



DEPARTMENT OF HEALTH & HUMAN SERVICES

Request by M. Davis 11/2/98

FOI Team

M2246n

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

~~CERTIFIED~~
~~RETURN RECEIPT REQUESTED~~

WARNING LETTER
99-DT-04

November 18, 1998

Mr. Mitch Halpert, Controller
Royal Wine Corp.
aka/KFP International
420 Kent Avenue
Brooklyn, NY 11211

Entry No.: 300-5505139-2
Product: Flavored Raisins

Dear Mr. Halpert:

An inspection was made of your firm on September 9, 1998 by Inspector Peter Trunk of the New York District Office. The inspection found that the referenced entry, consisting of [REDACTED] cases of flavored raisins, that had been detained by our office on February 12, 1998, was distributed at least in part into commerce without a proper release from the Food and Drug Administration (FDA). Our inspection found that [REDACTED] cases were distributed by your customer ([REDACTED], [REDACTED]) after the entry was detained. Our inspection also found that the remaining [REDACTED] cases which were returned to your firm were not exported under U.S. Customs supervision in that you did not have a signed CF-7512, or any other records signed by U.S. Customs, which document the export of the article.

This is a violation of Title 21, Code of Federal Regulations, Part 1.90 (21 CFR 1.90), which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from the FDA. The U.S. Customs Service issued a Notice of Refusal of Administration and Demand for Redelivery (copy enclosed) on May 4, 1998 for the above referenced entry.

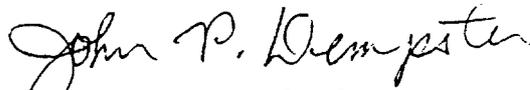
Failure to promptly correct this situation and prevent future distribution of entries prior to receipt of a May Proceed or Release Notice may result in regulatory action without further notice such as seizure, injunction or detention without physical examination of future entries. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act (the Act) and the regulations that are promulgated under that Act.

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Royal Wine Corp.
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Please notify us in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct this violation and to prevent it's recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which corrections will be made.

Your response should be directed to this office to the attention of Mr. John E. Klemmer, Compliance Office.

Sincerely yours,


Raymond V. Mlecko
for Acting District Director
Detroit District