Kim Chemicals Private Ltd. 10/16/17

10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS

Warning Letter 320-18-02

October 16, 2017

Mr. Bhagwan Chandanai
CEO
Kim Chemicals Private Ltd.
Plot No. G-13/16, MIDC, Taloja
Raigad, Maharashtra 410208
India

Dear Mr. Chandanai:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Kim Chemicals Private Ltd., at Plot No. G-13/16 MIDC, Taloja, Raigad, Maharashtra, from June 5 to 9, 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).

In addition, Kim Chemicals Private Ltd. manufactures unapproved new drug and misbranded drug products. Specifically, as formulated and labeled, Sofskin Vaporizing Chest Rub and Sofskin Pure Petroleum Jelly are unapproved new drugs in violation of section 505(a) of the FD&C Act 21 U.S.C. 355(a). Furthermore, Sofskin Vaporizing Chest Rub and Sofskin Pure Petroleum Jelly are misbranded under

section 502(x) of the FD&C Act 21 U.S.C. 352(x). Sofskin Pure Petroleum Jelly is further misbranded under section 502(c) of the FD&C Act 21 U.S.C. 352(c).

We reviewed your July 19, 2017 response in detail.

Your response is inadequate. Although you stated that “A GMP system with written procedures will be created and implemented,” your response lacks detail. You also did not include a retrospective review of CGMP deficiencies of your products already distributed to the United States.

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

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)).

For example, multiple batches of Vaporizing Chest Rub and **(b)(4)** failed to meet finished product specifications, including active ingredient content. Despite these failing test results, you shipped these drugs to the United States.

Additionally, your staff informed our investigator that batches are not routinely tested. Instead, your firm re-uses test results from a past batch produced several years ago, and enters those results on certificates of analysis for new batches.

Your brief response indicated that your firm is performing batch testing, but included no raw data or test results.

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)).

Your firm lacks an adequate quality control unit. You failed to establish written procedures for numerous functions. For example, there were no procedures for critical quality unit operations including, but not limited to, complaint handling, recalls, out-of-specification investigations, deviations, rejects, returns, and stability.

3. Your firm failed to ensure that laboratory records included complete data derived from all tests necessary to assure compliance with established specifications and standards (21 CFR 211.194(a)).

You had no records to support the analytical testing results reported on your certificate of analyses. Your firm indicated to our investigator that you document finished product analysis on a pad of paper, transcribe the test results onto a certificate of analysis, and then destroy the piece of paper. There is no assurance that the testing was conducted in the first place, and there is no record that any associated calculations were performed.

Data Integrity Remediation

Your quality system does not adequately ensure the accuracy and integrity of data to support the safety, effectiveness, and quality of the drugs you manufacture. We strongly recommend that you retain a qualified consultant to assist in your remediation.

In response to this letter, provide the following.

A. A comprehensive investigation into the extent of the inaccuracies in data records and reporting. Your investigation should include:

- A detailed investigation protocol and methodology; a summary of all laboratories, manufacturing operations, and systems to be covered by the assessment; and a justification for any part of your operation that you propose to exclude.
- Interviews of current and former employees to identify the nature, scope, and root cause of data inaccuracies. We recommend that these interviews be conducted by a qualified third party.
- An assessment of the extent of data integrity deficiencies at your facility. Identify omissions, alterations, deletions, record destruction, non-contemporaneous record completion, and other deficiencies. Describe all parts of your facility's operations in which you discovered data integrity lapses.
- A comprehensive retrospective evaluation of the nature of the data integrity deficiencies. We recommend that a qualified third party with specific expertise in the area where potential breaches were identified should evaluate all data integrity lapses.

B. A current risk assessment of the potential effects of the observed failures on the quality of your drugs. Your assessment should include analysesof the risks to patients caused by the release of drugs affected by a lapse of data integrity, and risks posed by ongoing operations.

C. A management strategy for your firm that includes the details of your global corrective action and preventive action plan. Your strategy should include:

- A detailed corrective action plan that describes how you intend to ensure the reliability and completeness of all of the data you generate, including analytical data, manufacturing records, and all data submitted to FDA.
- A comprehensive description of the root causes of your data integrity lapses, including evidence that the scope and depth of the current action plan is commensurate with the findings of the investigation and risk assessment. Indicate whether individuals responsible for data integrity lapses remain able to influence CGMP-related or drug application data at your firm.
- Interim measures describing the actions you have taken or will take to protect patients and to ensure the quality of your drugs, such as notifying your customers, recalling product, conducting additional testing, adding lots to your stability programs to assure stability, drug application actions, and enhanced complaint monitoring.
- Long-term measures describing any remediation efforts and enhancements to procedures, processes, methods, controls, systems, management oversight, and human resources (e.g., training, staffing improvements) designed to ensure the integrity of your company's data.
- A status report for any of the above activities already underway or completed.

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.

Unapproved New Drug and Misbranding Charges

Sofskin Vaporizing Chest Rub
Examples of claims observed on your product label for Sofskin Vaporizing Chest Rub that establish the intended uses of the product include, but may not be limited to, the following:

"Nasal Decongestant and Cough Suppressant"

"To temporarily relive nasal congestion, chest congestion, and cough due to the common cold. Temporarily relieves minor aches and pains."

Based on the above claims, Sofskin Vaporizing Chest Rub 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 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) it is intended to affect the structure or any function of the body. Specifically, this product is intended as a nasal decongestant and antitussive (cough suppressant).

OTC drug products such as Sofskin Vaporizing Chest Rub that are intended for nasal decongestant and cough suppressant indications are subject to the Final Monograph for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use (cough/cold final monograph). See 21 CFR Part 341. Sofskin Vaporizing Chest Rub must meet the formulation and labeling requirements described in the final cough/cold monograph for both nasal decongestants and cough suppressants. However, the product is not labeled or formulated in accordance with this final monograph for reasons explained below.

Sofskin Vaporizing Chest Rub is indicated, in part, for use as a nasal decongestant. However, the labeled active ingredients—menthol, camphor, and eucalyptus oil—are not consistent with the active ingredients for nasal decongestant drug products as described in the cough/cold final monograph. See 21 CFR 341.20.

Your product also is indicated, in part, as a cough suppressant. The cough/cold final monograph requires that topical cough suppressants contain 2.6% to 2.8% menthol. See 21 CFR 341.74(d)(2)(ii). However, your product is formulated with menthol **(b)(4)**. Furthermore, Sofskin Vaporizing Chest Rub is labeled to contain 1.0% eucalyptus oil. According to 21 CFR 341.40(u), camphor and menthol may be combined with 1.2% to 1.3% eucalyptus oil, provided that the product is available in a suitable ointment vehicle labeled in accordance with the allowable indications for cough suppressant drug products. Since Sofskin Vaporizing Chest Rub contains less than the required amount of eucalyptus oil that is allowed to be combined with

camphor and menthol, your product's active ingredients are not a permitted combination of active ingredients as described in 21 CFR 341(u).

Thus, as formulated and labeled, Sofskin Vaporizing Chest Rub does not comply with the final monograph described above. Furthermore, we are not aware of sufficient evidence to show Sofskin Vaporizing Chest Rub, as formulated and labeled, is generally recognized as safe and effective. Therefore, this product is a new drug within the meaning of section 201(p) of the FD&C Act 21 U.S.C. 321(p).

As a new drug, Sofskin Vaporizing Chest Rub may not be legally marketed in the United States absent approval of an application filed in accordance with section 505 of the FD&C Act 21 U.S.C. 355(a). Sofskin Vaporizing Chest Rub is not the subject of an FDA-approved application, and therefore, the current marketing of this product violates section 505(a) of the FD&C Act 21 U.S.C. 355(a)). Introduction of such products into interstate commerce is prohibited under section 301(d) of the FD&C Act 21 U.S.C. 331(d).

In addition to the above violations, Sofskin Vaporizing Chest Rub is misbranded under section 502(x) of the FD&C Act 21 U.S.C. 352(x) because the product's label fails to disclose a domestic address or domestic telephone number through which the responsible person may receive a report of a serious adverse event with such drug.

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). Therefore, the marketing of Sofskin Vaporizing Chest Rub violates this provision of the FD&C Act.

Sofskin Pure Petroleum Jelly
Examples of claims observed on your product label for Sofskin Pure Petroleum Jelly that establish the intended uses of the product include, but may not be limited to, the following:

"For the temporary protection of minor scrapes, burns and sunburn."

"Helps to temporarily protect chafed, chapped, cracked or windburned skin and lips."

Based on the above claims, Sofskin Pure Petroleum Jelly 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 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) it is intended to affect the structure or any function of the body. Specifically, this product is intended as a skin protectant.

OTC drug products intended as skin protectants, such as Sofskin Pure Petroleum Jelly, are subject to the Final Monograph for Skin Protectant Drug Products for Over-the-Counter Human Use (skin protectant final monograph). See 21 CFR Part 347. However, Sofskin Pure Petroleum Jelly is not labeled in accordance with this final monograph. The indications, "For the temporary protection of …sunburn" and "Helps to temporarily protect … windburned skin and lips" are not skin protectant indications described in this final rule. See 21 CFR 347.50(b).

Thus, as formulated and labeled, Sofskin Pure Petroleum Jelly does not comply with the final monograph described above. Furthermore, we are not aware of sufficient evidence to show Sofskin Pure Petroleum Jelly, as formulated and labeled, is generally recognized as safe and effective. Therefore, this product is a new drug within the meaning of section 201(p) of the FD&C Act 21 U.S.C. 321(p).

As a new drug, Sofskin Pure Petroleum Jelly may not be legally marketed in the United States absent approval of an application filed in accordance with section 505 of the FD&C Act 21 U.S.C. 355(a). Sofskin Pure Petroleum Jelly is not the subject of an FDA-approved application, and therefore, the current marketing of this product violates section 505(a) of the FD&C Act 21 U.S.C. 355(a). Introduction of such products into interstate commerce is prohibited under section 301(d) of the FD&C Act 21 U.S.C. 331(d).

In addition to the above violations, Sofskin Pure Petroleum Jelly is misbranded within the meaning of section 502(c) of the FD&C Act 21 U.S.C. 352(c) because the label fails to bear a complete statement of identity as required under 21 CFR 201.61. In the case of a drug that has an established name, the statement of identity must contain the established name and the general pharmacological action(s) or principal intended action(s) of the drug in the principal display panel. However, the principal display panel for this product fails to include the general pharmacological action(s) or principal intended action(s) of the product (i.e., skin protectant).

Sofskin Pure Petroleum Jelly is further misbranded under section 502(x) of the FD&C Act 21 U.S.C. 352(x) because the product’s label fails to disclose a domestic address or domestic telephone number through which the responsible person may receive a report of a serious adverse event with such drug.

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). Therefore, the marketing of Sofskin Pure Petroleum Jelly violates this provision of the FD&C Act.

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 August 21, 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 Kim Chemicals Private Ltd., Plot No. G-13/16 MIDC, Taloja, Raigad, Maharashtra, India, 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 3006370331.

Sincerely,
/S/
Thomas J. Cosgrove, J.D.
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research