



DEPARTMENT OF HEALTH & HUMAN SERVICES

D12258  
Public Health Service  
EB 2/28/97

CERTIFIED/RETURN RECEIPT REQUESTED

February 26, 1997

WARNING LETTER

Food and Drug Administration  
Kansas City District Office  
11630 West 80th Street  
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

Rebecca K. Will, Owner  
Molded Products Company  
601 Durant Street  
Harlan, Iowa 51537

Ref.# - KAN-97-009

Dear Ms. Will:

During an inspection of your firm located in Harlan, Iowa, on December 12, 1996, through January 13, 1997, our Investigator determined that your firm manufactures accessories for use with hemodialysis systems. These accessories are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act).

The above-stated inspection revealed that your hemodialysis accessories 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 Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, to include but not limited to, the following:

failure to maintain a complete Device Master Record for the "MPC-90 Med-Star Transducer Protector in that it is not signed and dated by a designated person, and it fails to include all required specifications for the product;

failure to use a validated test methodology for embrittlement testing of Transducer Protectors that have had specification changes;

failure to have and/or follow a written protocol concerning the stability program for longterm effects of gamma radiation on Transducer Protectors;

failure to provide validated documentation to support labeled claims on Transducer Protectors that they protect patients from bacteriological cross-contamination, protect patients from particulate cross-contamination, or are non-pyrogenic;

DISTRIBUTION:

Orig.: Addressee  
bcc: LF; FF(1932668); HFA-224; HFZ-300; HFI-35/DIB(via FOI);  
HFC-210; HFC-120(GWQAP); GDD; IBRF

failure to maintain a written maintenance schedule for injection molds used for Transducer Protectors;

failure to include in your quality audit program provisions for auditing your contract sterilizer.

At the conclusion of the inspection Form FDA 483, Inspectional Observations, listing observed deviations, was prepared, issued to and discussed with you. 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. You are responsible for investigating and determining the causes of the violations identified by FDA. 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.

We received and reviewed your faxed letter dated January 15, 1997, concerning the Form FDA 483 observations, prior to the issuance of this letter.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure, injunction, and/or civil penalties.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps, in addition to those covered in the letter that are being taken to correct the noted violations and to prevent their recurrence. 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 sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers  
District Director  
Kansas City District