



Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

May 23, 2001

Ref: 2001-DAL-WL-27

**WARNING LETTER**

**Certified Mail**  
**Return Receipt Requested**

Mr. Armand Petrossian  
President  
Petrossian, Inc.  
419 West 13<sup>th</sup> Street  
New York, New York 10014

Dear Mr. Petrossian:

We inspected your caviar repacking operation at 2510 Southwell, Suite 113, Dallas, Texas, on April 24-25, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123. These deviations, some of which were previously brought to your firm's attention, cause your seafood products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at [www.fda.gov](http://www.fda.gov).

Our inspection revealed your processing of seafood products deviates from the regulations contained in 21 CFR Part 123 as follows:

- You must have written HACCP plans to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6 (b). However, your firm does not have HACCP plans for caviar and roe to control food safety hazards identified by your firm.
- You must maintain complete sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11 (c). However, your firm had no sanitation monitoring records or procedures in all areas of sanitation, including the maintenance of hand-washing facilities.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. At the conclusion of the inspection your firm was issued a Form FDA-483 which is a list of the Investigators' observations of deviations noted during the

Page 2- Mr. Armand Petrossian, President  
Petrossian, Inc.  
May 23, 2001

inspection. A copy of the FDA-483 is enclosed. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizure, and/or obtaining a court injunction against further marketing of your seafood products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your corrections. Your reply should be sent to Gwendolyn Sue Gilbreath, Compliance Officer, at the above address.

Sincerely,



Michael A. Chappell  
Dallas District Director

MAC:gsg

Enclosure(s)

cc: Mr. Martin Adams  
Petrossian, Inc.

Mr. Mark S. Chester  
General Manager South Western Region  
Petrossian Paris  
2510 Southwell, Suite 113  
Dallas, Texas 75229