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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

August 28, 1997

WARNING LETTER BUF 97-23

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bruce H. Ritenburg, Jr.,
Chairman of the Board
NOG, Inc.
99 West 4th Street
Dunkirk, New York 14048

Dear Mr. Ritenburg:

An inspection of your manufacturing facility was performed on April 28, through May 1, 1997, by Food and Drug Administration (FDA) Investigator William P. Chilton. The inspection revealed serious violations of the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder.

Your variegate products are adulterated within the meaning of Section 402(a)(4) of the Act because they have been prepared, packed, or held under conditions whereby they may have been rendered injurious to health. These products were not manufactured in conformance with 21 Code of Federal Regulations (CFR), Parts 108, 113 and 114, as follows:

- **Failure to properly evaluate deviations from scheduled processes, and reprocess or dispose of products which did not receive sufficient thermal processes to render them safe (21 CFR 113.89).** An examination of processing records found water activity values exceeded the scheduled processes on several production days. For example, chocolate flavor variegate (Product 203, 7/18/96, 11/13/96, and 2/11/97); marshmallow variegate (Product 224B, 10/21/96); marshmallow variegate, all natural (Product 244, 1/24/96); and chocolate syrup (Product 502, 7/23/96), all showed water activity values ranging from 0.92 to 0.97, and pH values greater than 4.6. There were also numerous production days for the above products, and others, where your firm failed to record water activity values. Your firm presented no documentation to the Investigator showing product produced on the above dates had been set aside for evaluation, reprocessed, or destroyed.

- **Failure to record water activity values on numerous production days (21 CFR 113.40(i)).** Inspection of processing records found numerous instances of water activity values not being recorded for products with pH greater than 4.6, produced in 1996, and on 2/3/97.

- **Failure to have scheduled processes established by persons having expert knowledge of processing requirements for low-acid foods in hermetically sealed containers (21 CFR 113.83).**

- **Failure to file scheduled processes for your acidified food products and water activity controlled products (21 CFR 108.25(c)(2) and 108.35(c)(2)).** Your firm submitted filing forms for several of its scheduled processes in August 1996. These filing forms were returned to you by HFS-617 on October 8, 1996, for additional information. To date, your firm has not resubmitted these forms, and has no scheduled processes on file with FDA.

- **Failure to have acidification operations, product formulating systems, and container closure inspectors under the supervision of a person who has attended a school approved by the Commissioner (21 CFR 113.10 and 114.10).**

Examination of your records shows your firm varies its formulations for certain products, depending on the demands of your customers. On several occasions, water activity values of 0.85 or less were recorded. Because of the wide range of formulations, we recommend you contact a processing authority to determine which products are acidified foods, which are low-acid canned foods, and which are excluded from the regulations.

It is your responsibility to insure all foods manufactured and distributed by your firm meet the requirements of the Act, and regulations promulgated thereunder. You should take prompt action to correct these and all violations existing at your firm. Failure to take such action may result in regulatory action, such as seizure, and/or injunction, without further notice.

**Please notify this office in writing, within 15 days, of the specific steps you have taken to correct the noted violations, and prevent recurrence of similar violations.** Your response may be directed to Raymond D. Kent, Team Leader, at the above address.

Sincerely,

Cindy Kauzlowski

for Brenda J. Holman
District Director

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