



DEPARTMENT OF HEALTH & HUMAN SERVICES

97156d
New York District

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Edward Freund, President
V.I.P. Foods, Inc.
1080 Wyckoff Avenue
Ridgewood, NY 11385

July 23, 2003

Ref: NYK-2003-31

Dear Mr. Freund:

This letter is in reference to your company's manufacturing and labeling of products, as documented by our inspection of your manufacturing facility, located at the above address, on May 2, 5, and 8, 2003. This inspection was conducted to determine your company's compliance with the Federal Food, Drug and Cosmetic Act (the "Act") and applicable implementing regulations contained within Title 21 of the Code of Federal Regulations ("Code").

During the inspection, we collected a sample of your product, [REDACTED] "Sugar Free Instant Hot Chocolate Mix". Our review of the product label found violations of the Act and the Code. You can find copies of the Act and the Code through links in FDA's home page at www.fda.gov.

The product is misbranded within the meaning of sections 403(a)(1) and 403(r)(1)(A) of the Act. Section 403(a)(1) states that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. Section 403(r)(1)(A) provides that a food shall be deemed to be misbranded if its label or labeling contains an unauthorized nutrient content claim. A nutrient content claim is a claim that characterizes the level of a nutrient of the type required to be in nutrition labeling. Such a claim may be made only if the characterization of the level made in the claim uses terms defined in FDA regulations.

The "Sugar Free" claim on the label of the [REDACTED] "Sugar Free Instant Hot Chocolate Mix is false and misleading because, according to the Nutrition Facts panel on the product's label, the product contains 7 grams of sugar per serving. 21 CFR 101.60(c)(1) authorizes the claim of "Sugar Free" only in instances where the food contains less than 0.5 grams of sugars per serving, and where the food contains no ingredient that is a sugar or that is generally understood by consumers to contain sugars. With regard to this latter point, the ingredient statement for the [REDACTED] "Sugar Free Instant Hot Chocolate Mix declares the ingredient "dextrose", which is a sugar (a monosaccharide) as defined in 21 CFR 101.9(c)(6)(ii).

V.I.P. Foods, Inc.
Page 2

This letter is not meant to be an all-inclusive list of deficiencies in your products and their labels. It is your responsibility to ensure that all of your products are manufactured and labeled in compliance with the Act and the Code.

You should take prompt action to correct the above-referenced violations. Failure to promptly correct these violations may result in regulatory action without further notice. The Act provides for the seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

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 stated violations and to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time at which the corrections will be completed. Your reply should be sent to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

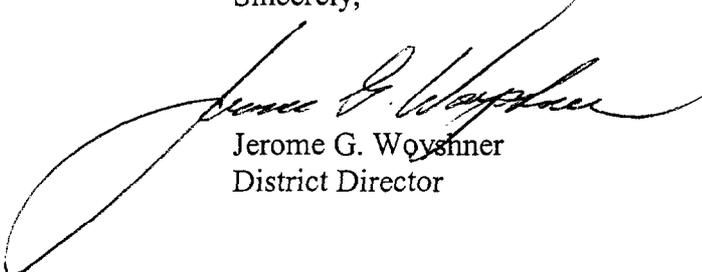
ADDITIONAL COMMENTS

During the inspection, a representative from your company stated that it was the company's intention to change the "Sugar Free" claim to "No Sugar Added." For your information, however, your product does not qualify for the claim "No Sugar Added". Under 21 CFR 101.60(c)(2), the term "No Sugar Added" may be used only if no amount of sugars is added during processing or packaging of the product in question, and if the product does not contain an ingredient which itself contains added sugars. As previously noted, the ingredient statement for the [REDACTED] Sugar Free Instant Hot Chocolate Mix declares the ingredient "dextrose", which is a sugar (a monosaccharide) as defined in 21 CFR 101.9(c)(6)(ii).

We also note that the product label contains information in a foreign language, namely French. In accordance with the requirements of 21 CFR 101.15(c)(2), if the label contains any representation in a foreign language, all words, statements, and other information required by the Act to appear on the label must also appear thereon in the foreign language.

If you have any questions concerning this letter, please contact Mr. Goldwitz at (718) 340-7000, ext. 5582.

Sincerely,



Jerome G. Woyshner
District Director