



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

94352d

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 3003833357

September 18, 2003

Jorge M. Amorim  
Troy E. Nitsche  
James L. Goodrich  
Giovanni's Aloha Foods, LLC  
96-1362 Waihona Street  
Pearl City, HI 96782

**WARNING LETTER**

Dear Msrs. Amorim, Nitsche, and Goodrich:

On February 19, 21, and April 14 and 15, 2003 we inspected your facility located at 96-1362 Waihona Street, Pearl City, HI. Our inspection and the analysis of collected samples documented significant violations of the Federal Food, Drug, and Cosmetic Act (the Act) that require your immediate attention, including the following:

FDA analysis of a sample (# 188982) collected from your firm on February 21, 2003, confirmed that Giovanni's Hot Sauce contains sodium bisulfite (a sulfite) at levels greater than 10 parts per million (ppm). As a result, Giovanni's Hot Sauce is misbranded under Section 403(k) of the Act for failing to declare sodium bisulfite in the list of ingredients as required by 21 CFR 101.100(a)(4), 101.22(j) and 101.4(a).

We acknowledge that after FDA informed you that sulfites needed to be declared on the label for Giovanni's Hot Sauce, you added a sticker stating, "INCLUDES SULFITES," to a total of [redacted] cases of product at your warehouse and at your distributor. Please note, however, that the actual sulfiting agent, Sodium Bisulfite, must be declared, including the parenthetical statement that it is a preservative. You also must declare the presence of the remaining undeclared ingredients of the REALEMON Lemon Juice, i.e., Water, Sodium Benzoate (Preservative) and Lemon Oil.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject the food to legal action. It is your responsibility to

assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure or injunction.

In addition, we note that the format used for the "Nutrition Facts" panels on the "HOT SAUCE" and "SCAMPI MARINADE" labels do not comply with the format requirements of 21 CFR 101.9(d). You may find our "Food Labeling Guide," which is available on our Internet site at <http://www.cfsan.fda.gov/~dms/flg-toc.html>, useful when revising your labels.

We also found that you have serious deviations from the Acidified Food regulations found in Title 21, Code of Federal Regulations, Parts 108 and 114 (21 CFR 108 and 114). Copies of 21 CFR 108 and 114 are enclosed for your ready reference. Failure to comply with any of the requirements of 21 CFR 108.25 and the mandatory portions of part 114 constitutes a prima facie basis for the immediate application of the emergency permit control provisions of Section 404 of the Act (21 CFR 108.25(a)).

FDA analysis of a sample of Giovanni's Scampi Marinade found water activities greater than 0.85 for 2 of 3 subsamples and a mean finished equilibrium pH value of 4.31. By definition, in accordance with 21 CFR 114.3(b), an acidified food is a food with a finished equilibrium pH of 4.6 or below and a water activity greater than 0.85. Based on this information, and the information provided in the inspection report, we concluded that the Giovanni's Scampi Marinade is an acidified food, subject to the requirements of 21 CFR Parts 108 and 114.

Under 21 CFR 108.25(c)(1), a commercial processor must, not later than 10 days after first engaging in the manufacture of acidified foods, register and file with the FDA information including, but not limited to, the name of the establishment, the principal place of business, the location of each establishment in which the processing is carried on, the processing method in terms of acidity and pH control, and the list of foods so processed in each establishment. You have failed to register your establishment with the FDA in the manner required by this provision. We have enclosed a copy of Form FDA 2541, the document upon which this information must be provided to FDA.

Also, under 21 CFR 108.25(c)(2), a commercial processor must, not later than 60 days after registration, and before packing any new product, provide the FDA with information on the scheduled processes, including, as necessary, conditions for heat processing and control of pH, salt, sugar, and preservative levels and source and date of the establishment of the process, for each acidified food in each container size. You have failed to provide the FDA with information on the scheduled processes as required by this provision. We have enclosed a copy of Form FDA 2541(a), the document upon which this information must be provided to FDA.

Furthermore, under 21 CFR 108.25(e) a commercial processor engaged in the processing of acidified foods must prepare and maintain files on a current procedure for use for

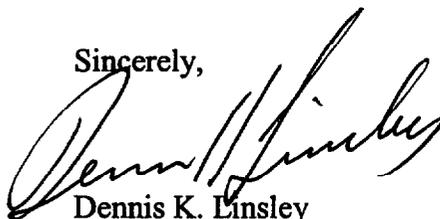
products under the processor's control, which the processor will ask the distributor to follow, including, but not limited to, plans for recalling products that may be injurious to health. You have failed to maintain such a plan, as required by this provision.

Finally, you have failed to follow production and process controls outlined in 21 CFR 114 for the safe manufacture of acidified food products. More specifically, you have failed to provide sufficient control that includes frequent testing and recording of results to ensure that the finished equilibrium pH values of Giovanni's Scampi Marinade are no higher than 4.6, as required by 21 CFR 114.80(a)(2); you have failed to maintain processing and production records to show adherence to a scheduled process, as required by 21 CFR 114.100(b); and you have failed to mark products with an identifying code, containing, among other items, the year, day, and period during which the food was packed, as required by 21 CFR 114.80(b). As a result of the violations under 21 CFR 114, the Giovanni's Scampi Marinade is adulterated within the meaning of Section 402(a)(4) of the Act in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline specific things you are doing to correct the deviations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Your response should be directed to Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Dennis K. Linsley  
District Director  
San Francisco District

Enclosures:

21 CFR 108  
21 CFR 114  
Forms FDA 2541 and 2541a