



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

January 2, 2001

WARNING LETTER
WL-CIN-4469-0

Mr. Peter H.C. Dauwalder, President
Bunker Hill Cheese Company, Inc.
6005 CR 77
Millersburg, Ohio 44654

Dear Mr. Dauwalder:

On July 26 and August 29, 2000 The U.S. Food and Drug Administration conducted an inspection of your cheese manufacturing plant in Millersburg, Ohio. During the inspection labels for products your firm produces were collected. A review of the labels used on cheese products manufactured for Beluga Caviar International, Inc. revealed "The French Yogurt Cheese (Regular, Sundried Tomato & Basil, Jalapeno Pepper, Peppercorn and Chive) has the nutrient content claim 'Low in Cholesterol', but the products do not qualify for making the claim. The French Yogurt Cheese contains 5 grams of saturated fat per labeled serving; however, in order to qualify for making a 'Low in Cholesterol' claim, the products must contain 2 grams or less of saturated fat per reference amount customarily consumed 21 CFR 101.62(d)(2)." This causes the product to be misbranded under the Federal Food, Drug and Cosmetic Act, section 403(r)(1)(A).

The labels for these Beluga Caviar International, Inc. French Yogurt Cheese products do not declare the firm listed on the label as the distributor, i.e. "Distributed by" or "Manufactured for". The absence of this label statement causes the labels to be in violation of section 403(e)(1).

"The statement of identity 'French Yogurt Cheese' causes your products to be misbranded under section 403(i)(1) of the act because it is not a common or usual name, or an appropriately descriptive term or phrase that describes the basic nature of the food (21 CFR 101.3(b)). Yogurt is a food that is defined by a standard of identity in 21 CFR 131.200. Cheese is also a food that is defined by a standard of identity in 21 CFR part 133. These terms may not be used as the statement of identity for your products unless the products meet the yogurt standards in 21 CFR 131.200 and one of the cheese standards in 21 CFR part 133."

The above cited violations are not intended to be an all-inclusive statement of the deficiencies which may exist in your product labeling. We understand that the labels were prepared, approved, and printed at the direction of Beluga Caviar International, Inc. and that you custom manufacture and label the product for that firm. However, you do have the responsibility not to misbrand and introduce misbranded food into interstate commerce.

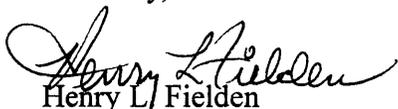
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action (such as seizure) without further notice.

The half pound package does not appear to be further processed except for adding labeling. These products are misbranded when shipped as presently labeled. You should consider obtaining a written labeling agreement from Beluga Caviar setting forth the labeling which will be applied by them to meet all labeling requirements of The Federal Food, Drug and Cosmetic Act.

Within 15 days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct the noted violations, including each step being taken to prevent the recurrence of similar violations.

Your reply should be directed to the Food and Drug Administration to the attention of Compliance Officer Leonard Jay Farr. You may contact Mr. Farr at 513-679-2700 if you have questions regarding this letter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Henry L. Fielden".

Henry L. Fielden

District Director

U.S. Food and Drug Administration

cc: Beluga Caviar International Inc.