

**WARNING LETTER**

May 17, 2004

Ref: FY04-SWID-006

Via Federal ExpressMr. Salvador Garcia
TBA Mexican Trade Grocery
1045 Bay Blvd. Suite A
Chula Vista, CA 91911

Dear Mr. Garcia:

On March 22, 2004, two trucks containing products that were being returned to Mexico by your firm, TBA Mexican Trade Grocery, 1045 Bay Blvd., Suite A, Chula Vista, CA 91911, arrived at the Otay Mesa Commercial Facility. The trucks were carrying over 55 individual line items of merchandise from 25 entries that had been refused admission by the United States Food and Drug Administration (the "FDA") and Customs and Border Protection ("Customs"). The products were manifested as "Immediate Exportation" on numerous Customs Form 7512, "Transportation Entry and Manifest of Goods subject to Customs Inspection and Permit." Upon examining the March 22, 2004 shipments to verify that the specific products that previously had been refused admission in fact were being returned, FDA Investigators determined that five items from three entries, entry numbers [REDACTED] and [REDACTED], had been substituted with product other than the product that was actually refused admission by FDA.

Specifically, on October 14, 2003, your firm offered for importation 50 cases of Herdez Brand canned squash flowers, which were declared on entry [REDACTED] (line 21). Pursuant to Section 381(a)(3) of the Federal Food, Drug and Cosmetic Act, Title 21 United States Code ("U.S.C."), §§ 301 et seq., an article being imported or offered for import into the United States may be refused admission if the article, among other reasons, is adulterated or misbranded. The 50 cases of Herdez Brand canned squash flowers were detained on October 15, 2003, because the canned squash flowers appeared to be adulterated within the meaning of 21 U.S.C. §342(a)(4). The manufacturer was not registered as a low acid canned food or acidified food manufacturer pursuant to FDA regulations at Title 21, Code of Federal Regulations ("C.F.R."), §108.25 (c)(1) or 21 C.F.R. §108.35 (c)(1). In addition, it appeared that the manufacturer had not filed information on its scheduled process as required by 21 C.F.R. §108.25 (c)(2) or 21 C.F.R. §108.35 (c)(2). FDA ultimately refused admission of

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this entry on November 10, 2003. During our examination of the canned squash flowers that your firm returned in the March 22, 2004 shipment, the FDA inspector found that the product that your firm presented for redelivery was not the Herdez Brand canned squash flowers that were refused admission, but instead another product manufactured by Grupo Agroindustrial San Miguel of Mexico.

Further, on October 30, 2003, your firm offered 10 cases of Lucas Brand Panzon Soft Candy for importation, which were declared on entry [REDACTED] (line 4/7). The entry was detained on November 3, 2003, because it appeared to be misbranded within the meaning of 21 U.S.C. §352(c) in that the required label or labeling did not appear to be in English as required by FDA regulations at 21 C.F.R. §101.15(c). The product is also a possible choking hazard. The product ultimately was refused admission by FDA on December 1, 2003. During our examination of the Lucas Brand Panzon Soft Candy that your firm presented for redelivery on March 22, 2004, the FDA inspector found that the redelivered product was in master cartons that were different from the cartons that contained the Panzon Soft Candy at the time of the original October 30, 2003 shipment.

Also, on October 30, 2003, your firm offered 20 cases of Nestlé Brand Canned Media Cream for importation, which were declared on entry [REDACTED] (line 2/1). The entry was detained on December 8, 2003, because it appeared to be misbranded within the meaning of 21 U.S.C. §352(a)(1) in that the nutritional labeling appeared to be false and misleading in any particular. Specifically, the labeling was not accurate and was formatted incorrectly. The product ultimately was refused admission by FDA on January 12, 2003. During our examination of the Nestlé Brand Canned Media Cream that your firm presented for redelivery on March 22, 2004, the FDA inspector found that the redelivered product was in master cartons that were different from the cartons that contained the Nestle Brand Canned Media Cream at the time of the original October 30, 2003 shipment.

In addition, on October 30, 2003, your firm offered 30 cases of Vaso Brand Kara Soft Candy for importation, which were declared on entry [REDACTED] (line 4/9). The entry was detained on November 11, 2003, because it appeared to be adulterated within the meaning of 21 U.S.C. §342(a)(3). Specifically, the product appeared to consist in whole or in part of a filthy, putrid, or decomposed substance (insect, rodent, and/or other animal filth, and mold), or to be otherwise unfit for food. The product ultimately was refused admission by FDA on January 5, 2003. During our examination of the Vaso Brand Kara Soft Candy that your firm presented for redelivery on March 22, 2004, the FDA inspector found that the redelivered product was in master cartons that were different from the cartons that contained the Vaso Brand Kara Soft Candy at the time of the original October 30, 2003 shipment.

Finally, on January 16, 2004, your firm offered 20 cases of La Costena brand Canned Chipotle Peppers in adobo sauce for importation, which were declared on entry [REDACTED] (line 6/6). The entry was detained on January 20, 2004, because it appeared to be adulterated within the meaning of 21 U.S.C. §342(a)(4) in that the manufacturer had not filed information on its scheduled process for this can size as required by 21 C.F.R. §108.25 (c)(2) or 21 C.F.R. §108.35 (c)(2). The product

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ultimately was refused admission by FDA on February 11, 2004. During our examination of the La Costena brand Canned Chipotle Peppers in adobo sauce that your firm presented for redelivery on March 22, 2004, the FDA inspector found that the redelivered product was in master cartons that were different from the cartons that contained the original January 16, 2004 shipment.

On March 24, 2004, you and your wife met with FDA Investigators and a FDA Compliance Officer. At this meeting, you and your wife indicated that your company rarely sells split cartons and never repackages product. You also stated that due to a lack of warehouse space you often sell imported product before they are released from FDA. You indicated that you inform the customer that it is their responsibility to hold the product until a FDA release has been obtained. Your wife admitted to selling product you had already paid liquidated damages on because it was cheaper than redelivering it.

Your firm, furthermore, has demonstrated a lack of willingness to comply with the importing procedures of both FDA and Customs, as evidenced by the large volume of violative goods your firm has imported from March 25, 2003 through March 25, 2004. Your firms repetitive importation of violative products has resulted in 95 refusals of admission being issued and 32 current detentions now pending a refusal decision. Further, your firm has made no attempt to contest the notices of detention issued by FDA, which advised you of potential violations of the laws and regulations enforced by FDA.

The sale of imported food products before their release from FDA is a violation of 21 C.F.R. § 1.90, which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA. Further, the introduction or delivery for introduction into interstate commerce of an adulterated or misbranded food is a prohibited act under 21 U.S.C. §331(a).

In addition, making fraudulent misrepresentations or false statements to a federal officials is a criminal offence under 18 U.S.C §§ 542 and 1001. Criminal charges of entry contrary to law pursuant to 18 U.S.C. § 545 may result in additional charges. 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 or recommended for civil money penalties pursuant to 19 U.S.C. §§1592 and 1592a, and liquidated damages may also be assessed for any article not redelivered.

It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Act and the regulations promulgated thereunder. Failure to prevent future violations may 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

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Administration, Attention: Brian Ravitch, Compliance Officer, 2320 Paseo De Las Americas, Suite 200, San Diego California 92154.

Sincerely,

A handwritten signature in black ink that reads "Robert J. Deininger". The signature is written in a cursive style with a large, stylized "R" and "D".

Robert J. Deininger
Director, Southwest Import District