

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FOOD GMP INSPECTION REPORT

1. Establishment Name and Address <i>(Include ZIP code)</i>	2. Date Inspected
	3. Product(s) Inspected
4. FEI#	5. State License or Permit Number
6. Name and Title of Responsible Plant Official	7. Telephone Number <i>(Include Area Code)</i>
8. Name and Title of Responsible Corporate Official	9. Telephone Number <i>(Include Area Code)</i>

INSTRUCTIONS:

Answer the following questions by checking the appropriate box. Explain "No", answers on continuation sheet(s).
Precede each explanation with the item number. Use "N/A" where questions are Not Applicable.

INSPECTION CRITERIA

No.	Plants and Grounds	Yes	No	N/A
1.	Are premises free of harborages and/or breeding places for rodents, insects and other pests?			
2.	Is adequate drainage provided to avoid contamination of facilities and products?			
3.	Is sufficient space provided for placement of equipment, storage of materials and for production operations?			
4.	Are floors, walls and ceilings constructed of easily cleanable materials and kept clean and in good repair?			
5.	Are food and food contact surfaces protected from contamination from pipes, etc., over working areas?			
6.	Are food processing areas effectively separated from other operations which may cause contamination of food being processed?			
7.	Are food products and processing areas protected against contamination from breakage of light bulbs and other glass fixtures?			
8.	Is air quality and ventilation adequate to prevent contamination by dust and/or other airborne substances?			
9.	Are doors, windows and other openings protected to eliminate entry by insects, rodents and other pests?			

Equipment and Utensils

10.	Are all utensils and equipment constructed of adequately cleanable materials and suitable for their intended uses?			
11.	Is the equipment designed and used in a manner that precludes contamination with lubricants, contaminated water, metal fragments, etc.?			
12.	Is the equipment installed and maintained so as to facilitate the cleaning of equipment and adjacent areas?			

INSPECTION CRITERIA

No.	Sanitary Facilities and Controls	Yes	No	N/A
13.	Is the water supply adequate in quantity and quality for its intended uses?			
14.	Are the water temperatures and pressures maintained at suitable levels for its intended use?			
15.	Is the sewage disposal system adequate?			
16.	Is the plumbing adequately sized, designed, installed and maintained in a manner to prevent contamination?			
17.	Are adequate toilet rooms provided, equipped and maintained clean and in good repair?			
18.	Are adequate handwashing and/or sanitizing facilities provided where appropriate?			
19.	Is all refuse properly stored and protected where necessary from insects, rodents and other pests and disposed of in an adequate manner?			

Sanitary Operations

20.	Is the facility kept clean and in good physical repair?			
21.	Is cleaning of facilities and equipment conducted in such a manner as to avoid contamination of food products?			
22.	Are detergents, sanitizers, hazardous materials and other supplies used in a safe and effective manner?			
23.	Are cleaning compounds and hazardous materials kept in original containers, stored separate from raw materials?			
24.	Are the processing areas maintained free of insects, rodents and other pests?			
25.	Are insecticides and rodenticides used and stored so as to prevent contamination of food?			
26.	Are all utensils and equipment cleaned and sanitized at intervals frequently enough to avoid contamination of food products?			
27.	Are single service articles stored, handled, dispensed, used and disposed of in a manner that prevents contamination?			
28.	Are utensils and portable equipment stored so as to protect them from splash, dust and other contamination?			

Processes and Controls

29.	Is responsibility for overall plant sanitation specifically assigned to an individual?			
30.	Are raw materials and ingredients adequately inspected, processed as necessary and stored to assure that only clean, wholesome materials are used?			
31.	Is ice (where used) manufactured from potable water and stored and handled in a sanitary manner?			
32.	Is food processing conducted in a manner to prevent contamination and minimize harmful microbiological growth?			
33.	Are chemical, microbiological, or extraneous material testing procedures used where necessary to identify sanitation failures of food contamination?			
34.	Are packaging processes and materials adequate to prevent contamination?			
35.	Are only approved food and/or color additives used?			

INSPECTION CRITERIA

No.	Processes and Controls	Yes	No	N/A
36.	Are products coded to enable positive lot identification, and are records maintained in excess of expected shelf-life?			
37.	Are weighing and measuring practices adequate to ensure the declared quantity of contents?			
38.	Are labels of products covered during inspection in compliance? (submit violative labels as exhibits)			
39.	Are finished products stored and shipped under conditions which will avoid contamination and deterioration?			

DETAILS OF MANUFACTURING PROCEDURES AND CONTROLS

Provide brief description of manufacturing processes and controls for product(s) inspected. Where appropriate, report times, temperatures, and other critical processing steps. If microbiological or any other type of contamination is suspected or encountered, fully describe the relationship between the routes of contamination and the process. Use flow charts where appropriate. If more space is needed, use continuation sheet.

No.	Personnel	Yes	No	N/A
40.	Are personnel with illness, sores, infections, etc., restricted from handling food products?			
41.	Do employees wear clean outer garments, use adequate hair restraints and remove excess jewelry when handling food?			
42.	Do employees thoroughly wash and sanitize hands as necessary?			
43.	Do employees refrain from eating, drinking and smoking and observe good food handling techniques in processing areas?			

CORRECTIONS AND SAMPLES

If any corrections were made as a result of this inspection or made as a result of a previous inspection (*including voluntary destructions, capital improvements, etc.*), complete Voluntary Correction section of cover sheet Form FDA 481 (E) CG.

If any samples were collected, list sample numbers and briefly describe samples.

DISCUSSIONS WITH MANAGEMENT

Indicate individual with whom inspection was discussed. Identify official (*name and title*) having authority to authorize corrections. Record any recommendations/warnings given, and management's response.

CONTINUATION SHEET

(Use additional sheets as appropriate.)

Signature of Inspector

Date