WARNING LETTER

Premier Trends LLC

MARCS-CMS 621313 — MARCH 14, 2022

Product:

Drugs

Recipient:

Ms. Shabana Baig

President/Co-Owner

Premier Trends LLC

4 Elisa Drive
Monroe Township, NJ 08831-3527
United States

Issuing Office:

Division of Pharmaceutical Quality Operations I

United States

Warning Letter 621313

March 14, 2022

Dear Ms. Baig:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Premier Trends LLC, FEI 3014373428, at 4 Elisa Dr, Monroe Township, NJ 08831-3527, from September 23, 2021, to September 29, 2021.

This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (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 product is 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).

Your drug product is misbranded under Section 502(o) of the FD&C Act, 21 U.S.C. 352(o) because your firm is not currently registered as required under section 510(i)(1) of the FD&C Act, 21 U.S.C. § 360(i)(1). In addition, on November 30, 2020, your firm discontinued the drug listing submission for Magic Heal (NDC 72168-786-12) and it has not been relisted.

We reviewed your October 9, 2021, response to our Form FDA 483 in detail. Your product is labeled for intended uses, such as "**MAGIC HEAL™** is a blend of unique imported essential oils, such as Neem and Karanja that have been known for centuries for their skin protection and soothing properties," and "**MAGIC**

HEAL'S soothing aroma…and is absorbed deep into the skin to nourish the rough and cracked skin into smooth and soft skin after only a few applications." Thus, Magic Heal is a "drug" as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because it is intended to affect the structure or any function of the body. Specifically, this product is intended for use as a skin protectant. Your response is inadequate because it did not provide sufficient detail or evidence of corrective actions to bring your operations into compliance with drug CGMP regulations.

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

CGMP Violations

1. Your firm failed to have, 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 (21 CFR 211.165(a)).

Your firm failed to test your over-the-counter (OTC) drug product, Magic Heal, for the identity and strength of each active ingredient prior to release for distribution. In addition, your firm lacked approved specifications for Magic Heal. Testing is essential to ensure that the drug products you manufacture conform to all pre-determined quality attributes appropriate for their intended use. Because you lacked adequate testing of each batch of your drug product, you do not know whether they conform to all appropriate finished product specifications and are suitable for release to consumers.

In response to this letter provide:
• a comprehensive, 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.
• a plan to ensure that products in the market are in compliance with appropriate specifications.
• a list of chemical and microbial test methods and specifications used to analyze each lot of your drug product before making lot disposition decision, and the associated written procedures.

2. Your firm failed to test samples of each component for identity and conformity with all appropriate written specifications for purity, strength, and quality. Your firm also failed to validate and establish the reliability of your component supplier's test analyses at appropriate intervals (21 CFR 211.84(d)(1) and (2)).

Your firm failed to test dimethicone active pharmaceutical ingredients (API) and other components, including neem oil, karanja oil, and lavender, prior to use in the manufacture of your drug product, Magic Heal. You also lacked approved specifications to assure API and other components conform with appropriate specifications for identity, strength, quality, and purity. Though you receive raw materials with a certificate of analysis from your suppliers, you have not performed appropriate incoming analysis of component lots upon receipt, including confirming the identity prior to use in production of your finished drug product. You also relied on your supplier's certificate of analysis without establishing the reliability of your component supplier's test analyses at appropriate intervals.

In response to this letter, provide:
• a comprehensive, independent review of your material system to determine whether all suppliers of components, containers, and closures, are each qualified and the materials are assigned appropriate expiration or retest dates. The review should also determine whether incoming material controls are adequate to prevent use of unsuitable components, containers, and closures.
• the chemical and microbiological quality control specifications you use to test and release each incoming lot

of components for use in manufacturing.
• a description of how you will test each component lot for conformity with all appropriate specifications for identity, strength, quality, and purity. If you intend to accept any results from your supplier's certificates of analysis instead of testing each component lot for strength, quality, and purity, specify how you will robustly establish the reliability of your supplier's results through initial validation as well as periodic re-validation. In addition, include a commitment to always conduct at least one specific identity test for each incoming component lot.

3. Your firm failed to routinely calibrate, inspect, or check according to a written program designed to assure proper performance of and to maintain adequate written records of calibration checks and inspections of automatic, mechanical, electronic equipment, or other types of equipment, including computers, used in the manufacture, processing, packing, and holding of a drug product (21 CFR 211.68(a)).

You used **(b)(4)** to manufacture your drug product, Magic Heal. You did not calibrate or verify the accuracy of the temperature-controlled function of the **(b)(4)** to ensure the manufacturing process is controlled for each batch. In addition, you failed to calibrate or qualify the scale you used to weigh drug components.

In response to this letter, provide an evaluation of all your manufacturing equipment to ensure they are suitable for the intended use. Additionally, provide your corrective action and preventive action (CAPA) plan to implement routine, vigilant operations management oversight of equipment. This plan should ensure, among other things, prompt detection of equipment performance issues, effective execution of repairs, adherence to appropriate preventive maintenance schedules, timely technological upgrades to the equipment, and improved systems for ongoing management review.

4. Your firm failed to establish and follow written procedures for the preparation of master production and control records designed to assure uniformity from batch to batch. Your firm also 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 211.186(a) and 211.188).

You did not prepare adequate master and batch production records for your drug product, Magic Heal. Your batch records lacked:

• Approval signatures in conformance to a master batch record
• Detailed manufacturing instructions
• Identity of equipment used
• Sampling information
• Yield

In addition, you made several changes to your manufacturing process without justification or change control. For example, you changed the amounts of dimethicone API and other drug components (e.g., neem oil, karanja oil, and lavender) added during manufacturing operations.

Without adequate batch records, you cannot assure the uniformity of your drug products from batch to batch.

In response to this letter provide:
• a risk assessment of products released to the U.S. market without adequate and approved production and control documentation.
• procedures you have implemented or revised to assure production records are completed as required and reviewed by your quality unit prior to release of products for distribution.
• your updated master batch record for Magic Heal.

5. Your firm failed to ensure that each person engaged in the manufacture, processing,

packing, or holding of a drug product has the education, training, and experience, or any combination thereof, to enable that person to perform his or her assigned functions (21 CFR 211.25(a)).

You failed to ensure that all personnel are qualified for the CGMP operations they perform. For example, your co-owner stated that he is the sole proprietor of the Magic Heal formulation, had full knowledge of the process, and performed all manufacturing operations. However, you lack evidence that your co-owner has the adequate experience to perform these functions nor has received the appropriate CGMP training.

Training is essential to ensure proper performance of job functions.

In response to this letter provide:
• a training plan to ensure that:
  o job functions and training needs are established and reviewed on an ongoing basis to monitor whether staff competencies are robust.
  o management responsibilities and oversight are defined.
  o training is conducted with sufficient frequency to assure employees maintain understanding of all applicable CGMP requirements.
  o all staff who conduct or supervise CGMP functions are properly trained in CGMP, so that your operations are performed in a manner that assures drug safety, identity, strength, quality, and purity.
  o qualified individuals perform training.
  o provisions are implemented for evaluating staff comprehension, training effectiveness, and ensuring appropriate modifications where needed.
• an assessment of the impact of the lack of appropriate training on marketed drug products.

6. Your firm failed to establish a 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)).

Your firm lacks a quality unit (QU) and approved written procedures defining QU responsibilities and controls. In addition, your firm failed to establish adequate written responsibilities and procedures for:
• Batch release
• Manufacturing processes
• Laboratory deviations and CAPAs
• Complaints
• Recalls
• Handling of drug product returns and rejects

In response to this letter, provide a comprehensive assessment and remediation plan to ensure your QU is given the authority and resources to effectively function. The assessment should also include, but not be limited to:
• a determination of whether procedures used by your firm are robust and appropriate.
• provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices.
• a complete and final review of each batch and its related information before the QU disposition decision.
• oversight and approval of investigations and discharging of all other QU duties to ensure identity, strength, quality, and purity of your product.

Quality System

Your firm's quality system is inadequate. See FDA's guidance document *Quality Systems Approach to Pharmaceutical CGMP Regulations* for help implementing quality systems and risk management approaches to meet the requirements of CGMP regulations 21 CFR, parts 210 and 211 at https://www.fda.gov/regulatory-

information/search-fda-guidance-documents/quality-systems-approach-pharmaceutical-current-good-manufacturing-practice-regulations (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-systems-approach-pharmaceutical-current-good-manufacturing-practice-regulations).

Repeat Violations at Facility

In a previous inspection, dated June 28, 2019, FDA cited similar CGMP observations. These findings were also communicated to you during a regulatory meeting on December 17, 2019.
However, your product continues to be marketed with intended uses that renders your product a drug, and the corrective actions that you have taken in response to the December 17, 2019, regulatory meeting remain inadequate.

Additionally, you did not propose specific remedial actions in your response to our current inspectional findings nor did you indicate whether you intend to comply with drug CGMP regulations. Repeated failures demonstrate that executive management oversight and control over the manufacture of drugs is inadequate.

CGMP Consultant Recommended

Based upon the nature of the violations we identified at your firm and because you failed to correct repeat violations, we strongly recommend engaging a consultant qualified as set forth in 21 CFR 211.34 to assist your firm in meeting drug 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 resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance.

Misbranding and Registration/Listing Violations

Based upon the information obtained from the September 29, 2021 inspection, Premier Trends LLC (FEI 3014373428) has been identified as a drug manufacturer for Magic Heal (NDC 72168-786-12). Under section 510(i)(1) of the FD&C Act (21 U.S.C. 360(i)(1)), Premier Trends LLC is required to submit registration information annually by electronic means for each establishment it owns or operates that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug that is in commercial distribution in the United States. Premier Trends LLC has not fulfilled its registration requirement. As a result, all drugs manufactured in this establishment are misbranded under Section 502(o) of the FD&C Act [21 U.S.C. 352(o)].

In addition, the drug listing submission for Magic Heal (NDC 72168-786-12) under the name and labeler code for Premier Trends LLC (FEI 3014373428) was discontinued on November 30, 2020 and has not been recertified. This date in drug listing, refers to the expiry date of the last lot manufactured. However, Premier Trends LLC continued manufacturing Magic Heal (NDC 72168-786-12) until at least September 29, 2021, when it was inspected. Under section 510 of the FD&C Act as amended and 21 CFR (21 U.S.C. 360(j)(1), 21 CFR 207.17 and 207.41), all drugs manufactured, prepared, propagated, compounded, or processed for U.S. commercial distribution must be listed with FDA. Failure to properly list drug products is prohibited and will render the drugs misbranded (21 U.S.C. 331(p) and 352(o).

The introduction or delivery for introduction of a misbranded drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Drug Production Cessation

If you discontinue manufacturing your OTC drug product, Magic Heal, or update your labels please inform us in writing. If you continue manufacturing this product, inform us how you will meet CGMP requirements.

Conclusion

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

Correct any violations promptly. Failure to promptly and adequately address this matter may result in regulatory or legal action without further notice including, without limitation, seizure, and injunction. Unresolved violations may also prevent other Federal agencies from awarding contracts.

Failure to address violations may also cause FDA to withhold issuance of Export Certificates. FDA may withhold approval of new applications or supplements listing your firm as a drug manufacturer until any violations are completely addressed and we confirm your compliance with CGMP. We may re-inspect to verify that you have completed corrective actions to address any violations.

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 complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to ORAPHARM1_RESPONSES@fda.hhs.gov. Your written notification should refer to Warning Letter #621313 and include FEI number 3014373428.

If you have questions regarding the content of this letter, please contact us through ORAPHARM1_RESPONSES@fda.hhs.gov, and “cc” Compliance Officer Nancy Scheraga (Nancy.Scheraga@fda.hhs.gov).

Sincerely,
/S/

Craig Swanson
Acting Program Division Director/District Director
Office of Pharmaceutical Quality Operations
Division I/New Jersey District

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