

VIA UNITED PARCEL SERVICE AND E-MAIL

Emergo Therapeutics, Inc.
Attention: Moise A. Khayrallah, Ph.D., Chief Executive Officer
6208 Fayetteville Road
Suite 104
Durham, North Carolina 27713

Re: Submission of Clinical Trial Results Information Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2026-134
NCT03887026, NCT04043923, and NCT04610047

Dear Dr. Khayrallah:

Based on an initial review of Food and Drug Administration (FDA) records, information from the ClinicalTrials.gov data bank operated by the National Library of Medicine, a part of the National Institutes of Health, and any available public information, it appears that Emergo Therapeutics, Inc. is the “responsible party”¹ for the above-identified clinical trials, which appear to be “applicable clinical trials”² subject to the requirements of section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11. A responsible party for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank certain results information for the clinical trial; such results information generally must be submitted no later than one year after the primary completion date³ of the applicable clinical trial, unless the responsible party has submitted a timely

¹ See sections 402(j)(1)(A)(ix) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(1)(A)(ix)) and 42 CFR 11.10 for the definition of “responsible party.”

² See sections 402(j)(1)(A)(i)-(iii) of the PHS Act (42 U.S.C. 282(j)(1)(A)(i)-(iii)) and 42 CFR 11.10 for the definition of “applicable clinical trial.”

³ See 42 CFR 11.10 for the definition of “primary completion date.” See *also* section 402(j)(1)(A)(v) of the PHS Act (42 U.S.C. 282(j)(1)(A)(v)), which defines “completion date.” As reflected in 42 CFR 11.10, the terms “primary completion date” and “completion date” are synonymous for the purposes of 42 CFR part 11.

certification of delay, a request for an extension for good cause, or a request for a waiver of the requirements for submission of results information.⁴

We note your company submitted an untimely certification for delayed submission of results information under 42 CFR 11.44(c)(1) for NCT03887026. Pursuant to 42 CFR 11.44(c), a responsible party may submit a certification for delayed submission of results information for an applicable clinical trial that studies an FDA-regulated drug product that was not approved by FDA for any use before the primary completion date and for which the sponsor intends to continue with product development and is either seeking, or may at a future date seek, FDA approval of the drug product. However, to be timely, any such certification for delayed submission of results information must be submitted before the standard submission deadline. If a timely certification for delayed submission of results information is submitted under 42 CFR 11.44(c)(1), the deadline for submitting results information is 30 calendar days after the earlier of (1) the date on which FDA approves the drug product for any use that is studied in the applicable clinical trial, or (2) the date on which the marketing application or premarket notification is withdrawn without resubmission for not less than 210 calendar days. With such certification for delayed submission of results information, the responsible party must submit results information not later than two years after the date on which the certification was submitted, except to the extent that 42 CFR 11.44(d) applies.

We note your company submitted a timely certification for delayed submission of results information under 42 CFR 11.44(c)(1) for NCT04043923 and NCT04610047. When a timely certification for delayed submission of results information is submitted under 42 CFR 11.44(c)(1), results information must be submitted no later than two years after the date on which the certification was submitted. See 42 CFR 11.44(c)(2).⁵ Notwithstanding that deadline, results information must be submitted sooner if 1) FDA approves the drug product for any use that is studied in the applicable clinical trial or 2) the marketing application or premarket notification is withdrawn without resubmission for not less than 210 calendar days; if either of these two scenarios occurs, results information must be submitted within 30 calendar days of such event. See 42 CFR 11.44(c)(1).

FDA has identified potential noncompliance related to the above-identified clinical trials, titled as follows:

⁴ See sections 402(j)(3)(E) and (H) of the PHS Act (42 U.S.C. 282(j)(3)(E) and (H)) and 42 CFR part 11, subpart C for results information submission requirements.

⁵ The regulation contains an exception, not applicable here, regarding the submission of partial results information. 42 CFR 11.44(c)(2) and (d).

- Efficacy and Safety of Single Doses of Norketotifen in Adult Subjects With Allergen-Induced Allergic Rhinitis in an Allergen Challenge Chamber
- A Phase 2b Double-blind, Randomized, Placebo-controlled, Parallel-group Study of the Efficacy and Safety of Norketotifen (NKT) in the Treatment of Acute Uncomplicated Influenza-like Illness (ILI) [NKT-202]
- A Phase 2b Double-blind, Randomized, Placebo-controlled, Parallel-group Study of the Efficacy and Safety of Norketotifen (NKT) in the Treatment of Acute Uncomplicated Influenza-like Illness (ILI) [NKT-203]

It appears that results information for the referenced applicable clinical trials has not been submitted to the ClinicalTrials.gov data bank. Moreover, it appears that your company failed to update the responsible party contact information for this clinical trial as required under 42 CFR 11.64(a)(1)(ii)(L).⁶ Your company should review its records of these clinical trials and determine whether your company submitted all required information. If your company determines that information is required and due for these clinical trials, please submit the information promptly.

Failure to submit clinical trial information⁷ required under section 402(j) of the PHS Act (42 U.S.C. 282(j)), including information required under the regulations found in 42 CFR part 11, is a prohibited act under section 301(jj)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 331(jj)(2)). Beginning 30 calendar days after you receive this letter, FDA intends to further review and assess the above-identified clinical trials. If FDA determines that your company has failed to submit any clinical trial information required under section 402(j) of the PHS Act (42 U.S.C. 282(j)), including its implementing regulations in 42 CFR part 11, your company may receive from FDA a Notice of Noncompliance,⁸ and FDA may thereafter initiate an enforcement action against your company.

As requested, please review your company's clinical trial records and submit any required results information to the ClinicalTrials.gov data bank. We also request that you review all applicable clinical trials for which your company is the responsible party to ensure compliance with all ClinicalTrials.gov registration and results information submission requirements. You can access the ClinicalTrials.gov website at <https://register.clinicaltrials.gov>.

⁶ For applicable clinical trials initiated on or after January 18, 2017, such as the referenced clinical trials, 42 CFR 11.64(a)(1)(ii)(L) requires that responsible party contact information be "updated not later than 30 calendar days after a change in the responsible party or the contact information for the responsible party." If your company is no longer the responsible party for this clinical trial, your company should notify FDA and must update this information in the ClinicalTrials.gov data bank.

⁷ See sections 402(j)(1)(A)(iv) of the PHS Act (42 U.S.C. 282(j)(1)(A)(iv)) and 42 CFR 11.10 for the definition of "clinical trial information."

⁸ See section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii)).

We request that you submit a written response to FDA within 30 calendar days after you receive this letter, stating the actions you have taken in response to this letter. If you believe that your company has complied with applicable requirements, please provide us with your reasoning and include any supporting information for our consideration.

Your written response, and any questions or concerns about this letter, should be sent via email to the FDA at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any e-mail communications.

Sincerely yours,

{See appended electronic signature page}

Laurie Muldowney, M.D.
Deputy Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

cc: (b) (4), (b) (6), Regulatory Affairs Manager
Authorized Sponsor Representative for Emergo Therapeutics, Inc.

(b) (4)

Emergo Therapeutics Clinical Trials

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LAURIE B MULDOWNNEY
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