WARNING LETTER

ShangRao Chunyu Technology Co., Ltd.

MARCS-CMS 610194 — FEBRUARY 03, 2021

Delivery Method:

VIA UPS

Product:

Drugs

Recipient:

Mr. Daniel Suer

CEO

ShangRao Chunyu Technology Co., Ltd.

Xuri Zone
Shangrao Economic-Technical Development Area
Shangrao Shi Jiangxi Sheng, 334100
China

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

Warning Letter 320-21-24

February 3, 2021

Dear Mr. Suer:

Your firm is registered as a human drug manufacturer. The U.S. Food and Drug Administration (FDA) conducted testing of a consumer antiseptic rub drug product (also referred to as a consumer hand sanitizer), labeled as Instant – Hand Sanitizer – Moisturizing. This drug product was declared to be manufactured at your facility, Shangrao Chunyu Technology Co., Ltd., FEI 3015958566, at Xuri Zone, Shangrao Economic-Technical Development Area, Shangrao, Jiangxi 334100, China. Following an attempt to import Instant – Hand Sanitizer – Moisturizing into the United States, it was detained and refused admission at the border.

The results of the FDA laboratory testing of a batch of this product detained at the border demonstrate that this drug product declared to be manufactured at your facility is adulterated within the meaning of section 501(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act), 21 U.S.C. 351(c), in that its strength, purity, or quality falls below that which it purports or is represented to possess. In addition, this product is adulterated within the meaning of section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)), in that the subpotency demonstrates that the quality assurance within your facility is not functioning in accordance with Current Good Manufacturing Practice (CGMP) requirements.

Adulteration Violation

Instant – Hand Sanitizer – Moisturizing, declared to be manufactured at your facility, is labeled to contain 75% of the active ingredient alcohol ethyl alcohol (ethanol). However, FDA laboratory testing of a batch of this product detained at the border found that the drug product contained an average of only 58% ethanol volume/volume. This hand sanitizer drug product is adulterated under section 501(c) of the FD&C Act in that the active ingredient of ethanol is present at levels in the product lower than that which is declared on its label.

CDC recommends***1*** that, if soap and water are not readily available, consumers use an alcohol-based hand sanitizer that contains not less than 60% alcohol (ethanol). This is the minimum active ingredient concentration of ethanol specified in the 1994 Tentative Final Monograph for Health-Care Antiseptic Drug Products (59 FR 31402), as further amended by "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016).

On September 8, 2020, FDA held a teleconference with you and Pragmatic Compliance, LLC, your registered U.S. Agent. We requested additional information concerning your CGMP operations, including test methods for your finished product. In your response, you provided your test method for release of finished hand sanitizer products. The method you submitted uses a **(b)(4)** that is unsuitable for the testing of finished hand sanitizers that contain materials other than ethanol and water in their **(b)(4)**. The use of this unsuitable device to test your finished hand sanitizer products violates CGMP requirements (see 21 CFR 211.160(b) (requiring the use of scientifically sound and appropriate test procedures to, among other things, assure that drug products conform to appropriate standards of identity, strength, quality, and purity).

In response to this letter, provide the following:

• A detailed investigation into how the hand sanitizer drug product described above, which was labeled as containing 75% ethanol, in fact contained 58% ethanol.
• A list of all raw materials used to manufacture all of your hand sanitizer drug products, including the suppliers' names, addresses, and contact information.
• A list of all batches of any hand sanitizer drug products shipped to the United States by your firm, and a full reconciliation of all material you distributed.
• For all batches distributed to the U.S., provide a third-party analysis using validated test methods for ethanol content. For out-of-specification (OOS) batches, provide your action plan to address any product quality or patient safety risks for your drug products in U.S. distribution, including potential customer notifications and recalls.
• Copies of the complete batch records for all batches distributed to the U.S.
• A complete, comprehensive, and independent assessment of your laboratory practices, procedures, methods, equipment, documentation, and analyst competencies. Based on this review, provide a detailed plan to remediate and evaluate the effectiveness of your laboratory system.

The subpotency of a drug product declared as manufactured at your facility demonstrates that the quality assurance within your facility is not functioning in accordance with CGMP requirements under section 501(a)(2)(B) of the FD&C Act.2

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 evaluate your operations and to assist your firm in meeting CGMP requirements, if your firm intends to resume manufacturing drugs for the U.S. market. We also recommend that the qualified consultant perform a comprehensive audit of your entire operation for CGMP compliance and that the consultant evaluates the completion and efficacy of your corrective actions and preventive actions before you pursue resolution of your firm's compliance status with FDA. 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.

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations associated with your drug products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations.

Note that FDA placed all drugs and drug products manufactured by your firm on Import Alert 66-78 on November 6, 2020, as the methods used in and controls used for the manufacture, processing, packing, or holding of these products do not appear to conform to current good manufacturing practices within the meaning of section 501(a)(2)(B) of the FD&C Act. Drugs and drug products that appear to be adulterated or misbranded may be detained or refused admission without physical examination.

All drugs and drug products manufactured by your firm may remain listed on this import alert, until there is evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved, and the Agency has confidence that future entries will be in compliance with the Act. This may include an inspection prior to the Agency considering the appearance of adulteration to be addressed.

If you decide you want to manufacture drugs for the United States in the future, request a Regulatory Meeting to discuss corrective actions.

This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done to address any violations and to prevent their recurrence. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices. If you cannot do so 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.

Please identify your response with FEI 3015958566 and ATTN: Bryce Hammer.

Sincerely,
/S/

Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

CC:
Registered U.S. Agent
Jerry Doane
Pragmatic Compliance LLC
15815 SW 11th Court Rd
Ocala, FL 34473-8916

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1 https://www.cdc.gov/handwashing/hand-sanitizer-use.html

2 Due to an increased demand for alcohol-based hand sanitizers during the COVID-19 pandemic, FDA published the Guidance for Industry: *Temporary Policy for Preparation of Certain Alcohol- Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)* on March 19, 2020, and subsequently updated the guidance several times, most recently on August 7, 2020. This guidance communicates the Agency's temporary policy that we do not intend to take action against firms for CGMP violations under section 501(a)(2)(B) of the FD&C Act if such firms prepare alcohol-based hand sanitizers for consumer use (or for use as health care personnel hand rub) during the public health emergency, provided certain circumstances described in the guidance are present. These circumstances include preparation of hand sanitizer products using only the ingredients and formulas set forth in the guidance. In addition to the violative sample results detailed above that demonstrate the subpotency of a hand sanitizer product declared as manufactured at your facility, a review of the drug product's labeling further indicates that the product is not prepared consistent with FDA's temporary policy set forth in the guidance. Therefore, this product does not fall within the Agency's temporary policy not to take action against firms manufacturing hand sanitizer products for violations of section 501(a)(2)(B) of the FD&C Act.

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