**From:** Kaslow, David
**To:** (b) (6)
**Subject:** RE: Media Inquiring about deaths in Moderna"s KidCOVE trial
**Date:** Tuesday, January 7, 2025 12:39:00 PM

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Dear (b) (6),

Thank you.

Be well,
David

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**From:** (b) (6) @fda.hhs.gov>
**Sent:** Tuesday, January 7, 2025 12:38 PM
**To:** (b) (6) @fda.hhs.gov>; (b) (6) @fda.hhs.gov>; Kaslow, David <David.Kaslow@fda.hhs.gov>; (b) (6) @fda.hhs.gov>; (b) (6) @fda.hhs.gov>; (b) (6) @fda.hhs.gov>
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Otherwise, what do people think of responding with something along the lines of: "FDA is not aware of, nor has it received any reports of death that occurred in children enrolled in the Moderna COVID-19 Vaccine KidCOVE clinical trial." (b) (6) is still checking to see if there was a VAERS report that came to them instead of the IND. I would think that they would have looped us in though?

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Hi (b) (6)

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**Importance:** High

Hi all,

I'm not sure who the lead MO is for Moderna's COVID-19 vaccine for

peds these days, but several inquiries are coming in about one or possibly two deaths in Moderna's KidCOVE peds trial that is alleged to have occurred after the authorization, possibly overseas.

I did a Google search and found this article. I noticed that FDA is already quoted and when I asked about it, I was informed that a high-level response was provided that pointed to the decision memo, as the initial question asked about deaths reported "in the trial that led to the agency's EUA for Moderna…"

This inquiry is a bit different as I assume that the trial was still ongoing with the authorizations that occurred after the initial authorization, including the 2024-2025 formula. Did any peds deaths occur during this trial? (b) (6) is checking on the PM aspect.

Requested turnaround is today.

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**From:** (b) (6)
**To:** (b) (6)
**Subject:** RE: Media Inquiring about deaths in Moderna"s KidCOVE trial
**Date:** Tuesday, January 7, 2025 5:43:34 PM
**Attachments:** image001.png

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Thanks all- looks good!

(b) (6)

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(b) (6)
(b) (6)
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
White Oak Building 71
Silver Spring, MD 20993
Cell: (b) (6)

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Thank you all so very much!

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Thanks (b) (6) ! Agree with what's written in the response. I checked through all the other CSRs that just got submitted with the sBLA this morning too and the only other death besides this one was an adolescent due to gunshot wound.

(b) (6)

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**Sent:** Tuesday, January 7, 2025 5:07 PM
**To:** (b) (6) @fda.hhs.gov>; (b) (6) @fda.hhs.gov>; Kaslow, David <David.Kaslow@fda.hhs.gov>; (b) (6) @fda.hhs.gov>; (b) (6) @fda.hhs.gov>; (b) (6) @fda.hhs.gov>

**Subject:** RE: Media Inquiring about deaths in Moderna's KidCOVE trial

Hi all,

(b) (6) and I just hung up with (b) (6) and disclosure experts regarding this response. Edits are included on what we plan to send forward.

(b) (6) I want to make sure that you are comfortable with it.

Thanks,
(b) (6)

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I've been informed that we can say that FDA is aware of and has received the report referenced in the article. However, we can't provide any additional information or provide any context. I don't think that this approach would be very helpful.

I've taken another approach- see what you think of my proposed response.

Thanks,
(b) (6)

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**Subject:** RE: Media Inquiring about deaths in Moderna's KidCOVE trial

Thanks (b) (6) I'm seeking guidance on what we can say from a

disclosure perspective and when I get that, I'll draft a response for folks to review.

(b) (6)

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Cite disclosure/privacy regs that we cannot provide information on clinical trial participants.

FDA has not received any reports of death that suggest a causal relationship with Moderna COVID-19 Vaccine in children enrolled in the Moderna COVID-19 Vaccine KidCOVE clinical trial.

**Commented [(b) (6) 1]:** (b) (6) will provide the specifics here.

**Commented [(b) (6) 2]:** I assume this is an accurate statement.

**Commented (b) (6) 3R2]:** Could we just include the last sentence?

**Commented (b) (6) 4R2]:** I think that the context of what is required reporting is needed for the reporter.

**Commented [(b) (6) 5]:** (b) (6) - just double-checking that this is accurate?

(b) (6)

**Commented (b) (6) 6R5]:** Yes agree!