

VIA E-MAIL

ContraFect
Attention: Cara Cassino, M.D., Chief Medical Officer
28 Wells Avenue
Yonkers, New York 10701
ccassino@contrafect.com

Re: Submission of Clinical Trial Results Information & Certification to
Accompany Certain Drug Product, Biological Product, and Device Product
Submissions Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2021-127
NCT03163446, IND 113473

Dear Dr. Cassino:

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 ContraFect 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 of the applicable clinical trial, unless the responsible party has submitted a certification

¹ See section 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 section 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.”

of delay, a request for an extension for good cause, or a request for a waiver of the requirements for submission of results information.³

FDA has identified potential noncompliance related to the above-identified clinical trial, titled “A Multicenter, Double-Blind, Randomized, Comparative Study of the Safety, Tolerability, Efficacy, and Pharmacokinetics of CF-301 vs Placebo in Addition to Standard-of-Care Antibacterial Therapy for the Treatment of Adult Patients with Staphylococcus Aureus Blood Infections (Bacteremia) Including Endocarditis.” It appears that results information for the referenced applicable clinical trial has not been submitted to the ClinicalTrials.gov data bank.⁴ 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 results information is required and due for this clinical trial, please submit the results information promptly.

Failure to submit clinical trial information⁵ 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)). FDA intends to further review and assess the above-identified clinical trial beginning 30 calendar days after you receive this letter. 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,⁶ and FDA may thereafter initiate an administrative action seeking a civil monetary penalty.⁷ In addition to civil

³ See section 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.

⁴ We acknowledge that on April 15, 2020, your company initiated the submission to the NLM Protocol Review System (PRS) of a “certify initial approval” request to delay the deadline to submit results information for NCT03163446. However, your company did not complete the process for submitting a “certify initial approval” request, and the preliminary steps taken by your company do not constitute submission of a certification of delay under 42 CFR 11.44(c). Moreover, even if your company had submitted its certification for delayed submission, it would not have been timely under 42 CFR 11.44(c), because it was not made before the standard submission deadline of March 7, 2020.

⁵ 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.”

⁶ See section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii)).

⁷ 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.” “If 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 [receipt of a statutory Notice of Noncompliance issued 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.” Section 303(f)(3)(B) of the FD&C Act (21 U.S.C. 333(f)(3)(B)). These civil monetary 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

monetary 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.

As requested, please review your company's clinical trial records and submit any required results information to the ClinicalTrials.gov data bank. You can access the ClinicalTrials.gov website at <https://register.clinicaltrials.gov>.

We also note that it appears that your company, which is the sponsor of investigational new drug application (IND) 113473, failed to provide to FDA the certification (i.e., Form FDA 3674) required under section 402(j)(5)(B) of the PHS Act (42 U.S.C. 282(j)(5)(B)) to accompany certain drug product submissions. Specifically, at the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355), such application must be accompanied by a certification that all applicable requirements of section 402(j) of the PHS Act (42 U.S.C. 282(j)) have been met.⁸ The protocol for the applicable clinical trial NCT03163446 was submitted to IND 113473 in a protocol amendment on September 2, 2016; however, it appears that at the time this protocol amendment was submitted to FDA, your company did not submit to FDA the certification required by section 402(j)(5)(B) of the PHS Act (42 U.S.C. 282(j)(5)(B)). The failure to submit a certification under section 402(j)(5)(B) of the PHS Act (42 U.S.C. 282(j)(5)(B)) is a prohibited act under section 301(jj)(1) of the FD&C Act (21 U.S.C. 331(jj)(1)).

If you have any questions about this letter, you may call Mark S. Miller, Pharm.D., at (301) 796-2798. Please have the FDA reference number provided at the top of this letter available when you call. Alternatively, you may email him at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any e-mail communications.

We request that you submit a written response to FDA within 30 calendar days after you receive this letter, stating the actions that 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. Please direct your response to the address below and include the FDA reference number in all correspondence relating to this matter.

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.

⁸ We note that the implementing regulations for section 402(j) of the PHS Act (42 U.S.C. 282(j)), codified at 42 CFR part 11, were promulgated on September 21, 2016, with an effective date of January 18, 2017. See Final Rule for Clinical Trials Registration and Results Information Submission, 81 Fed. Reg. 64,982 (Sept. 21, 2016). Therefore, these regulations are not applicable to the protocol amendment you submitted to your IND on September 2, 2016, with the protocol for applicable clinical trial NCT03163446.

Mark S. Miller, Pharm.D., BCPS, RAC
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Sincerely yours,

{See appended electronic signature page}

David C. Burrow, Pharm.D., J.D.
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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/

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