U.S. FOOD & DRUG ADMINISTRATION

Via UPS
Return Receipt Requested

November 12, 2024

Mr. Sebastien Moulard
President
Silliker Inc. *dba* Merieux NutriSciences
401 N. Michigan Avenue
Suite 1400
Chicago, IL 60611

Dear Mr. Moulard:

The U.S. Food and Drug Administration (FDA) inspected your contract testing laboratory, Silliker Inc. *dba* Merieux NutriSciences, FEI 3017442763, at 2183 SE Hawthorne Road, Gainesville, Florida from April 22 to 25, 2024.

This untitled letter summarizes violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, the drugs you tested are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your May 16, 2024 response to our Form FDA 483 in detail. Your response, that you "will not be providing a substantive response to the Form 483," is inadequate because you failed to provide supportive documentation for evaluation or adequate evidence of corrective actions taken to bring your operations into compliance with CGMP.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. **Your firm failed to establish adequate written responsibilities and procedures applicable to the quality control unit and to follow written procedures applicable to the quality control unit (21 CFR 211.22(d)).**

Your firm's quality unit (QU) failed to establish adequate procedures describing QU roles, responsibilities, and authorities. For example, your QU failed to ensure that:

- Appropriate procedures were in place outlining the roles and responsibilities for your QU.

- Thorough investigations into out-of-specification (OOS) test results were performed according to your standard operating procedures (SOPs).

- CGMP training was performed and documented according to your SOPs.

Your firm's quality systems are inadequate. See FDA's guidance document *Quality Systems Approach to Pharmaceutical CGMP Regulations* for help implementing quality systems and risk management approaches to meet the requirements of CGMP regulations 21 CFR, parts 210 and 211 at https://www.fda.gov/media/71023/download.

2. **Your firm failed to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity (21 CFR 211.160(b)).**

Your firm lacked appropriate laboratory controls to ensure the accuracy of the reported results from your drug product testing. For example, while your firm has a procedure requiring method suitability verification of the test methods used for all drug products, you confirmed to our investigators that you have not performed method suitability verification of test methods used on drug products you test. In addition, your firm lacked appropriate antimicrobial neutralization and growth promotion testing of your microbiological media prior to your drug product testing.

Your clients rely on your laboratory data for critical information about the quality of their drugs. It is important that your test methods are properly verified or validated, and that you use appropriate test methods to enable your clients to make proper decisions (e.g., lot disposition). Results generated using unverified or unvalidated methods can mislead customers and may put consumers at risk.

Responsibilities of a Contract Testing Lab

FDA considers contractors as extensions of the manufacturer's own facility. Your failure to comply with CGMP may affect the quality, safety, and efficacy of the drugs you test for your clients. It is essential that you understand your responsibility to operate in full compliance with CGMP, and that you inform all your customers of any OOS results or significant problems encountered during the testing of these drugs.

For additional information refer to FDA's guidance document *Contract Manufacturing Arrangements for Drugs: Quality Agreements* at https://www.fda.gov/media/86193/download.

Drug Testing Ceased

We acknowledge that you have deregistered and committed to cease testing "for relevant customer products" at this facility. In response to this letter, clarify the steps you will take to ensure your customers are aware that your firm is not a drug testing facility.

If you plan to resume any operations regulated under the FD&C Act, notify this office before resuming your operations. You are responsible for resolving all deficiencies and systemic flaws to ensure your firm is capable of ongoing CGMP compliance. In your notification to the Agency, provide a summary of your remediations to demonstrate that you have appropriately completed all corrective action and preventive action (CAPA).

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations.

This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 30 working days. Specify what you have done to address any violations and to prevent their recurrence. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices. If you cannot complete corrective actions within 30 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 3017442763 and ATTN: Bryce Hammer.

Sincerely,

/*Francis Godwin*/

Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research