Deserving Health International Corp 12/18/17

10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS

Warning Letter 320-18-17

December 18, 2017

Mr. Bernard Armani
President
Deserving Health International Corp.
13160 Vanier Place, Unit 110
Richmond, British Columbia, V6V 2J2
Canada

Dear Mr. Armani:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Deserving Health International Corp. at 13160 Vanier Place, Unit 110, Richmond, British Columbia, from July 10 to 14, 2017.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211.

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products 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 August 4, 2017, response in detail.

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

1. Your firm failed to 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)).

Your firm failed to implement an appropriate manufacturing process that can assure sterility of your Symbio Muc Eye Drops 5X homeopathic drug product, which you purport to be sterile. This product is indicated for ophthalmic use, including for “red and irritated eyes” and “ allergy eyes.”

Your process was not capable of reproducibly preventing contamination and producing sterile units. The method used by your firm to attempt sterilization relied on a **(b)(4)** containing an **(b)(4)**. This method is not suitable for its intended use.

You also manufactured this product using unsuitable water. The drug product was produced using non-sterile, **(b)(4)** water.

In your response, you stated that you are in the process of qualifying sterile processing equipment.

Your response could not be fully evaluated because you failed to provide evidence that your Symbio Muc Eye Drops 5X homeopathic drug product distributed to the United States meets sterility requirements. The response also did not address potential risks to patients, or indicate that you would perform a risk assessment for all batches of purportedly sterile drug products distributed to the United States.

In response to this letter, we request that you provide the following.

- Details about the improvements you are making to your facility and process to ensure that all units you purport to be sterile are produced under appropriate aseptic processing conditions.
- A corrective action plan that includes use of purified water for all your products, and specifies appropriate testing limits for microbiological and chemical quality.

2. Your firm failed to establish an adequate quality control unit and procedures applicable to the quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling, and drug products (21 CFR 211.22(a) and (d)).

You lacked quality oversight for finished drug products manufactured in your facility, including a sterile homeopathic drug product, Symbio Muc Eye Drops 5X.

You failed to establish written procedures for numerous functions. For example, there were no procedures addressing the quality control unit, deviations, investigations, stability studies, quality review of incoming materials, finished product batch release, and various other basic drug manufacturing operations.

Further, your quality control unit lacked documentation to demonstrate acceptability of batch manufacturing and quality. For instance, you lacked records relating to:

- annual product reviews;

- full batch record review to evaluate if instructions were followed, and to assure that any errors or anomalies were fully investigated; and
- approval or rejection of your drug products.

During the inspection, our investigator determined that your production manager conducts the final batch review and releases the finished drug product, which is a quality control unit responsibility.

In your response, you stated you are in the process of creating a standard operating procedure which defines, in writing, the roles and responsibilities of the quality control unit.

Your response was not adequate or could not be fully evaluated due to a lack of supporting documentation. You failed to provide documentation, sufficient details, and scientific justification to support that you are establishing appropriate operational functions, systems, programs, and related procedures to assure product quality. You also failed to address the potential effects of your lack of quality oversight on the quality of all drugs that you manufactured without such oversight and which remain within expiry. For example, you produced a product that contains *penicillium notatum*, which can result in penicillin contamination, and did not address the related risks to that marketed product or whether cross-contamination of other products may have occurred.

In response to this letter, we request that you provide your plan for establishing an adequate quality control unit. Include any procedures you have implemented that address the responsibilities and functions of your quality control unit.

Also provide an action plan to promptly address risks posed by marketed products that may contain penicillin, and clarify whether you will be using fully-segregated facilities for any future production.

See FDA's guidance document, *Quality Systems Approach to Pharmaceutical CGMP Regulations*, for help implementing modern quality systems and risk management approaches to meet the requirements of CGMP regulations (21 CFR, parts 210 and 211), at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070337.pdf.

3. Your firm failed to conduct at least one test to verify the identity of each component of a drug product. Your firm also failed to test each component for conformity with all appropriate written specifications for purity, strength, and quality (21 CFR 211.84(d)(1) & (2)).

You did not test each raw material lot for identity before permitting use of the component in manufacture of your drug products. For instance, you failed to perform identity tests on components including but not limited to glycerin, salicylic acid, and *penicillium notatum* used in your finished drug products.

Furthermore, you failed to determine whether each component lot conformed with all appropriate written specifications for purity, strength, and quality before using them.

In your response, you stated you are in the process of qualifying your suppliers of all raw materials used to manufacture the over-the-counter and homeopathic products you distribute to the United States. However, you did not address your critical failure to test all components for identity and other appropriate specifications prior to use, and you did not address how this may affect the quality or safety of all of your products within expiry and shipped to the U.S.

In response to this letter, we request that you provide a risk assessment for any drug products manufactured using components which were not adequately tested and controlled. Include all products within expiry and distributed within the U.S.

4. Your firm failed to perform, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release, and conduct appropriate laboratory testing for each batch of drug product required to be free of objectionable microorganisms (21 CFR 211.165(a) and (b)).

You released finished drug products without testing. For example, you did not test any of your finished drug products, including Baby Specialty Cream, Formula H Balm, or Acne Prone Skin Gel, to determine whether they conformed to the identity and strength stated on the label. In addition, you did not test for other quality attributes, including microbial attributes, to ensure each batch conforms with appropriate specifications for total count and absence of objectionable organisms.

In response to this letter, describe your corrective action plan to ensure that you fully test drug product batches before you release or reject them, as appropriate. Include your release testing procedures describing your testing requirements for each product, as well as validated test methods and appropriate acceptance criteria.

Additionally, include an action plan and timelines for conducting tests of retain samples to determine the identity and strength of active ingredients, preservative content, and microbiological quality of drug products distributed to the United States that are within expiry, as appropriate. If such testing reveals substandard quality drug products, provide your corrective actions, including notifying customers and considering the need for product recalls.

CGMP consultant recommended

Based upon the nature of the violations we identified at your firm, we strongly recommend engaging a consultant, qualified as set forth in 21 CFR 211.34, to assist your firm in meeting CGMP requirements. It is essential that you initiate a comprehensive assessment of your company’s manufacturing operations to ensure that systems and processes, and ultimately, the products manufactured, conform to 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 fully resolving any deficiencies at your firm, and ensuring ongoing CGMP compliance.

Recall and cessation of production

We acknowledge that you agreed to recall Symbio Muc Eye Drops 5X homeopathic drug product due to a lack of sterility assurance in September 2017. Additionally, you stated in your response that you have **(b)(4)**.

Conclusion

Violations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these violations, for determining the causes, for preventing their recurrence, and for preventing other violations.

FDA placed your firm on Import Alert 66-40 on November 2, 2017.

Until you correct all violations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug manufacturer.

Failure to correct these violations may also result in FDA refusing admission of articles manufactured at Deserving Health International Corp., 13160 Vanier Place, Unit 110, Richmond, British Columbia, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

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 violations 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 CDER-OC-OMQ-Communications@fda.hhs.gov or mail your reply to:

Carla Norris
Compliance Officer
U.S. Food and Drug Administration
White Oak Building 51, Room 4359
10903 New Hampshire Avenue
Silver Spring, MD 20993
USA

Please identify your response with FEI 3012271380.

Sincerely,
/S/
Francis Godwin
Acting Director
Office of Manufacturing Quality

Office of Compliance
Center for Drug Evaluation and Research