



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

May 30, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: NYK-2001-80

Mr. Manny Stern
Member
Felicia Foods LLC
D/B/A Hudson Valley Foods
372 Main Street
Poughkeepsie, NY 12601

Dear Mr. Stern:

An inspection of your firm on January 11, 16 & 24, 2001, by Investigator Joseph Milcetic revealed an acidified food product, pickled ginger, was processed at your facility in violation of sections 402 and 403 of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21 of the Code of Federal Regulations (21 CFR).

The lot of pickled ginger processed with stevia is adulterated under section 402 (a)(2)(C) of the Act because it contains stevia, which is an unapproved food additive. Unapproved food additives are considered unsafe under section 409 of the Act.

Your pickled ginger is also misbranded under section 403 of the Act and Title 21, Code of Federal Regulations (CFR), Part 101 Food Labeling. Our review of the labels disclosed the following:

- (a) Failure to declare ingredients on the label. Ingredients must be listed by their common or usual name in descending order of predominance by weight [21 CFR 101.4 (a)(1)].
- (b) Failure to include the street address, city, state and zip code for the statement of the place of business [21 CFR 101.5 (d)].

The above violations are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure that all of 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 recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

In addition, the inspection revealed several violations of 21 CFR 108.25 and 114 as follow:

1. Your firm failed to register and file with the FDA information including, but not limited to, the name of your establishment, principal place of business, the location of each establishment in which that processing is carried on, the processing method in terms of acidity and pH control, and a list of foods so processed in each establishment [108.25 (c)(1)].

All processors must register and file with the FDA not later than 10 days after first engaging in the manufacture, processing or packing of acidified foods in accordance with 21 CFR 108.25 (c)(1).

2. Your firm failed to file a scheduled process for each acidified food in each container size [108.25 (c)(2)].

The Investigator reported that [REDACTED] provided a scheduled process to your firm. However, your firm has not filed any process for acidified ginger with the FDA on Form FDA 2541a.

3. Operators of your processing and packaging systems are not under the supervision of a person who has attended a school approved by the Commissioner for giving instruction in food handling techniques, food protection principles, personal hygiene and plant sanitation practices, pH controls and critical factors in acidification [21 CFR 108.25(f) and 114.10].
4. Your firm failed to process each acidified food in conformity with at least a scheduled process filed with the FDA [21 CFR 108.25 (c)(3)(i)].

Your firm did not follow the scheduled process recommended by your processing authority. The temperature and the amount of sugar specified in the scheduled process were not adhered to during production. For example, the production batch sheet showed [REDACTED] added to the ginger at a temperature of [REDACTED], while the scheduled process calls for [REDACTED]. The production sheet shows that [REDACTED] pounds of sugar was used while the scheduled process specified that [REDACTED] pounds of sugar is required to make the [REDACTED]. In addition, there was no record identifying pickled ginger using stevia from those ginger products using regular sugar.

5. Your firm failed to mark each container with an identifying code specifying the establishment where the product is packed, the product contained, and the year, day and period during which it was packed [21 CFR 114.80 (b)].

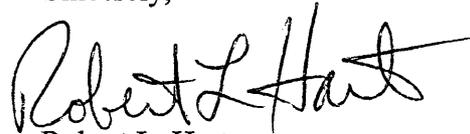
Your firm did not have an identifying code showing different lots of pickled ginger made with sugar and stevia. For these two different products, the production batch sheet identified pickled ginger with sugar. Your firm is apparently not aware of the need to have separate records for each lot of product.

6. Your firm did not maintain any records showing the examination of raw materials, packaging materials, and finished product that verify compliance with FDA regulations [21 CFR 114.100 (a)].
7. Your firm did not prepare and maintain a current procedure for recalling products under your control and for implementing recall programs should a need arise [21 CFR 108.25 (e)].

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 working days, state the reasons for delay and the time within which corrections will be completed.

Your response should be sent to Lillian C. Aveta, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions, Ms. Aveta's telephone number is 718-662-5576.

Sincerely,



Robert L. Hart
Acting District Director
New York District

Enclosure: Form FDA 483