



WARNING LETTER

December 29, 2003

Ref: FY04-SWID-004

VIA FED-EX

Mr. Fernando Acosta Valenzula
T J Candy Corporation
909 S. Greenwood Ave. Suite L
Montebello, CA 90640

Dear Mr. Valenzula:

On September 10, 2003, your firm T J Candy Corporation, offered for import into the United States seventy (70) cases of Super Pepino (Cucumber) lollipops under customs entry 965-0090186-1 (line 1/5). On September 16, 2003 the U.S. Food and Drug Administration (FDA) notified your firm that the lollipops lacked English labeling, which is a violation of Section 403 (f) (misbranding) of the Federal Food Drug and Cosmetic Act ("The Act") and that the line entry was subject to refusal of admission pursuant to Section 801(a)(3) of the Act. Your firm submitted no information to overcome the appearance of this violation and the line entry was subsequently refused admission on October 6, 2003.

Section 801 (8) of the Federal Food, Drug, and Cosmetic Act ("Act") also directs the Secretary of the Treasury to cause the destruction of any such shipment refused admission, unless it is exported within 90 days of the date of the notice, or within such additional time as may be permitted pursuant to such regulations.

On November 20, 2003, FDA documented your substitution of the refused product during examination of the merchandise at the Otay Mesa Commercial Port of entry in San Diego California. Under line entry 965-0090186-1 (line 1/5), the lollipops that were redelivered for exportation and which were examined by FDA Investigators were found to be packaged whereby the principal display panel was different than that of the original product imported on September 10, 2003, in that the redeliver products' principal display panel was different that the display panels taken during FDA sampling of line entry 965-0090186-1 (line 1/5) on September 12, 2003. In addition, on December 9, 2003, you signed an affidavit and supplied an invoice of sale for the purchase of seventy (70) cases of Super Pepino from Azteca Candy of Santa Ana California. In your affidavit, you stated that you purchased similar product from a domestic wholesaler to use as substitution for the refused product to be exported, which you sold in September of 2003.

The sale of imported food products while subject to refusal is a violation of Title 21, Code of Federal Regulations, Section 1.90, which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA

In addition, making fraudulent misrepresentations or false statements to federal officials is a criminal offence under Title 18, United States Code, sections, 542 and 1001 (18 U.S.C §§ 542 and 1001). Criminal charges of entry contrary to law (18 USC 545) may result in addition to the charges mentioned above. Criminal offenses can result in

imprisonment or fines or both. Further, when evidence demonstrates the article presented to FDA for examination is not from the original entry, but was substituted for the entry, the article may be seized under Title 19, United States Code, Section 1595a (c) (19 U.S.C. § 1595a(c)) and liquidated damages may also be assessed for any articles not redelivered.

It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act, and the regulations promulgated thereunder. Failure to prevent future violations of this nature can result in regulatory action without further notice such as seizure, injunction, and/or criminal prosecution. Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. Your written reply should be addressed to the Food and Drug Administration, Attention: Brian Ravitch, Compliance Officer, 2320 Paseo De Las Americas, Suite 200, San Diego California 92154.

Sincerely,

/s/

Todd Cato for Robert J. Deininger
Director, Southwest Import District