**DEPARTMENT OF HEALTH AND HUMAN SERVICE** Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20742

May 8, 2014

VIA EXPRESS DELIVERY

Mr. Mukesh Gupta, Managing Partner
Maitri Food Industries
Flat No. 18
Maitri Apartments, Sector-9
Rohini, Delhi, India 110085

Reference No. # 428820

Dear Mr. Gupta:

The U.S. Food and Drug Administration (FDA) inspected your food facility Maitri Food Industries located at I-188, Sector-3, Bawana Industrial Area, Delhi, India on November 18-21, 2013. During that inspection, we found that you had serious violations from the Current Good Manufacturing Practice (CGMP) regulation, Title 21, Code of Federal Regulations, Part 110 (21 CFR 110). At the conclusion of the inspection, the FDA investigator issued a FDA-483, Inspectional Observations, listing the deviations found at your facility. You promised to make corrections to the observations noted on the FDA-483 however, to date we have not received a response. Based on the inspection findings, your food products are adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. §342(a)(4)] in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and FDA's regulations through links on FDA's home page www.fda.gov.

Your significant deviations are as follows:

1. Your firm failed to implement effective control measures to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests, as required by 21 CFR 110.35(c). Specifically, you have no systems to manage pests, and our investigator observed the following:

    a. A rodent-type animal running from the hallway towards the kitchenette on the first floor.
    b. Apparent rodent excreta pellets (too numerous to count) on piles of in-process grains and wheat bran stored in the basement.
    c. Various dead and live insect-like eggs, larva, and adults crawling inside bags of wheat flour, wheat bran, and on in-process grain piled on the basement floor.

2. Your firm failed to provide adequate screening or other protection against pests, as required by 21 CFR 110.20(b)(7). Specifically, our investigator observed the following:

    a. Windows without adequate screening in the grain holding area in the basement.
    b. An open loading dock on the ground floor across from the wheat grind and wheat flour filling areas.

3. Your firm failed to provide sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food, as required by 21 CFR 110.20(b)(1). Specifically, our investigator observed the following:

    a. Empty used bags, at least three feet high, filled an entire dark room next to the in-process grain storage area.
    b. Bags of wheat bran stored directly on the basement floor and by the wall, without adequate space between the wall and the bags.

4. You firm failed to convey, store, and minimize the potential for waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, and ground surfaces, as required by 21 CFR 110.37(f). Specifically, our investigator observed piles of waste (dust and bran) on basement floors, and full bags of waste not being replaced.

5. Your firm failed to design and construct your holding, conveying, and manufacturing systems in a way that enables them to be maintained in an appropriate sanitary condition, as required by 21 CFR 110.40(d). Specifically, our investigator observed the following:

    a. Grain entry chutes in the holding area for grains open to outside foot and vehicle traffic, and only accessible from a narrow entry in the basement.
    b. First sieve and destoner machines located in a narrow corner where there are no adequate systems to remove dust and food debris.

6. Your firm failed to maintain buildings, fixtures, and other physical facilities of the plant in a sanitary condition and in sufficient repair to prevent food from becoming adulterated, as required by 21 CFR 110.35(a). Specifically, our investigator observed the following:

    a. Ducts used to convey product between various floors during different stages of production loosely tied together with torn plastic bags, and connected between floors with cracked cement and peeling paint.
    b. Rusting grinder machine and product conveying ducts.

7. Your firm failed to ensure raw materials, other ingredients, and rework be held in bulk, or in containers designed and constructed so as to protect against contamination, as required by 21 CFR 110.80(a)(5). Specifically, our investigator observed grains in the process of being reworked stored directly on an unclean basement floor and in close proximity to open bags of bran designated for cattle feed.

8. Your firm failed to provide adequate lighting in all areas where food is examined, processed, or stored, as required by 21 CFR 110.20(b)(5). Specifically, our investigator observed inadequate or absence of lighting in the basement where incoming grains are stored; in the first sieving and destoning area, and wheat bran are stored; first and second floor in-process grain storage; and in the second sieving area.

   Further, your firm failed to provide safety-type light bulbs and fixtures over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage, as required by 21 CFR 110.20(b)(5). Specifically, our investigator observed inadequately shielded fluorescent light tubes throughout the facility and above grinders.

Please respond in writing within 30 working days from your receipt of this letter. Your response should include documentation that would assist us in evaluating your corrections, such as changes to your pest management, sanitation, or any other useful information, to protect food against contamination. Submission of the information in English will assist in our review.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Good Manufacturing Practice regulation (21 CFR 110), and all applicable regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Sheena Crutchfield, Compliance Officer, Office of Compliance, Division of Enforcement, Food Adulteration Assessment Branch (HFS-607), 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have any questions regarding this letter, you may contact Ms. Sheena Crutchfield via email at sheena.crutchfield@fda.hhs.gov.

Sincerely,

/s/

Peter Koufopoulos
Acting Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition