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DEPARTMENT OF HEALTH & HUMAN SERVICES

May 16, 2000

Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

WARNING LETTER
SJN-00-10

CERTIFIED MAIL
Return Receipt Requested

Moisés Caraballo
President
Quality Fruits Products Corp.
P.O. Box 3052
Yauco, Puerto Rico 00698

Dear Mr. Caraballo:

Investigator German Rivera from our Food and Drug Administration (FDA), Mayaguez, PR Post, conducted an inspection of your food product manufacturing facility located at Susua Baja Industrial Urbanization, Yauco, P.R. 00689 on August 17 to September 29, 1999. At the conclusion of the inspection the Investigator presented and discussed with Ms. Arleen Caraballo, Quality Assurance Manager, an FDA-483, Inspectional Observations form.

During the inspection our Investigator collected a sample of canned chick peas and obtained labels for various beans/peas, tomato sauce and juice beverage products. Our review of your labels, found serious misbranding violations in accordance with the Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR) Part 101 - Food Labeling , as follows:

1. The "Food Club" brand canned white beans that your firm manufactures under contract are misbranded in that they contain disodium EDTA but the label fails to declare this additive [403(a), 403(i) (2) and 21 CFR 101.22(j)].

2. The labels for "El Valle" canned pink, white and red beans are false and misleading in that, although they declare the common and usual name on the principal display panel, the ingredient section declares that they contain "pinto beans"[403(a), 21 CFR 101.4, 101.18(b)].

3. Your "El Valle" brand juice (orange, passion fruit, grapefruit and fruit punch) products packed in one (1) gallon containers are misbranded because they are made from two or more ingredients, but the labels fail to bear the common or usual name of each ingredient [403(i)(2) and 21 CFR 101.4]. For example; citric acid and gum agar, are added to all your juices but the list of ingredients on the labels declares they contain 100% juice only. They are also misbranded because they contain the chemical preservative sodium benzoate and their labels fail to declare both the presence of the chemical preservatives and a description of the function of the preservatives [403(a), 403(i)(2), 403(k), 21 CFR 101.4 and 21 CFR 101.22(j)].

4. Your "El Valle" brand tomato sauce is misbranded in that it is made from two or more ingredients, but the labels fail to bear the common or usual name of each ingredient. The food additive agar-agar, sugar, and citric acid are added to formulate the tomato sauce but these are not declared in the ingredient sections of the label [403(i)(2) and 21 CFR 101.4].

5. Your "El Valle" brand juice beverages in one (1) gallon containers are also misbranded because the labels fail to bear a declaration of net quantity of contents on the principal display panel as required in 21 CFR Part 101.105, [403(e), 21 CFR 101.1, and 21 CFR 101.105]. However if a net weight statement is embossed on the plastic container, this is deemed to be substantial.

The inspection and the FDA-483 also documented deviations from Title 21, Code of Federal Regulations, Part 108 & 113, Thermally Processed Low Acid Foods Packaged in Hermetically Sealed Containers and Part 110 Good Manufacturing Practice Regulations. These deviations are concerning the methods used in, or the controls used for manufacturing bean and pea products, and other food products, as follows:

- You failed to report to FDA changes to the scheduled processes filed in August 1995 for the continuous agitating retort processing of canned beans and peas that you are now routinely using. Although these changes consist of using higher processing temperatures and/or longer processing time from what you originally submitted, and from what more recently your processing authority has certified, they have become regularly scheduled processes which require to be promptly filed in accordance with 21 CFR 108.35(c)(2)(ii).

- Your firm uses emergency ([redacted] processes, whenever temperature drops occur that have not been appropriately qualified by an authorizing process authority. Your process authority has reviewed and certified an emergency ([redacted]) process for pink and red kidney beans, but the specified parameters are not rigorously followed and this process is used for other canned bean and pea products without proper scientific data and substantiated by a process authority in accordance with 21 CFR 113.40(c)(9). The emergency process parameters used are also inconsistent and actually improvised at the time of each incident. We refer you to FDA-483, observations #3.

- Your production records show at least twenty three (23) instances since January 1997 when emergency ([redacted]) processes were used due to temperature drops in which the critical factors of temperature and time were not adequately controlled, failing to use established and consistent parameters, and not appropriately recording these events, [21 CFR 113. 40(c)(9) 113.89 & 113.100]. For example, records for chick peas lot QJSGZ and pigeon peas lot QARGG show temperature drops below 250° F for a prolonged period of time, yet although the temperature recorder chart were annoted, the charts were not marked to record the start and stop times of the process. Your only qualified process (documented for pink and red beans) established the minimum requirements time to be 17 min at 260° F (29 min at 250° F). No deviation or incident reports were prepared nor were there documented product evaluation done. We refer you to FDA-483, observations #3 & #4. In addition, your records show that when product evaluations are done due to process deviations, these are not done by a competent processing authority, nor in accordance with procedures recognized by the processing authority as required in 21 CFR 113.89.

- Your firm failed to consistently record process and production information at appropriate intervals and at the time they are observed by the operator in accordance with 21 CFR 113.40(g)(1)(ii)(e), 113.40(g)(2)(ii)(c), 113.100(a), & 113.100(a)(4). For example; the daily process records for lots QAXJK and QTJJG failed to report the retort's "time steam on" and the time when the drain valve and vent were closed, and the daily process record for lot #

QDSHG failed to report the retort's initial rotary speed. We refer you to FDA-483, observations #6.

- Your firm failed to review and sign processing and production records after the actual process and before release for distribution by a qualified representative of the plant management as required in 21 CFR 113.100(b). At least 19 instances in the past two (2) years show failure to sign and/or date the processing and productions records. We refer you to FDA-483, observations #5.

- You failed to provide for adequate sanitary facilities and controls over sanitary conditions and practices, such as: poorly equipped and badly maintained handwash and toilet facilities; broken and missing window screens to protect against pests in food production and storage areas; and spillage, poorly stored food, and messy raw material storage areas [21 CFR 110.20 and 110.37]. We refer you to FDA-483, observation #7, #8 and #9.

Furthermore, regarding use of disodium EDTA in canned beans, a petition has been filed for the use of calcium disodium EDTA and disodium EDTA in all legumes. The Centers preliminary evaluation determined that there is no resulting increase in exposure to EDTA. However, you have labeling discrepancies in that the labels for "Food Club" pink and pinto beans incorrectly declare calcium disodium EDTA in place of the actual ingredient, disodium.

Your "El Valle" canned bean labels are incorrect in that they declare the presence of calcium, when actually they contain calcium chloride. Additionally, several of your "Food Club" brand beans are deficient in that they contain calcium chloride but the label fail to declare the presence of this additive [21 CFR 101.4].

Regarding the "El Valle" green pigeon peas, the label identifies three ingredients, green pigeon peas, water and salt on the principal display panel, however it lacks a separate ingredient statement. This product label does not have a list of ingredients as required in 21 CFR 101.4.

The labels on your "El Valle" juice beverages are misleading in that they depict a vignette that displays recognizable (characterizing) flavors of various different fruits, (e.g., a pineapple, an orange, tamarind, etc.). This implies that all of the fruits shown are in the products, however, with the exception of your "fruit punch" which contain some, most of your juice products contain one characterizing flavor, (e.g. Parcha (passion fruit) concentrate).

Also, your beverages that contain juice or juice derivatives (e.g. concentrate, pulp, etc.) require a warning statement if they have not been processed as defined in 21 CFR 101.17(g). Our Investigator provided you with guidance regarding the requirements under this regulation. Note that before November 1999 you could had complied with this regulation by providing signs or placards, in lieu of a warning statement on the product labels, [21 CFR 101.17(g)(4)(i), 21 CFR 101.17(g)(4)(ii)]. That alternative will expired by the time this letter reaches you.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As the most responsible official at the firm, it is your responsibility to assure that this facility is operated in compliance with the applicable FDA laws and regulations. You can request a copy of the pertinent sections of 21 CFR cited for your reference if needed.

Although these observations warrant consideration for formal regulatory follow-up, we are affording you an opportunity to voluntarily correct the noted deviations. Failure to promptly correct these may result in regulatory action without further notice. These actions include seizure and/or injunction.

Please notify the San Juan District 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 these or similar violations. An adequate response would include a review of pertinent processing records by your process authority.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00901-3223, Attention: Andres Toro, Compliance Officer.

Sincerely,

Mildred R. Barber

Mildred R. Barber
District Director

cc: Ms. Arleen Caraballo
Quality Control Manager
Quality Fruits Products Corp.
P.O. Box 3052
Yauco, Puerto Rico 00698