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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

April 26, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: NYK-2002-28

Mr. Pepe Avilardo Carrera
President
Marcelina's Mexican Food, Inc.
917 Flushing Avenue
Brooklyn, NY 11206-4602

Dear Mr. Carrera

We inspected your firm, located at 917 Flushing Avenue, Brooklyn, NY, on March 7 & 18, 2002. During the inspection, labeling for your Mexican style cheese sold under the labels, "Queso El Azteca-QUESO HEBRA (OAXACA)", "PIAXTLA-MEXICAN STYLE CHEESE-FRESH WHITE CHEESE" and "Queso El Azteca-QUESO FRESCO-(FRESH WHITE CHEESE)" was collected. Review of the various labels for this product found serious violations of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations Part 101 - Food Labeling (21 CFR Part 101).

The Queso El Azteca-QUESO HEBRA (OAXACA), PIAXTLA-MEXICAN STYLE CHEESE-FRESH WHITE CHEESE and Queso El Azteca-QUESO FRESCO-(FRESH WHITE CHEESE) are misbranded within the meaning of Section 403(q)(1) of the Act in that all of the labels used for these products fail to bear nutrition labeling as required by 21 CFR 101.9 and the product is not exempt from this requirement under 403(q)(5) of the Act.

The product labeled as "Queso El Azteca QUESO HEBRA (OAXACA)" is also misbranded under section 403(i)(1) since the label fails to bear the common or usual name of the food as required by 21 CFR 101.3(b) in English as required by 21 CFR 101.15(c).

Firms with fewer than 100 employees and products fewer than 100,000 units may qualify for exemption from the nutritional labeling requirements. However, businesses are responsible for filing for exemption, on an annual basis, for each product line. Although it appears that you do

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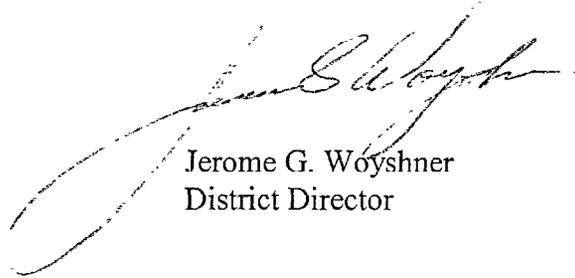
not qualify for this exemption because of your sales volume, a sample Small Business Food Labeling Exemption Notice has been included with this letter for your information.

The above violations are not meant to be an all-inclusive list of deficiencies in your product and its labeling. It is your responsibility to ensure that your product is in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

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 noted violations. Copies of revised labels for your product should also be submitted. If corrective actions cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to Compliance Officer Lillian C. Aveta, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issues in this letter, please contact Ms. Aveta at (718) 662-5576.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jerome G. Woyshner', is written over a large, faint, circular watermark or stamp.

Jerome G. Woyshner
District Director