

From: [CDER Executive Operations](#)
To: [Michael Carome](#)
Subject: Public Citizen DC - ESETT
Date: Wednesday, July 7, 2021 3:34:34 PM
Attachments: [image013.png](#)

Dear Dr. Carome:

Thank you for your June 8, 2021 letter requesting that the Office for Human Research Protections (OHRP) and the US Food and Drug Administration (FDA) do a compliance oversight investigation into the completed clinical trial, entitled “Established Status Epilepticus Treatment Trial (ESETT)”, [clinicaltrials.gov](#) number NCT03434028.

We take the concerns you raised very seriously. FDA and OHRP staffs have discussed your letter and we will review the points that you raised with leadership.

Thank you again for contacting the Agency regarding this important matter.

Sincerely,

CDER Executive Operations
Office of Executive Programs
Center for Drug Evaluation and Research

