



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service  
Mid-Atlantic Region

Telephone (201) 331-2909

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

December 27, 1996

**WARNING LETTER**

Ronald Kaplan  
President  
Kaplan & Zubrin  
2nd and Kaighn Avenue  
Camden, New Jersey 08103

REVIEWED BY R. J. [Signature] / 1/28  
C.O. DATE

File No: 97-NWJ-10

Dear Mr. Kaplan:

On October 18, 1996 samples of your products were collected by an Investigator from the New Jersey District Office (FDA), and analyzed by our laboratory for the presence of FD&C Yellow #5. Products collected were packed in one gallon glass jars and identified as: KZ Kosher Whole Pickles (code 289); Pickle Chips (unlabeled, code 262) and Garden State Kosher Pickle Chips (uncoded). Samples were also collected of Natural Pickle Flavor, an ingredient used in the manufacturing of your products. These products are foods as defined by Section 201 of the Food, Drug and Cosmetic Act (the Act) and subject to regulations under Title 21 of the Code of Federal Regulations (CFR).

Products labeled as KZ Kosher Whole Pickles and Garden State Kosher Pickle Chips are considered to be misbranded under Section 403(i) of the Act. Our laboratory analysis indicated that all samples collected contain FD&C Yellow #5 and therefore are not in conformance with labeling requirements under 21 CFR 74.705(d)(2). Be advised that the presence of FD&C Yellow #5 must also be declared on your unlabeled product, Pickle Chips.

The requirement to declare FD&C Yellow #5 was brought to your attention during a recent inspection conducted by New Jersey State Health Department (NJSHD). In a letter dated May 8, 1996, to Mr. William Howard NJSHD, you committed to the immediate relabeling of all affected products in retail distribution that do not declare the presence of FD&C Yellow #5.

The above violation concerning this labeling requirement is not meant to be all-inclusive of deficiencies concerning your labels. It is your responsibility to assure that all your products are labeled in compliance with all applicable statutes enforce by FDA.

You should take prompt action to correct this deviation. Failure to promptly implement corrective action may result in regulatory action without further notice, such as seizure.

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

Your reply should be directed to the New Jersey Office of the Food and Drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,



MATTHEW H. LEWIS  
District Director  
New Jersey District

CERTIFIED MAIL -  
RETURN RECEIPT REQUESTED

cc: 

New Jersey State Health Department  
CN369  
3635 Quaker Bridge Road  
Trenton, New Jersey 08625-0369  
Attn: Gary Wolf