

**VIA FEDERAL EXPRESS**Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751**WARNING LETTER****FLA-02-41****May 21, 2002**

Joseph A. Badia, President  
Badia Spices, Inc.  
P.O. Box 226497  
Miami, Florida 33172

Dear Mr. Badia:

We inspected your firm located at the above address on April 1 and 4, 2002, and again on April 16 and 17, 2002. Both inspections were conducted as follow-up inspections to your firm's voluntary recall of Sesame Seed Ajonjoli (Lot #030502), confirmed as being positive for *Salmonella* by the State of Florida Department of Agriculture and Consumer Services (FDACS) on March 29, 2002. During our first inspection in April, we collected Sample 143929, which represented a portion of the suspected lot. We have confirmed FDACS results and find that you have serious deviations from Current Good Manufacturing Practice Requirements for Foods (21 CFR Part 110). The deviations discovered during our recent inspections find your Sesame Seed Ajonjoli (Lot #030502) and certain of your manufacturing practices to be in violation of Section 402(a)(1) and Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), U.S.C. § 301 et seq. You can find this Act and these regulations through links in FDA's Internet home page at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

1. In accordance with Section 402(a)(1) of the Act, a food shall be deemed to be adulterated if it bears or contains any deleterious substance, which may render it injurious to health. FDA Sample 143929 (Sesame Seed Ajonjoli Lot #030502), collected on April 4, 2002, at your manufacturing facility, was found to be positive for *Salmonella* by FDA's Southeast Regional Laboratory, confirming the findings by FDACS on March 29, 2002. In addition, FDACS confirmed the presence of *Salmonella* on Ground Oregano in February of 2002, and twice on Paprika in February of 2001, and August of 2000. All four findings have resulted in recalls of these products by your firm.
2. In accordance with Section 402(a)(4) of the Act, a food shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. During the inspection on April 16 and 17, 2002, FDA Investigator Raymond Lyn listed eleven (11) items on the Form FDA 483 (Inspectional Observations) issued to you at the end of the inspection. Some of the

violations included: failure to perform microbiological testing on incoming bulk spices; failure to clean and sanitize food-contact surfaces; failure to provide adequately equipped hand washing facilities in the plant; and failure to provide adequate control of flying insects. All observations cited were violations of 21 CFR Part 110-Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. A copy of the Form FDA 483 has been enclosed for your review.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and all applicable Good Manufacturing Practice Regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. We may, without further notice, take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from receipt of this letter. Your response should outline the specific things you are doing to correct and prevent the recurrence of these deviations. You may wish to include documents in your response that support your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct the remaining deviations.

For your information, we have not received a response to the certified letter sent to you on March 18, 2002. The issues discussed in that informational letter may also be addressed in your response to us concerning this correspondence. Some of the corrective measures discussed in that letter may have a direct impact on the methods you use to correct the current situation.

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,



Emma Singleton  
District Director  
Florida District

Enclosure:  
Form FDA 483