on Friday. Always a good outcome when we are able to

(b)(5)

(b)(5)

Action items:

(b)(5)

Thanks all!

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



-----Original Appointment-----

From: Plude, Denise (NIH/OD) [E] **On Behalf Of** Berger, Adam (NIH/OD) [E]

Sent: Wednesday, July 1, 2020 3:56 PM

To: Berger, Adam (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; McNeilly, Patrick (FDA/OC); Less, Joanne (FDA/OC); Markert, David (FDA/OC); Foltz, Bridget A (FDA/OC); Jorgenson, Lyric (NIH/OD) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]; Hammond, Christopher (NIH/OD) [E]; McInerney, Julia (NIH/OD) [E]; Sheehan, Jerry (NIH/NLM) [E]; Fine, Anna (NIH/NLM/NCBI) [E]; Merlis, Maura (NIH/OD) [E]; Zayas Caban, Teresa (NIH/NLM) [E]; Norton, Marci (FDA/OC); Katz, Donna (FDA/OC); Flamberg, Gemma (FDA/OC)

Cc: Hardesty, Rebecca (NIH/OD) [E]; Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov); Brown, Sheila (OGCP)

Subject: Review of Transfer of Notices of Noncompliance

When: Friday, July 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: webex

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Draft Process for Transfer of Information Related to Notices of Noncompliance

(b)(5)

Page 056 of 220 to Page 086 of 220

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

From: Fine, Anna (NIH/NLM/NCBI) [E]
Sent: Tue, 25 Aug 2020 20:15:40 +0000
To: Berger, Adam (NIH/OD) [E]
Cc: Culp, Michelle (NIH/OD) [E]; Tonsing-Carter, Alyssa (NIH/OD) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]
Subject: RE: Review of Transfer of Notices of Noncompliance


Hi Adam,

Thanks for reviewing and suggesting an alternative approach, those sound great to us please do send forward to FDA with those edits.

Anna

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Sent: Friday, August 21, 2020 4:35 PM
To: Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>
Cc: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Anna,

(b)(5)

Suggesting edit to the following:

(b)(5)

(b)(5)

Let us know your thoughts on the above. We will send to FDA after hearing back from you.

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>
Sent: Friday, August 14, 2020 1:00 PM
To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Cc: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

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To: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; McNeilly, Patrick (FDA/OC) <Patrick.Mcneilly@fda.hhs.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerney, Julia (NIH/OD) [E] <julia.mcinerney@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>
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<alyssa.tonsing-carter@nih.gov>; Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>

Subject: RE: Review of Transfer of Notices of Noncompliance

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Action items:

(b)(5)

Thanks all!

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



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From: Plude, Denise (NIH/OD) [E] **On Behalf Of** Berger, Adam (NIH/OD) [E]

Sent: Wednesday, July 1, 2020 3:56 PM

To: Berger, Adam (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; McNeilly, Patrick (FDA/OC); Less, Joanne (FDA/OC); Markert, David (FDA/OC); Foltz, Bridget A (FDA/OC); Jorgenson, Lyric (NIH/OD) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]; Hammond, Christopher (NIH/OD) [E]; McInerny, Julia (NIH/OD) [E]; Sheehan, Jerry (NIH/NLM) [E]; Fine, Anna (NIH/NLM/NCBI) [E]; Merlis, Maura (NIH/OD) [E]; Zayas Caban, Teresa (NIH/NLM) [E]; Norton, Marci (FDA/OC); Katz, Donna (FDA/OC); Flamberg, Gemma (FDA/OC)
Cc: Hardesty, Rebecca (NIH/OD) [E]; Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov); Brown, Sheila (OGCP)
Subject: Review of Transfer of Notices of Noncompliance
When: Friday, July 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: webex

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From: Berger, Adam (NIH/OD) [E]
Sent: Mon, 31 Aug 2020 21:18:03 +0000
To: Berger, Adam (NIH/OD) [E];Culp, Michelle (NIH/OD) [E];McNeilly, Patrick (FDA/OC);Less, Joanne (FDA/OC);Markert, David (FDA/OC);Foltz, Bridget A (FDA/OC);Jorgenson, Lyric (NIH/OD) [E];Williams, Rebecca (NIH/NLM/NCBI) [E];Hammond, Christopher (NIH/OD) [E];McInerney, Julia (NIH/OD) [E];Sheehan, Jerry (NIH/NLM) [E];Fine, Anna (NIH/NLM/NCBI) [E];Merlis, Maura (NIH/OD) [E];Zayas Caban, Teresa (NIH/NLM) [E];Norton, Marci (FDA/OC);Katz, Donna (FDA/OC);Flamberg, Gemma (FDA/OC)
Cc: Hardesty, Rebecca (NIH/OD) [E];Brown, Sheila (OGCP) (FDA/OC)
Subject: RE: Review of Transfer of Notices of Noncompliance
Attachments: Violation-Notices (24 Sept 2019)_For_FDA - FDA Comments_NLM_Response_27 Nov 2019 - OGC 2.24.20 NLM2AF7.30.pptx, Transfer of Notices of Noncompliance_02-04-2020 (004) - OGC 2.24.20 NLM3 OSP.docx, Transfer of Notices of Noncompliance_02-04-2020 (004) - OGC 2.24.20 NLM3 OSP clean.docx

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As a reminder, here are the outstanding action items from the call:

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Sent: Monday, July 27, 2020 5:08 PM
To: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; McNeilly, Patrick (FDA/OC) <Patrick.Mcneilly@fda.hhs.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerney, Julia (NIH/OD) [E] <julia.mcinerney@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayasocaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>
Cc: Hardesty, Rebecca (NIH/OD) [E] <rebecca.hardesty@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>; Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>
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Office of the Director | National Institutes of Health
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adam.berger@nih.gov | (301) 827-9676



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Sent: Wednesday, July 1, 2020 3:56 PM

To: Berger, Adam (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; McNeilly, Patrick (FDA/OC); Less, Joanne (FDA/OC); Markert, David (FDA/OC); Foltz, Bridget A (FDA/OC); Jorgenson, Lyric (NIH/OD) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]; Hammond, Christopher (NIH/OD) [E]; McInerney, Julia (NIH/OD) [E];

Sheehan, Jerry (NIH/NLM) [E]; Fine, Anna (NIH/NLM/NCBI) [E]; Merlis, Maura (NIH/OD) [E]; Zayas Caban, Teresa (NIH/NLM) [E]; Norton, Marci (FDA/OC); Katz, Donna (FDA/OC); Flamberg, Gemma (FDA/OC)

Cc: Hardesty, Rebecca (NIH/OD) [E]; Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov); Brown, Sheila (OGCP)

Subject: Review of Transfer of Notices of Noncompliance

When: Friday, July 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

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Draft Process for Transfer of Information Related to Notices of Noncompliance

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Page 095 of 220 to Page 106 of 220

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From: Berger, Adam (NIH/OD) [E]
Sent: Wed, 2 Sep 2020 21:15:23 +0000
To: Michelle (NIH/OD) Culp [E] (michelle.culp@nih.gov); Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov)
Subject: FW: Review of Transfer of Notices of Noncompliance
Attachments: Transfer of Notices of Noncompliance_02-04-2020 (004) - OGC 2.24.20 NLM3 OSP FDA clean.docx, Transfer of Notices of Noncompliance_02-04-2020 (004) - OGC 2.24.20 NLM3 OSP FDA.docx

Am I thinking about this incorrectly? (b)(5)

(b)(5)

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>
Sent: Wednesday, September 2, 2020 2:24 PM
To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerny, Julia (NIH/OD) [E] <julia.mcinerny@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>
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Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam,

(b)(5)

(b)(5)

Pat

Patrick J. McNeilly, Ph.D.

Captain, USPHS

Senior Health Policy Analyst

**Office of Good Clinical Practice
U.S. Food and Drug Administration**



This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>

Sent: Monday, August 31, 2020 5:18 PM

To: Berger, Adam C (NIH) <adam.berger@nih.gov>; Culp, Michelle A (NIH) <michelle.culp@nih.gov>; McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>; Markert, David <David.Markert@fda.hhs.gov>; Foltz, Bridget A <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric A (NIH) <lyric.jorgenson@nih.gov>; Williams, Rebecca J (NIH) <williamsre@mail.nih.gov>; Hammond, Chris W (NIH) <christopher.hammond2@nih.gov>; McInerny, Julia W (NIH) <julia.mcinerny@nih.gov>; Sheehan, Jerry R (NIH) <sheehanjr@mail.nlm.nih.gov>; Fine, Anna M (NIH) <anna.fine@nih.gov>; Merlis, Maura C (NIH) <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH) <teresa.zayascaban@nih.gov>; Norton, Marci <Marci.Norton@fda.hhs.gov>; Katz, Donna <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>

Cc: Hardesty, Rebecca S (NIH) <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) <Sheila.Brown@fda.hhs.gov>

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From: Plude, Denise (NIH/OD) [E] **On Behalf Of** Berger, Adam (NIH/OD) [E]

Sent: Wednesday, July 1, 2020 3:56 PM

To: Berger, Adam (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; McNeilly, Patrick (FDA/OC); Less, Joanne (FDA/OC); Markert, David (FDA/OC); Foltz, Bridget A (FDA/OC); Jorgenson, Lyric (NIH/OD) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]; Hammond, Christopher (NIH/OD) [E]; McInerny, Julia (NIH/OD) [E]; Sheehan, Jerry (NIH/NLM) [E]; Fine, Anna (NIH/NLM/NCBI) [E]; Merlis, Maura (NIH/OD) [E]; Zayas Caban, Teresa (NIH/NLM) [E]; Norton, Marci (FDA/OC); Katz, Donna (FDA/OC); Flamberg, Gemma (FDA/OC)

Cc: Hardesty, Rebecca (NIH/OD) [E]; Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov); Brown, Sheila (OGCP)

Subject: Review of Transfer of Notices of Noncompliance

When: Friday, July 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: webex

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Draft Process for Transfer of Information Related to Notices of Noncompliance

(b)(5)

Page 113 of 220 to Page 126 of 220

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

From: Culp, Michelle (NIH/OD) [E]
Sent: Thu, 3 Sep 2020 13:53:17 +0000
To: Berger, Adam (NIH/OD) [E]; Tonsing-Carter, Alyssa (NIH/OD) [E]
Subject: RE: Review of Transfer of Notices of Noncompliance

Agree.

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Sent: Thursday, September 3, 2020 9:50 AM
To: Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

I am relooking at what Pat wrote and (b)(5)

(b)(5)

(b)(5)

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>
Sent: Thursday, September 3, 2020 8:53 AM
To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

(b)(5)

(b)(5)

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Sent: Wednesday, September 2, 2020 5:15 PM
To: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>
Subject: FW: Review of Transfer of Notices of Noncompliance

Am I thinking about this incorrectly? (b)(5)

(b)(5)

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>
Sent: Wednesday, September 2, 2020 2:24 PM
To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerny, Julia (NIH/OD) [E] <julia.mcinerny@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>
Cc: Hardesty, Rebecca (NIH/OD) [E] <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam,

(b)(5)

(b)(5)

Pat

Patrick J. McNeilly, Ph.D.

Captain, USPHS

Senior Health Policy Analyst

**Office of Good Clinical Practice
U.S. Food and Drug Administration**



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From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>

Sent: Monday, August 31, 2020 5:18 PM

To: Berger, Adam C (NIH) <adam.berger@nih.gov>; Culp, Michelle A (NIH) <michelle.culp@nih.gov>; McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>; Markert, David <David.Markert@fda.hhs.gov>; Foltz, Bridget A <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric A (NIH) <lyric.jorgenson@nih.gov>; Williams, Rebecca J (NIH) <williamsre@mail.nih.gov>; Hammond, Chris W (NIH) <christopher.hammond2@nih.gov>; McInerny, Julia W (NIH) <julia.mcinerny@nih.gov>; Sheehan, Jerry R (NIH) <sheehanjr@mail.nlm.nih.gov>; Fine, Anna M (NIH) <anna.fine@nih.gov>; Merlis, Maura C (NIH) <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH) <teresa.zayascaban@nih.gov>; Norton, Marci <Marci.Norton@fda.hhs.gov>; Katz, Donna <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>

Cc: Hardesty, Rebecca S (NIH) <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) <Sheila.Brown@fda.hhs.gov>

Subject: RE: Review of Transfer of Notices of Noncompliance

Hi all,

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As a reminder, here are the outstanding action items from the call:

(b)(5)

Best,
Adam

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>

Sent: Monday, July 27, 2020 5:08 PM

To: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; McNeilly, Patrick (FDA/OC) <Patrick.Mcneilly@fda.hhs.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerney, Julia (NIH/OD) [E] <julia.mcinerney@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>

Cc: Hardesty, Rebecca (NIH/OD) [E] <rebecca.hardesty@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>; Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>

Subject: RE: Review of Transfer of Notices of Noncompliance

Hi all,

Just want to thank everyone for the great call on Friday. Always a good outcome when we are able to

(b)(5)

(b)(5)

Action items:

(b)(5)

Thanks all!

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



-----Original Appointment-----

From: Plude, Denise (NIH/OD) [E] **On Behalf Of** Berger, Adam (NIH/OD) [E]

Sent: Wednesday, July 1, 2020 3:56 PM

To: Berger, Adam (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; McNeilly, Patrick (FDA/OC); Less, Joanne (FDA/OC); Markert, David (FDA/OC); Foltz, Bridget A (FDA/OC); Jorgenson, Lyric (NIH/OD) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]; Hammond, Christopher (NIH/OD) [E]; McInerny, Julia (NIH/OD) [E]; Sheehan, Jerry (NIH/NLM) [E]; Fine, Anna (NIH/NLM/NCBI) [E]; Merlis, Maura (NIH/OD) [E]; Zayas Caban, Teresa (NIH/NLM) [E]; Norton, Marci (FDA/OC); Katz, Donna (FDA/OC); Flamberg, Gemma (FDA/OC)

Cc: Hardesty, Rebecca (NIH/OD) [E]; Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov); Brown, Sheila (OGCP)

Subject: Review of Transfer of Notices of Noncompliance

When: Friday, July 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

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From: Berger, Adam (NIH/OD) [E]
Sent: Thu, 10 Sep 2020 13:58:47 +0000
To: Rebecca (NIH/NLM/NCBI) Williams [E] (williamsre@mail.nih.gov)
Cc: Fine, Anna (NIH/NLM/NCBI) [E];Michelle (NIH/OD) Culp [E] (michelle.culp@nih.gov);'Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov)'
Subject: FW: Review of Transfer of Notices of Noncompliance
Attachments: Transfer of Notices of Noncompliance_02-04-2020 (004) - OGC 2.24.20 NLM3 OSP FDA clean.docx, Transfer of Notices of Noncompliance_02-04-2020 (004) - OGC 2.24.20 NLM3 OSP FDA.docx

Hi Becky,

(b)(5)

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
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Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>
Sent: Wednesday, September 2, 2020 2:24 PM
To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerny, Julia (NIH/OD) [E] <julia.mcinerny@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>;

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Cc: Hardesty, Rebecca (NIH/OD) [E] <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) (FDA/OC)
<Sheila.Brown@fda.hhs.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam,

(b)(5)

Pat

Patrick J. McNeilly, Ph.D.
Captain, USPHS

Senior Health Policy Analyst

**Office of Good Clinical Practice
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David <David.Markert@fda.hhs.gov>; Foltz, Bridget A <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric A (NIH) <lyric.jorgenson@nih.gov>; Williams, Rebecca J (NIH) <williamsre@mail.nih.gov>; Hammond, Chris W (NIH) <christopher.hammond2@nih.gov>; McInerney, Julia W (NIH) <julia.mcinerney@nih.gov>; Sheehan, Jerry R (NIH) <sheehanjr@mail.nlm.nih.gov>; Fine, Anna M (NIH) <anna.fine@nih.gov>; Merlis, Maura C (NIH) <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH) <teresa.zayascaban@nih.gov>; Norton, Marci <Marci.Norton@fda.hhs.gov>; Katz, Donna <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>

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Action items:

(b)(5)

Thanks all!

Best,
Adam

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Draft Process for Transfer of Information Related to Notices of Noncompliance

(b)(5)

Page 139 of 220 to Page 152 of 220

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of the Freedom of Information and Privacy Act

From: Berger, Adam (NIH/OD) [E]
Sent: Wed, 21 Oct 2020 20:55:52 +0000
To: Markert, David (FDA/OC);Culp, Michelle (NIH/OD) [E];Less, Joanne (FDA/OC);Foltz, Bridget A (FDA/OC);Jorgenson, Lyric (NIH/OD) [E];Williams, Rebecca (NIH/NLM/NCBI) [E];Hammond, Christopher (NIH/OD) [E];McInerny, Julia (NIH/OD) [E];Sheehan, Jerry (NIH/NLM) [E];Fine, Anna (NIH/NLM/NCBI) [E];Merlis, Maura (NIH/OD) [E];Zayas Caban, Teresa (NIH/NLM) [E];Norton, Marci (FDA/OC);Katz, Donna (FDA/OC);Flamberg, Gemma (FDA/OC)
Cc: Hardesty, Rebecca (NIH/OD) [E];Brown, Sheila (OGCP) (FDA/OC)
Subject: RE: Review of Transfer of Notices of Noncompliance
Attachments: Transfer of Notices of Noncompliance_10-19-2020 marked.docx, Transfer of Notices of Noncompliance_10-19-2020 clean.docx

Hi David,

Following up on Pat's message below. Apologies for the delay in getting back to you on this. We are

(b)(5)

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



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Hi Adam,

(b)(5)

Pat

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Senior Health Policy Analyst

**Office of Good Clinical Practice
U.S. Food and Drug Administration**



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From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Sent: Monday, August 31, 2020 5:18 PM
To: Berger, Adam C (NIH) <adam.berger@nih.gov>; Culp, Michelle A (NIH) <michelle.culp@nih.gov>; McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>; Markert,

David <David.Markert@fda.hhs.gov>; Foltz, Bridget A <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric A (NIH) <lyric.jorgenson@nih.gov>; Williams, Rebecca J (NIH) <williamsre@mail.nih.gov>; Hammond, Chris W (NIH) <christopher.hammond2@nih.gov>; McInerny, Julia W (NIH) <julia.mcinerny@nih.gov>; Sheehan, Jerry R (NIH) <sheehanjr@mail.nlm.nih.gov>; Fine, Anna M (NIH) <anna.fine@nih.gov>; Merlis, Maura C (NIH) <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH) <teresa.zayascaban@nih.gov>; Norton, Marci <Marci.Norton@fda.hhs.gov>; Katz, Donna <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>

Cc: Hardesty, Rebecca S (NIH) <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) <Sheila.Brown@fda.hhs.gov>

Subject: RE: Review of Transfer of Notices of Noncompliance

Hi all,

Just wanted to circle back with everyone on the notices of noncompliance process. Attached are the slides and process document which have been updated to reflect the agreement everyone came to on the 7/24 call (much thanks to NLM!). Please let us know if there are any concerns on either document.

As a reminder, here are the outstanding action items from the call:

(b)(5)

Best,
Adam

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>

Sent: Monday, July 27, 2020 5:08 PM

To: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; McNeilly, Patrick (FDA/OC) <Patrick.Mcneilly@fda.hhs.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerny, Julia (NIH/OD) [E] <julia.mcinerny@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>

Cc: Hardesty, Rebecca (NIH/OD) [E] <rebecca.hardesty@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>; Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>

Subject: RE: Review of Transfer of Notices of Noncompliance

Hi all,

Just want to thank everyone for the great call on Friday. Always a good outcome when we are able to

(b)(5)

(b)(5)

Action items:

(b)(5)

Thanks all!

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



-----Original Appointment-----

From: Plude, Denise (NIH/OD) [E] **On Behalf Of** Berger, Adam (NIH/OD) [E]

Sent: Wednesday, July 1, 2020 3:56 PM

To: Berger, Adam (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; McNeilly, Patrick (FDA/OC); Less, Joanne (FDA/OC); Markert, David (FDA/OC); Foltz, Bridget A (FDA/OC); Jorgenson, Lyric (NIH/OD) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]; Hammond, Christopher (NIH/OD) [E]; McInerney, Julia (NIH/OD) [E]; Sheehan, Jerry (NIH/NLM) [E]; Fine, Anna (NIH/NLM/NCBI) [E]; Merlis, Maura (NIH/OD) [E]; Zayas Caban, Teresa (NIH/NLM) [E]; Norton, Marci (FDA/OC); Katz, Donna (FDA/OC); Flamberg, Gemma (FDA/OC)

Cc: Hardesty, Rebecca (NIH/OD) [E]; Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov); Brown, Sheila (OGCP)

Subject: Review of Transfer of Notices of Noncompliance

When: Friday, July 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

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Draft Process for Transfer of Information Related to Notices of Noncompliance

(b)(5)

Page 159 of 220 to Page 169 of 220

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

From: Berger, Adam (NIH/OD) [E]
Sent: Thu, 22 Oct 2020 13:36:02 +0000
To: Markert, David
Subject: RE: Review of Transfer of Notices of Noncompliance

That sounds great. Thanks David.

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: Markert, David <David.Markert@fda.hhs.gov>
Sent: Thursday, October 22, 2020 9:18 AM
To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam,

Thank you for getting back to us. I don't have any questions right now. (b)(5)

(b)(5)

Regards,
David

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Sent: Wednesday, October 21, 2020 4:56 PM
To: Markert, David <David.Markert@fda.hhs.gov>; Culp, Michelle A (NIH) <michelle.culp@nih.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>; Foltz, Bridget A <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric A (NIH) <lyric.jorgenson@nih.gov>; Williams, Rebecca J (NIH) <williamsre@mail.nih.gov>; Hammond, Chris W (NIH) <christopher.hammond2@nih.gov>; McInerny, Julia W (NIH) <julia.mcinerny@nih.gov>; Sheehan, Jerry R (NIH) <sheehanjr@mail.nlm.nih.gov>; Fine, Anna M (NIH) <anna.fine@nih.gov>; Merlis, Maura C (NIH) <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci <Marci.Norton@fda.hhs.gov>; Katz, Donna <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>
Cc: Hardesty, Rebecca S (NIH) <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) <Sheila.Brown@fda.hhs.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi David,

Following up on Pat's message below. Apologies for the delay in getting back to you on this. We are

(b)(5)

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>

Sent: Wednesday, September 2, 2020 2:24 PM

To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerny, Julia (NIH/OD) [E] <julia.mcinerny@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>

Cc: Hardesty, Rebecca (NIH/OD) [E] <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>

Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam,

(b)(5)

(b)(5)

Pat

Patrick J. McNeilly, Ph.D.

Captain, USPHS

Senior Health Policy Analyst

**Office of Good Clinical Practice
U.S. Food and Drug Administration**



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As a reminder, here are the outstanding action items from the call:

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Best,
Adam

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Subject: RE: Review of Transfer of Notices of Noncompliance

Hi all,

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(b)(5)

(b)(5)

Action items:

(b)(5)

Thanks all!

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



-----Original Appointment-----

From: Plude, Denise (NIH/OD) [E] **On Behalf Of** Berger, Adam (NIH/OD) [E]

Sent: Wednesday, July 1, 2020 3:56 PM

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Cc: Hardesty, Rebecca (NIH/OD) [E]; Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov); Brown, Sheila (OGCP)

Subject: Review of Transfer of Notices of Noncompliance

When: Friday, July 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

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From: Berger, Adam (NIH/OD) [E]
Sent: Thu, 22 Oct 2020 13:28:03 +0000
To: Fine, Anna (NIH/NLM/NCBI) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]
Cc: Culp, Michelle (NIH/OD) [E]; Tonsing-Carter, Alyssa (NIH/OD) [E]
Subject: RE: Review of Transfer of Notices of Noncompliance
Attachments: RE: Review of Transfer of Notices of Noncompliance, image001.png, image002.png, image003.jpg, image004.jpg, image005.jpg, image006.jpg, image007.jpg

Quick update as David just responded a few mins ago. Not sure why he only responded to me. See attached.

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>
Sent: Thursday, October 22, 2020 9:25 AM
To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>
Cc: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

No worries, I was just going through my notes too in preparation for our check-in meeting on Nov 6. Thanks for moving along!

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Sent: Wednesday, October 21, 2020 4:59 PM
To: Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>
Cc: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Anna,

Sorry for this dropped ball! (b)(5)

Best,

Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
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Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>
Sent: Wednesday, October 21, 2020 2:18 PM
To: Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Cc: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi OSP colleagues,

Any updates on this one?

Thanks,
Anna

From: Fine, Anna (NIH/NLM/NCBI) [E]
Sent: Wednesday, September 30, 2020 10:44 AM
To: Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Cc: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam,

I want to follow-up on Letter of Non-Compliance, have we heard back from FDA?

Anna

From: Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>
Sent: Thursday, September 10, 2020 5:23 PM
To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>

Cc: Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam –

(b)(5)

Becky

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Sent: Thursday, September 10, 2020 9:59 AM
To: Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>
Cc: Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>
Subject: FW: Review of Transfer of Notices of Noncompliance

Hi Becky,

(b)(5)

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
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Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>
Sent: Wednesday, September 2, 2020 2:24 PM
To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Less, Joanne (FDA/OC)

<Joanne.Less@fda.hhs.gov>; Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerney, Julia (NIH/OD) [E] <julia.mcinerney@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>
Cc: Hardesty, Rebecca (NIH/OD) [E] <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam,

(b)(5)

Pat

Patrick J. McNeilly, Ph.D.

Captain, USPHS

Senior Health Policy Analyst

**Office of Good Clinical Practice
U.S. Food and Drug Administration**



✘ ✘ ✘ ✘ ✘

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Sent: Monday, August 31, 2020 5:18 PM
To: Berger, Adam C (NIH) <adam.berger@nih.gov>; Culp, Michelle A (NIH) <michelle.culp@nih.gov>; McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>; Markert, David <David.Markert@fda.hhs.gov>; Foltz, Bridget A <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric A (NIH) <lyric.jorgenson@nih.gov>; Williams, Rebecca J (NIH) <williamsre@mail.nih.gov>; Hammond, Chris W (NIH) <christopher.hammond2@nih.gov>; McInerny, Julia W (NIH) <julia.mcinerny@nih.gov>; Sheehan, Jerry R (NIH) <sheehanjr@mail.nlm.nih.gov>; Fine, Anna M (NIH) <anna.fine@nih.gov>; Merlis, Maura C (NIH) <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH) <teresa.zayascaban@nih.gov>; Norton, Marci <Marci.Norton@fda.hhs.gov>; Katz, Donna <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>
Cc: Hardesty, Rebecca S (NIH) <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) <Sheila.Brown@fda.hhs.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

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(b)(5)

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Adam

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<alyssa.tonsing-carter@nih.gov>; Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>

Subject: RE: Review of Transfer of Notices of Noncompliance

Hi all,

Just want to thank everyone for the great call on Friday. Always a good outcome when we are able to

(b)(5)

Action items:

(b)(5)

Thanks all!

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



-----Original Appointment-----

From: Plude, Denise (NIH/OD) [E] **On Behalf Of** Berger, Adam (NIH/OD) [E]

Sent: Wednesday, July 1, 2020 3:56 PM

To: Berger, Adam (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; McNeilly, Patrick (FDA/OC); Less, Joanne (FDA/OC); Markert, David (FDA/OC); Foltz, Bridget A (FDA/OC); Jorgenson, Lyric (NIH/OD) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]; Hammond, Christopher (NIH/OD) [E]; McNerny, Julia (NIH/OD) [E]; Sheehan, Jerry (NIH/NLM) [E]; Fine, Anna (NIH/NLM/NCBI) [E]; Merlis, Maura (NIH/OD) [E]; Zayas Caban, Teresa (NIH/NLM) [E]; Norton, Marci (FDA/OC); Katz, Donna (FDA/OC); Flamberg, Gemma (FDA/OC)
Cc: Hardesty, Rebecca (NIH/OD) [E]; Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov); Brown, Sheila (OGCP)
Subject: Review of Transfer of Notices of Noncompliance
When: Friday, July 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: webex

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From: Markert, David
Sent: Thu, 22 Oct 2020 13:17:39 +0000
To: Berger, Adam (NIH/OD) [E]
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam,

Thank you for getting back to us. I don't have any questions right now. (b)(5)

(b)(5)

Regards,
David

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Sent: Wednesday, October 21, 2020 4:56 PM
To: Markert, David <David.Markert@fda.hhs.gov>; Culp, Michelle A (NIH) <michelle.culp@nih.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>; Foltz, Bridget A <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric A (NIH) <lyric.jorgenson@nih.gov>; Williams, Rebecca J (NIH) <williamsre@mail.nih.gov>; Hammond, Chris W (NIH) <christopher.hammond2@nih.gov>; McInerny, Julia W (NIH) <julia.mcinerny@nih.gov>; Sheehan, Jerry R (NIH) <sheehanjr@mail.nlm.nih.gov>; Fine, Anna M (NIH) <anna.fine@nih.gov>; Merlis, Maura C (NIH) <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci <Marci.Norton@fda.hhs.gov>; Katz, Donna <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>
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Hi David,

Following up on Pat's message below. Apologies for the delay in getting back to you on this. We are

(b)(5)

(b)(5)

Let me know if you have any questions.

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>

Sent: Wednesday, September 2, 2020 2:24 PM

To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerny, Julia (NIH/OD) [E] <julia.mcinerny@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>

Cc: Hardesty, Rebecca (NIH/OD) [E] <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>

Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam,

(b)(5)

Pat

Patrick J. McNeilly, Ph.D.

Captain, USPHS

Senior Health Policy Analyst

**Office of Good Clinical Practice
U.S. Food and Drug Administration**



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Cc: Hardesty, Rebecca S (NIH) <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) <Sheila.Brown@fda.hhs.gov>

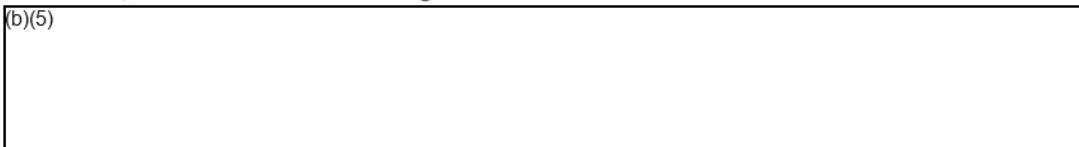
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Action items:

(b)(5)

Thanks all!

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health

6705 Rockledge Drive, Suite 750
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adam.berger@nih.gov | (301) 827-9676



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Subject: Review of Transfer of Notices of Noncompliance

When: Friday, July 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

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From: Culp, Michelle (NIH/OD) [E]
Sent: Tue, 10 Nov 2020 20:06:04 +0000
To: Markert, David (FDA/OC)
Cc: Berger, Adam (NIH/OD) [E]; Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov)
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi David,

(b)(5)

Best regards,
Michelle

From: Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>
Sent: Thursday, October 22, 2020 9:18 AM
To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam,

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(b)(5)

(b)(5)

Regards,
David

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Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam,

(b)(5)

(b)(5)

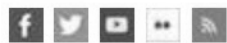
Pat

Patrick J. McNeilly, Ph.D.

Captain, USPHS

Senior Health Policy Analyst

**Office of Good Clinical Practice
U.S. Food and Drug Administration**



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Action items:

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Thanks all!

Best,
Adam

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From: Plude, Denise (NIH/OD) [E] **On Behalf Of** Berger, Adam (NIH/OD) [E]

Sent: Wednesday, July 1, 2020 3:56 PM

To: Berger, Adam (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; McNeilly, Patrick (FDA/OC); Less, Joanne (FDA/OC); Markert, David (FDA/OC); Foltz, Bridget A (FDA/OC); Jorgenson, Lyric (NIH/OD) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]; Hammond, Christopher (NIH/OD) [E]; McInerny, Julia (NIH/OD) [E]; Sheehan, Jerry (NIH/NLM) [E]; Fine, Anna (NIH/NLM/NCBI) [E]; Merlis, Maura (NIH/OD) [E]; Zayas Caban, Teresa (NIH/NLM) [E]; Norton, Marci (FDA/OC); Katz, Donna (FDA/OC); Flamberg, Gemma (FDA/OC)

Cc: Hardesty, Rebecca (NIH/OD) [E]; Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov); Brown, Sheila (OGCP)

Subject: Review of Transfer of Notices of Noncompliance

When: Friday, July 24, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: webex

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From: Berger, Adam (NIH/OD) [E]
Sent: Thu, 3 Dec 2020 14:29:18 +0000
To: Markert, David (FDA/OC);Culp, Michelle (NIH/OD) [E];Less, Joanne (FDA/OC);Foltz, Bridget A (FDA/OC);Jorgenson, Lyric (NIH/OD) [E];Williams, Rebecca (NIH/NLM/NCBI) [E];Hammond, Christopher (NIH/OD) [E];McInerney, Julia (NIH/OD) [E];Sheehan, Jerry (NIH/NLM) [E];Fine, Anna (NIH/NLM/NCBI) [E];Merlis, Maura (NIH/OD) [E];Zayas Caban, Teresa (NIH/NLM) [E];Norton, Marci (FDA/OC);Katz, Donna (FDA/OC);Flamberg, Gemma (FDA/OC);Tonsing-Carter, Alyssa (NIH/OD) [E]
Cc: Brown, Sheila (OGCP) (FDA/OC)
Subject: RE: Review of Transfer of Notices of Noncompliance
Attachments: FDAAA801ViolationSearchBox term and What's New 12.1.2020.pptx

Hi David,

(b)(5)

Much appreciated and speak with you shortly!

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Sent: Wednesday, October 21, 2020 4:56 PM
To: Markert, David <David.Markert@fda.hhs.gov>; Culp, Michelle A (NIH) <michelle.culp@nih.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>; Foltz, Bridget A <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric A (NIH) <lyric.jorgenson@nih.gov>; Williams, Rebecca J (NIH) <williamsre@mail.nih.gov>; Hammond,

Chris W (NIH) <christopher.hammond2@nih.gov>; McInerny, Julia W (NIH) <julia.mcinerny@nih.gov>; Sheehan, Jerry R (NIH) <sheehanjr@mail.nlm.nih.gov>; Fine, Anna M (NIH) <anna.fine@nih.gov>; Merlis, Maura C (NIH) <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci <Marci.Norton@fda.hhs.gov>; Katz, Donna <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>
Cc: Hardesty, Rebecca S (NIH) <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) <Sheila.Brown@fda.hhs.gov>
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adam.berger@nih.gov | (301) 827-9676



From: McNeilly, Patrick <Patrick.Mcneilly@fda.hhs.gov>
Sent: Wednesday, September 2, 2020 2:24 PM
To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerny, Julia (NIH/OD) [E] <julia.mcinerny@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>
Cc: Hardesty, Rebecca (NIH/OD) [E] <rebecca.hardesty@nih.gov>; Brown, Sheila (OGCP) (FDA/OC)

<Sheila.Brown@fda.hhs.gov>

Subject: RE: Review of Transfer of Notices of Noncompliance

Hi Adam,

(b)(5)

Pat

Patrick J. McNeilly, Ph.D.

Captain, USPHS

Senior Health Policy Analyst

**Office of Good Clinical Practice
U.S. Food and Drug Administration**



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Sheehan, Jerry R (NIH) <sheehanjr@mail.nlm.nih.gov>; Fine, Anna M (NIH) <anna.fine@nih.gov>; Merlis, Maura C (NIH) <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH) <teresa.zayascaban@nih.gov>; Norton, Marci <Marci.Norton@fda.hhs.gov>; Katz, Donna <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>

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<teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>

Cc: Hardesty, Rebecca (NIH/OD) [E] <rebecca.hardesty@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>; Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>

Subject: RE: Review of Transfer of Notices of Noncompliance

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Action items:

(b)(5)

Thanks all!

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



-----Original Appointment-----

From: Plude, Denise (NIH/OD) [E] **On Behalf Of** Berger, Adam (NIH/OD) [E]

Sent: Wednesday, July 1, 2020 3:56 PM

To: Berger, Adam (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; McNeilly, Patrick (FDA/OC); Less, Joanne (FDA/OC); Markert, David (FDA/OC); Foltz, Bridget A (FDA/OC); Jorgenson, Lyric (NIH/OD) [E]; Williams, Rebecca (NIH/NLM/NCBI) [E]; Hammond, Christopher (NIH/OD) [E]; McInerney, Julia (NIH/OD) [E]; Sheehan, Jerry (NIH/NLM) [E]; Fine, Anna (NIH/NLM/NCBI) [E]; Merlis, Maura (NIH/OD) [E]; Zayas Caban, Teresa (NIH/NLM) [E]; Norton, Marci (FDA/OC); Katz, Donna (FDA/OC); Flamberg, Gemma (FDA/OC)

Cc: Hardesty, Rebecca (NIH/OD) [E]; Alyssa (NIH/OD) Tonsing-Carter [E] (alyssa.tonsing-carter@nih.gov); Brown, Sheila (OGCP)

Subject: Review of Transfer of Notices of Noncompliance

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Page 201 of 220 to Page 206 of 220

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(b)(5)

of the Freedom of Information and Privacy Act

From: Fine, Anna (NIH/NLM/NCBI) [E]
Sent: Thu, 3 Dec 2020 14:35:19 +0000
To: Berger, Adam (NIH/OD) [E]
Subject: RE: Review of Transfer of Notices of Noncompliance

Thank you Adam!

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Sent: Thursday, December 3, 2020 9:29 AM
To: Markert, David (FDA/OC) <David.Markert@fda.hhs.gov>; Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>; McInerny, Julia (NIH/OD) [E] <julia.mcinerney@nih.gov>; Sheehan, Jerry (NIH/NLM) [E] <sheehanjr@mail.nlm.nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>; Merlis, Maura (NIH/OD) [E] <maura.merlis@nih.gov>; Zayas Caban, Teresa (NIH/NLM) [E] <teresa.zayascaban@nih.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>
Cc: Brown, Sheila (OGCP) (FDA/OC) <Sheila.Brown@fda.hhs.gov>
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Sent: Wednesday, October 21, 2020 4:56 PM

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Senior Health Policy Analyst

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From: Fine, Anna (NIH/NLM/NCBI) [E]
Sent: Fri, 19 Feb 2021 17:56:23 +0000
To: Berger, Adam (NIH/OD) [E];Culp, Michelle (NIH/OD) [E]
Cc: Griffing, Derek (NIH/NLM/NCBI) [E];Williams, Rebecca (NIH/NLM/NCBI) [E]
Subject: RE: Procedures for Transmitting Notices of Noncompliance to NIH
Attachments: NLM SOP - FDA Notice of NonCompliance 2.19.21.docx, FDA Metadata TemplateNLMedit.docx

Hi Adam,

(b)(5)

Thanks,
Anna

From: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Sent: Friday, January 29, 2021 4:48 PM
To: Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>
Cc: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Tonsing-Carter, Alyssa (NIH/OD) [E] <alyssa.tonsing-carter@nih.gov>; Fine, Anna (NIH/NLM/NCBI) [E] <anna.fine@nih.gov>
Subject: FW: Procedures for Transmitting Notices of Noncompliance to NIH

Hi Becky,

(b)(5)

Best,
Adam

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
adam.berger@nih.gov | (301) 827-9676



From: Markert, David <David.Markert@fda.hhs.gov>
Sent: Friday, January 29, 2021 4:06 PM

To: Berger, Adam (NIH/OD) [E] <adam.berger@nih.gov>
Cc: Culp, Michelle (NIH/OD) [E] <michelle.culp@nih.gov>; Williams, Rebecca (NIH/NLM/NCBI) [E] <williamsre@mail.nih.gov>; Less, Joanne (FDA/OC) <Joanne.Less@fda.hhs.gov>; Foltz, Bridget A (FDA/OC) <Bridget.Foltz@fda.hhs.gov>; Norton, Marci (FDA/OC) <Marci.Norton@fda.hhs.gov>; Katz, Donna (FDA/OC) <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma (FDA/OC) <Gemma.Flamberg@fda.hhs.gov>; Hammond, Christopher (NIH/OD) [E] <christopher.hammond2@nih.gov>
Subject: RE: Procedures for Transmitting Notices of Noncompliance to NIH

I inadvertently left Chris Hammond off my last email. Have a great weekend everyone.


-David

From: Markert, David

Sent: Friday, January 29, 2021 4:03 PM

To: Berger, Adam C (NIH) <adam.berger@nih.gov>
Cc: Culp, Michelle A (NIH) <michelle.culp@nih.gov>; Williams, Rebecca J (NIH) <williamsre@mail.nih.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>; Foltz, Bridget A <Bridget.Foltz@fda.hhs.gov>; Norton, Marci <Marci.Norton@fda.hhs.gov>; Katz, Donna <Donna.Katz@fda.hhs.gov>; Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>
Subject: Procedures for Transmitting Notices of Noncompliance to NIH

Hi Adam,

 Procedures for transmitting Notices of Noncompliance to NIH are attached for your review and input. Our apologies for the delay in getting the procedures to you. Thank you for being so patient.

As always, let us know if you have any questions. Also, please let us know the NIH email address to which the Notice of Noncompliance metadata document should be sent.

Regards,
David

David E. Markert
Senior Regulatory Counsel

Office of Good Clinical Practice
U.S. Food and Drug Administration
Tel: (301) 796-0752
David.Markert@fda.hhs.gov

From: Culp, Michelle (NIH/OD) [E]
Sent: Mon, 22 Feb 2021 20:04:38 +0000
To: Markert, David (FDA/OC)
Cc: Foltz, Bridget A (FDA/OC); Adam (NIH/OD) Berger [E]
(adam.berger@nih.gov); Rebecca (NIH/NLM/NCBI) Williams [E] (williamsre@mail.nih.gov); Fine, Anna
(NIH/NLM/NCBI) [E]; Griffing, Derek (NIH/NLM/NCBI) [E]
Subject: NLM SOP for Transmitting Notices of Non-compliance
Attachments: NLM SOP - FDA Notice of NonCompliance 2.19.21.docx, FDA Metadata
TemplateNLMedit.docx

Dear David,

(b)(5)

Best regards,
Michelle

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Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act