

**DEPARTMENT OF HEALTH AND HUMAN
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. STATE LICENSE OR PERMIT NUMBER
5. NAME AND TITLE OF RESPONSIBLE PLANT OFFICIAL	6. TELEPHONE NUMBER <i>(Include Area Code)</i>
7. NAME AND TITLE OF RESPONSIBLE CORPORATE OFFICIAL	8. 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
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 effectivly 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 oponings 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
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 frequent 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		
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		

INSPECTION CRITERIA

NO.	PROCESSES AND CONTROLS	YES	NO
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
40.	Are personnel with 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