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Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

June 15, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Diane W. Cannon
President
Food Processors of New Mexico
5330 Williams Street SE
Albuquerque, New Mexico 87105

Ref # - DEN 98-12

PURGED

Dear Ms. Cannon:

An inspection of your food manufacturing facility was conducted on February 26, 1998, by Consumer Safety Officers (CSOs) Barbara White and Cynthia Jim. This inspection was conducted in follow-up to a violative inspection of your facility conducted on June 23 and 24, and July 3 and 8, 1997, by CSO Barbara J. White. These inspections showed deviations from Title 21, Code of Federal Regulations, Part 114, (21 CFR 114) and 21 CFR 108.25.

These deviations cause the products processed by your firm to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (the Act), section 402(a)(4), in that they have been prepared, packed, or held under conditions whereby they may have been rendered injurious to health.

Our inspection revealed that your firm is not in compliance with the requirements of the acidified food regulations (21CFR 108.25 and 114). The following is a list of the deviations from the mandatory provisions of the regulations with which your firm is not in compliance:

1. Your firm failed to file your scheduled processes with the FDA (21 CFR 108.25(c)(2)).

At the time of our inspections, no scheduled processes had been filed for any of your products. Process filing forms were received by the LACF Registration Coordinator, CFSAN on March 20, 1998. However, review of these forms revealed several problems with the information provided and the forms have been returned to you (separate letter from CFSAN).

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2. Your firm did not always employ appropriate quality control procedures to ensure that finished foods do not present a health hazard (21 CFR 114.80(a)).

The high pH levels found in three of your products and the wide range of pH values found in your Chile con Queso (lot 7128) are indicative of the lack of appropriate quality control procedures. These results may be due to such things as the lack of formulation control or other factors.

3. Your firm does not always exercise sufficient control, including frequent testing and recording of results, so that the finished equilibrium pH values for acidified foods are not higher than 4.6 (21 CFR 114.80(a)(2)).

Your firm failed to use proper procedures when testing for the pH value of your products. For example, the temperature of the product is not determined prior to pH testing, the pH meter is not calibrated properly in that the probe is not calibrated with two buffer solutions, and the potentiometer probe is not stored in distilled or deionized water as required by the manufacturer. In addition, procedures for testing in-process pH are not adequate to determine if the proper amount of acid or acid food has been added to ensure that the entire batch will have a pH of 4.6 or below. Your procedure for the green chiles consisted of sampling the liquid portion after the acid was added rather than taking a proportionate amount of liquid and peppers, blending them and testing the pH. The same procedure was used for the Fire Salsa. Samples collected during the June/July, 1997 inspection (Stewed Green Chile, lot 7174 and Chile con Queso, lot 7128) revealed pH levels above 4.6 - the process you filed for the stewed green chile lists a maximum pH of [X] and the process for the Chile con Queso lists a maximum pH of [X]. Your firm also did not record on production records the [X] hour pH reading (the time at which your firm has determined that equilibrium pH is reached)

4. Your firm did not always maintain processing and production records showing adherence to scheduled processes (21 CFR 114.100(b)).

Batch records did not contain the equilibrium pH values of your products at [X] hours, not all records noted the product code, and not all batch records showed a list of ingredients nor the amounts of each added. In addition, records documenting the time and temperature of the thermal process do not indicate the start and finish time of the process.

5. Your firm does not note all departures from scheduled processes having a possible bearing on public health or the safety of the food, identify the affected portion of the product, record these deviations in a separate file (or log), delineate the deviations, the action taken to rectify them and the disposition of the portion of the product involved (21 CFR 114.100(c)).

Your firm has no record or file in which to record process deviations, the methods and results of evaluations nor the disposition of affected lots. Three products have been found in the past to have pH levels greater than 4.6. These instances were not noted by your firm nor properly handled.

6. Your firm does not always maintain accurate and complete records showing initial distribution of finished product (21 CFR 114.100(d)).

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No distribution records could be found for Papa Felipe's Salsa.

7. Your firm has not had your scheduled processes established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods (21 CFR 114.83).

The process filing forms (FDA 2541a) you recently submitted list the process establishment source as "[X X X X X X X X X X]". This appears to be the title of the [X X X X X X] manual. This is not a legitimate process source. During the 1997 inspection, our investigator was informed that Mr. Cannon and Mr. Clark established the processes. Proper process establishment should consider such things as formulation for products such as salsas and sauces, solid-liquid ratios for products such as peppers in brine and ingredient pH variations. Even minor variations in ingredient pH with products such as peppers may require the addition of varying amounts of acid to properly control pH at or below 4.6. The high pH levels found in several of your products may be indicative of improperly established processes.

Significant deviations were discussed with you at the end of our June and July 1997 inspection, and our inspection of February 1998 showed few corrections.

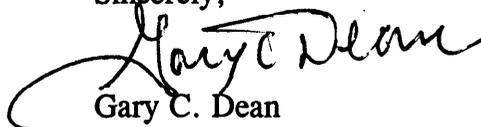
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include seizure, or issuance of an order of need for a Temporary Emergency Permit.

We request that you reply in writing within 5 working days of your receipt of this letter stating the action you will take to bring your firm into compliance with the law. Your response should include your plans regarding the two lots named in this letter which have not been recalled. If corrective action has not yet been completed and cannot be completed within 5 working days, please state the reason for the delay and the time frame within which corrections will be implemented. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Ms. Shelly L. Maifarth, Compliance Officer, at the address on the letterhead. Please contact Ms. Maifarth at (303) 236-3046 if you have any questions regarding this matter.

Sincerely,



Gary C. Dean
District Director

cc: Phillip A. Clark
Vice-President
Food Processors of New Mexico
5330 Williams Street SE
Albuquerque, New Mexico 87105