DATE ASSGND	FEI #:	ASSIGNMT#	INSP. BASIS	DATE INSP. START	DATE INSP. END	DISTRICT
FIRM NAME:			STREET:			
CITY:	STATE:	ZIP:	COUNTY:	PHONE:		PAC:

ENDORSEMENT

This firm was inspected under the provisions of FDA Contract 221-03-4122.

The PREVIOUS INSPECTION on revealed: . The previous inspection was classified .
Corrections since the last inspection include: .

MANUFACTURER: ( ) Yes ( ) No
Major products manufactured: .
Is 25% or more of the output sold wholsale? ( ) Yes ( ) No

WAREHOUSE: ( ) Yes ( ) No
Check one of more if applicable, and identify major products warehoused.
( ) Soft Drinks Only ( ) Soft Drinks / Snack Foods ( ) Bakery Product Drop Point ( ) Grain
( )Produce ( ) Fresh Fish / Seafood ( ) Frozen Foods / Ice ( ) Alcoholic Products Only
( ) Multiple Foods ( ) Candy / Tobacco ( ) Ice Cream – Dairy ( ) Other .

Manuf./Warehouse firm REPACKER of any food products? ( ) Yes ( ) No - If "Yes," major repacked products:

Firm is: ( ) Interstate: % Interstate Sales ( ) Intrastate Only
Firm operation hours:
Establishment Size:
Firm Registered? ( ) Yes ( ) No - If "No," does the firm intend to register? ( ) Yes ( ) No - Remarks:
Firm informed of information regarding food security, the BT Act definitions, exemptions and penalties for failure to register, etc., is available at the following website: http://www.cfsan.fda.gov/~dms/fsbtact.html ( ) Yes ( ) No - Remarks:

Current INSPECTION FINDINGS: ( ) No Insanitary conditions noted.
General deficiencies - ( ) Rodents ( ) Insects ( ) Birds ( ) Equipment ( ) Employee Practices
( ) Premises ( ) Seafood HACCP ( ) Other:
Itemized list of deficiencies:
1.

Refusals? ( ) No ( ) Yes – Describe refusals:
Samples collected? ( ) No ( ) Yes – Describe samples:
Inspection Classified: ( ) NAI ( ) VAI ( ) OAI ( ) NOEI ( ) OOB ( ) INACTIVE
Remarks:

ESTABLISHMENT CHANGES: ( ) New Firm ( ) None ( ) Name ( ) Address ( ) Ownership
( ) Size ( ) Prod Code ( ) Est Type ( ) Registration ( ) Other :

A report of this inspection was issued to (name/title): . Corrective action(s) and/or promises made by the firm's management:

Inspected performed by_____.

Follow-up Inspection: ( ) Routine ( ) Compliance

Distribution: Orig to BLT-DO File; Copies to:

DATE ASSGND	FEI #:	ASSIGNMT#	INSP. BASIS	DATE INSP. START	DATE INSP. END	DISTRICT
FIRM NAME:				STREET:		
CITY:	STATE:	ZIP:	COUNTY:		PHONE:	PAC:

PRODUCTS COVERED						
EST TYP	**PAC**	PRODUCT CODE	**PRODUCT DESCRITION / REMARKS**	CLASSIFICTN	HOURS	**RESCHEDULE DATE**

COMPLIANCE ACHIEVEMENT DATA			
PROBLEM TYPE	**CORRECTIVE ACTION** (Additional corrective actions on next page)	**DATE ACTION VERIFIED**	**REASON FOR CORRECTION**

INSPECTOR'S NAME / SIGNATURE	**DATE**
SUPERVISOR'S NAME / SIGNATURE /	**DATE**

INSTRUCTIONS FOR COMPLETING FORM

HEADER

Date Assigned: FDA Assigned Date (Usually the month and year indicating the beginning of the contract.)
FEI# and Assignment#: FDA Assigned. FDA will enter this data if you do not have these numbers.
Inspection Basis: **2** = Routine Priority. **1** = High Priority (Usually follow-up inspection to a violative inspection.)
Firm Name: Official Firm Name. If firm name has been changed enter the new name and check appropriate box in the ESTABLISHMENT CHANGES section.
Street, City, State, Zip: Address of firm location inspected. If address has changed enter new address.
Phone: Contact telephone number of firm.
PAC: (Program Assignment Code)

ENDORSEMENT

Provide a concise and brief summary of the key findings and issues from the inspection. Include a summary of any warnings given to management and the essence of their response.

The endorsement of the inspection is prepared by the supervisor on the 481 form. However, some supervisors may require the investigator to prepare proposed endorsements. Normally the endorsement consists of:

1. The reason for the inspection, e.g., state contract inspection. State the subject of the assignment and reference.
2. A brief history of previous findings including classification of previous EI, any action taken by the state and/or corrective action taken by the firm in response to inspectional observations from the previous inspection.
3. A concise summary and evaluation of current findings and samples collected.
4. Refusals, voluntary corrections or promises made by the firm's management.

INSPECTION CLASSIFIED

NAI = No Action Indicated. No written inspectional observations were issued to the firm.
VAI = Voluntary Action Indicated. Written observations were issued to the firm. Firm corrected deficiencies and/or promised to correct deficiencies. No regulatory action considered as a result of the inspection observations.
OAI = Official Action Indicated. Regulatory action considered as a result of written observations issued to the firm.

If multiple products are inspected and result in different classifications per product, the overall inspection should be classified with the most significant product classification. For example, if one product has a classification of NAI and a second VAI, the overall inspection classification should be VAI.

PRODUCTS COVERED

Establishment Type: M = Manufacturer, W = Warehouse
PAC (Program Assignment Code): **03S001** – Food Manufacturer/Warehouse Inspections; **03S002** – Seafood HACCP Inspection; **21005** – Label Review
Product Code: Use the FDA product code builder to create the code. **Hold the Ctrl key down** and **click on the text in the header** ("PRODUCT CODE") to go to the web link for the product code builder program. All products must have an accurate seven character FDA product code.
Product Description: Give a general description of the product (i.e., baby food, fresh fruit, etc.)
Hours: Enter the amount of hours worked during the inspection for each PAC.
Reschedule Date: Enter the reschedule Date. (format: MM/YY) NAI/VAI inspections 1 year. VAI/OAI inspections depend on FDA or State regulatory requirements and/or follow-up action considered.

ESTABLISHMENT CHANGES: Indicates firm changes since the previous inspection.

Establishment Size (Gross Sales)**:**

0	$0.00	to	$24,999.00
1	$25,000.00	to	$49,999.00
2	$50,000.00	to	$99,999.00
3	$100,000.00	to	$499,999.00
4	$500,000.00	to	$999,999.00
5	$1,000,000.00	to	$4,999,999.00
6	$5,000,000.00	to	$9,999,999.00
7	$10,000,000.00	to	$24,999,999.00
8	$25,000,000.00	to	$49,999,999.00
9	Greater than $50,000,000.00		

COMPLIANCE ACHIEVEMENT DATA *(Complete this section to document corrections during current inspection and/or since previous inspection.)*

PROBLEM TYPE:

1 = Contamination
2 = GMP Violation
3 = Labeling
4 = Other
5 = Plan Review (HACCP plan, Preconstruction plan, etc.)
6 = Standards Deviation

CORRECTIVE ACTION:

1 = Building/ Preconstruction/ Construction Correction
2 = Destruction of Product
3 = Discontinued Product
4 = Formulation Correction
5 = HACCP Correction
6 = Label Correction
7 = Manufacturing Equipment Correction
8 = Manufacturing Process Correction/Analytical Methodology Correction
9 = Other
10 = Other Control Correction
11 = Personnel Correction
12 = Product Conversion
13 = Product Reconditioned
14 = Repaired Problem
15 = Reworked Product
16 = SOP Correction
17 = Sanitation Correction
18 = Suspend Distribution

REASON FOR CORRECTION:

1 = Result of Establishment Inspection (current inspection - on the spot correction),
2 = Result of Close-Out Meeting with Establishment Management (no 483 issued, current or prior inspection 483 , verbal warnings, and 483 responses),
3 = Other