Sewaren Innovative Pharmaceutical Packaging dba SIPP 5/22/17

U.S. FOOD & DRUG ADMINISTRATION

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May 22, 2017

WARNING LETTER

VIA UPS OVERNIGHT
Hank Incognito, Owner
Sewaren Innovative Pharmaceutical Packaging dba SIPP
994 Rahway Avenue Suite 1
Avenel, NJ 07001-1946

17-NWJ-02

Dear Mr. Incognito:

From April 18, 2016 to June 28, 2016, U.S. Food and Drug Administration (FDA) Investigators inspected your facility, Sewaren Innovative Pharmaceutical Packaging dba SIPP, located at 994 Rahway Avenue Suite 1, Avenel, NJ 07001-1946. During the inspection, the Investigators noted that drug products you produced failed to meet the conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a] for exemption from certain provisions of the FDCA. 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 June 28, 2016. FDA acknowledges receipt of your firm's response, dated July 12, 2016. FDA also acknowledges the statement in your response letter indicating your firm's intent to "voluntarily cease[] sterile compounding activities, effective February 19, 2016." Based on this inspection, it appears that you produced drug products that violate the FDCA.

A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(l)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(l) and 355].***1*** Receipt of valid prescriptions for individually-identified patients is one of the conditions for the exemptions under section 503A.

B. Failure to Meet the Conditions of Section 503A

During the inspection, FDA Investigators noted that drug products produced by your firm failed to meet the conditions of section 503A. For example, the Investigators noted that your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.

Therefore, you compounded drug products that do not meet the conditions of section 503A and are not eligible for the exemptions in that section from the FDA approval requirement of section 505 of the FDCA, the requirement under section 502(f)(l) of the FDCA that labeling bear adequate directions for use, and the requirement of compliance with CGMP under section 501(a)(2)(B) of the FDCA. In the remainder of this letter, we refer to your drug products that do not qualify for exemptions under section 503A as the "ineligible drug products".

Specific violations are described below.

C. 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 observed that your firm 's **(b)(4)**, where aseptic processing occurs, was located in an unclassified room.

Furthermore, the manufacture of the ineligible drug products is subject to FDA's CGMP regulations, Title 21, Code of Federal Regulations (CFR), parts 210 and 211. The FDA Investigators observed significant CGMP violations at your facility, causing the ineligible drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations included, for example:

1. Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure. (21 CFR 211.42(c)(10)(iii))

2. Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes. (21 CFR 211.113(b))

3. Your firm failed to establish a written testing program designed to assess the stability characteristics of drug products and to use results of such stability testing to determine appropriate storage conditions and expiration dates. (21 CFR 211.166(a))

It is a prohibited act under section 301 (k) of the FDCA [21 U.S.C. § 331 (k)] 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.

Misbranded Drug Products

The ineligible drug products you compounded are intended for conditions not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses.***2*** Accordingly, these ineligible drug products are misbranded under section 502(f)(l) of the FDCA. 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 misbranded.

D. Corrective Actions

We have reviewed your firm's response to the Form 483. We acknowledge your statements indicating your firm's intent to "voluntarily cease[] sterile compounding activities" following an inspection of your firm by the New Jersey Board of Pharmacy, and to "agree[] not to re-start sterile compounding activities without the Board's consent."

Please be aware that section 501 (a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A.

Should you continue to compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the drug CGMP regulations. Before doing so, you must comply with the requirements of section 505 and section 502(f)(1), and fully implement corrections that meet the minimum requirements of the CGMP regulations.***3***

In addition to the issues discussed above, you should note that CGMP requires the implementation of quality oversight and controls over the manufacture of drugs, including the safety of raw materials, materials used in drug manufacturing, and finished drug products. *See* section 501 of the FDCA. If you choose to contract with a laboratory to perform some functions required by CGMP, it is essential that you

select a qualified contractor and that you maintain sufficient oversight of the contractor's operations to ensure that it is fully CGMP compliant. Regardless of whether you rely on a contract facility, you are responsible for assuring that drugs you produce are neither adulterated nor misbranded. *See* 21 CPR 210.1(b), 21 CPR 200.10(b).

FDA strongly recommends that if you decide to resume production of sterile drugs, your management first 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 could be useful in conducting this comprehensive evaluation.

E. 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.

If you decide to resume sterile operations, you should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing if you have taken any specific steps to correct the violations cited in this letter, or you may inform us that you do not intend to resume production of sterile drugs. If you intend to resume production of sterile drugs in the future, 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 violated the FDCA, include your reasoning and any supporting information for our consideration. In addition to taking appropriate corrective actions, you should notify this office 15 days prior to resuming production of any sterile drugs in the future.

Your written notification should refer to the Warning Letter Number above 17-NWJ-02. Please address your reply to:

Barbara Wilimczyk-Macri
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

If you have questions regarding the contents of this letter, please contact Barbara Wilimczyk-Macri at (973) 331-4951.

Sincerely,

/S/
Diana Amador-Toro,
District Director,
New Jersey District,
Office of Regulatory Affairs,
U.S. Food and Drug Administration
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

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1 We remind you that there are conditions other than those discussed in this letter that must be satisfied to qualify for the exemptions in section 503A of the FDCA.
2 Your ineligible drug products are not exempted from the requirementsof section 502(f)(1) of the FDCA by regulations issued by FDA (see, e.g., 21 CFR 201.115).
3 In this letter, we do not address whether your proposed corrective actions would resolve the CGMP violations noted above.