



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region g1558d

Telephone (973) 526-6010

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

July 26, 2001

WARNING LETTER

Certified Mail
Return Receipt Requested

Mr. Robert Kasky
President
R-Kane Products, Inc.
8351 National Highway
Pennsauken, New Jersey 08110

File No.: 01-NWJ-32

Dear Mr. Kasky:

An inspection of your facility, located at 8351 National Highway, Pennsauken, NJ, was conducted from January 3 through January 8, 2001. During this inspection, our investigators collected several samples of various products and labels. Our review revealed that the Tiny-Meal Bars, FI-PRO-TEIN Bar, and Gel-lite 15 High Protein Gelatin Desserts are considered misbranded according to Section 403(r)(1)(A) of the Federal Food, Drug & Cosmetic Act (the Act).

Title 21, Code of Federal Regulations, 101.54(b)(1) allows the use of the term "high" if the product contains 20% or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV). The DRV for protein is 50g, therefore 20% of this is 10g. The Tiny-Meal Bars – Peanut, Almond, Raspberry, and Mandarin Orange; FI-PRO-TEIN Bar; and Gel-lite 15 High Protein Gelatin Desserts – Raspberry, Cherry, and Strawberry Banana, do not meet this minimum requirement for use of the term "high." These products are labeled to contain only 7-8g of protein.

In addition to the above, we also observed a Nutrition Labeling and Education Act (NLEA) deficiency with regard to Pro-Cal 100 Balanced Dietary Food Supplement -- Vanilla, Chocolate, and Strawberry. Because these products are not labeled as dietary supplements, the FDA must evaluate them as conventional foods and follow the labeling regulations as outlined in 21 CFR 101.9. The specific deficiency is as follows:

Pro Cal 100 -- Vanilla, Chocolate, and Strawberry

The amount of calories from fat should be rounded to the nearest 5g increment.

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your label or at your facility. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA and manufactured in accordance with all applicable regulations. You should perform a complete and thorough review of all of your product labels and revise them as necessary.

R-Kane Products, Inc.
Pennsauken, NJ 08110

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Please notify this office within 15 working days of receipt of this letter outlining the specific steps you have taken to correct the violations noted above and to prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time needed to complete the correction. Please submit your response to: U.S. Food & Drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attn: Sarah A. Della Fave, Compliance Officer.

Sincerely,

Edward H. Ellsworth, for
Douglas I. Ellsworth
District Director
New Jersey District