



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

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

Telephone: 504-253-4500
FAX: 504-253-4566

April 5, 2000

WARNING LETTER NO. 2000-NOL-20

***FEDERAL EXPRESS
OVERNIGHT DELIVERY***

Robert C. Hoy, President
Gulf Food Products Co., Inc.
509 Commerce Point
Harahan, Louisiana 70123

Dear Mr. Hoy:

On October 27-28 and November 2, 1999, an investigator of the U.S. Food and Drug Administration (FDA) conducted an inspection of your facility, located at 509 Commerce Point, Harahan, Louisiana. During the inspection, the investigator collected samples of various labels for the dried shrimp packed by your firm. Our review of the labels reveals that they cause the product to be in violation of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, *Code of Federal Regulations* (21 CFR), Part 101 – Food Labeling, as follows:

- The firm's "Sun-Done" and "Stu-Wee's" brand products are misbranded within the meaning of Section 403(q)(1) because the label does not bear nutritional labeling and the firm is not exempt.

The above violation is not meant to be all-inclusive description of deficiencies on the labels used by your firm. Other label violations can subject the food to legal action. It is your responsibility to assure that all your products are labeled in compliance with all applicable statutes enforced by FDA.

Also, the "Three Star Brand" product is misbranded because the nutrient "Calories" is not in bold type as required by 21 CFR 101.9(d)(1)(iv).

In addition to the labeling deficiencies, the investigator observed Hazard Analysis Critical Control Points (HACCP) and insanitary conditions that were on the FDA-483 and FD-3501 forms issued at the close of the inspection. These will be addressed in a separate letter from this office.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the FDA

Form FDA-483. However, you should notify this office in writing, within 15 working days of receipt of this letter, of the specific 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 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Hardin at (504) 253-4519.

Sincerely,



Richard D. Debo
Acting District Director
New Orleans District

Enclosure: Form FDA-483