U.S. FOOD & DRUG ADMINISTRATION

VIA UNITED PARCEL SERVICE AND E-MAIL

LIB Therapeutics, Inc.
Attention: Evan A. Stein, M.D., Ph.D., Chief Executive Officer and Chief Medical Officer
5375 Medpace Way
Cincinnati, Ohio 45227

Re: Submission of Clinical Trial Results Information Pursuant to 42 U.S.C. 282(j)
FDA Reference Number: CDER-2026-118
NCT04034485, NCT04790513, NCT04797104, NCT04797247, and NCT04806893

Dear Dr. Stein:

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 LIB 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 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]

[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

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

- "Randomized, Open-Label, Cross-Over, Phase 3 Study to Evaluate the Efficacy and Safety of LIB003 With Evolocumab in Homozygous Familial Hypercholesterolemia Patients on Stable Lipid-Lowering Therapy"

- "Randomized, Open-label, Phase 3 Study to Evaluate the Efficacy and Safety of LIB003, Evolocumab and Alirocumab in CVD Patients, or at High Risk for CVD, on Stable Lipid-Lowering Therapy Requiring Additional LDL-C Reduction (LIBerate-H2H)"

- "Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Long-Term Efficacy and Safety of LIB003 in Heterozygous FH Patients on Stable Lipid-Lowering Therapy Requiring Additional LDL-C Reduction"

- "Study to Evaluate the Long-Term Efficacy and Safety of LIB003 in Patients With Cardiovascular Disease on Stable Lipid-Lowering Therapy Requiring Additional LDL-C Reduction"

- "Study to Evaluate the Long-Term Efficacy and Safety of LIB003 in Patients With Cardiovascular Disease, or at High Risk for Cardiovascular Disease, on Stable Lipid-Lowering Therapy Requiring Additional LDL-C Reduction"

It appears that results information for the referenced trials has not been submitted to the ClinicalTrials.gov data bank.[5] Your company should review its records of these clinical trials and determine whether your company submitted all required results information. If your company determines that results information is required and due for these clinical trials, please submit the results information promptly.

Failure to submit clinical trial information[6] 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

[5] We acknowledge that, as recently as October 20, 2024, your company entered results information for NCT04797104 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).
[6] *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."

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,[7] and FDA may thereafter initiate an administrative action seeking a civil money penalty.[8] 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.

[7] *See* section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. 282(j)(5)(C)(ii)).

[8] 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.

Should you have any questions or concerns regarding this letter, please e-mail FDA at CDER-OSI-Advisory@fda.hhs.gov. Please include the FDA reference number with any e-mail communications. Your written response, including FDA reference number, should be addressed to:

Miah Jung, Pharm.D., M.S.
ClinicalTrials.gov Program
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 5342
10903 New Hampshire Avenue
Silver Spring, MD 20993

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

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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