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Public Health Service
Mid-Atlantic Region



DEPARTMENT OF HEALTH & HUMAN SERVICES

Telephone (201) 331-2905

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

May 21, 1997

James B. Kelly
President
Bayard-Prete Candy Co., Inc.
3400 Haddonfield Rd.
Pennsauken, New Jersey 08109

WARNING LETTER

CFN: 2220259
File No: 97-NWJ-35

Dear Mr. Kelly,

The analyses of samples of Traditional American Chocolates, 18 oz., code EGO601 and Chocolate Easter Eggs, 16 oz. code EGG605 manufactured by your firm for the [redacted] revealed the products to be misbranded under Section 403(i) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our laboratory analysis indicates that the Traditional American (Assorted) Chocolates were found to contain undeclared peanuts, almonds, walnuts and cashews in whole or in part. It was further determined that the labeling for this product and the Chocolate Easter Eggs lacked ingredients statements as required under 21 Code of Federal Regulations (CFR) Section 101.4(a)(1). Both product labels also lacked the name and place of business of the manufacturer, packer, or distributor as required under 21 CFR Section 101.5(a).

During the 3/7,10,12,13/97 inspection of your manufacturing facility conducted by investigators of the Food and Drug Administration, samples of product labeling and formulations were collected and reviewed. It was revealed that some labels for bulk packaged products may not accurately identify the products or the ingredients used. It was noted that the designation "MILK CHOC", which appears in 1/4 inch high letters, is used to describe a variety of confections such as "ORANGE JELLIES", "RASPBERRY JELLY", and "VANILLA BUTTER CREAMS" which appear in 3/16 inch high letters. This is false and misleading in that the ingredients statement for the Vanilla Butter Creams lists chocolate as an ingredient and it is not listed at all on the Orange Jellies and Raspberry Jelly labels. Products which contain milk chocolate as an added ingredient cannot accurately be called "Milk Chocolate". In order for a product to be called "Milk Chocolate" it must conform to the standard of identity as set forth in 21 CFR Section 163.130. A copy of this section is attached for your information. Furthermore, each ingredient of milk chocolate must also be listed.

The above violations concerning labeling requirements are not meant to be an all-inclusive list of deficiencies of your labels.

Bayard-Prete Candy Co., Inc.
Pennsauken, New Jersey 08109
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It is your responsibility to become familiar with the labeling regulations as well as the new regulations promulgated under the Nutrition Labeling and Education Act and to make the appropriate changes to bring your labeling into compliance with all applicable statutes enforced by FDA. A copy of FDA's Food Labeling Guide is enclosed for your reference.

Please notify this office within 15 working days after receipt of this letter of the specific steps you have taken to correct the violations, including the explanation of each step being taken to prevent recurrence. Failure to correct these violations as proposed may result in regulatory action without further notice. We acknowledge that you have initiated a voluntary recall of the Macy's Assorted Chocolates as well as the Coconut Cream Eggs, Butter Cream Eggs, and Chocolate Fudge Eggs in the interest of public safety and health.

Your reply should be directed to the Food and Drug Administration, Attention Richard T. Trainor, Compliance Officer.

Sincerely yours,



CHARLES B. THORNE
Acting District Director
New Jersey District

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED

RTT:np