1.0 PURPOSE

______________ shall ensure that all products supplied comply with federal, state, and local regulations. In accordance with 21CFR5.35, ______________ recognizes the authority of the Food and Drug Administration to inspect the facility with proper notification. To ensure that all inspectors are treated uniformly, the following procedures shall be followed.

2.0 SCOPE

______________ shall be responsible for ensuring that all products meet with regulatory standards.

3.0 SAFETY & ENVIRONMENTAL CONSIDERATIONS

N/A

4.0 FREQUENCY

These guidelines apply to anytime an inspection is conducted.

5.0 RESPONSIBILITY

• TASK
  o Documentation of inspections is the responsibility of ______________.
  o Documentation of inspections will be filed and maintained for ________.
  o Files will be accessed electronically at ______________ and in paper in ______________.

• VERIFICATION
  o The Inspection Team Leader, __________, will record all necessary information on the inspection log.
  o This information includes:
    ▪ Date
    ▪ Time
    ▪ Reason for inspection
    ▪ Samples taken
    ▪ Infractions noted

• PAPERWORK REVIEW
  o Copies of the Inspection Report from the FDA will be supplied to the plant supervisor and if applicable, the company owner.
6.0 PROCEDURE

6.1 FDA Inspections

6.1.1 FDA inspections may legally occur anytime during plant operation/production.

6.1.2 When an FDA inspector(s) request entry, notify ______________, ______________, and ______.

6.1.3 Assemble pre-designated individuals for inspection.

6.1.4 Obtain proper identification from inspector:

6.1.4.1 Form 482 (Notification of Inspection)

6.1.4.2 FDA Identification Card

6.1.4.3 Retain inspector’s name and contact information for further communication

6.1.4.4 Have the inspector sign in

6.1.5 Inquire as to the reason for inspection:

6.1.5.1 Routine

6.1.5.2 Complaint

6.1.6 Information that the FDA is entitled to during an inspection:

6.1.6.1 Listing of products shipped

6.1.6.2 Product samples

6.1.6.3 Pesticide use information

6.1.6.4 Label Information

6.1.6.5 Shipping records of products received

6.1.6.6 Open access to manufacturing operation

6.1.6.7 Traceability Records

6.1.6.8 Test and results relevant to Form 482

6.1.7 Information that the FDA may request, but must be given only by direction from ________:

6.1.7.1 Production figures

6.1.7.2 Product coast/pricing information

6.1.7.3 Description of manufacturing process

6.1.7.4 Quality control records

6.1.7.5 Organizational charts

6.1.7.6 Product development records

6.1.7.7 Consumer complaints

6.1.7.8 Recipes

6.1.7.9 Cleaning schedules

6.1.8 Samples

6.1.8.1 If inspector takes samples, insist on obtaining split samples.

6.1.8.2 Put whatever product/ingredient is being samples on hold until test results have been verified.

6.1.8.3 Immediately notify customers of any product shipped to them from the sampled lots.

6.1.8.4 Obtain analyses of the sample(s) from an independent testing laboratory.

6.1.9 Information Sharing/Signatures

6.1.9.1 Answer questions truthfully, put do not volunteer information.

6.1.9.2 Do not answer any questions concerning the operation, management, programs, customers, products, shipments, or personnel unless you are the designated company representative.

6.1.9.3 Do not engage in conversation with any other employee, phone caller, or visitor concerning the above topics.

6.1.9.4 You are not required by law to sign Form 482.
6.1.9.5 If you do not agree with the actions being taken by the FDA or if you have a question about the jurisdiction of the agency in a particular matter, you can contact the FDA’s Office of the Ombudsman to seek a resolution.

FDA Office of the Ombudsman
10903 New Hampshire Avenue
WO 32, Room 4231
Rockville, MD 20903
Telephone: 301-796-8530
FAX: 301-847-8628
E-mail: ombuds@oc.fda.gov (sending confidential information by electronic mail is not recommended)

6.1.9.6 At the conclusion of an inspection, the FDA official is required by law to leave the manufacturer a written report setting forth any conditions or practices which, in the inspector’s judgment, do not conform with regulations. It is important that the guide understand all comments written on the report. If anything is not understood, it must be clarified so that all problems and concerns may be fixed. If the guide disagrees with any or part of the report they might, after supplying additional information, get the inspector to change or strike the contested points from the record. Otherwise the guide should request the inspector to note the points of disagreement.

6.1.9.7 Information regarding what to expect during your inspection may be found at:
http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074974.htm

6.2 NYS Department of Agriculture and Markets Inspections

6.2.1 Regular inspections that are routinely conducted by NYS Ag & Markets:
6.2.1.1 Plant Sanitation Inspection – 90 days
6.2.1.2 Pasteurizer Inspection – 90 days
6.2.1.3 Product Sampling – monthly
6.2.1.4 Label review for accuracy – as needed
6.2.1.5 Product Weight Checks

6.2.2 Plant inspections include but are not limited to monitoring the following:
6.2.2.1 Plant cleanliness
6.2.2.2 Protection from contamination
6.2.2.3 Ingredient Storage / Handling
6.2.2.4 Equipment Design / Cleanliness
6.2.2.5 Product storage / handling
6.2.2.6 Product Labeling
6.2.2.7 Categories

7.0 ATTACHMENT/DOCUMENTATION

7.1 FDA Form 482

8.0 SIGNATURES AND APPROVALS

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<thead>
<tr>
<th>Role</th>
<th>Name and Title</th>
<th>Signature</th>
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