# Manufactured Food Establishment Inspection Report

**Utah Department of Agriculture & Food — Division of Regulatory Services**
**PHONE:** **FAX:**
**WEB:** **EMAIL:**

**Start Date:** 2020-09-23 13:14:15
**End Date:** 2020-09-24 09:20:50
**Duration:** 20h 6m 35s
**EHS:** 10056
**Secondary EHS:**

A

| Name of Establishment | Location/Address | City/Town | Zip |
|---|---|---|---|
| NATURES FUSIONS | 57 N 1380 W | OREM | 84057 |

| Establishment Type and Category | Customer# | Purpose of Inspection |
|---|---|---|
| Dietary Supplements | 215542 | Routine |

Based on an inspection this day, the items recorded below identify the violations in operations or facilities which must be corrected by the next routine inspection or such shorter period of time as may be specified below or in writing by the agency. Failure to comply with any time limit for CORRECTIONS specified in this notice may result in additional regulatory action.

Critical items are highlighted in bold. Critical Violation are directly linked to public health risk, food adulteration, and/or known contributors to foodborne illness. Non-Critical Violations do not directly relate to foodborne illness risk, but are preventive measures that include practices and procedures which effectively control environmental conditions. Left uncorrected, non-critical violation can undermine the overall food safety program of an establishment and lead to the development of critical violations. OUT* indicates chronic violation.

## cGMP Inspection Item Details

| | | |
|---|---|---|
| 1. Preventive Controls (21 CFR 117) | N/A | **A.** Has the firm conducted a hazard analysis? |
| | N/A | **B.** Does the firm have a Food Safety Plan (written Preventive Controls Program)? |
| | N/A | **C.** Does the firm have written monitoring, corrective action, verification and validation procedures? |
| | N/A | **D.** Is the facility controlling their processes that are necessary to control a hazard? This could include pasteurization, cook step, acidification, water activity, etc. |
| | N/A | **E.** Is the facility receiving, storing or using allergens? If the allergens are non-common, facility needs to have cross-contact control, sanitation control, and proper declarations on labels. |
| | N/A | **F.** Are ready to eat products exposed to the environment prior to packaging? Has the firm implemented sanitation controls and an environmental monitoring program to protect the food from contamination? |
| | N/A | **G.** Has the firm developed a written recall plan? |
| | N/A | **H.** Has the facility developed and implemented a written supply chain program? |
| | N/A | **I.** Does the facility employ a Preventive Controls Qualified Individual (PCQI) to develop and oversee the implementation of the Food Safety Plan? |
| 2. Training (21 CFR 117.4) | IN | **A.** Are all individuals that are engaged in manufacturing, processing, packing, or holding food qualified individuals or under supervision of a person that is a qualified individual? |
| | IN | **B.** Have all individuals that are engaged in manufacturing, processing, packaging, or holding food received training in the principles of food hygiene as appropriate to the food, the facility and the individual's assigned duties? |

| | | |
|---|---|---|
| 3. Personnel (21 CFR 117.10) | IN | **A.** Are personnel with illness, sores, infections, etc., restricted from handling food products? |
| | IN | **B.** Do employees maintain adequate personal cleanliness, wear clean outer garments, use adequate hair restraints and remove excess jewelry when handling food? |
| | N/O | **C.** Do employees thoroughly wash and sanitize hands as necessary? |
| | IN | **D.** Do employees refrain from eating, drinking and smoking and observe good food handling techniques in processing areas? |
| | IN | **E.** Are employee clothing and belongings stored away from food handling and equipment and utensil washing areas? |
| 4. Plants and Grounds (21 CFR 117.20) | IN | **A.** Are premises free of harborages and/or breeding places for rodents, insects and other pests? |
| | IN | **B.** Are roads, yards, parking lots and adjacent properties maintained in a manner that prevents them from becoming a source of contamination? |
| | IN | **C.** Is adequate drainage provided to avoid contamination of facilities and products? |
| | IN | **D.** Is sufficient space provided for placement of equipment, storage of materials and for production operations? |
| | IN | **E.** Are floors, walls and ceilings constructed of easily cleanable materials and kept clean and in good repair? |
| | IN | **F.** Are food and food contact surfaces protected from contamination from pipes, etc., over working areas? |
| | IN | **G.** Are food processing areas effectively separated from other operations which may cause contamination of food being processed? |
| | IN | **H.** Are food products and processing areas protected against contamination from breakage of light bulbs and other glass fixtures? |
| | IN | **I.** Is air quality and ventilation adequate to prevent contamination by dust and/or other airborne substances? |
| | IN | **J.** Are doors, windows and other openings protected to eliminate entry by insects, rodents and other pests? |
| 5. Sanitary Operations (21 CFR 117.35) | IN | **A.** Is the facility and equipment kept clean and in good physical repair? |
| | IN | **B.** Is cleaning of facilities and equipment conducted in such a manner as to avoid contamination of food products? |
| | IN | **C.** Are cleaning compounds and hazardous materials kept in original containers and used in a safe and effective manner? |
| | IN | **D.** Are processing areas maintained free of insects, rodents, and other pests? |
| | IN | **E.** Are all utensils and equipment cleaned and sanitized at intervals frequently enough to avoid contamination of food products? |
| | IN | **F.** Are single service articles stored, handled, dispensed, used and disposed of in a manner that prevents contamination? |

| | | |
|---|---|---|
| 6. Sanitary Facilities and Controls (21 CFR 117.37) | IN | **A.** Is the water supply adequate in quantity and quality for its intended uses? |
| | IN | **B.** Are the water temperatures and pressures maintained at suitable levels for its intended use? |
| | IN | **C.** Is the sewage disposal system adequate and is plumbing including floor drains adequately sized, designed, installed and maintained in a manner to prevent contamination? |
| | IN | **D.** Are plumbing systems adequately designed and installed such that there is no back-flow or cross connections between water supplies and waste water discharge systems? |
| | IN | **E.** Are adequate toilet rooms provided, equipped and maintained clean and in good repair? |
| | IN | **F.** Are adequate handwashing and/or sanitizing facilities provided where appropriate? |
| | IN | **G.** Is refuse properly handled, stored and protected where necessary from insects, rodents and other pests, and disposed of in an adequate manner? |
| 7. Equipment and Utensils (21 CFR 117.40) | IN | **A.** Are all utensils, equipment and food contact surfaces constructed of adequately cleanable, corrosion resistant and non-toxic materials and suitable for their intended uses? |
| | IN | **B.** Is the equipment designed and used in a manner that precludes contamination with lubricants, contaminated water, metal fragments, etc.? |
| | N/A | **C.** Are freezers and cold storage areas equipped with appropriate temperature measuring or recording devices? |
| | N/A | **D.** Are instruments used to monitor conditions that control the growth of undesirable microorganisms in food adequate in number and maintained for their intended use? |
| | N/A | **E.** Is air or other gases introduced into the food or used in cleaning of food contact equipment handled in a way to prevent it from becoming a source of contamination? |
| 8. Processes and Controls (21 CFR 117.80) | IN | **A.** Are raw materials and ingredients adequately inspected, processed, and stored to assure that only clean, wholesome materials are used? |
| | IN | **B.** Is food processing and packaging conducted in a manner to prevent contamination and minimize harmful microbiological growth? |
| | N/A | **C.** Are batters, breading, sauces and other similar preparations that are used repeatedly over time, treated and maintained so as to prevent cross-contamination and growth of microorganisms? |
| | IN | **D.** Are chemical, microbiological, or extraneous material testing procedures used where necessary to identify sanitation failures or food contamination? |
| | IN | **E.** Are packaging processes and materials adequate to prevent contamination? |
| | IN | **F.** Are only approved food and/or color additives used? |
| | N/O | **G.** Are in-process, rework, and finished products stored and shipped under conditions which will avoid contamination and deterioration? |
| | IN | **H.** Are adequate steps taken to ensure raw materials or other ingredients are not contaminated with microorganisms or that they are otherwise processed or treated during manufacturing to eliminate microorganisms? |
| | IN | **I.** Are adequate measures taken to protect against inclusion of metal or other extraneous materials in food? |
| | IN | **J.** Does the firm have any process controls to control significant hazards and do these control appear to be adequate? (e.g. cooking, formulation [pH, aw, etc.] cooling, and refrigeration)? |

| | | |
|---|---|---|
| 9. Warehousing and Distribution (21 CFR 117.93) | IN | **A.** Is storage and transportation of food conducted under conditions to prevent allergen cross-contact, contamination of food, and deterioration of the food or its container? |
| 10. Human Food By-Products for use as Animal Food (21 CFR 117.95) | IN | **A.** Are human food by-products for use as animal food held in appropriate containers and under conditions that protect against contamination? |
| 11. Allergen Control (21 CFR 117 Various) | IN | **A.** Are personnel hygienic practices sufficient to prevent allergen cross-contact? |
| | IN | **B.** Does the firm's allergen controls include adequate equipment design, equipment cleaning and sanitizing between runs, separation of operations, or dedicated equipment for allergens and non-allergen containing products? |
| | IN | **C.** Is there physical separation of allergenic and non-allergenic ingredients, are allergen and allergen containing products clearly labeled and identified, and is processing conducted in a manner and scheduled to avoid allergen cross-contact? |
| | IN | **D.** Is processing conducted in a manner or scheduled to avoid allergen cross-contact of food during processing, rework, and finished products? |
| | IN | **E.** Are allergenic ingredients properly declared on food product labels? |
| 12. Records (21 CFR 117 Various) | IN | **A.** Do the firm's records include adequate information to identify the facility, the date of the activity, product and lot code, and the signature or initials of the person performing the activity? |
| | IN | **B.** Does the firm have and maintain training records? |
| | IN | **C.** Were the training records provided by the firm upon request during an inspection? |

## TEMPERATURE OBSERVATIONS

[No Temperature Observations]

## GENERAL NOTES / COMMENTS

Industrial Hemp/CBD, Cannabis (THC) Processing, and Kratom in Utah:

* Policies and regulations regarding Industrial CBD/Hemp, or Cannabis dispensed products can be found at rules.utah.gov, R68-22 and R68-28. An additional certification/permit will need to be provided if products contain these oils/ingredients.

* Cody James is the Cannabis Program Manager. He is the best point of contact for any questions related to Industrial CBD/Hemp, or Cannabis processing in Utah. Please contact him at (801) 982-2376 or email at codyjames@utah.gov.

* Miles Maynes is the Lead Inspector for cannabis/hemp. He is an additional contact regarding questions related to processing, distribution, storage, permitting, etc. of cannabis or hemp products. He can be contacted at (801) 982-2380 or email at mmaynes@utah.gov.

* Melissa Ure is the UDAF Policy Analyst & Hearing Officer. She is another point of contact regarding any questions related to Industrial Hemp/CBD or Cannabis Processing in Utah. Please call her at (801) 982-2216 or email at mure@agutah.gov.

COVID-19 Precautions

Hand sanitizer, information posters for safety English/ Spanish, wash-hand policy, mask mandate if social distancing is breached. A nurse is staffed for further knowledge and expectations.

## INSPECTION INFORMATION

**File Review:**

This was a routine inspection and my file review consisted of reviewing the pre-operational inspection report.

**Administrative Information**
CJ Peterson is the President and CEO. Lori Peterson is the C.I.O. and is the best contact for inspection purposes. Matt Peterson is the C.M.O.
Kayla Mann is the Documentation Specialist is another point of contact.
Tatia Nelson is the Project Manager and can be emailed at tatia@naturesfusions.com.

Packaging supplies are received from suppliers located in Europe and Asia, and other suppliers located in Canada. Essential oils are received from international suppliers. The company known as Vigone Co. supplies the chemicals for dietary supplements, which is located within the US.

**Preventative Controls and/or HACCP**
Ingestible products are 1% of the overall gross annual sales. Qualified facility attestation is fequir3d to be filed with FDA.

Finish and ingredient testing is conducted by Green Scientific for CBD and Hemp. Essential oils are tested in Florida.

Batch testing for primary and secondary product.

Allergen introduced is Tree-nut (almond) and possible coconut. Currently, a Peristaltic pump is utilized to segregate equipment from allergen cross-contact.

Supplier approval is achieved through vetting.

**Product Inspected and Current Risk Assessment**
This company serves as a contract manufacturer. Production includes mixing full spec\pure spec CBD and Hemp derived product into tinctures. Pre-workout, encapsulation and tableting is projected in the future. The Pre-workout is marketed as a supplement. Essential oils are marketed as a topical/cosmetic and hand-sanitizers are labeled as a pharmaceutical.

**Evidence Developemnt**
I reviewed the Halls Breathe Arometherapy Inhaler, non medicated. Cherry Flavored with a "Do not ingest" statement. The product is made with Menthol.

**Discussion with Management / Corrective Action**
We discussed verification at receiving and ensuring COAs are correct when a supplier has changed to a different laboratory.

**Supplemental Field**

## PHOTOS
[No Photos]

## SIGNATURES

Person in Charge (Print): **Lori Peterson**
Date: **2020-09-23 15:35:03**
Signature:

EHS (Print): **Dave Gunnell**
Date: **2020-09-24 09:20:30**
Signature:

## FOLLOW-UP

Follow-up Required: NO