

Inspections, Compliance, Enforcement, and Criminal Investigations

Victus, Inc.



Department of Health and Human Services

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

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

FLA-10-06

December 21, 2009

Enrique J. Lopez,
President
Victus, Inc.
4918 SW 74th Ct
Miami, FL 33155-4400

Dear Mr. Lopez:

During an inspection of your firm located in Miami, Florida on April 20, 2009, through April 22, 2009, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is the medical device specification developer of sterile, IV (intravascular) infusion devices. Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or 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** (CFR), Part 820. We received a response from Ms. Ileana Yanes, Manager QA/RA & Management Representative, dated May 11, 2009, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you. We address this response 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 procedures for ensuring complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting, as required by 21 CFR 820.198(a)(3).

Specifically, your firm received complaint number 0109005 from **(b) (4)** regarding "clogging" during use of your firm's Secure Flow infusion pump as well as complaint number 1208029 from **(b) (4)** regarding "leakage" at the Y-connector on your firm's Dosi-Flow LV. Administration set. According to your firm's Complaint Report Form, 05-FOR-006, for both complaints, there is no indication that either of these complaints were evaluated to determine if the events were reportable under the Medical Device Reporting regulation. On your firm's Complaint Report Form for these complaints, there is a section which contains "yes" and "no" check boxes located next to "MDR Event." On both complaints referenced above, neither box is checked. There is also no discussion within your firm's Complaint Report Form regarding Medical Device Reporting for these events.

2. Failure to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited, as required by 21 CFR 820.22.

Specifically,

i) Your firm's Audit Procedure, 05-SOP-028, states in step 4.2 "Auditors shall be qualified by training or experience before conducting any audit and audits shall be conducted by individuals who do not have responsibility for the matters being audited." According to your firm's Change Order Form, 05-FOR-018 for CCN# 0146, "Ileana Yanes", Victus' QA and RA Manager, originated a document change request to affect multiple procedures, however according to an "Official Memorandum" on company letterhead, "Ileana Yanes" also inspected the firm's Document Control Function on April 13, 2009, as part of a periodic evaluation.

ii) Your firm's Audit Procedure, 05-SOP-028, and the Victus 2008 and 2009 Audit Plans, do not include provisions for conducting quality audits of all major quality criteria including design controls, MDR and corrections and removal.

Your response to this observation, dated May 11, 2009, appears to be adequate.

Our inspection also revealed that the 84" IV Administration Set with one Needle Free "Y"-port (Catalog # 270071), 84" IV Administration Set with two Needle Free "Y"- ports (Catalog # 270072), 84" IV Administration Set with two Needle Free "Y"- ports and Check Valve (Catalog # 270080) and the IV Administration Set with Needle-Free "Y" Port (Catalog # 270001) are adulterated under Section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to Section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under Section 520(g) of the Act, 21 U.S.C. 360j(g). These devices are also misbranded under Section 502(o) the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce these devices into commercial distribution, as required by Section 510(k) of the Act, 21 U.S.C. 360(k). For a device requiring premarket approval, the notification required by Section 510(k) of the Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency per 21 CFR 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at <http://www.fda.gov/cdrh/devadvice/3122.html>. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

Specifically, there have been multiple changes to your firm's cleared IV Administration Sets. These uncleared changes include:

- i) A change in material of the component **(b) (4)** to ABS **(b) (4)** on Product Numbers 270001, 270071, 270072 and 270080. This differs from your firm's original 510(k) K030246 component spike.
- ii) An addition of a new component **(b) (4)** part number **(b) (4)** on Product Number 270001 and 270080. **(b) (4)** were not present in your firm's original 510(k) K030246 encompassing the referenced product numbers.

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 the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money 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.

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. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. 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 response should be sent to: Winston R. Alejo, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions about the content of this letter please contact: Mr. Alejo at (407) 475-4731.

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 applicable laws and administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (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 these violations, and take prompt actions to correct the violations and to bring your products into compliance.

Finally, your firm has not addressed whether it will pursue a voluntary correction to or removal of any such products that are currently in distribution. As stated in previous paragraphs of this Warning Letter, your devices mention above are considered to be adulterated under Sections 501(f)(1)(B) and 501(h) of the Act, 21 U.S.C. 351(f)(1)(B) and 351(h), and misbranded under Section 502(O) of the Act, 21 U.S.C. 352(O). FDA has concerns regarding their safety and effectiveness. Should your firm undertake a voluntary correction or removal of these devices, it must submit a written report to FDA within 10 days of initiating such an action, as specified 21 CFR 806.10(a) & (b). See 21 CFR 806.10 for additional requirements governing reports of voluntary corrections and removals.

Sincerely yours,
/S/

Emma R. Singleton
Director, Florida District