



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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Warning Letter

May 5, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gregory S. Deneen
President
Deneen & Company
1590 San Mateo Lane
Santa Fe, NM 87505

Ref#: DEN-03-15

Dear Mr. Deneen:

On February 10 through 13, 2003, the Food and Drug Administration (FDA) conducted an inspection of your food processing plant located at 1590 San Mateo Lane, Santa Fe, New Mexico. This inspection revealed that you manufacture acidified foods at this facility, including but not limited to: Roasted Corn & Black Bean Salsa, Fire-Roasted Salsa, and Roasted Tomato Chutney.

As a manufacturer of acidified food products, you are required to comply with both the Federal Food, Drug, and Cosmetic Act (the Act), and the federal regulations relating to the processing of acidified food products. These regulations are described in Title 21, Code of Federal Regulations, Part 108, Emergency Permit Control (21 CFR 108), and Part 114, Acidified Foods (21 CFR 114). The Emergency Permit Control Regulation is issued under Section 404 of the Act, and allows FDA to control the manufacture of acidified foods by emergency permit only, if violative conditions exist. You can find this Act, and the Emergency Permit Control and Acidified Foods Regulations through links in FDA's home page at <http://www.fda.gov>. Current Good Manufacturing Practice in

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Manufacturing, Packing, or Holding Human Food Regulations are found in 21 CFR Part 110.

During our inspection, our investigator documented deviations from the Act and the above-mentioned regulations relating to the processing of acidified foods, specifically the Emergency Permit Control, the Acidified Food, and the Good Manufacturing Practice Regulations. These deviations cause your acidified food products to be adulterated and in violation of section 402(a)(4) of the Act, in that they have been prepared, packed, or held under unsanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health. At the conclusion of the inspection, you were presented with an FDA Form 483, List of Inspectional Observations, listing deviations found during the inspection.

The deviations of concern are as follows:

- Your firm failed to provide the Food and Drug Administration on FDA Form 2541a (food canning establishment process filing form for all methods except aseptic), information on the scheduled processes for your products, including, as necessary, conditions for heat processing and control of pH, salt, sugar, and preservative levels; and the source and date of the establishment of the process for each acidified food in each container size not later than 60 days after registration and before packing any new product (21 CFR 108.25(c)(2)).

Our review of information obtained during FDA's inspection reveals that your firm produces acidified foods; specific examples are Roasted Corn & Black Bean Salsa, Fire-Roasted Salsa, and Roasted Tomato Chutney. Based on information obtained during our inspection and our review of the product formulas for the above products, we have determined that these products, as presently formulated, are acidified foods. Review of FDA's files reveals that your firm has not filed scheduled process information for the above products, nor any other acidified products manufactured by your firm. We have notified you of this requirement via FDA 483, issued by our investigators at the close of our inspections on August 28, 1996, March 10, 1997, May 10, 2000, April 26, 2001, and February 13, 2003. In addition to these notifications, we have advised you of your failure to have your scheduled processes on file with the FDA by letters dated February 12, 1997, and July 3, 2000. Copies of these documents are attached to this letter to refresh your memory.

- Your firm does not take pH readings with sufficient control to assure that the finished equilibrium pH values for acidified foods are not higher than 4.6 (21 CFR 114.80(a)(2), and 114.90(a)(6)).

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Our inspection showed that you routinely test the pH of food immediately out of the kettle, without allowing the product to reach pH equilibrium. You have no documentation that your products are at equilibrium at this time. You do not separate solid and liquid ingredients, nor blend ingredients, to determine the true pH of the product. Finally, you do not use proper technique in taking a pH sample as required by the regulations, in that you do not take the pH sample at thermal equilibrium of the electrode system and the sample, and the pH probes are not cleaned properly between samples.

- Your firm does not always ensure that instruments used for measuring pH are accurate and adequately maintained (21 CFR 110.40 (f)).

During FDA's inspection of your acidified foods manufacturing facility, our Investigator reported that on 2/13/03, your firm's pH meter indicated a pH reading of distilled water of 4.1, whereas the FDA pH meter read the pH as 6.2, much closer to the expected reading for distilled water. Your firm has no 7.0 pH buffer to properly calibrate your pH meter, only a ~~X~~ buffer, which is not adequate to determine if your meter is performing accurately. In addition, you do not calibrate your pH meter each day of use, and do not keep a record of the dates the meter is calibrated. Finally, you do not have instructions from the manufacturer for the maintenance, calibration, standardization, and use of your pH meter.

Note: We have notified you of problems with the way you have taken your pH readings via FDA 483, issued by our investigators at the close of our inspections on August 28, 1996, March 10, 1997, May 10, 2000, April 26, 2001, and February 13, 2003. In addition to these notifications, we have advised you of your failure to properly take pH readings by letter dated July 3, 2000. Copies of these documents are attached to this letter.

- Your firm does not mark each container with an identifying code permanently marked, visible to the naked eye which specifies the establishment where the product was packed, and the product contained therein. (21 CFR 114.80(b)).

You have been notified of the requirement to have the establishment and/or the product on your code via FDA 483, issued by our investigators at the close of our inspections on March 10, 1997, May 10, 2000, April 26, 2001, and February 13, 2003. In addition to these notifications, we have advised you of the requirement to have the product identified on your code by letter dated July 3, 2000. Copies of these documents are attached to this letter.

- You have no record of anyone at your firm attending a school approved by the Commissioner for giving instruction in food-handling techniques, food-protection principals, personal hygiene, plant sanitation practices, pH controls and critical

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factors in acidification, and who has been identified by that school as having satisfactorily completed the course of instruction. Operators of processing and packaging systems shall be under the operating supervision of a person who has successfully attended such a school. (21 CFR 108.25(f) and 114.10).

- Your firm does not have a log identifying all departures from scheduled processes which may have a possible bearing on public health or the safety of the food. These departures are not recorded and made the subject of a separate file delineating them, the action taken to rectify them, and the disposition of the portion of the product involved. (21 CFR 114.100 (c)).
- All plant equipment and utensils are not designed and of such material as to be adequately cleanable and maintained. Further, the design, construction, and use of this equipment and utensils does not preclude the adulteration of food with contaminants. (21 CFR 110.40(a))

For example, your firm has foam rubber attached to the outside of the vat and the filler, which is crumbling and not easily cleanable; other pieces of equipment are held together with adhesive tape which is not easily cleanable.

This letter is not intended to be an all-inclusive list of deficiencies at your facility and we remind you that it is your responsibility to ensure that you operate your processing facility in compliance with the Food, Drug, and Cosmetic Act, the mandatory requirements of Emergency Permit Control (21 CFR Part 108), and the Good Manufacturing Practice and Acidified Foods Regulations (21 CFR Parts 110 and 114), as applicable.

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.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. 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 implemented. Corrective actions should also indicate the person responsible for effecting correction, and include any supporting documentation indicating correction has been achieved.

Your reply should be sent to Shelly L. Maifarth, Compliance Officer, at the address provided in the letterhead.

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For your information, our investigator collected a sample of Coyote Cocina Roasted Corn & Black Bean Salsa (171880) during this inspection. Twelve jars of the product were examined for pH determination. We found a pH range of 4.0-4.03 on these twelve jars.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Belinda Collins". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

B. Belinda Collins
District Director

Attachments

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