



DEPARTMENT OF HEALTH AND HUMAN SERVICES

g1067d  
Food and Drug Administration  
Kansas City District  
Southwest Region  
11630 West 80<sup>th</sup> Street  
P.O. Box 15905  
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

March 30, 2001

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER**

Ref. KAN-2001-02

Mr. Donald A. Blackman, Owner  
Garden Complements Inc.  
1700 Guinotte  
Kansas City, Missouri 64120

Dear Mr. Blackman:

An inspection of your firm on July 18-27, 2000, revealed that an acidified food, Three-Bean Salsa, is processed at your facility. The investigator's observations revealed several deviations from the Good Manufacturing Practices (GMP) regulations for acidified foods (21 CFR 114) and the Emergency Permit control regulations (21CFR 108.25). These deviations cause your Three Bean Salsa to be adulterated within the meaning of Section 402(a)(4) of the Federal Food Drug and Cosmetic Act in that it was prepared and packed under conditions whereby it may have been rendered injurious to health.

The following deviations from 21 CFR 108.25 and 114 were observed:

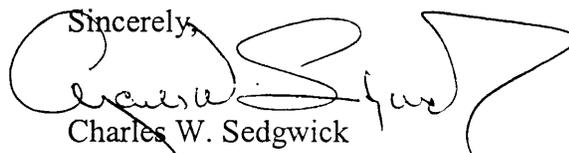
1. At the time of the inspection, your firm was not registered with FDA as an acidified food manufacturer. [21 CFR 108.25(c)(1)]
2. Your three-bean salsa does not have a scheduled process on file with FDA. [21 CFR 108.25(c)(2)].
3. Your firm does not have processing/production batch records to document control over the acidification process of the three-bean salsa. [21 CFR 114.100(b)]
4. Operations of process and packaging systems are not under the supervision of a person who has attended a Better Process school approved by the commissioner [21 CFR 114.10]
5. Your firm does not conduct pH testing or maintain documentation of pH testing for three-bean salsa. [21 CFR 114.80(a)(2)]
6. Products are not marked with an identifying code, minimally containing the year, day and period during which the food was packaged. [21 CFR 114.80(b)]

The above is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of acidified foods, you are responsible for assuring that the products you produce and distribute are in compliance with the law.

You should take prompt action to correct these violations and establish appropriate procedures that will prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

We request a response to this letter within fifteen (15) working days addressing any procedures implemented. All the items stated in your response will be verified during our next inspection. If you have further questions or concerns, you should reply directly to Monica R. Maxwell, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is stylized with large, sweeping loops and a long, trailing flourish on the right side.

Charles W. Sedgwick  
District Director  
Kansas City District