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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

New York District

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

March 19, 2004

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Ref: NYK-2004-09

Mr. Robert Gruenebaum  
President  
Interstate Baking Corp.  
290 Dyckman Street  
New York, NY 10034-5352

Dear Mr. Gruenebaum:

We inspected your firm, located at 290 Dyckman Street, New York, NY on February 10 & 13, 2004. During the inspection, we collected a sample of your "Assorted Cookies" awaiting shipment. Review of the label for these assorted cookies and labels for two of the cookies therein which are also sold separately, "Chocolate Covered Leaves" and "NUT SANDWICH COOKIES", 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).

These cookie products are misbranded within the meaning of Section 403(q)(1) of the Act in that all of the labels used for these products fail to bear nutrition labeling as required by 21 CFR 101.9 and the products are not exempt from this requirement under 403(q)(5) 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. A sample Small Business Food Labeling Exemption Notice has been included with this letter for your information.

We acknowledge receipt of your letters dated February 17, 2004 to me, and undated to FDA Northeast Regional Laboratory Food Chemistry Branch Director, Keroline Simmonds. In your letter to me, you said that, as a corrective action, you would employ a consultant to correct the label for the "Assorted Cookies" sampled during this inspection to include all ingredients therein. In your letter to Ms. Simmonds, you responded to the FDA "704(d)" letter dated February 20, 2004, reporting the analysis of FDA sample 267449 of "Assorted Cookies" collected at your

firm. The "704(d)" letter reported the presence of FD&C Yellow #5 and FD&C Red #40 in this product although these color additives were not declared on the label. Your letter said your corrective action would be to relabel the "Assorted Cookies" awaiting shipment to include all ingredients. However, both of your letters are silent on the subject of nutrition labeling.

In a telephone conversation with Compliance Officer Lillian Aveta on February 27, 2004, you further said you would, as a corrective action, relabel all baked products awaiting shipment to list all ingredients therein. We will be verifying this during a follow-up inspection. However, on the subject of nutrition labeling, you indicated that you intended to apply for a small business exemption for nutrition labeling but had not yet done so. Regardless of this requirement, the shipment of these cookies was scheduled for the first week of March 2004.

All of the above labeling violations were previously brought to your attention during the inspection of October 21, 2003. At that time, you informed the FDA investigator that various color additives observed on the premises, including FD&C Yellow # 5, were used in almost all products without declaration on the label. The requirement to declare all ingredients in product labeling was discussed with you in detail at the conclusion of this previous inspection, and you indicated you would respond within two weeks regarding corrections in this regard. You were also provided with instructions for filing an NLEA exemption at that time. Nevertheless, a response to the prior inspection was never received and the current inspection found recurring label violations.

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

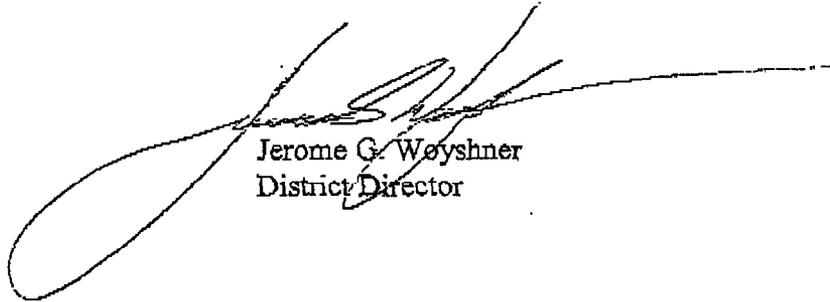
Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective actions cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to Compliance Officer Lillian C. Aveta, 158-15 Liberty Avenue,

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Jamaica, NY 11433. If you have questions regarding any issues in this letter, please contact Ms. Aveta at (718) 662-5576.

Sincerely,

A large, stylized handwritten signature in black ink, written over the typed name and title. The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Jerome G. Woyshner  
District Director