



DEPARTMENT OF HEALTH & HUMAN SERVICES

91644d

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Richard Classey
Vice President and General Manager
Oak Tree Farm Dairy, Inc.
544 Elwood Road
East Northport, NY 11731

August 16, 2001

Ref: NYK-2001-113

Dear Mr. Classey:

On May 17 and June 5 and 7, 2001, we inspected your beverage manufacturing facility located at the above address. During the inspection, we collected a sample of your "OAKTREE REAL BREWED ICED TEA" product and labels for your "OAKTREE FRUIT PUNCH" and "OAKTREE ALL NATURAL LEMONADE" products. Our analysis of the iced tea and review of the labels found serious violations of the Federal Food, Drug, and Cosmetic Act ("the Act") and Title 21, *Code of Federal Regulations*, Part 101 – Food Labeling (21 CFR 101).

The "OAKTREE REAL BREWED ICED TEA" is misbranded under Section 403(i)(2) of the Act in that it contains the color additive "FD&C Red No. 40", but the certified color additive fails to be declared on the product label in the statement of ingredients by its specific name, as required (21 CFR 101.22(k)(1)). The product is also misbranded under Section 403(k) of the Act because it contains an artificial coloring that is not declared on the label.

The "OAKTREE FRUIT PUNCH" is misbranded under Section 403(k) of the Act because it contains sodium benzoate and potassium sorbate, which are not declared on the product label. A food to which a chemical preservative is added must declare the common or usual name of that ingredient and a description of its function, e.g., "preservative", as required by 21 CFR 101.22(j).

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your product labels. Other label violations can subject the foods to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration ("FDA").

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction.

As you know, during the inspection, our investigator also reviewed the labels and formulations for your “OAKTREE ALL NATURAL LEMONADE” and “OAKTREE FRUIT PUNCH”. Your lemonade label fails to declare the ingredient, citric acid, which is declared as an ingredient on the label of the lemonade concentrate used to make your lemonade. Further, your fruit punch label fails to declare the ingredients, grape juice, artificial fruit punch flavor, propylene glycol, sodium benzoate, and potassium sorbate, which are declared as ingredients on the label of the fruit punch concentrate used to make your fruit punch. Also, your fruit punch label declares the ingredients, concentrated pineapple juice, gum arabic, glycerol ester of wood resin, and blue 1. However, these ingredients are not found in the fruit punch concentrate used to make your fruit punch and are not listed as ingredients in your fruit punch formulation. The investigator discussed these labeling discrepancies with you at the conclusion of the inspection.

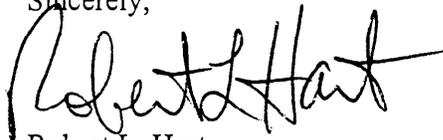
The term “all natural” on the “OAKTREE ALL NATURAL LEMONADE” label is inappropriate because the product contains potassium sorbate. Although FDA has not established a regulatory definition for “natural,” we discussed its use in the preamble to the food labeling final regulations (58 *Federal Register* 2407, January 6, 1993, copy enclosed). FDA’s policy regarding the use of “natural,” means nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food. The same comment applies to use of the terms “100 % NATURAL” and “ALL NATURAL” on the “OAKTREE REAL BREWED ICED TEA” label because it contains citric acid.

Further, the declaration of potassium sorbate in the ingredient statement on the “OAKTREE ALL NATURAL LEMONADE” label must be followed by a description of its function, e.g., “preservative”, as required by 21 CFR 101.22(j).

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. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time within which the corrections will be completed.

Your reply should be directed to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions concerning the violations noted, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,



Robert L. Hart
Acting District Director

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Cc: HFR-NE1

Cc: HFR-NE100

Cc: HFR-NE140/QA file

Cc: HFR-NE150

Cc: HFR-NE1500/O. Vitillo

Cc: HFS-607

Cc: HFA-224

Cc: HFC-210 (CFN 2490662)

Cc: HFI-35/redacted copy

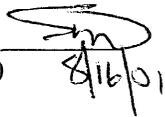
Cc: EF (Oak Tree Farm Dairy, Inc., CFN 2490662)

Cc: legal file (NYK-2001-113)

Cc: BAG

DCB approval

FACTS 8743-0

A handwritten signature, possibly "m", is written over a horizontal line. Below the line, the date "8/16/01" is written.