1.0 Purpose

The purpose of this procedure is to outline the actions for handling regulatory inspections from the Food and Drug Administration (FDA). Facility/plant managers must be aware of the requirements in this procedure or appoint an individual as an appropriate surrogate. This is important because the FDA inspector's aim is to find evidence of violation and inspections may be adversarial proceeding in which evidence arising from on-site inspections may be used against the facility.

2.0 Scope

This procedure applies to all Company-owned facilities registered with the FDA.

3.0 Equipment & Definitions

Item	Explanation
Equipment:	
Form 482	Notice of Inspection: This form is presented along with the FDA auditor's credentials. This form should be accepted and is simply a notice to inspect.
Form 483	Objectionable Observations: This form is only issued if the inspection reveals observations that the inspector feels are objectionable. This form is issued after an inspection.
Form 484	Receipt of Sample: This form is issued if the inspector obtains a physical sample during the inspection.

Definitions:	
Food Safety Plan	The term food safety plan is interchangeable with the term HACCP. New regulations refer to this plan as a food safety plan.
Preventive Control	The term preventive control means a control to eliminate or reduce an identified hazard to an acceptable level. Preventive controls could include engineered controls such as CCPs, sanitation controls, allergen controls, and supply-chain controls.

4.0 Reference Documents & Forms

Policy 3.1 FDA Registration and Regulatory Inspections
Policy 3.2 Recall Program and Testing
Procedure 3.2-01 Recall Plan

5.0 Frequency

The established frequency for FDA inspections for low-risk facilities is every five years; however, history has shown that facilities are inspected much more frequently.

6.0 Procedure

1. **Preliminary steps**: FDA inspections should be handled with care and preparation efforts should be made. The following items have been recommended to better prepare for FDA inspections:

1.1. The FDA can legally inspect any facility during "reasonable hours", which has been interpreted by courts as normal business operations.[1] Therefore, regardless of time of day, a properly identified inspector may not be denied access. The facility should be prepared to be inspected during any hours of operation.

1.2. Facilities/plant managers must designate an individual and an alternate with responsibility for inspections. These individuals must be familiar with FDA inspection techniques (FDA's Investigations Operations Manual, Chapter 5), possess a thorough understanding of the facility's food safety plan(s), and have a thorough knowledge of the Company's business practices. It is also important to note that the designated individuals' demeanor and attitude are significant factors in the efficiency and outcome of an inspection. Treat the inspectors in a courteous and respectful manner.

1.3. Inspectors will inquire about the facility, often asking for the size of the facility, number of employees, processing shifts, environmental conditions, raw materials, methods for data collection, FDA registration, and supervisory training records. It is important to gather this information prior to an inspection and have it available for quick access.

1.4. Most inspections include an immediate inspection followed by document reviews to demonstrate compliance with applicable regulations. Facilities should designate an area for document review and ensure that records can be retrieved within a reasonable timeframe. The maximum timeframe to retrieve records is 24 hours.[2] In addition, inspectors may ask for records outside of their jurisdiction such as financial documents, personnel information, etc. In these cases, respectfully decline access. It is important for designated individuals to understand and know which records the FDA can access. A table is provided in appendix 1: discoverable document list and functions as a general guideline for their jurisdiction. The regulations can also be consulted.[3] If a question still exists, please consult NSM Quality Assurance or Legal Counsel.

1.5. Facility managers must be familiar with their food safety plans and not just the monitoring procedures. A large amount of the documentation which supports the plan is electronically available through hyperlinks. Managers must be able to understand what is being asked for and how to retrieve the documentation.

2. **The Inspection**:

2.1. **Inspector Arrival**: Politely request to see the inspector's credentials. If the inspector will not furnish credentials, do not permit the inspector to access the facility. Record identifying information from credentials such as agency district, phone number, etc. If the inspector doesn't provide one, request the form 482, which is a notice to inspect. Inquire about the purpose of the visit and/or inspection and document the purpose. Instruct the inspector to review the local safety and GMP acknowledgment form while signing into the visitor's log. The inspector may decline to sign the acknowledgement form but is required to sign the visitor's log.

[1] E.g. *Durovic v. Palmer*, 342 F.2d 634, 637 (7th Cir. 1965)
[2] 21 CFR 117.315(c)
[3] 21 CFR 117 Subpart F

2.2. **Inspection Team Notification**: Immediately notify the plant/facility manager, quality assurance and chief chemist, if available, and the warehouse manager. The plant/facility manager should notify the V.P of quality, the V.P. of operations, and legal counsel. The personnel receiving the inspector should direct the inspector to a conference room or similar setting while pertinent personnel are gathered. It is important to have a trained person lead the inspection and have a secondary person take detailed notes during the inspection.

2.3. **Interacting with the Inspector**: Interact with the inspector in a professional manner and do not be argumentative, disrespectful, or hostile. Be cooperative within reason and attempt to limit the scope of the investigator's inquiries. Always provide truthful information and do not attempt to delay investigation. During the inspection, concisely answer all direct questions but do not volunteer unsolicited information. Kindly ask the inspectors to direct all questions to assigned escorts and not the employees.

2.4. **Inspection**: If applicable, direct the focus of the inspection to cGMP areas where the product is classified as a food product; the white centrifugals and subsequent processing. Always escort the inspector and do not permit the inspector to wander freely. Try to lead the inspector only to areas requested by the inspector. If the inspector brings up issues of which the designated escort agrees, it is appropriate for the designated person to remedy the issue immediately in the inspector's presence. If the inspector requests any of the following, please follow requirements accordingly.

2.4.1. **Product Samples**: If the inspector requests to take a sample of final product or ingredients, permit the inspector to do so but insist that the inspector split the sample for the facility to retain. Place the lot on Quality Hold and request a signed receipt (form 484) from the inspector.

2.4.2. **Record Reviews**: The FDA can reasonably ask to see records pertaining to manufacturing, packaging, labeling, storage, and distribution but cannot ask for product formulations, financial data, pricing data, personnel data, research data, or sales data.

2.4.3. **Record Copies**: If the inspector requests copies of records, document all records that the inspector obtains; make two copies. Request a signed receipt from the inspector for the records obtained.

2.4.4. **Photographs**: The FDA's investigations operations manual section 5.3.4 permits the FDA to obtain photos. There is currently not clear legal consensus regarding the FDA's right to use photographic evidence during inspections. Refusal of photographs can be interpreted by the inspector as a refusal to permit inspection. Company stance has been to permit photographs. This should only occur if the inspector notes deficiencies. If the inspector requests to take a photograph, immediately take a duplicate photograph for company records. If it is noted that the inspector is focusing on small details, take additional photos from different angles or widen the shot to provide broader contexts.

2.4.5. **Affidavits**: If the inspector writes one or more affidavits for the facility personnel to sign as part of the inspection process, personnel should not sign such

affidavits. Incidentally, the FDA will not sign an affidavit if asked to do so by the facility.

2.5. **Food Safety Modernization Act Requirements**: The FSMA regulations have significantly increased the FDA's authority and has since regulated many aspects of food processing that weren't in the scope of their powers of inspection. Some additional changes and brief explanations are outlined below:

2.5.1. **Food Safety Plan**: Current regulations[4] have made the Company's food safety plans (HACCP) regulated and they will be inspected by FDA officials. These plans are uploaded to the corporate intranet. In most cases, our facilities have implemented preventive controls for the hazard of metal. This was determined by a raw material risk assessment in conjunction with the hazard analysis. The hazard analysis documentation is available through either the corporate intranet or linked from the flowchart of an electronic food safety plan. All supporting documentation is linked from the food safety plan and includes, preventive controls qualified individual (PCQI) certificates, FDA GRAS classification, scientific references (validation), hazard analysis, supporting procedures (monitoring, corrective action), validation documentation, and supply-chain documentation, if applicable.

2.5.2. **Supply-Chain Program**: Facilities receiving sugar will have a supply-chain program[5]. Sugar processing and handling has the potential to be prone to metal contaminants. Every effort is made to ensure that sugar supplied to your facility, if applicable, has controls in place to address the hazard. The established verification procedures are documented on form 10.13-01 Sugar Supplier Assessment and include an onsite audit conducted by a qualified auditor. This audit verifies that suppliers are controlling metal hazards. All associated records are available electronically through the National Sugar Marketing Approved Sugar Supplier Register. Supporting records include a documented approval, audit certificate, audit report, and a copy of their local food safety plan.

2.5.3. **Foreign Supplier Verification Program (FSVP)**: This will not apply to many facilities as NSM nor Amalgamated import sugar. The FSVP portion is handled by our partner, Sucden. However, all applicable documentation is available through the supply-chain program. Packaging is also considered food and is subject to FSVP. The hazard analysis has not identified any hazards in packaging that would require a preventive control. Therefore, there are not verification activities associated with the FSVP.

2.5.4. **Recall Plan**: A recall plan is now required for all products with a hazard requiring a preventive control and may be audited during FDA inspection. Recall information is documented in Policy 3.2 Recall Program & Testing and in Procedure 3.2-01 Recall Plan.

2.6. **Inspection Conclusion/ Exit Interview**: After the inspection, form 483 may be presented. If so, this will catalog the area(s) of concern or deficiency. Accept the form,

[4] 21 CFR 117 Subpart C
[5] 21 CFR 117 Subpart G

but do not sign it even if requested to do so. The inspector may explain observations made during the inspection. Listen closely but do not agree with the observations as stated. Escort the inspector from the property. Notify the VP of quality immediately after the inspection and communicate the results, any observations, and if there were samples, photos, or records taken.

7.0 History

1. 11/02/2016: New Procedure based on new regulatory requirements and the prior regulatory inspection procedure (2009).

8.0 Attachments

1. Discoverable Document List

Appendix 1: Discoverable Document List

General Records[6]	
Product labels	Ingredient documentation
Specifications	Production records
Laboratory records / product testing	Returned product records
Consumer complaints (only if there is evidence of harm to consumers)	Certificates of Analysis for Ingredients
Incident reporting and responses	Promotional documentation for marketing products
FDA registration	
Current Good Manufacturing Documentation § 117 Subpart B	
Written hygiene policies or procedures	Shipping records
Standard operating procedures	Water testing records
Integrated pest management records	Equipment calibration records
Employee training records	Product/ingredient receiving inspections
Cleaning records	
Food Safety Plan § 117.190[7]	
Food Safety Plan	Hazard Analyses
Monitoring (preventive control/CCP)	Corrective action
Verification of monitoring	Verification of corrective action
Calibration of equipment, if applicable	Reanalysis
Preventive control qualified individual records	Recall procedure
Supply-Chain Program Records (for facilities receiving sugar) § 117.475[8]	
The written supply-chain program (food safety plan).	Documentation that a receiving facility that is an importer follows the foreign supplier verification program outlined in part 1, subpart L. (packaging material)
Documentation of the approval of a supplier (intranet)	Written procedures for receiving materials (food safety plan).
Documentation demonstrating the use of written procedures (local inspection and receiving records).	Documentation of the appropriate supplier verification activities, if applicable (intranet).
Documentation of the conduct of an onsite audit (intranet).	Documentation of actions taken with respect to supplier non-conformance (corrective actions).
Documentation of verification of supply-chain-applied control other than the receiving facility. Corporate verification.	

[6] These are common records that fall into FDA jurisdiction and is not intended to be an exhaustive list.

[7] Some of the records listed in this subpart may not be specifically listed but are required sections of the food safety plan.

[8] Many of the records listed in this subpart do not apply to sugar operations. Listed are only those items that might apply.