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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

WARNING LETTER
2008-DT-12

September 2, 2008

Mr. Albert S. Batshon, President
Jerusalem Manufacturing Natural Foods & Wholesalers, Inc.
6470 Miller Road
Dearborn, Michigan 48126-2364

Between March 12 and April 17, 2008, we inspected your food manufacturing, repackaging, and warehousing facility located at 6470 Miller Road, Dearborn, Michigan. During the inspection, our investigators collected samples of your finished products and product labeling. Our sample analysis and label review found that your products violate provisions of the Federal Food, Drug and Cosmetic Act (the Act) and FDA regulations in Title 21, Code of Federal Regulations (21 CFR). You may find the Act and the FDA regulations in the CFR through links in FDA's website at <http://www.fda.gov>.

The violations we noted are as follows:

Your Jerusalem World Pure Foods brand Turnip Pickle is adulterated under section 402(c) of the Act [21 U.S.C. 342(c)] because it contains a color additive that is unsafe within the meaning of section 721(a) of the Act [21 U.S.C. 379e(a)]. During our inspection, FDA collected a sample of your Turnip Pickle product. Our analysis found the product contained the color additive Rhodamine B (C.I. 45170). Section 721(a) deems a color additive to be unsafe unless its use is in conformity with a regulation listing the additive for such use. The chloride and stearate salts of Rhodamine B were formerly listed as D&C Red No. 19 and D&C Red No. 37, respectively. However, in 1983 FDA terminated the listings of these compounds for use in coloring ingested drugs and cosmetics based on the agency's conclusion that they are carcinogens when ingested [21 CFR 81.10(q)(1)]. There is no regulation listing Rhodamine B as safe for use in coloring any food.

Your Jerusalem brand Pita Bread, Spelt Wheat Free, is misbranded under section 403(w) of the Act [21 U.S.C. 343(w)] in that the label fails to declare the presence of the major food allergen wheat, as required by section 403(w)(1).

Section 201(qq) of the Act [21 U.S.C. 321(qq)] defines as "major food allergens" milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils. A food is misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

- The word “Contains,” followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredients [section 403(w)(1)(A) of the Act, 21 U.S.C. 343(w)(1)(A)], or
- The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived (e.g. “spelt (wheat)”), except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of an ingredient that is not a major food allergen) [section 403(w)(1)(B) of the Act, 21 U.S.C. 343(w)(1)(B)].

Your Jerusalem brand Pita Bread, Spelt Wheat Free, is manufactured with spelt, which is *Triticum spelta* L. The term “wheat” in section 201(qq) of the Act means any species in the genus *Triticum*. Thus, for purposes of section 201(qq), wheat includes grains such as spelt. See Guidance for Industry, Questions and Answers Regarding Food Allergens, Section II, #27, <http://www.cfsan.fda.gov/~dms/alguid4.html>.

Your Jerusalem brand Pita Bread, Spelt Wheat Free, is further misbranded under section 403(a)(1) of the Act [21 U.S.C. 343(a)(1)] in that its labeling is false and misleading. The label for the Jerusalem Pita Bread contains the statement “SPELT WHEAT FREE” on the principal display panel. This statement falsely claims that this product does not contain wheat; however, as explained above, this product contains spelt, which is a species of wheat.

Your Jerusalem World Pure Foods brand Turnip Pickle products in 32 oz. and 20 lb. containers are misbranded within the meaning of section 403(e)(2) of the act [21 U.S.C. 343(e)(2)] in that the label used on these products fails to disclose the correct net weight as required by 21 CFR 101.105. During the inspection, the investigator determined that you use a single label, which declares “NET WT. 20 OZ,” for several different-sized containers of this product. This label is placed not only on 20 oz. jars but also on 32 oz. jars and on 20 lb. plastic pails. Additionally, the net weight of pickle products must be expressed in terms of gallons and quart, pint, and fluid ounce subdivisions thereof [21 CFR 101.105(r)]. However, the label on the 20 lb. pails fails to comply with this requirement. Further, the outside cardboard box packaging declares incorrect net weights for the inner finished product. Specifically, a box labeled “16 oz.” appeared to contain 10 oz. jars of this product, and a box labeled “32 oz.” appeared to contain 20 oz. jars. A supplemental statement describing the net quantity of contents at a location other than the principal display panel must do so in nondeceptive terms [21 CFR 101.105(o)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. Other violations can also subject your products to legal action. It is your responsibility to assure that all of your products are in compliance with all applicable statutes and regulations enforced by FDA. You may find it useful to visit our website at

<http://www.cfsan.fda.gov> when reviewing your products and their labeling.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and injunction.

Please notify this office within fifteen (15) working days from your receipt of this letter of the specific things that you are doing to correct the violations described above. You should include in your response documentation of your corrective actions, such as revised labels, revised procedures, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

We also offer the following label comments:

During the inspection, the investigator noticed that the label of the beet powder, a raw material used in the Turnip Pickle product, lists as sub-ingredients "maltodextrin and citric acid." These sub-ingredients must be declared in the ingredient statement on the Turnip Pickle label, as required by 21 CFR 101.4(b)(2), unless they are incidental additives under 21 CFR 101.100(a)(3). The revised labels must list all ingredients in accordance with 21 CFR 101.4. In addition, beet powder is a non-certified color additive (21 CFR 73.40) that must be declared in accordance with 21 CFR 101.22(k)(2) and 403(k). Non-certified color additives may be declared by a term such as "Artificial Color" (or by an equally informative term that makes clear that a color additive has been used in the food), or by the use of a statement such as "Colored with beet powder" or "beet powder added for color."

In the absence of a translation of the foreign characters on the label for the Turnip Pickle product, we cannot determine what information is declared in the foreign language. You should ensure that all information required to appear on the label appears in the foreign language, as required by 21 CFR 101.15(c)(2), as well as in English.

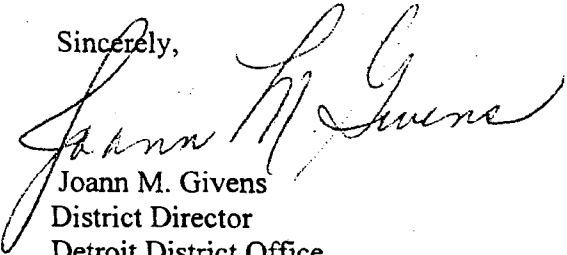
We note that in the nutrition labels for the Turnip Pickle product, the abbreviated footnote "Percent Daily Values are based on a 2,000 calorie diet" is provided in lieu of the full footnote required by 21 CFR 101.9(d)(9). Only packages that have a total surface area of 40 or less square inches available to bear labeling may use this abbreviated footnote (21 CFR 101.9(j)(13)(ii)(2)(C)). As we do not know the total surface area of the different sizes of the Turnip Pickle product, we cannot determine whether the abbreviated footnote is permissible. You should ensure that your use of this abbreviated footnote complies with 21 CFR 101.9(j)(13)(ii)(2)(C).

Please send your reply to the Food and Drug Administration, Attention: Judith A. Jankowski, Detroit District Office, 300 River Place, Suite 5900, Detroit, Michigan 48207.

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If you have any questions regarding any issues in this letter, please contact Judith A. Jankowski at 313-393-8125.

Sincerely,



Joann M. Givens
District Director
Detroit District Office

cc: Mr. Ronnie Batshon, General Manager
Jerusalem Manufacturing Natural Foods & Wholesalers, Inc.
6470 Miller Road
Dearborn, Michigan 48126-2364