



VIA E-MAIL

September 8, 2021

Saint Luke's Health System
Attention: Donna Buchanan, Ph.D.
Director of Clinical Research Operations
4401 Wornall Road
Kansas City, Missouri 64111
dbuchanan@saint-lukes.org

Re: Submission of Clinical Trial Results Information Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2021-129
NCT02653482

Dear Dr. Buchanan:

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 Saint Luke's Health System 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

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."

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.³

FDA has identified potential noncompliance related to the above-identified clinical trial, titled “Dapagliflozin Effect on Symptoms and Biomarkers in Patients with Heart Failure (DEFINE-HF),” a 12-week randomized, double-blind, placebo-controlled trial to evaluate the effects of once-daily dapagliflozin 10 mg on heart failure disease-specific biomarkers, symptoms, health status, and quality of life in subjects with chronic heart failure with reduced systolic function. It appears that results information for the referenced applicable clinical trial has not been submitted to the ClinicalTrials.gov data bank.⁴ Your institution should review its records of this clinical trial and determine whether your institution submitted all required results information. If your institution 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 Public Health Service Act (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 institution 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 institution 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 monetary penalties, violations of section 301(jj) of the

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 December 19, 2020, your institution initiated the submission of results information for NCT02653482 to the National Library of Medicine’s Protocol Registration and Results System (PRS); however, your institution did not enter complete results information or complete the process for submitting results information, and the preliminary steps taken by your institution do not constitute submission of results information under 42 CFR 11.44(a).

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 Federal Food, Drug, and Cosmetic Act (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 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 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.

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 institution’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>. If you have any questions about this letter, you may call Miah Jung, Pharm.D., M.S., at 240-402-3728. Please have the FDA reference number provided at the top of this letter available when you call. Alternatively, you may e-mail 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 you have taken in response to this letter. If you believe that your institution 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.

Miah Jung, Pharm.D., M.S.
Acting Branch Chief
Compliance Enforcement Branch
Division of Enforcement and Postmarketing Safety
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Building 51, Room 5219
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely yours,

David
Burrow -S

Digitally signed by David Burrow -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=David Burrow -S,
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David C. Burrow, Pharm.D., J.D.
Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration