

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

New York District

Food & Drug Administration  
158 - 15 Liberty Avenue  
Jamaica, New York 11433-1034

May 10, 2002

**WARNING LETTER****CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED***Ref: NYK-2002-29*

Mr. Anthony Mongiello  
President  
Formaggio Italian Cheese Specialties, Inc.  
170 Lynhurst Avenue  
Staten Island, New York 10305

Dear Mr. Mongiello:

We inspected your firm Formaggio Italian Cheese Specialties, Inc., located at 170 Lynhurst Avenue, Staten Island, New York on February 26<sup>th</sup>, 2002. During the inspection, physical samples and labeling for your product, **"FORMAGGIO...All Natural Fresh Mozzarella"** were collected. Review of the labeling 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)*.

This product is misbranded within the meaning of Section 403 (q)(1) of the Act in that the label fails to bear nutrition information as required by 21 CFR 101.9. The product is not exempt from Section 403 (q)(1) by any of the statutory exemptions provided under Section 403 (q)(5) of the Act. The product is also misbranded within the meaning of Section 403 (e)(2) of the Act in that it is in package form and the label fails to bear an accurate statement of the net weight. The product does not appear to be subject to any reasonable variations or exemptions to Section 403 (e)(2) of the Act.

Firms with fewer than 100 employees and products fewer than 100,000 units may qualify for exemption from the nutrition labeling requirements. However, businesses are responsible for filing for the exemption, on an annual basis, for each product line. Although it appears that you do 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 concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies. It is your responsibility to assure that all of your products are in compliance with the statutes and regulations enforced by the Food and Drug Administration (FDA).

Formaggio Italian Cheese Specialties, Inc. – May 10, 2002

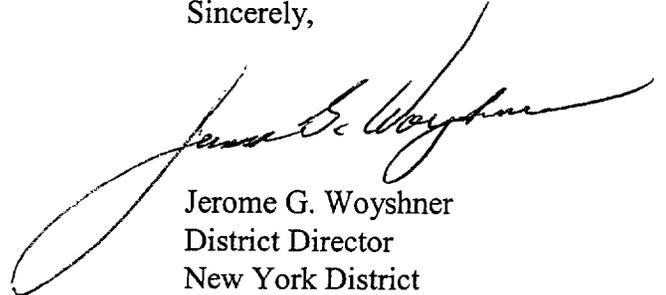
**NYK-2002-29**

**Page #2**

You should take the prompt action to correct these labeling violations and prevent their future recurrence. Failure to promptly correct these violations may result regulatory action without further notice. Possible actions include seizure and/or injunction. You should 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 action cannot be completed within 15 days, state the reasons for the delay and the time frame at which the corrections will be completed.

***Your reply should be directed to Compliance Officer Arthur S. Williams, Jr., Food and Drug Administration, 158 - 15 Liberty Avenue, Jamaica, New York 11433-1034. If you have questions, regarding any issues set forth in this letter, please contact Mr. Williams at (718)662-5568.***

Sincerely,



Jerome G. Woyshner  
District Director  
New York District