King of Pops 8/3/17

U.S. FOOD & DRUG ADMINISTRATION

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

August 3, 2017

VIA UNITED PARCEL SERVICE
NEXT DAY - SIGNATURE REQUIRED

Nicholas Carse, COO
Steven Carse, CEO
King of Pops, LLC
337 Elizabeth Street, NE, Suite B
Atlanta, GA 30307

WARNING LETTER
(17-ATL-10)

On June 12-14, 2017 the U.S. Food & Drug Administration (FDA) conducted an inspection of your ice pop manufacturing facility located at 4845 Chateau Avenue, #D, North Charleston, SC 29405. The FDA investigators observed serious violations of the Current Good Manufacturing Practice (CGMP) in Manufacturing, Packing, or Holding Human Food regulations, found in Title 21 of the Code of Federal Regulations Part 110[1] (21 CFR 110). The violations, which include evidence of active rodent activity, render the products held at your facility adulterated within the meaning of Section 402(a)(4) of the Federal Food Drug and Cosmetic Act (the Act) [21 United States Code (U.S.C) § 342(a)(4)] in that they have been 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 pertinent FDA regulations through links on FDA's website at **www.fda.gov (http://www.fda.gov/)**.

The serious CGMP violations noted during the inspection were outlined on a FORM FDA 483, Inspectional Observations, issued to Ross H. Reynolds, Production Manager at the close of the inspection. Mr. Reynolds also provided a FDA-483 response on June 28, 2017. Copies of both documents are enclosed for your information.

The violations observed during the inspection include the following:

1. You failed to take 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, our investigators discovered evidence of insect and rodent activity near foods stored in your food processing facility. For example, the following were observed in the production areas of the facility during the inspection:

a. Approximately 55 rodent excreta pellets (REPs) in the rear right corner of the production facility underneath food storage rack **(b)(4)**.

b. Approximately 45 REPs located inside of a raw ingredient storage box that contained **(b)(4)** and other ingredients on the middle rack of storage rack **(b)(4)**.

c. Approximately 16 REPs in the rear middle wall of the production facility underneath food storage rack **(b)(4)**.

d. Approximately 20 REPs on the interior and exterior of the water heater basin located in the front right corner of the production facility.

e. Approximately 3 REPs on the front middle wall located underneath the cook table.

f. Approximately 7 live fly-like insects throughout the production area that were observed landing on food contact surfaces, production surfaces, and where food was being stored.

Physical sample #INV999614 was collected during the inspection and was analyzed by our laboratory. The analysis of this sample confirmed the material collected from the locations identified in a-d above consisted of rodent excreta pellets. The analytical results for this sample confirm the presence of rodent activity within your facility.

Your firm's response states that there are ongoing inspections and required actions being taken to eliminate any and all pests from the interior and peripheral areas of the facility, and there is **(b)(4)** monitoring and inspection being performed by the production facility manager. The response also states the facility is back to a **(b)(4)** pest elimination program until the issues are [full] resolved. We do not consider this corrective action to be adequate as no evidence was provided that allows us to more thoroughly evaluate the effectiveness of the described corrective action.

2. You failed to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food and food-contact surfaces as required by 21 CFR 110.35(a). Specifically, our investigators observed what appeared to be residual food debris on food production equipment including a **(b)(4)**, and processing table **(b)(4)**.

Your firm's response states that unused and unwanted items will be eliminated from the facility to greatly reduce clutter making the cleaning and sanitation of equipment that is used on a regular basis much more effective. It is unclear how the removal of items from the facility translates to more effective cleaning and sanitation of equipment that is used on a regular basis. As a result we do not consider this corrective action to be adequate. Additional explanation for this corrective action is needed to include how the described correction will be effective and long lasting as well as any evidence of the correction before we are able to more thoroughly evaluate the firm's response.

3. Your plant is not constructed in such a manner as to allow floors, walls, and ceilings to be adequately cleaned and kept clean and kept in good repair, as required by 110.20(b)(4). Specifically, floors in the production room are pitted, have peeling paint and are cracked. Such areas are not able to be easily cleaned and provide harborage sites where pathogenic microorganisms are able to grow and survive. In addition there were areas with visible standing water and what appeared to be accumulated debris around production tables and food storage racks. The debris present provides the nutrients necessary for the microorganisms to grow while the standing water fosters the growth and contributes to the spread of pathogenic organisms within the facility.

Your firm's response states the facility floors underwent renovation and application of an **(b)(4)** and that the current floor condition will be discussed and likely be re-sealed during the off season. Although the response states the issue "will be discussed" and the likely actions that may be taken, this response does not demonstrate a correction of this observation. We do not consider the firm's response to this observation to be adequate as there wasn't any evidence provided that allows a more thorough evaluation of the response and no timeframe was provided for planned actions.

4. You failed to maintain gloves, used in food handling of finished food products, in an intact, clean, and in sanitary condition, as required by 21 CFR 110.10(b)(5). Specifically, on 6/12-13/17 our investigators observed production employees touching non-food contact surfaces such as their face, a ball cap, sink handles, compost buckets, refrigerator handles, and trash cans and then return to handling food contact equipment without changing their gloves or washing their hands.

Your firm's response states that training was performed **(b)(4)** which was prior to the current inspection and appears to have been ineffective based on the observation made. The response does not make any commitment for additional training or provide any evidence that additional training was performed following the inspection that specifically addresses the observed deficiency with the employees involved in an effort to prevent future recurrence of the violation. We do not consider the firm's response to this observation to be adequate.

5. You failed to provide adequate floor drainage in all areas where floors are subject to flooding as required by 21 CFR Part 110.37(b)(4). Specifically, our investigator observed an approximately 2' x 4' area of water that was pooling in an area of the floor that contained cracks and peeling floor coating. Standing water fosters the growth of pathogenic microorganisms and contributes to the spread of such organisms within the facility.

Your firm's response states the tubing of the water cooling system to the **(b)(4)** has been replaced. Further measures include the "possibility" of a floor drain installation in the off season. We do not consider this corrective action to be adequate as no evidence was provided that allows us to more thoroughly evaluate the effectiveness of the described corrective action and no estimated completion date for the planned action was provided.

6. You failed to maintain all plant equipment and utensils, as required by 21 CFR 110.40(a). Specifically, our investigators observed production table **(b)(4)** to be constructed of a **(b)(4)** and have multiple exposed screws and nails. The top of the table appeared to be rusted, pitted, and corroded. Such surfaces that are not able to be easily cleaned can serve as harborage sites and lead to the growth and proliferation of pathogenic microorganisms.

Your firm's response states that table **(b)(4)** will be removed and replaced with a **(b)(4)**. This appears to be a planned correction rather than a completed correction. We are not able to consider the corrective action to be adequate in the absence of any evidence of the completed correction or an estimated completion date if the correction will be made at a future date.

7. You failed to properly store equipment and remove litter and waste that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures, as required by 21 CFR 110.20(a)(1). Specifically, during the inspection our investigators observed coolers, boards and pallets

stored against the building. Such items can serve as a harborage area for pests outside the facility while gaps in the building structure can allow entrance of such pests into the facility.

Your firm's response states that any and all equipment, litter and [wasted] has been removed from the perimeter of the building and will be regularly monitored and cleaned when necessary. We do not consider this corrective action to be adequate as no evidence was provided that allows us to more thoroughly evaluate the effectiveness of the described corrective action

8. You failed to provide, where necessary, adequate screening or other protection against pests as required by 21 CFR 110.20(b)(7). Specifically, during the inspection our investigators observed an air gap approximately seven inches long and one half inch wide in the **(b)(4)** of the production facility. Such gaps can allow rodents and pests to access areas where food is manufactured and stored. Rodents and pests are known to carry disease causing organisms that can cause harm to consumers. In addition they can cause physical contamination of food ingredients and food processing areas like the rodent excreta pellets identified further above in item 1.

Your firm's response states that air gaps will be sealed off with a door sweep to control pest entry into the facility. We are satisfied with the evidence provided and will more thoroughly evaluate the adequacy and effectiveness of the corrective action during our next inspection.

9. You failed to provide safety-type light bulbs and lighting fixtures suspended over exposed food, as required by 21 CFR 110.20(b)(5) to protect against food contamination in case of glass breakage. Specifically, during the inspection our investigators observed unshielded lights located directly over areas where food is prepared.

Your firm's response states that the current light bulb covers will be replaced with clear fluorescent tube guards. Although the described corrective action appears to correct the identified deficiency, the picture of the clear fluorescent tube guard does not provide sufficient evidence of the completed correction. An example of evidence that demonstrates such completion is a sales receipt/invoice for the purchased items. In the absence of such evidence we are not able to perform a more thorough evaluation of the response.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations. You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Section 743 of the Act (21 U.S.C. 379j-31) authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including re-inspection-related costs. A re-inspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Re-inspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA's arranging, conducting, and evaluating the results of the re-inspection and assessing and collecting the re-inspection fees (21 U.S.C. 379j-31(a)(2)(B)).

For a domestic facility, FDA will assess and collect fees for re-inspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any re-inspection-related costs.

Please respond to this office in writing within 15 working days from your receipt of this letter. In your response identify the procedures you have taken or will take to completely correct the current violations and prevent similar ones. Please include the timeframe in which the corrections will be completed and provide documentation that will

effectively assist us in evaluating whether the corrections have been made and their adequacy. If you are unable to complete the corrective actions within 15 working days, identify the reason for the delay and the time within which you will complete the corrections.

Please send your reply to Janice L. King, Compliance Officer, at the address listed in the letterhead. If you have questions regarding any issue in this letter, please contact Ms. King at (843) 746-2990, x16.

Sincerely,
/S/
Ingrid A. Zambrana
District Director
U.S. Food & Drug Adminisration
FDA Atlanta District
Office of Human and Animal Foods- Division 3 East
(Georgia- North Carolina-South Carolina)
Office of Regulatory Affairs

Cc: Atlanta District File (FEI: 3009134823)

Cc:
Ross H. Reynolds, Production Manager
King of Pops, LLC
4845 Chateau Avenue, #D
North Charleston, SC 29405

[1] Part 110 was modernized and codified in Subpart B of Part 117 by the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR Part 117) (PC rule). An establishment will continue to be subject to Part 110 until the Part 117 compliance date applies according to the size of the business. See ***http://www.fda.gov/Food/GuidanceRegulation/FSMA/(/Food/default.htm)ucm334115.htm#Compliance_Dates (/Food/default.htm)*** for PC rule compliance dates.

More in 2017 (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)