SNOKIST GROWERS
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November 9, 2011

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Food and Drug Administration
22201 23rd Drive SE
Bothell, WA 98021-4421
Attention: Lisa M. Althar, Compliance Officer

Re: Response to Warning Letter SEA 12-02, issued October 20, 2011

Snokist Growers has received, reviewed and acted upon each of the observations listed in the Warning Letter SEA 12-02, dated October 20, 2011. Please accept this letter and the attachments as Snokist Growers response. We consider current Good Manufacturing Practices (cGMPs), product safety and the quality of our food of paramount importance. We are committed to meeting the requirements of cGMPs and Food Safety Programs; producing products in accordance with explicit specifications that define the quality of the products; maintaining the superior quality of our products and services through periodic analysis, evaluation, and continual improvement of our quality management system; improving the quality of our products by meeting the customer's requirements and expectations; increasing customer satisfaction; and conforming to the full legal and statutory requirements of the United States and any country/region where our products are utilized.

Regarding each of the items listed in the Warning Letter:

1. We appreciate and share the FDA concern regarding the safety of any reconditioned products. We understand that an elimination of any adulterant and verification of the reduction of any potentially harmful byproducts are key steps in supplying consumers with safe products. We have conducted an analysis under the direction of our Process Authority, (b) (4) from (b) (4) to determine if any of the mycotoxins known to constitute a food safety hazard are likely to be present in reconditioned products. A copy of this analysis is attached as Exhibit 1. Basically it concludes that the only mycotoxin of concern in apple products is patulin. A number of countries have introduced regulations specifying maximum permitted levels in susceptible products. The FDA has set an upper limit of 50 ppb for patulin in apple juice and apple products.

   The (b) (4) report states that due to heat stability, it is difficult to destroy patulin via pasteurization, which may only slightly decrease the patulin levels in the product. Therefore, Snokist Growers has revised our Rework Policy to include testing for patulin both prior to reprocessing and after reprocessing. The patulin testing results from the reconditioned product

will be utilized for verification that any detectable patulin level is within the specification set forth by the FDA of ≤ 50 ppb as a criteria of finished product quality control release for shipment. We have included a copy of the revised Snokist Rework Policy as Exhibit 2. The modification of this policy will ensure that we handle any reprocessed product in accordance with 21 CFR 110.80(b)(9) and that our production process maintains the integrity of the product in question.

2. Reasonable precautions are being taken to insure production procedures do not contribute to contamination. Specific to the observation,
    a. All double seams are evaluated for overlap, counter sink, thickness, height, body hook, cover hook and tightness several times each shift. If any measurement is out of specification, a recheck is performed. If it is still out of specification, a seamer mechanic is notified and any adjustments made to the seamer are noted on the. Product from that line is placed on hold from the time of the last good check to the time the correction is made. See Exhibits 3and 4 for an example of the seam check report and follow-up to an out-of-specification condition.
    b. A warehouse sanitation audit is performed (b) (4) and results noted on the appropriate form (Exhibit 5). Any pallet containing evidence of a leaking can is moved to a specified area where it is further inspected and any leaking cans are removed.

3. We are constantly looking for any condensate in our processing operations that may be a source of contamination. As stated in our response letter dated June 22, 2011 we have installed a cover over the (b) (4) on the cup line and have insulated and/or covered the water line and rerouted the water drain line over the apple slice conveyor (b) (4) . Photos of these areas are included as Exhibits 6, 7 and 8.

   Since our responses to the FDA observations were submitted on June 22, we have processed only a small amount of apple products. We have been concentrating on our cherry and pear processing areas and have taken similar steps to reduce condensate in processing areas. Some of these steps include (b) (4) to isolate steam (source of condensate) at the seamers and cookers, insulating and covering water pipes over processing areas, covering can runs from fillers to seamers and increasing the use of heaters in processing areas to reduce humidity that can cause condensation.

   The leak that was causing hydraulic fluid to drip onto the housing of the apple slice conveyor has been corrected and a drip pan installed under the hydraulic line. In our response to the FDA observations, we stated that we would begin replacing the current hydraulic fluid with a food grade fluid that meets H1 standards within the next 12 months. **It will not be possible to replace the hydraulic fluid within 15 days from the date of the FDA warning letter due to the** (b) (4) (b) (4) **<u>We are planning on having this complete by June 30, 2012.</u>**

4. New hand washing stations have been purchased and installed in both the apple and pear processing areas. Photos of these areas are included as Exhibits 9 and 10. Monitoring of employees use of these stations has been added to supervisory duties. As stated in our initial response, hand sanitizing stations are established at each work area and employees will continue to use hand sanitizers provided before starting work and after each absence from their work station.
5. This observation was corrected immediately during the inspection. Supervisors and Sanitation inspection personnel are looking for and will correct any situation where placement of objects above a food processing line could cause contamination. This observation is part of the GMP

check-off sheet that is completed during each shift of production. A copy of a recent check-off sheet is included as Exhibit 11.

6. The (b) (4) sliced apple diverters noted in the inspection have been replaced and a photo is included as Exhibit 12. Maintenance supervisors and GMP inspectors are looking for any source of contamination throughout the process. This check has been added to the daily GMP check-off sheet. (See Exhibit 11)
7. The outlet of the potable water line has been moved so that it terminates above the product level in the final hold tank and the potable water line to Tank (b) (4) has also been moved so that it is above the food level. Photos of the changes are included as Exhibits 13 and 14.
8. Warehouse inspections are conducted on (b) (4) basis to check for any pallets that may contain damaged or leaking cans in order to remove the source of any fruit fly or other pest activity. Pallets that are found with damaged or leaking cans are moved to a designated area where they are placed until they can be further inspected. Any leaking cans are removed and destroyed. Any cans with secondary damage from leaking cans are either cleaned and returned to stock or are sold as salvage.

   The Warehouse Sanitation Audit is performed (b) (4) and a copy of a completed audit form is attached as Exhibit 5. Each audit lists the date and time of any observation and provides a notation when corrective action is completed.

9. GMP and warehouse audits that are conducted throughout the plant are looking for any gaps or openings in walls, doors and windows that might provide entry for pests. Any item that is found is noted with a timeline for corrective action. Specific to the FDA observation, all gaps have been repaired and the window in the women's restroom has had a screen installed.

In addition to the above 9 items specified in Warning Letter SEA 12-02, Snokist would like to include the following items that are relevant to the FDA Observations:

1. Snokist has purchased (b) (4) monitors from (b) (4) These "dud detectors" have been installed on our (b) (4) line. In addition, the dud detector (b) (4) will be installed on (b) (4) (b) (4) line by 11/15/11 and (b) (4) dud detector will be installed on the (b) (4) line after modifications are completed. The target date for these modifications is 12/30/11. A copy of the purchase order for the additional dud detectors is included as Exhibit 15.
2. Free chlorine that was used in the can coolers has been replaced with (b) (4) supplied by (b) (4) Minimum residual levels at (b) (4) are targeted at (b) (4) ppm. Snokist believes this is an effective chemical to reduce bacteriological loading in the cooling water and reduces the amount of residual chlorine discharged to the river under our permit.
3. Training of can tear down personnel was completed prior to the start of pear processing in August, 2011. A technical representative from our can supplier, (b) (4) was brought in to conduct training for all can tear down personnel, canning supervisors and mechanics. Each tear down person is required to pass a test to show their understanding of the specifications and procedures. A copy of the training attendance sheet and the test is attached as Exhibits 16and 17. We are using Snokist's Procedure for Out-of-Spec Seam Checks (Exhibit 18) to determine any corrective action needed and the Seamer Repair log (Exhibit 19) to document any action taken to correct out of specification readings. Cans with seams that are out of specification after a recheck are placed on hold for further quality control evaluation (Exhibit 20).
4. During the audit, (b) (4) totes of applesauce that were in storage were embargoed by WSDA, pending approval of our rework policy. In July, 2011 we requested and received approval from Claudia Coles of WSDA to dispose of (b) (4) of these totes by (b) (4) method. Copies of the report and disposal forms are attached as Exhibit 21.

5. WSDA Item 4A noted the floor surface at the pulper machine with exposed aggregate and pooling liquid. This area has been resurfaced and a photo is included as Exhibit 22.

All of the corrective actions listed above have been completed except for the replacement of our current hydraulic fluid with food grade, for which we are asking for a time extension.

We appreciate the FDA's efforts and take these observations with the utmost seriousness. After you have had an opportunity to review this response, we would welcome the FDA to verify the adequacy of these corrective actions and assess their implementation with the goal of receiving a close-out letter that we can use to remove any restrictions that have currently been placed on us by the USDA.

Sincerely yours,

Jim Davis

Jim Davis
President

Copy: Claudia Coles, WSDA
(b) (4) Consulting

Snokist Response to FDA Warning Letter SEA 12-02

List of Exhibits

Exhibit #1 Mycotoxin Analysis -- (b) (4)

Exhibit #2 Snokist Rework Policy

Exhibit #3 Seam Check Report 9/28/11

Exhibit #4 Seam Check Report 11/1/11

Exhibit #5 Warehouse Sanitation Audit

Exhibit #6 Photo: (b) (4) Cover

Exhibit #7 Photo: Insulated Water Line

Exhibit #8 Photo: Water Drain Line - Relocated

Exhibit #9 Photo: Hand Wash Station – Apple Line

Exhibit #10 Photo: Hand Wash Station – Pear Line

Exhibit #11 Check-Off Sheet for GMP's And Corrective Actions

Exhibit #12 Photo: Apple Slice Line Diverter Replacement

Exhibit #13 Photo: Air Gap -- Final Hold Tank

Exhibit #14 Photo: Air Gap -- Tank (b) (4)

Exhibit #15 Purchase Order for Additional Dud Detectors

Exhibit #16 Seam Check Training Attendance Sheet

Exhibit #17 Seam Check Training Test

Exhibit #18 Snokist Procedure for Out -of-Spec Seam Checks

Exhibit #19 Seamer Repair Log

Exhibit #20 Hold Tickets

Exhibit #21 Embargo Report and Disposal Record

Exhibit #22 Photo: Apple Line Floor Repair