WARNING LETTER

Spectrum Laboratory Products, Inc.

MARCS-CMS 579958 — JUL 31, 2019

Delivery Method:

VIA UPS

Product:

Drugs

Recipient:

Mr. Randy Burg

President/CEO

Spectrum Laboratory Products, Inc.

14422 S. San Pedro Street
Gardena, CA 90248
United States

Issuing Office:

Division of Pharmaceutical Quality Operations I

10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
United States

WARNING LETTER

CMS #579958

07/31/2019

VIA UPS OVERNIGHT

Mr. Randy Burg
President/CEO
Spectrum Laboratory Products, Inc.
14422 S. San Pedro Street
Gardena, CA 90248

Dear Mr. Burg:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Spectrum Laboratory Products, Inc., FEI 2246824, at 755, 769, and 777 Jersey Avenue, New Brunswick, New Jersey, from February 19, 2019 to March 12, 2019.

This warning letter summarizes significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API 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).

Your firm repackages and relabels many drugs for commercial distribution in the United States. A review of FDA's drug listing database confirms that some of these drugs are not currently listed with FDA as required by section 510 of the FD&C Act, 21 U.S.C. 360(j)), which is prohibited under section 301(p) of the FD&C Act, 21 U.S.C. 331(p)). Failure to properly list a drug with the FDA will also render it misbranded under section 502(o) of the FD&C Act, 21 U.S.C. 352(o)).

In addition, your potassium bicarbonate, sodium bicarbonate, progesterone, ferric subsulfate solution and tobramycin sulfate API are misbranded under sections 502(a) of the FD&C Act, 21 U.S.C. 352(a).

We reviewed your April 1, 2019, response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence.

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

1. Failure to transfer all quality or regulatory information received from the API manufacturer to your customers and to reference the original manufacturer on your certificates of analysis.

You omitted the names and addresses of the original manufacturers of your repackaged API on certificates of analysis (COA) you issued to your customers. For example, you omitted the manufacturer information on your COA or labels for potassium bicarbonate USP, sodium bicarbonate USP, progesterone (micronized powder) USP, and ferric subsulfate solution, USP. You distributed these API with incomplete information to your customers, including compounding pharmacies.

In your response, you asserted that your current practice is sufficient. Your response stated you maintain traceability and your customers can request information regarding the original manufacturer if they sign a non-disclosure agreement. However, your COA do not provide the identity of the original manufacturer to your customers. Your response is inadequate in that you do not commit to ensure that your COA contain true and accurate information about the original manufacturer. Note, in your response to the FDA Warning Letter issued to your California Facility, you proposed **(b)(4)** on your COA instead of providing accurate information to your customers. The **(b)(4)** on the COA is not an acceptable method of providing the actual manufacturer's name and is not true and accurate information.

Customers and regulators rely on COA for information about the quality and source of drugs and their components. Omitting information from the COA compromises supply chain accountability and traceability, and may put consumers at risk.

See *Guidance for Industry: Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients and Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients—Questions and Answers* for more information on how API, from original manufacturers as well as API repackagers and relabelers, should be labeled and should clearly identify the original API manufacturer as the API moves through the supply chain. The guidance can be found at: https://www.fda.gov/media/71518/download and https://www.fda.gov/media/112426/download.

In response to this letter, provide the following:
 A remediated program for generating COA, including systems and procedures to assure that COA issued by your firm include necessary original manufacturer information.

 A retrospective review to determine how your failure to provide required information may have affected drug quality. Indicate any actions you have taken or will take, such as notifying customers, or invalidating previously issued COA for any drugs still within their labeled retest dates.
 Examples of recently-issued COA that include specific information regarding the original manufacturer, including a copy of their original batch certificate.

Observations at Multiple Sites

FDA cited similar CGMP deviations at another facility in your company's network. We issued a warning letter to Spectrum Laboratory Products, Inc., FEI 2020632, in Gardena, California on June 4, 2019, citing similar CGMP deviations for lack of supply chain traceability. These failures at multiple sites demonstrate that management oversight and control over the manufacture of drugs are inadequate.

Your executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance. You should immediately and comprehensively assess your company's global manufacturing operations to ensure that systems, processes, and the products manufactured conform to FDA requirements.

CGMP Consultant Recommended

We acknowledge that you committed to using a consultant to assist in meeting FDA requirements.

Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance.

Concerns Regarding Glycerin

Your product list collected during the inspection, which is also available on your website, included the drug glycerin. The use of glycerin contaminated with diethylene glycol (DEG) has resulted in various lethal poisoning incidents in humans worldwide. See FDA's guidance document, *Testing of Glycerin for Diethylene Glycol*, to help you meet CGMP requirements when distributing glycerin for use in drug products, including testing for DEG and recommendations for supply chain integrity, including ensuring drug product manufacturers, such as you customers, know the true identity of the manufacturer of glycerin, at https://www.fda.gov/media/71029/download.

Drug Listing Violation

According to the sales record obtained at the time of inspection, Spectrum Laboratory Products Inc., FEI 2246824, repackages and relabels drugs for commercial distribution in the United States, of which some have not been listed with FDA as required by the law.

Examples include bismuth subsalicylate, clobetasol propionate, and dextromethorphan hydrobromide. Under section 510 of the FD&C Act, as amended, and 21 CFR 207, all drugs manufactured, prepared, propagated, compounded, or processed for U.S. commercial distribution must be listed with the FDA. See 21 U.S.C. 360(j)(1); see also 21 CFR 207.17 and 207.41.

Failure to properly list a drug product is prohibited and will render the drug misbranded. See 21 U.S.C. 331(p) and 352(o).

Misbranding Violations

The potassium bicarbonate, sodium bicarbonate, progesterone, ferric subsulfate solution and tobramycin sulfate API labels identify Spectrum but do not designate the firm's role. Since these API labels bear only Spectrum's name without further qualifications, the labels falsely represent that Spectrum is the sole drug

manufacturer. (See 21 CFR 201.1(h)(2)). Therefore, the API are misbranded under section 502(a) of the FD&C Act, 21 U.S.C. 352(a), because the labels are false and misleading.

Conclusion

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

If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b) and allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

Correct the deviations cited in this letter promptly. Failure to promptly correct these deviations may result in legal action without further notice including, without limitation, seizure and injunction. Unresolved deviations in this warning letter may also prevent other Federal agencies from awarding contracts.

FDA may also withhold approval of requests for export certificates and approval of pending new drug applications or supplements listing your facility as a supplier or manufacturer until the above deviations are corrected. We may re-inspect to verify that you have completed your corrective actions.

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your deviations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to orapharm1_responses@fda.hhs.gov. Your written notification should refer to FEI #2246824 and Warning Letter CMS#579958. If you have any questions, contact Compliance Officer James Mason at james.mason@fda.hhs.gov or 570-262-0519.

Sincerely,
/S/

Diana Amador-Toro
Program Division Director/District Director
U.S. Food and Drug Administration
OPQO Division I/New Jersey District

cc:

Mr. Thomas N. Tyner
Vice President of Quality & Technical Service
Spectrum Laboratory Products, Inc.
14422 S. San Pedro Street
Gardena, CA 90248

Mr. Ibad Tirmizi
Director of Quality Assurance and Quality Control
Spectrum Laboratory Products, Inc.

769 Jersey Avenue
New Brunswick, NJ 08901

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