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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile: 504-253-4520

June 10, 2002

WARNING LETTER NO. 2002-NOL-33

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Carlo J. Gallo, Jr., President
Gulf Coast Blenders, Inc.
4119 Tchoupitoulas Street
New Orleans, Louisiana 70115

Dear Mr. Gallo:

United States Food and Drug Administration (FDA) investigators inspected your food manufacturing facility, located at 4119 Tchoupitoulas Street, New Orleans, Louisiana, during April 11 - 12, 15 - 16 & 19, 2002. The inspection was conducted to determine compliance with FDA's Current Good Manufacturing Practice requirements in Manufacturing, Packing, or Holding Human Food, Title 21, *Code of Federal Regulations*, Part 110. During the inspection, our investigators documented numerous insanitary conditions, which caused the ingredients and finished food products manufactured, packed, and/or held at your facility to become adulterated. The adulterated ingredients and finished food products are in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, in that they had been held under insanitary conditions whereby they may have become contaminated with filth.

Evidence of apparent rodent activity was observed in, on, and near food products stored in your facility and in your food processing areas. This evidence included live and dead rodents, rodent excreta pellets, rodent urine stains, and gnawed food products. Evidence of apparent rodent urine stains and rodent gnawing was observed on several different food products including seasoning blends, fish fry mixes, breading mixes, biscuit mix, beignet mix, pancake mix, and cornbread mix.

Our investigation of the general conditions in the warehouse revealed: an approximately 1" x 4" opening to the outdoors at the west corner of the south wall overhead dock door; and, an approximately 1/2" diameter opening to the outdoors at the bottom south side of the double doors between the main two-story storage area and the finished product storeroom. In addition, our investigators documented an approximately 1" diameter hole in the foam insulation located between the northeast corner upstairs packaging and storage area wall and an iron support beam. This hole was approximately 14" above the floor.

On April 12 & 15, 2002, while producing finished food product, none of the four employees were observed wearing protective coverings over their street clothes. On April 15, 2002, two employees were observed wearing dangling earrings while handling open bags of ingredients.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your facility is operated in a sanitary manner.

We are aware that on April 12, 15, & 19, 2002, you voluntarily destroyed a variety of finished food products, approximately 9,335 pounds of finished product, found contaminated during the inspection. We are in receipt of your April 15 & 19, 2002, letters with attached destruction inventory reports for April 12, 15, & 19, 2002.

At the conclusion of the inspection, you were presented with a list of deficiencies on a Form FDA 483, Inspectional Observations. You should take prompt action to correct these violations and to prevent the recurrence of similar violations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure, injunction, and/or prosecution.

You should notify this office, in writing, within 15 days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, please state the reason for the delay and the time by which the corrections will be completed.

Your response should be directed to Rebecca A. Asente, Compliance Officer, U.S. Food and Drug Administration, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. Should you have any questions concerning the contents of this letter, you may contact Ms. Asente at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483