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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

WARNING LETTER
NWE-3-97W

no response
necessary
276 1/28/97

January 22, 1997

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Christopher W. Nessen
President/Owner
Meninno Brothers, Inc.
63 Cummings Park
Woburn, MA 01801

Dear Mr. Nessen:

During an inspection of your firm conducted on August 7, 1996 through August 16, 1996 our investigators determined you manufacture several acidified food products.

During this inspection, our investigators collected labels for each of your products. The Food and Drug Administration (FDA) has limited our label review to the following three products, which we have determined to be sufficiently representative of the labeling deficiencies of your products: Meninno Brothers Garlic Italian Marinated Mushrooms, Meninno Brothers Mushroom Salad, and Vista Farms Fat Free Crisis Cooking Sauce (garlic & ginger style). These products are considered to be misbranded in that they fail to bear nutrition labeling as required by Section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Part 101.9. They are further misbranded within the meaning of section 403(r)(2)(B) of the Act in that the labels bear the statement "Fat Free," which is a nutrient content claim under 21 CFR 101.62(b), but the labels fail to bear the referral statement as required by 21 CFR 101.13(g).

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in accordance with all statutes enforced by the FDA.

You should take prompt action to correct the above violations and to establish procedures to prevent recurrence of these or similar violations. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the above noted violations, including an explanation of each step being taken to prevent recurrence of similar violations. If there are any delays in implementing corrective action, state the reason for delay and the time period within which the corrections will be completed.

In addition to the labeling violations noted above, which cause your products to be misbranded, the following additional deficiencies were noted during our label review:

1. The principal display panel (PDP) for the above products fails to bear a declaration of the net quantity of contents, as required by 21 CFR 101.105. The net quantity of contents statement should be in terms of weight (avoirdupois pound and ounce) if the food is a mixture of solid and liquid, as are the Meninno Brothers Marinated Mushrooms and Mushroom Salad (21 CFR 101.105(a) and (b)).
2. The net quantity of contents declaration for the Vista Farms "Fat Free" Crisis Cooking Sauce (garlic & ginger style) is expressed in terms of fluid measure. Therefore, use of the term "Net Wt." in the net quantity of contents statement is inappropriate. The term "Net" or "Net Contents" may be used when the net quantity of contents is stated in terms of fluid measure (21 CFR 101.105(j)(3)).
3. The net quantity of contents declaration for the Meninno Brothers Mushroom Salad and Vista Farms Crisis Cooking Sauce (garlic & ginger style) does not meet the minimum required type size of one-eighth inch in height, as required by 21 CFR 101.105(i)(2).
4. Unless all of the mandatory labeling information appears on the PDP of the label, the information not specifically required to appear on the PDP (i.e. the list of ingredients; name and place of business of the manufacturer, packer, or distributor; and the nutrition labeling information) must appear together, without intervening material, on the information panel (21 CFR 101.2(a) and (e)). Foods in packages that have a total surface area available to bear

labeling greater than 40 square inches, but whose PDP and information panel do not provide sufficient space to accommodate all required information, may use any alternate panel that can be readily seen by consumers for the nutrition label.

5. The serving size on the Meninno Brothers Garlic Italian Marinated Mushrooms fails to be expressed in terms of common household measures (e.g., 2 tbsp., ½ cup, etc.) and it should be based on an appropriate reference amount, as required by 21 CFR 101.9(b) and 21 CFR 101.12(b).

Safe procedures for manufacturing, processing and packing acidified foods are essential to assure an environment conducive to the growth of Clostridium Botulinum is not created. Anaerobic conditions, low acidity (i.e. pH greater than 4.6), normal room temperatures, and adequate moisture/nutrients favor growth and toxin production by these bacteria. During this inspection, our investigators observed several deviations from the regulations for acidified foods contained in 21 CFR Part 114, as follows:

1. Sufficient controls, including frequent testing and recording of pH values, do not exist to assure a finished equilibrium pH value of 4.6 or lower, as required by 21 CFR 114.80(a)(2).
2. Processing and production records are not properly maintained to show adherence to a scheduled process, as required by 21 CFR 114.100(b), nor are the records maintained for a minimum of three years from the date of production, as required by 21 CFR 114.100(e).
3. Results of testing and examination of jars, conducted often enough to assure the containers suitably protect the food from leakage or contamination, are not properly maintained, as required by 21 CFR 114.80(a)(4).
4. Products are not effectively marked with an identifying code, minimally containing the year, day, and period during which the food was packed, as required by 21 CFR 114.80(b).
5. Acceptance examinations of raw materials are not performed and documented, as required by 21 CFR 114.100(a).
6. Records are not maintained covering product distribution, as required by 21 CFR 114.100(d).
7. Your firm does not have a plan for recalling products that may be injurious to health, as required by 21 CFR 108.25(e).

Registration and process filing is required for all commercial manufacturers, processors, or packers of acidified foods by 21 CFR 108.25(c). Under separate cover you will receive forms FD254I and FD254IA, Registration and Process Filing forms, respectively.

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When you respond within fifteen (15) days, as requested above, please let us know what actions you are taking or will take in response to the later noted labeling and manufacturing deviations cited on page 2 and 3.

You may address your response to David K. Elder, Compliance Officer, at the address noted above. If you have any questions concerning these matters, please contact Mr. Elder at (617)279-1675x125.

Sincerely,



James A. Rahto
District Director
New England District Office