



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Mid-Atlantic Region

528

Telephone (201) 331-2909

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

August 12, 1997

WARNING LETTER

Mr. Donato Clemente, President
VMF Corporation
120 Leuning Street
South Hackensack, New Jersey 07606

File No: 97-NWJ-46

Dear Mr. Clemente:

An Investigator from the New Jersey District Office of the Food & Drug Administration, conducted an inspection of your bread manufacturing facility located at 120 Leuning Street, Hackensack, NJ, from January 21, 27 & 31, 1997. Documentary samples of product labeling were collected for Medium French Bread and Italian Style Taralli, sold under the trade names Central Bakery and Clemente Bakery.

Our review of the above bread product labels reveals that these products are misbranded, in that they fail to bear nutrition labeling as required under Section 403(q)(1) of the Federal Food, Drug & Cosmetic Act (Act) and Title 21 of the Code of Federal Regulations (CFR), Part 101.9. These products do not appear to be eligible for exemption under section 403(q)(5) from this requirement and have been labeled on or after August 8, 1994.

"Italian Style Taralli" is also misbranded within the meaning of section 403(i)(1) of the Act in that its label fails to bear the common or usual name of this product, or in the absence thereof, an appropriately descriptive term or phrase for the product. While we do not object to the use of the term "taralli" as a fanciful term on the label, we do not consider taralli to be the common or usual name of any food. If the product complies with any of the bakery products standards in CFR Part 136, then it must be named using the nomenclature provided in the relevant standard. Alternatively, if the product does not conform to any other the standards in CFR Part 136, it must be named using a nonstandardized term that is adequately descriptive and that is not false or misleading (21 CFR 101.3)

The above violations are not intended to be an all-inclusive list of labeling deficiencies. It is your responsibility to assure compliance with regulations as required under the Nutrition Labeling and Education Act of 1990 (NLEA). You should take

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REVIEWED BY Meredith WTR 8/12/97
C.O. DATE

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prompt action to correct these label deficiencies. Failure to promptly correct these violations may result in regulatory action being initiated by the agency without further notice. These actions may include seizure and/or injunction.

You should review labels for all product lines to assure they are in conformance with labeling regulations. For example:

Each individual fat or oil must be identified by its specific common or usual name as required by 21 CFR 101.4(b)(4).

If the product is bread or a similar type bakery product, then the serving size of the referenced product should be based on a 50-gram reference amount (21 CFR 101.12 - Table 2). If the referenced product is a soft bread stick or bagel, or similar type of bakery product, then the serving size of the referenced product should be based on a 55-gram reference amount (21 CFR 101.12 - Table 2).

Ingredients must be declared in descending order of predominance by weight as required by 21 CFR 101.4 (For example: it is unlikely that salt is the primary ingredient, before flour, in Sesame Seed Tarallini products).

A copy of FDA's Food Labeling Guide is included with this letter, which will assist you in reviewing all labels for conformance with labeling regulations. Also, please note that deficiencies listed above for Medium French Bread and Italian Style Taralli products may be applicable to other product lines.

While the Medium French Bread and Italian Style Taralli products are not exempt from bearing a nutrition label under Section 403(q)(5) of the Act due to the large volume (over 100,000 units) produced annually, you may wish to review the annual production amounts of other bread types to determine their eligibility for exemption. If product lines meet the criteria of under 100,000 units produced after May 8, 1997, you will need to request exempted status for each product on an annual basis. A sample exemption notice is included with this letter.

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 these violations. If corrective actions cannot be accomplished within 15 working days, state the reason for the delay and the time within which the corrections will be

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completed. Your reply should be sent to the New Jersey District Office, Food & Drug Administration, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,



DOUGLAS ELLSWORTH
District Director
New Jersey District

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

ATTACHMENTS: FDA Food Labeling Guide
FDA Exemption Notice

MBM:np