



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

HFI-35  
12/22/97  
728

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (714) 798-7600

**WARNING LETTER**

December 8, 1997

WL 9-8

John M. Polovina, President  
Charles Polo & Co.  
12714 Hoover Street  
Garden Grove, CA 92841

Dear Mr. Polovina:

During an inspection of your establishment located in Garden Grove, CA, on November 19-21, 1997, our investigators determined that your establishment manufactures sterile insufflation tubing sets. Sterile insufflation tubing sets are devices defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act(the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Device Regulation, as specified in Title 21, Code of Federal Regulations(CFR), Part 820, as follows:

1. Failure to maintain a device master record (DMR) which includes, or refers to the location of, information required by 21 CFR 820.181. For example, our inspection determined that your firm has no documentation describing the production process specifications, quality assurance procedures, component specifications, or packaging and labeling specifications including methods and processes used for your insufflation tubing sets.
2. Failure to conduct process validation for the manufacture of your insufflation tubing sets, information required by 21 CFR 820.75. For example, our inspection disclosed that your firm does not have sufficient documentation to demonstrate a high degree of assurance that the sterilization processing controls will consistently produce a product meeting its predetermined specifications and quality attributes.

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. The specific violations noted in this letter and in the FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality

symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class II devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved for export until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunctions, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to underlying systems problems necessary 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 completed.

Your reply should be addressed to:

Dannie Rowland  
Compliance Officer  
Food and Drug Administration  
19900 MacArthur Blvd Suite 300  
Irvine, CA 92612.

Sincerely yours,



Elaine Messa  
District Director

DER/jm