

From: Graham, Barney (NIH/VRC) [E]
Sent: Wed, 11 Mar 2020 13:02:33 +0000
To: Kathleen Neuzil
Subject: Fwd: FDA non-hold comments for 20-0003
Attachments: Doc 2 20-0003 Informed Consent Form V2.0 3-10-20.pdf, ATT00001.htm

FYI

I indicated that I thought the [REDACTED] (b) (4)

BG

Sent from my iPhone

Begin forwarded message:

From: "Buchanan, Wendy (NIH/NIAID) [E]" <[REDACTED] (b) (6)>
Date: March 10, 2020 at 6:30:06 PM EDT
To: Bennett Hamilton <[REDACTED] (b) (6)>, Sun Wellington
<[REDACTED] (b) (6)>, "Morabito, Kaitlyn (NIH/VRC) [E]"
<[REDACTED] (b) (6)>, "Graham, Barney (NIH/VRC) [E]" <[REDACTED] (b) (6)>,
"Ledgerwood, Julie (NIH/NIAID) [E]" <[REDACTED] (b) (6)>
Cc: "Roberts, Chris (NIH/NIAID) [E]" <[REDACTED] (b) (6)>, "Pikaart-Tautges, Rhonda
(NIH/NIAID) [E]" <[REDACTED] (b) (6)>, "Beigel, John (NIH) [E]"
<[REDACTED] (b) (6)>, "Makhene, Mamodikoe (NIH/NIAID) [E]"
<[REDACTED] (b) (6)>, "Elsafy, Mohamed (NIH/NIAID) [C]"
<[REDACTED] (b) (6)>
Subject: RE: FDA non-hold comments for 20-0003

[REDACTED] (b) (4) attached.

Wendy L Buchanan, BSN, MS
Nurse Consultant
Respiratory Diseases Branch
DMID/NIAID/NIH/DHHS
5601 Fishers Lane
Room 8E38, MSC 9825
Bethesda, Maryland 20892-9825
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From: Roberts, Chris (NIH/NIAID) [E] (b) (6) >
Sent: Monday, March 9, 2020 5:19 PM
To: Bennett Hamilton <(b) (6)>; Graham, Barney (NIH/VRC) [E] (b) (6) >; Sun Wellington <(b) (6)>
Cc: Corbett, Kizzmekia (NIH/VRC) [E] (b) (6) >; Pikaart-Tautges, Rhonda (NIH/NIAID) [E] (b) (6) >; Buchanan, Wendy (NIH/NIAID) [E] (b) (6) >; Beigel, John (NIH) [E] (b) (6) >; Makhene, Mamodikoe (NIH/NIAID) [E] (b) (6) >; Morabito, Kaitlyn (NIH/VRC) [E] (b) (6) >; Elsafy, Mohamed (NIH/NIAID) [C] (b) (6) >; Andrea Carfi <(b) (6)>; Arega, Janice (NIH/NIAID) [E] (b) (6) >; Hoang, Binh (NIH/NIAID) [E] (b) (6) >; Corbett, Kizzmekia (NIH/VRC) [E] (b) (6) >; Mascola, John (NIH/VRC) [E] (b) (6) >
Subject: RE: FDA non-hold comments for 20-0003

We would prefer to have it by tomorrow noon. (b) (4)

Chris

From: Hamilton Bennett (b) (6)
Sent: Monday, March 9, 2020 5:04 PM
To: Graham, Barney (NIH/VRC) [E] (b) (6) >; Sun Wellington (b) (6)
Cc: Roberts, Chris (NIH/NIAID) [E] (b) (6) >; Corbett, Kizzmekia (NIH/VRC) [E] (b) (6) >; Pikaart-Tautges, Rhonda (NIH/NIAID) [E] (b) (6) >; Buchanan, Wendy (NIH/NIAID) [E] (b) (6) >; Beigel, John (NIH) [E] (b) (6) >; Makhene, Mamodikoe (NIH/NIAID) [E] (b) (6) >; Morabito, Kaitlyn (NIH/VRC) [E] (b) (6) >; Elsafy, Mohamed (NIH/NIAID) [C] (b) (6) >; Andrea Carfi (b) (6) >; Arega, Janice (NIH/NIAID) [E] (b) (6) >; Hoang, Binh (NIH/NIAID) [E] (b) (6) >; Corbett, Kizzmekia (NIH/VRC) [E] (b) (6) >; Mascola, John (NIH/VRC) [E] (b) (6) >
Subject: RE: FDA non-hold comments for 20-0003

Chris and John,

Could you please clarify your preferred timing for the [REDACTED] (b) (4)

Also, could you please share the [REDACTED] (b) (4) for reference?

Thank you,

Hamilton Bennett

Director, Vaccine Access and Partnerships | Moderna

Tel: [REDACTED] (b) (6) | Cell: [REDACTED] (b) (6) modernatx.com

From: Graham, Barney (NIH/VRC) [E] [REDACTED] (b) (6)
Sent: Monday, March 9, 2020 10:19 AM
To: Wellington Sun <[REDACTED] (b) (6)>
Cc: Roberts, Chris (NIH/NIAID) [E] [REDACTED] (b) (6)>; Corbett, Kizzmekia (NIH/VRC) [E] [REDACTED] (b) (6)>; Pikaart-Tautges, Rhonda (NIH/NIAID) [E] [REDACTED] (b) (6)
Buchanan, Wendy (NIH/NIAID) [E] [REDACTED] (b) (6)>; Beigel, John (NIH) [E] [REDACTED] (b) (6)>; Makhene, Mamodikoe (NIH/NIAID) [E] <[REDACTED] (b) (6)>; Hamilton Bennett <[REDACTED] (b) (6)>; Morabito, Kaitlyn (NIH/VRC) [E] [REDACTED] (b) (6)>; Elsafy, Mohamed (NIH/NIAID) [C] <[REDACTED] (b) (6)>; Andrea Carfi [REDACTED] (b) (6) Arega, Janice (NIH/NIAID) [E] [REDACTED] (b) (6)>; Hoang, Binh (NIH/NIAID) [E] [REDACTED] (b) (6)>; Corbett, Kizzmekia (NIH/VRC) [E] [REDACTED] (b) (6)>; Mascola, John (NIH/VRC) [E] [REDACTED] (b) (6)>
Subject: RE: FDA non-hold comments for 20-0003

[REDACTED] (b) (4)

Barney

From: Wellington Sun <[REDACTED] (b) (6)>
Sent: Monday, March 9, 2020 9:51 AM
To: Graham, Barney (NIH/VRC) [E] [REDACTED] (b) (6)>
Cc: Roberts, Chris (NIH/NIAID) [E] [REDACTED] (b) (6)>; Pikaart-Tautges, Rhonda (NIH/NIAID) [E] <[REDACTED] (b) (6)>; Buchanan, Wendy (NIH/NIAID) [E] [REDACTED] (b) (6)>; Beigel, John (NIH) [E] [REDACTED] (b) (6)>; Makhene, Mamodikoe (NIH/NIAID) [E] [REDACTED] (b) (6); Bennett Hamilton [REDACTED] (b) (6)>; Morabito, Kaitlyn (NIH/VRC) [E] [REDACTED] (b) (6); Elsafy, Mohamed (NIH/NIAID) [C] [REDACTED] (b) (6)>; Andrea Carfi <[REDACTED] (b) (6)>; Arega, Janice (NIH/NIAID) [E] <[REDACTED] (b) (6)>; Hoang, Binh (NIH/NIAID) [E] [REDACTED] (b) (6)>; Corbett, Kizzmekia (NIH/VRC) [E]

(b) (6)>; Mascola, John (NIH/VRC) [E] (b) (6)>
Subject: RE: FDA non-hold comments for 20-0003

May I use that information in (b) (4)

From: Graham, Barney (NIH/VRC) [E] (b) (6)
Sent: Monday, March 9, 2020 9:39 AM
To: Wellington Sun <(b) (6)>
Cc: Roberts, Chris (NIH/NIAID) [E] (b) (6)>; Pikaart-Tautges, Rhonda (NIH/NIAID) [E] (b) (6)>; Buchanan, Wendy (NIH/NIAID) [E] (b) (6)>; Beigel, John (NIH) [E] (b) (6)>; Makhene, Mamodikoe (NIH/NIAID) [E] (b) (6)>; Hamilton Bennett (b) (6)>; Morabito, Kaitlyn (NIH/VRC) [E] (b) (6)>; Elsafy, Mohamed (NIH/NIAID) [C] (b) (6)>; Andrea Carfi (b) (6)>; Arega, Janice (NIH/NIAID) [E] <(b) (6)>; Hoang, Binh (NIH/NIAID) [E] (b) (6)>; Corbett, Kizzmekia (NIH/VRC) [E] (b) (6)>; Mascola, John (NIH/VRC) [E] (b) (6)>
Subject: Re: FDA non-hold comments for 20-0003

(b) (4)

Barney

Sent from my iPhone

On Mar 9, 2020, at 9:22 AM, Wellington Sun <(b) (6)> wrote:

Hi Barney,
Thanks for this excellent summary. (b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4)

Thanks,
Wellington

From: Graham, Barney (NIH/VRC) [E] (b) (6)>
Sent: Saturday, March 7, 2020 10:21 AM
To: Roberts, Chris (NIH/NIAID) [E] (b) (6)>; Pikaart-Tautges, Rhonda (NIH/NIAID) [E] (b) (6)>; Buchanan, Wendy (NIH/NIAID) [E] (b) (6)>; Beigel, John (NIH) [E] (b) (6)>; Makhene, Mamodikoe (NIH/NIAID) [E] <(b) (6)>; Hamilton Bennett (b) (6)>; Wellington Sun (b) (6)>; Morabito, Kaitlyn (NIH/VRC) [E] <(b) (6)>; Elsafy, Mohamed (NIH/NIAID) [C] (b) (6)
Cc: Arega, Janice (NIH/NIAID) [E] <(b) (6)>; Hoang, Binh (NIH/NIAID) [E] (b) (6)>; Corbett, Kizzmekia (NIH/VRC) [E] (b) (6)>; Mascola, John (NIH/VRC) [E] (b) (6)>
Subject: RE: FDA non-hold comments for 20-0003

This is the updated document I promised (b) (4)



Barney

From: Roberts, Chris (NIH/NIAID) [E] <(b) (6)>
Sent: Friday, March 6, 2020 4:55 PM
To: Pikaart-Tautges, Rhonda (NIH/NIAID) [E] (b) (6)>; Buchanan, Wendy (NIH/NIAID) [E] (b) (6)>; Beigel, John (NIH) [E] <(b) (6)>; Makhene, Mamodikoe (NIH/NIAID) [E] (b) (6)>; Bennett Hamilton (b) (6)>; Sun Wellington <(b) (6)>; Morabito, Kaitlyn (NIH/VRC) [E] (b) (6)>; Graham, Barney (NIH/VRC) [E] (b) (6)>; Elsafy, Mohamed (NIH/NIAID) [C] (b) (6)>
Cc: Arega, Janice (NIH/NIAID) [E] (b) (6)>; Hoang, Binh (NIH/NIAID) [E] (b) (6)>
Subject: RE: FDA non-hold comments for 20-0003

Hi Hamilton, Wellington

(b) (4)

Chris

From: Pikaart-Tautges, Rhonda (NIH/NIAID) [E] <[REDACTED] (b) (6)>

Sent: Friday, March 6, 2020 2:31 PM

To: Roberts, Chris (NIH/NIAID) [E] [REDACTED] (b) (6)>; Buchanan, Wendy (NIH/NIAID) [E] [REDACTED] (b) (6)>; Beigel, John (NIH) [E] [REDACTED] (b) (6)>; Makhene, Mamodikoe (NIH/NIAID) [E] [REDACTED] (b) (6)>; Bennett Hamilton [REDACTED] (b) (6)>; Sun Wellington [REDACTED] (b) (6)>; Morabito, Kaitlyn (NIH/VRC) [E] [REDACTED] (b) (6)>; Graham, Barney (NIH/VRC) [E] [REDACTED] (b) (6)>; Elsafy, Mohamed (NIH/NIAID) [C] [REDACTED] (b) (6)

Cc: Arega, Janice (NIH/NIAID) [E] [REDACTED] (b) (6)>; Hoang, Binh (NIH/NIAID) [E] [REDACTED] (b) (6)>

Subject: FDA non-hold comments for 20-0003

Importance: High

Hi all,

We just received the non-hold comments from the FDA.

(b) (4)

Rhonda

(b) (6)

From: Pikaart-Tautges, Rhonda (NIH/NIAID) [E]
Sent: Monday, March 2, 2020 3:48 PM
To: Roberts, Chris (NIH/NIAID) [E] (b) (6)>; Buchanan, Wendy (NIH/NIAID) [E] (b) (6); Beigel, John (NIH) [E] (b) (6)>; Makhene, Mamodikoe (NIH/NIAID) [E] (b) (6); Hamilton Bennett (b) (6); Wellington Sun (b) (6); Morabito, Kaitlyn (NIH/VRC) [E] (b) (6); Graham, Barney (NIH/VRC) [E] (b) (6)>; Elsafy, Mohamed (NIH/NIAID) [C] (b) (6)>
Cc: Arega, Janice (NIH/NIAID) [E] (b) (6); Susan Wong (b) (6)>; Hoang, Binh (NIH/NIAID) [E] (b) (6)>
Subject: Just received the safe to proceed call from the FDA for 20-0003
Importance: High

Hi all,

The FDA just called, we are safe to proceed.

Non-hold comments will be assembled and will come later.

Rhonda

Rhonda Pikaart-Tautges
 Sr. Regulatory Affairs Manager, COR III
 Office of Regulatory Affairs, DMID, NIAID, NIH, DHHS
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 Bethesda, MD 20892-9826 (Courier/Express Mail: Rockville, MD 20852)
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 Direct phone and voice mail: (b) (6)
 Telework: Tuesday, Friday
 IM Skype
 e-mail: (b) (6)

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(b) (4)