Shanwei Honghui Daily Appliance Co., Ltd. 12/5/17

Via UPS **Warning Letter** 320-18-14

December 5, 2017

Mr. Weishan Song
Operation Director
Shanwei Honghui Daily Appliance Co., Ltd.
Chunzai Garden Wuya Hong Cao Town
Shanwei, Guangdong Province, 516626
China

Dear Mr. Song:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Shanwei Honghui Daily Appliance Co., Ltd., at Chunzai Garden Wuya Hong Cao Town, Shanwei, Guangdong Province, from July 31 to August 3, 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 23, 2017 response in detail. In your response, you accepted the violations cited on the FDA Form 483 and blamed your lack of FDA experience. Your response was inadequate and lacked detail. While you provided various documents, you did not specifically address the deficiencies identified during

the inspection. You also did not conduct a retrospective review of your products already distributed to the United States under the violative conditions detailed below.

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

1. Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(a)).

For example, based on photographic evidence collected by our investigator, your filling machines used to manufacture over the counter (OTC) drug products for the U.S. market were filthy and were surrounded by cardboard and dirty rags. Your firm also failed to sanitize your **(b)(4)** system since its installation more than 10 years ago.

2. Your firm failed to follow written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess, and to document same at the time of performance (21 CFR 211.100(b)).

Your firm did not follow production and process procedures. For example, Standard Operating Procedure (SOP) HH/QB-03 *Control of Critical Production Steps* requires controlling raw materials, conducting microbiological testing of **(b)(4)** and finished drug products, cleaning equipment, documentation, in-process testing, and product release. Your response confirmed that your firm failed to follow these procedures.

3. 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)).

Your firm had no test records to support the release of drug products for the U.S. market. Your engineer and quality assurance supervisor stated that no microbiology tests were performed, there was no record of pH testing, and that the concentration of active ingredients such as **(b)(4)** and **(b)(4)** were not determined. You stated that some tests were sent to a contract testing laboratory. However, you did not provide any test reports during the inspection.

4. Your firm failed to ensure the identity of components, including your active ingredients and excipients from various suppliers (21 CFR 211.84(d)(1) and (2)).

Your firm did not perform any identification tests for incoming materials, including active ingredients and excipients. You stated that you relied on Certificates of Analysis (CoA) from suppliers that had not been qualified. Your firm had not

established the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

5. Your firm failed to prepare batch production and control records with complete information relating to the production and control of each batch of drug product produced (21 CFR 211.188).

Your firm failed to provide batch records for **(b)(4)** of **(b)(4)** batches manufactured for the U.S. market. You stated to our investigator that there was not a batch record for each batch.

Consultant Recommended
Based upon the nature of 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. 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 all deficiencies and ensuring ongoing CGMP compliance at any Shanwei Honghui site.

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 continuing to refuse admission of articles manufactured at Shanwei Honghui Daily Appliance Co., Ltd., at Chunzai Garden Wuya Hong Cao Town, Shanwei, Guangdong Province, 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:

Marisa Heayn
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 3011155936.

Sincerely,
/S/
Francis Godwin
Acting Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research