U.S. FOOD & DRUG ADMINISTRATION

VIA UNITED PARCEL SERVICE AND E-MAIL

Rigel Pharmaceuticals
Attention: Jill DeFratis, Executive Director of Clinical Operations
611 Gateway Boulevard, Suite 900
South San Francisco, California 94080

Re: Submission of Clinical Trial Results Information Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2026-129
NCT04629703

Dear Ms. DeFratis:

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 Rigel Pharmaceuticals is the "responsible party"[1] for the above-identified clinical trial, which appears to be an "applicable clinical trial"[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 date[3] of the applicable clinical trial, unless the responsible party has submitted a timely certification of delay, request for an extension for good cause, or request for a waiver of the requirements for submission of results information.[4]

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[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.
[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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

We note your company submitted a timely certification for delayed submission of results information under 42 CFR 11.44(b)(1). When a timely certification for delayed submission of results information is submitted for an applicable clinical trial, results information must be submitted no later than two years after the date on which the certification was submitted. See 42 CFR 11.44(b)(2).[5] Notwithstanding that deadline, results information must be submitted sooner for an applicable clinical trial if: (i) FDA approves the drug product for the use that is studied in the trial; (ii) FDA issues a letter that ends the regulatory review cycle for the marketing application but does not approve the drug product for the use that is studied in the trial; or (ii) the marketing application seeking approval of the drug product's new use is withdrawn without resubmission for not less than 210 calendar days. If any of these three scenarios occurs, results information must be submitted within 30 calendar days after the earliest of such event. See 42 CFR 11.44(b)(1).

FDA has identified potential noncompliance related to the above-identified clinical trial, titled "Double-Blind, Randomized, Placebo-Controlled, Multi-Center Phase 3 Study to Evaluate the Efficacy and Safety of Fostamatinib in COVID-19 Subjects." It appears that results information for the referenced trial has not been submitted to the ClinicalTrials.gov data bank.[6] Your company should review its records of this clinical trial and determine whether your company submitted all required results information. If your company determines that information is required and due for this clinical trial, please submit the results information promptly.

Failure to submit clinical trial information[7] 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 trial. 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

[5] The regulation contains an exception, not applicable here, regarding the submission of partial results information. See 42 CFR 11.44(d).
[6] We acknowledge that, as recently as March 26, 2026, your company entered results information for NCT04629703 into the National Library of Medicine Protocol Registration and Results System (PRS); however, your company did not complete the process for submitting results information, and the preliminary steps taken by your company do not constitute submission of results information under 42 CFR 11.44(a)
[7] *See* section 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)).

thereafter initiate an administrative action seeking a civil money penalty.[9] In addition to civil money penalties, violations of section 301(jj) of the FD&C Act (21 U.S.C. 331(jj)) could result in other regulatory action, such as injunction and/or criminal prosecution, without further notice.

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.

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 regarding 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

[9] Pursuant to section 303(f)(3)(A) of the FD&C Act (21 U.S.C. 333(f)(3)(A)), "[a]ny person who violates section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding." Moreover, section 303(f)(3)(B) of the FD&C Act (21 U.S.C. 333(f)(3)(B)) provides that "[i]f a violation of section 301(jj) [of the FD&C Act (21 U.S.C. 331(jj))] is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii) [of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii))], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected." These civil money penalty amounts reflect the amounts found in the statute. These amounts are updated annually to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. No. 101-410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461, note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, November 2, 2015). For the most up-to-date amounts, please see 45 CFR 102.3.

cc: Lisa Rojkjaer, Executive Vice President, Chief Medical Officer
Rigel Pharmaceuticals

Asif Siddiqui, Vice President, Regulatory Affairs
Rigel Pharmaceuticals

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 MULDOWNEY
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