



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

September 5, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-96

Jerry Mascio, Owner/President
San Gennaro Foods, Inc.
9620 Martin Luther King Jr. Way South
Seattle, Washington 98188-5630

WARNING LETTER

Dear Mr. Mascio:

On May 15 and 16, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 9620 Martin Luther King Jr. Way South, Seattle, Washington. At the conclusion of the inspection, you were presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 108 - Emergency Permit Control and Part 114 - Acidified Foods regulations. A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the Polenta products processed by your firm are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Parts 108.25 and 114.

The deviations were as follows:

1. The Polenta production records for April 19, 2000, show that four of [REDACTED] batches produced on that day had a pH value in excess of 4.6 in violation of 21 CFR Part 114.80 (a) (1).
2. Your process for producing Polenta was not established by a quantified person who has expert knowledge in the acidification and processing of acidified foods, as required under 21 CFR Part 114.83.
3. Your firm was not registered with the FDA as an acidified food processor. 21 CFR part 108.25(c)(1) requires a commercial processor of acidified foods to register with the FDA. Additionally, 21 CFR Part 108.25(c)(2) requires you to provide the FDA with information on your scheduled processes for acidified foods.

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4. Your firm did not employ any individuals that have attended the Better Processed Control School for Acidified and Low Acid Canned Foods. 21 CFR Part 114.10 requires all operators of processing and packaging personnel to be under the operating supervision of someone who has attended an approved school.
5. The Polenta production records for April 19, 2000, do not document the final pH for each individual batch of Polenta as required under 21 CFR Part 114.100(a) and (b), and two of the [REDACTED] batches produced on that day had no pH measurements taken.

The above violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,


for Charles M. Breen
District Director

Enclosures:

Form FDA 483
21 CFR Part 108 and 114
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement