

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-06-33

August 17, 2006

David T. Slick, Sr., President
Command Medical Products
15 Signal Ave.
Ormond Beach, Florida 32174-2984

Dear Mr. Slick:

During an inspection of your firm located in Ormond Beach, Florida on May 11, 12, 15-17 and 19, 2006, an investigator from the Food and Drug Administration (FDA) determined that your firm manufactures Huber IV Sets and is a contract manufacturer of various other IV Sets. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are medical devices because they are intended for use in diagnosing or treating a medical condition or to affect the structure or a function of the body

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. We received your firm's responses dated June 19, 2006 and August 1, 2006 to the List of Inspectional Observations, Form FDA-483 (FDA 483) issued to you on May 19, 2006. We address these responses below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain the requirements, including quality requirements, that must be met by suppliers and contractors, as required by 21 CFR § 820.50(a). For example, your firm failed to evaluate suppliers and contractors to ensure their adherence to the QS Regulation. Your purchasing control procedure is inadequate in that the written survey sent to suppliers fails to include any requirement to demonstrate adequate process validation, calibration, or maintenance of equipment. In addition, your firm uses a contractor to produce tubing by [REDACTED] for its Command Huber Infusion Set and you failed to determine if the inner/outer diameter of the tubing is altered by the heat used during sterilization process (FDA 483, Item #1).

We have reviewed your response and have concluded that it is inadequate because the survey that you will provide to suppliers only requires a reply of yes or no to questions of whether processes have been validated and if validation documentation is available. Your firm should request documentation from the supplier in order that it can be reviewed to assure it is adequate. In addition, the documentation that you supplied of 30 samples of tubing measured for inner and outer diameter pre- and post-sterilization is inadequate to show that sterilization does not affect tubing diameter because it is unclear whether these 30 samples are from one lot or multiple lots. If the 30 samples are from one lot, you should include samples from multiple lots to demonstrate consistency over multiple lots. If the 30 samples are from multiple lots, you should identify how many samples are from each lot and why each number is statistically relevant to demonstrate consistency.

2. Failure to document the monitoring and control methods during the validation of processes the results of which cannot be fully verified by subsequent inspection and test, as required by 21 CFR § 820.75(a)(2). For example, your firm failed to document control of cooling water temperature, circulation of cooling water in the cooling tank, and the length of the cooling tank during extrusion validation. These parameters can affect the cooling process and thus the physical properties of the resulting tubing (FDA 483, Item #5).

We have reviewed your response and have concluded that it is inadequate because it does not include documentation to allow FDA to assess the adequacy of your actions. Please provide documentation that the validation has been sufficiently completed and provides adequate results.

3. Failure to analyze complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR § 820.100(a)(1). For example, your firm's analysis of complaints and reports of nonconforming product is inappropriate in that it does not include a comparison of the number of defective units exhibiting specific failure modes over time (FDA 483, Item #6).

We have reviewed your response and have concluded that it is inadequate because the trending documents that you have provided fail to include enough description to determine whether trending is done on the number of defective units in the complaints or on the number of complaints themselves. We are unable to determine what specific failure mode "Product" and "ACT" designations represent.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Also, 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.

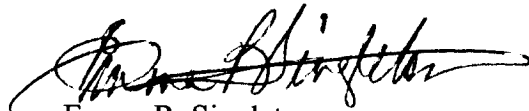
Additionally, no pre-market submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. If your planned corrections will occur over time, please include a time table for implementation of those corrections. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Brant M. Schroeder, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4763.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with the applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a long horizontal flourish extending to the right.

Emma R. Singleton
Director, Florida District