South Coast Specialty Compounding, Inc. 3/20/17

Los Angeles District
19701 Fairchild, Irvine CA 92612-2506
Telephone: 949-608-2900
Fax: 949-608-4417

WARNING LETTER

UNITED PARCEL SERVICE
SIGNATURE REQUIRED

March 20, 2017

WL# 21-17

Mr. Dennis Saadeh
Senior Director of Corporate Development West
ImprimisRx CA
9257 Research Drive
Irvine, CA 92618-4286

Dear Mr. Saadeh,

From February 23, 2016 to March 14, 2016, U.S. Food and Drug Administration (FDA) investigators inspected your facility, ImprimisRx CA, formerly known as South Coast Specialty Compounding Inc. dba Park Compounding, located at 9257 Research Drive, Irvine, CA 92618-4286. The investigators noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on March 14, 2016. FDA acknowledges receipt of your facility's responses, dated April 4, 2016 and May 23, 2016, as well as the response received January 31, 2017. Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Violations of the FDCA

Adulterated Drug Products

The FDA investigators noted that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigators noted: improper movement of the lyophilizer which exposed product to lower than ISO 5 quality air; employees with exposed neck and forehead while filling sterile syringes; the use of non-sterile wipes to clean counters, work surfaces, scales and equipment; and sterilized vials and stoppers stored in an unclassified area for an indefinite time, increasing the risk they will become contaminated.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, it is a prohibited act under section 301(k) of the FDCA to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

B. Corrective Actions

We have reviewed your firm's responses to the Form 483.

Regarding the insanitary condition observations in the Form 483, your proposed corrective actions appear to adequately address the deficiencies. However, in regards to your proposed facility modification to relocate the lyophilizer in an ISO 5 environment, we are unable to fully evaluate the adequacy of the changes and the completed actions. Specifically, your response did not include a description of the specific changes to the facility (e.g. new layout) and what interim controls your firm put in place during the facility modification. In addition, we are unaware what controls and /or actions you will take after the modification.

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

C. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

Within fifteen working days of receipt of this letter, please notify this office in writing of the additional steps that you have taken to correct violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction.

Please send your reply to:

Kelly Sheppard, Director
Compliance Branch
U.S. Food and Drug Administration
Los Angeles District
19701 Fairchild Rd.
Irvine, CA 92612-2445

If you have questions regarding the contents of this letter, please contact Ms. Jessica Mu via email at Jessica.Mu@fda.hhs.gov or by phone at (949) 608-4477. Please reference CMS number 509499 in your response.

Sincerely,
/S/
Steven E. Porter
District Director
Los Angeles District

Cc: Ricardo Burgos, Director of Quality Assurance
Imprimis Pharmaceuticals, Inc.
12264 El Camino Real, Suite 350
San Diego, CA 92130

Virginia Herold, Executive Officer
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1625 N. Market Street
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