

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 02/12/2010 - 03/04/2010*
	FEI NUMBER 1000124040

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Kanaiyalal N. Patel, President

FIRM NAME Basic Food Flavors, Inc.	STREET ADDRESS 3950 East Craig Road
CITY, STATE, ZIP CODE, COUNTRY North Las Vegas, NV 89030-7504	TYPE ESTABLISHMENT INSPECTED Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Failure to manufacture, package, and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically,

Your existing manufacturing process inside building 3950 E. Craig Road was not designed with the necessary steps to control microbial contamination as evidenced by the following:

- (A) (b) (4) samples from one remaining finished product lot of your HVP (b) (4) were analyzed and found positive for Salmonella by your private laboratory. This was documented by Certificate of Analysis (b) (4) dated 2/19/2010.
- (B) Environmental samples collected from building 3950 E. Craig Road found Salmonella on non-food contact surfaces near some food processing equipments throughout this facility. These findings were documented on the following private laboratory certificates of analysis provided to the FDA.
 - (1) Certificate of Analysis (b) (4) dated 1/21/2010
(b) (4) environmental samples collected on 1/13/2010 were found positive for Salmonella.
 - (2) Certificate of Analysis (b) (4) dated 2/8/2010
(b) (4) environmental samples collected on 1/26/2010 were found positive for Salmonella.
 - (3) Certificate of Analysis (b) (4) dated 2/18/2010
(b) (4) environmental samples collected on 2/8/2010 were found positive for Salmonella. (b) (4) (b) (4) environmental samples were collected from the Grinding/Packing Room where powder product is further mixed with other ingredients and packaged into finished products.

After receiving the first private laboratory analytical results (Certificate of Analysis (b) (4) dated 1/21/2010) indicating the presence of Salmonella in your facility, you continued to distribute HVP paste and powder products until 2/15/2010. Furthermore, from 1/21/2010 to 2/20/2010, you continued to manufacture HVP paste and

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powder products under the same processing conditions that did not minimize microbial contamination.

OBSERVATION 2

Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food-contact surfaces.

Specifically,

On 2/14/2010, we observed disassembled equipment with accumulation of food debris and accumulation of dark brown colored liquid. According to your firm's Quality Assurance/Food Technologist these surfaces have been cleaned and ready to be assembled for production. The specific food contact surfaces observed are described as follows:

1. Light brown residue was observed on the ledge close to the hinge of the east door of Large Paste Mixer.
2. Dark brown liquid was observed inside the Still (b) (4) outlet to the paste mixers. Still (b) (4) is (b) (4) holding tanks that feed in-process material into the paste mixers.
3. Brown residue and dark brown liquid were observed on the stainless steel filter screen and inside its housing.
(b) (4)
4. Dark brown liquid residue was observed inside the (b) (4) conveying pipe located after the hopper outlet of Belt Dryer (b) (4). We were informed by your firm's Quality Assurance/Food Technologist that during production, this pipe transports (b) (4).
5. Brown residue was observed on the inside surface of exit end of the white PVC pipe located between Mixers (b) (4) and (b) (4) inside the Grinding/Packing Room. This PVC pipe is used for diverting overflow product that can be eventually incorporated into a finished product.

During production on 2/18/2010, it was observed that paste product comes in contact with the surface of the ledge referenced in bullet #1

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OBSERVATION 3

The plant is not constructed in such a manner as to allow floors to be adequately cleaned and kept clean and kept in good repair.

Specifically, during our inspection, we observed cracks and crevices on the floor area directly underneath and around the following areas:

1. Inlets and outlets of the (b) (4) Paste Mixers where these parts are disassembled for cleaning and left exposed until production begins.
2. Shakers (b) (4) inside the Grinding/Packing Room where finished powder products are handled, mixed, and packed.

Moreover, we observed floor fractures and crevices along the trench drains in the Evaporator/Paste Mixers/Belt Dryers areas. Standing water was also observed in the floor areas nearby these trench drains. We observed production employee and forklift traffic in these areas and into the Grinding/Packing Room where finished powdered products are packed.

Your firm's environmental sample results were positive for *Salmonella* from or near these floor areas.

OBSERVATION 4

Plumbing is not adequately installed and maintained to provide adequate floor drainage.

Specifically, during the our inspection of the Evaporator/Paste Mixers/Belt Dryers areas, we observed standing, grey/black liquid in the square drain at the north end of the building while you were manufacturing hydrolyzed vegetable protein (HVP) paste into powder products. Further, we sensed an odor in the vicinity of this drain, which collects discharge water from the east and west trench drains.

Your firm's environmental sample results were positive for *Salmonella* from or near these drain areas.

*** DATES OF INSPECTION:**

02/12/2010(Fri), 02/13/2010(Sat), 02/14/2010(Sun), 02/15/2010(Mon), 02/16/2010(Tue), 02/18/2010(Thu), 02/19/2010(Fri), 02/22/2010(Mon), 02/23/2010(Tue), 02/24/2010(Wed), 02/26/2010(Fri), 03/01/2010(Mon), 03/02/2010(Tue), 03/04/2010(Thu)

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