



January 7<sup>th</sup>, 2020

To Whom It May Concern:

We have received your inquiry related to the potential for cross-contamination with allergenic material within our processing environment. This inquiry, as we understand it, is three-fold: allergens intentionally added as part of the product formulation; allergen-containing products manufactured on common lines or equipment; and allergen presence in the facility as a whole. Accordingly, we have provided responses based on that understanding and the reasonable probability for presence of the allergenic material in question.

Please be advised that while we can assure you that these products are formulated in accordance with the product specification (allergens disclosed), we cannot guarantee that they are produced in an allergen-free environment.

With regard to products manufactured on common lines or equipment, we have provided a point-in-time assurance of allergen presence or absence. Although this is subject to change, I do want to assure you that we continually employ Good Manufacturing Practices (GMPs). As such, we schedule all production in accordance with a matrix whereby allergens are introduced to the production lines from least to most. In addition, each establishment is federally inspected and complies with all applicable regulatory requirements to include HACCP and SSOP.

With regard to allergen presence in the facility as a whole, we have provided a point-in-time assurance of allergen presence or absence in relation to the production areas. We are not providing any assurances related to non-production areas (e.g. break rooms, cafeteria, team member lockers/refrigerated coolers, etc.). Again, we continually employ GMPs. To that end, we have numerous programs related to team member hygiene designed to ensure that a sanitary environment is maintained. These programs are monitored as per the HACCP plan and the SSOP and subject to verification by federal inspectors.

Finally, with regard to our specific sanitation procedures and allergen precautions, we regret that this information is proprietary and cannot be disclosed. I apologize for any inconvenience this may cause.

If you have any additional questions or concerns, please do not hesitate to contact me.

Sincerely,

Alison Griffino  
Director, Regulatory Compliance  
FSQA Regulatory Compliance

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