



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

55 pgs HFI-35  
Public Health Service  
#14596

**Food and Drug Administration**  
7200 Lake Ellenor Drive  
Orlando, Florida 32809

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-98-17

January 2, 1998

William A. Hawkins, President  
Sherwood, Davis & Geck  
1915 Olive Street  
St. Louis, Missouri 63103-1642

Dear Mr. Hawkins:

We are writing to you because on December 3-12, 1997 FDA Investigator R. Kevin Vogel collected information that revealed serious regulatory problems involving the various types of sterile/non-sterile medical, dental needles and syringes, which are manufactured and distributed by your firm located in Deland, Florida.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

The inspection revealed that the 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 the manufacture, processing, packing, storage or distribution are not in conformance with the Current Good Manufacturing Practice (GMP) requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to establish and implement procedures to investigate, correct and prevent the recurrence of foreign material, e.g., blood on needles. Your firm also failed to verify that your current SOP ensured corrective and preventive action was effective; to adequately record your firm's investigations of reported events; and to take appropriate action to warn users of unapproved uses of the Spinal Needle after your firm received reports of use of the device for amniocentesis.

- Failure to validate processes and manufacturing operations adequately to ensure all specifications are met, e.g., the MEC/IBD protocol does not declare process parameters, procedure for the inspection of samples, acceptance criteria and verification of repeatability of the process; the failure to adequately document procedures to follow when the MEC/IBD line is shutdown; failure to adequately document the Bluntip cannula assembly machine (#50) because only two additional lots were run after the first was rejected during process validation; validation of the DI water system failed to include conductivity as a requirement of acceptance criteria and no alert/action limits are documented; and no verification or validation was conducted to change the regeneration frequency of the DI water system from weekly to two and then to four weeks during the period of July 1995 to December 1997 based on conductivity readings.
- Failure to report MDR event identified as MDR DL1997-1-29-254 (blood on needle) dated December 10, 1996 to FDA within the required 30 day time period (The MDR report was made to FDA on January 29, 1997); failure to obtain information related to a complainant, who reportedly was tested after the incident; and failure to test reserve samples during the investigation of a complaint when it was determined that no other samples were available.
- Failure to provide adequate personnel to ensure the Quality Assurance program is adequately staffed and managed, e.g., a quality engineer who left the position in April of 1997 has not been replaced even though a February 1997 memo proposed the corrective action but was not implemented until November of 1997.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. 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 Inspectional Observations (FDA-483), issued to R. Bradley Harris, Plant Manager, at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

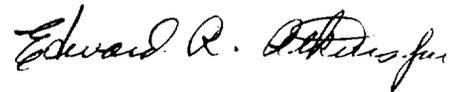
It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food & Drug Administration, Florida District, 7200 Lake Ellenor Dr., Suite 120, Orlando, Florida 32809.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for the conformance of your devices with the Good Manufacturing Practice and the Quality System Regulations and does not necessarily address other obligations you have under the law. You may obtain general information about all of the FDA requirements for manufacturers of medical devices by contacting this office or through the Internet at <http://www.fda.gov>.

A letter signed by Frank J. Fucile, Vice President, Regulatory Affairs dated December 22, 1997 responding to the Inspectional Observations (FDA 483) issued on December 12, 1997 has been received by this office. The response advised that some corrections have already been made and promised that some corrections will be completed by February 27, 1998 and others will be completed by March 31, 1998. Please provide updates to this response as corrections are made for our review. Your responses will be reviewed as they are received and a determination to conduct a verification inspection will be made after all of your promised corrections are complete and you confirm that your facility is in conformance with the Quality System regulations. The response has been made part of your firm's file.

If you have more specific questions about the Quality System Regulation and how it affects your particular devices, or about the content of this letter, please contact Tim Couzins at (407) 648-6823, ext. #264.

Sincerely,



Douglas D. Tolen  
Director, Florida District

cc: Dennis Kozlowski, President and CEO  
Tyco International, Ltd.  
Exeter, New Hampshire

bcc:

HFZ-300

HFA-224

~~HFI-36/Purged~~

HFC-210 (CFN: 1017768)

HFC-240

HFR-SE250/MAC/EI JKT

HFR-SE250/TGF

HFR-SE250/PRD

HFR-SE250/Vogel

HFR-SE200/RF

HFR-SE240/TJC Chron/LGL JKT/WL File