



## GDP FOOD INSPECTION AGENDA

### Inspection Activity

**I. Ocular Inspection** [declared office address]

**1.1 Premise** [ accessibility, suitability, display of FDA License to Operate (LTO)]

**1.1.1 Opening Meeting** [ Introduction/ Stating Purpose of Inspection/, Presentation of Inspection Agenda, Accomplishment of Attendance Sheet]

**1.1.2 Document Review**

**Note:** presentation/provision of the following documents will depend or based on the findings noted during inspection [ as applicable and necessary]

**GENERAL DOCUMENTS**

- Proof of payment for renewal and variation/amendment of LTO and CPR in case of change of location/activity/supplier/manufacturer /formulation/label etc.
- Organizational Chart
- Credentials of the Qualified Person/Compliance Safety Officer
- Job Description [ JD] / Duties and responsibilities, Training Plan/Training Records/Competency Profile of the Key Personnel involved in the operation
- Valid Proof of Business Name Registration / Business Permit
- Valid Proof of Occupancy [ Office and Warehouse Facility]
  - ❖ Affidavit of Undertaking with the corresponding list of clients [ name and complete address of client/s if no warehouse facility is declared
- Valid Certificate of Product Registration
  - ❖ Product List indicating the product name, supplier/ manufacturer, registration number and validity, status of registration for new products (initial), renewal, and or amendment
  - ❖ Copy of FDA approved product label; Letter of exhaustion for old labels used
- Distribution Records [ Proforma/Commercial Invoice/Bill of Lading/ Airway Bill/ Packing List/ Sales Invoice/Delivery Receipt]
- Standard Operating Procedures [product recall, complaint, return /damaged/ expired products, disposal/ destruction, compliance to Good Storage and Distribution Practices (GDSP): Sanitation Program, Pest Control Program, Stock Management Control, Dispatch and Transport] etc.]



### **SPECIFIC DOCUMENTS**

#### **For Distributor-Importer**

- Proforma Invoice /Valid Foreign Agency Agreement/ Appointment/Distributorship Agreement/ Letter of Appointment
- Compliance to CGMP [ GMP Certificate or its equivalent ]
- Appropriate Test Result or Certificate of Analysis routinely conducted in country of origin or source that would indicate or show safety of the product

#### **For Distributor-Exporter**

- Valid notarized Distributorship Agreement or Letter of Appointment between FDA-licensed manufacturer and exporter
- Valid CPR

#### **For Distributor -Wholesaler**

- Valid notarized Distributorship Agreement or Letter of Appointment between the applicant and FDA-licensed source

#### **For product under Food Fortification and Asin Law**

- Notarized Affidavit of Undertaking for salt used as industrial
- LTO and MOA with the manufacturer for salt and staple food - intended for iodization/re-iodization and fortification/re-fortification
- Certificate of Analysis for Vitamin A and /or Iron, Iodine

## **II. Ocular inspection of warehouse/s depot [ Dry and Cold storage facility/ies following compliance to Good Storage and Distribution Practices ( GDSP ) within the area of jurisdiction:**

- Premises [ suitability, access/security, sanitation, ventilation, Lighting etc.]
- Storage Fixtures Storage fixtures [palettes, steel racks/cabinet]
- Storage equipment/s [Temperature monitoring System: Monitoring Device]
- Storage area/s for various products
- Segregated areas for recalled/damaged/expired/returned products



- Stock Management and Control
- Physical examination of the product/s
  - ❖ Conformance to Mandatory labeling requirements ( pre-packed foods)
  - ❖ Conformance to Mandatory labeling requirements for specific products based on standards [ food supplement/s, bottled water, staple products, iodized salt]
- Collection of samples when necessary

III. **Ocular inspection of Transport Vehicle**

IV. **Report Writing** (Observation and findings/recommendation/directives)

V. **Exit Meeting** (discussion observation and findings/recommendation/Accomplishment of Attendance Sheet)