U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Access Litigation and Freedom of Information Branch
10903 New Hampshire Avenue
Building 71, Room 1114
Silver Spring, MD 20993-0002

Submitted via FDA's ONLINE FOIA PORTAL

May 19, 2026

Re: Freedom of Information Act Request for serious adverse events associated with NCT06252285

To Whom It May Concern:

CHD is a non-profit organization that works to expose causes of health epidemics, eliminate toxic exposures, hold those responsible accountable, seek justice for those injured, and establish safeguards to prevent future harm. CHD's areas of focus include the health effects of vaccination, and public health agencies' efforts to monitor and ensure vaccine safety.

This request concerns Moderna's clinical trial assessing the safety and immunogenicity of mRNA-1365, an mRNA vaccine targeting respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) and mRNA-1345, an mRNA vaccine targeting RSV, in participants aged 5 months to < 24 months (NCT05743881). The trial began in February 2023, and was halted on July 17, 2024. All references below are to this trial.

According to an FDA briefing document, dated December 12, 2024,[1] on July 17, 2024 the sponsor paused the study, because two or more children tested positive for RSV.

On July 19, 2024 the FDA put the trial for the investigational new drug on hold because:

> 1. Human participants are or would be exposed to an unreasonable and significant risk of illness or injury, per 21 CFR 312.42(b)(1)(i).
>
> 2. The IND does not contain sufficient information, as required under 21 CFR 312.23, to assess the risks to participants of the proposed studies, per 21 CFR 312.42(b)(1)(iv).

The response to a Freedom of Information request submitted to the UK's National Health Service Health Research Authority (NHSHRA), revealed that during the trial, there were nine Suspected Unexpected Serious Adverse Drug Reactions (SUSARs).

[1] Vaccines and Related Biological Products Advisory Committee Meeting, December 12, 2024. FDA Briefing Document. Considerations for Respiratory Syncytial Virus (RSV) Vaccine Safety in Pediatric Populations.

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552 (FOIA) and the implementing regulations of your agency, please provide:

1. All communications, reports, updates, notifications and any other transfers of information about this trial between the Sponsor and CBER since July 1, 2024:
    a) concerning safety issues with these products; this is to include reports etc. concerning safety issues that may be part of any agency process.
    b) concerning the pausing or halting of the trial.
2. Details of all notifications of Suspected Unexpected Serious Adverse Drug Reactions (SUSARs) arising at any time in this trial.
3. All Periodic Benefit Risk Evaluation Reports (PBRERs) for this trial.

Guidance Regarding the Search and Processing of Requested Records:

Please search all locations, agency departments, and systems likely to have responsive records, regardless of format, medium, or physical characteristics, using all tools available to your agency to conduct a complete and efficient search for potentially responsive records. If some portions of the requested records are properly exempt from disclosure, please disclose any reasonably searchable non-exempt portions of the requested records, describing any redacted, deleted or withheld material in detail and specifying the statutory basis for the exemption in addition to the reasons the exemption applies. Please also indicate whether and how the "foreseeable harm" standard applies to each redaction. If a request is denied in whole, please state the specific reason(s) why it is not reasonable to segregate portions of the record for release. Finally, please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest.

Fees:

We ask that you waive fees associated with this request, for two reasons. First, Children's Health Defense (CHD) is a member of the media. To advance its mission, CHD disseminates public health information and data. CHD "gathers information of interest to the general public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience" via its daily online news publication,[2] website,[3] broadcast media channel[4] and social media platforms.[5] See 5 U.S.C. § 552(a)(4)(A)(ii). Thus, CHD should not be charged search and review fees. *See id.*

Second, a fee waiver is required because "disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of

[2] See The Defender https://childrenshealthdefense.org/defender.
[3] See https://childrenshealthdefense.org.
[4] See CHD.TV https://live.childrenshealthdefense.org.
[5] 5 https://twitter.com/ChildrensHD; https://rumble.com/user/childrenshealthdefense.

the requester." See 5 U.S.C. § 552(a)(4)(A)(iii). The subject of this request concerns the operations of the taxpayer-funded FDA. The disclosures are in the public interest because they will likely contribute significantly to the public's understanding of the Agency's activities in connection with ensuring vaccine safety. As a 501(c)(3) nonprofit organization, CHD makes this request primarily and fundamentally for non-commercial purposes, and will disseminate records provided in response to this request through one or more of its media channels. Accordingly, CHD qualifies for a fee waiver.

Conclusion:

CHD and the FDA share a common mission to promote public health and transparency in government. If you have any questions regarding how to construe this request for records or believe that further discussions regarding search and processing would facilitate a more efficient production of the records, please do not hesitate to contact CHD to discuss this request at brenda.baletti@childrenshealthdefense.org. By working together at the outset, we can decrease the likelihood of costly and time-consuming litigation in the future.

CHD looks forward to working with your agency on this request. Thank you for your time and attention to this matter.

Sincerely,

Brenda Baletti, Ph.D.
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The Defender
Children's Health Defense
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