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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751VIA FEDERAL EXPRESSWARNING LETTER

FLA-02-65

October 1, 2002

Ralph L. Mongru, Owner
Tropical Nutty Delight
2212 Mary Sue Street
Largo, Florida 33774

Dear Mr. Mongru:

On May 21, 28, 29, and 30, 2002, we inspected your Low-acid Canned Food (LACF) factory located at 13131 56th Court, North #304, Clearwater, Florida, 33760. We found that you have serious deviations from the LACF regulations (21 CFR Part 108 and 113). Your firm's failure to comply with the mandatory provisions of 21 CFR Part 108.35 and 113 renders your Low-acid Canned Food adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your milk-based peanut flavored beverage is adulterated in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You can find the Act and the Low-acid Canned Food regulations through links in FDA's home page at www.fda.gov.

The mandatory requirements of 21 CFR Part 113 and 21 CFR Part 108.35 with which you are not presently in compliance include the following:

Your firm did not provide sufficient information needed for FDA to determine the adequacy of your scheduled process for the milk-based peanut flavored beverage that you manufacture, as requested in writing by FDA [21 CFR Part 108.35(c)(3)(ii)]. Additionally, you did not provide FDA with evidence to show that this process was established by qualified persons having expert knowledge of thermally processed low-acid foods in hermetically sealed containers (21 CFR Part 113.83).

You provided what you told the investigator was a scheduled process (Exhibit 3, Establishment Inspection Report (EIR) 5/21, 28-30/02) for the milk-based peanut flavored beverage you manufacture. You told the investigator that the scheduled process was provided to you by your process authority, Mr. Steve Stephany. Upon review, Exhibit 3 appears to be four test runs (4 retort batch operations with varying processing times and temperatures) recorded on TND Process Logs dated 12/19/95. Spoilage results listed on the log for these batches ranged from 14% to 69%. There does not appear to be any specific scheduled process parameter recommendations (critical limits for processing time and temperature, etc.) or any authorization (signature of Mr. Steve Stephany, your firm's processing authority) on Exhibit 3. We, therefore, do not consider Exhibit 3 as a specific scheduled process sufficient to adequately describe or authorize a specific scheduled process for a specific product.

If you intend to continue to manufacture this product, you first need to engage the services of a person or persons qualified in and having expert knowledge of thermally processed low-acid foods in hermetically sealed containers to establish a scheduled process for your milk-based peanut flavored beverage that is adequate to ensure commercial sterility for this product. You must provide FDA with pertinent scheduled process information provided by your process authority including processing method, type of retort, times and temperatures of processing, sterilizing value, critical control factors, affecting heat penetration, and source and date of establishment of the process in order to comply with 21 CFR Part 108.35(c)(2). You also need to ensure that the other deviations listed below are corrected before you begin processing. Finally, you must process your products in conformity with at least the minimum filed scheduled process recommended by your processing authority. Deviations requiring correction include:

- Your firm did not maintain complete records of processing and production information. Specifically, you did not record the product code, the approximate number of containers per coding interval, the initial temperature, the mercury and glass and recording thermometer readings, time steam on, temperature up to processing temperature, time steam off, venting time and temperature to which vented [21 CFR Part 113.100(a)].
- Your firm failed to install at least one mercury-in-glass (MIG) thermometer on each retort. Specifically, your American retort that you use to process your milk-based peanut flavored beverage is not equipped with a MIG thermometer [21 CFR Part 113.40(a)(1)].
- Your firm does not adjust the temperature recording device (TRD) for the American retort used to process your milk-based peanut flavored beverage to agree as nearly as possible with the known accurate MIG thermometer [21 CFR Part 113.40(a)(2)]. Specifically, you told the investigator you have not used the TRD in over a year.
- Your firm failed to equip retorts with automatic steam controllers to maintain retort temperatures. Specifically, your American retort that you use to process your milk-based peanut flavored beverage is not equipped with an automatic steam controller [21 CFR Part 113.40(a)(4)].
- Your retort venting procedure does not ensure removal of air from the retort before processing is started. Specifically, you told the investigator that you do not vent the American retort that you use to process your milk-based peanut flavored beverage prior to the start of processing [21 CFR Part 113.40(a)(12)].
- Your firm did not record observations during visual closure examinations performed at intervals of sufficient frequency to ensure proper closure [21 CFR Part 113.60(a)].
- The container identification code on your milk-based peanut flavored beverage does not include the year packed, day packed, or period during which the product was packed. Specifically, your manufacturing code (e.g."APR 2003") which is the expiration period of the product, does not differentiate between different cooks made within the same month or between cooks made in different periods of the same day [21 CFR Part 113.60 (c)].
- Your firm did not file a process with FDA for your milk-based peanut flavored beverage with information as to the scheduled process including processing method, type of retort, times and temperatures of processing, sterilizing value, critical control factors affecting heat penetration, and source and date of establishment of the process [21 CFR Part 108.35(c)(2)].

The process your firm sent in to FDA on December 21, 1996, (EIR, Exhibit 6) had in the comments block "Hold product in retort from [REDACTED]". This filing was returned to you in order for you to provide more information about the process. To date, you have not returned that process filing with additional information requested by FDA.

During the inspection, our investigators noted that you agreed to all of the observations listed on the FDA 483; however, you would not commit to take any corrective actions. In addition, you also stated that you would continue shipping product, if orders were received.

We also noted that although your original procedure for processing product in the retort was to load the retort with [REDACTED] layers of bottles, [REDACTED] bottles per layer, you told the investigator that you now add an additional [REDACTED] layer of [REDACTED] bottles to reduce the number of cooks per batch. You are reminded that in accordance with 21 CFR Part 108.35(c)(3)(i) as a commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers, you are required to process each low-acid food in each container size in conformity with at least the scheduled process and modifications filed pursuant to 21 CFR Part 108.35(c)(2).

We also noted that you are not under the supervision of a person who has attended a school approved by the Commissioner for giving instruction in processing operations and who has satisfactorily completed the prescribed course of instruction [21 CFR Part 108.35(g) and 21 CFR Part 113.10].

The above violations are not meant to be an all-inclusive list of deficiencies in your plant. 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, and/or injunction and issuance of an Order of Need to obtain and hold a Temporary Emergency Permit.

Our Florida District Office will be available to answer questions that you may have about this matter. Specifically, you may contact Diane J. Englund, Compliance Officer, at (407) 475-4741 concerning any issues discussed in this letter.

Sincerely,



for Emma Singleton
District Director
Florida District Office

Enclosures:

Exhibits 3 and 6-EIR 5/21, 28-30/02