



DEPARTMENT OF HEALTH & HUMAN SERVICES

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

September 18, 2001

WARNING LETTER

2001 - DT - 30

Mr. S. Nicholas Ayoub
Executive Vice President
Vital Concepts, Inc.
5090 Kendrick Court, S.E.
Grand Rapids, MI 49512

Dear Mr. Ayoub:

Investigator Leslie A. Paul conducted an inspection of your firm dated June 4-8, 2001. At the conclusion of that inspection, Investigator Paul issued to Ms. Wanda Jane Burnell, Manufacturing Manager, a FORM FDA-483, List of Inspectional Observations, (copy attached). The inspection found that your firm is operating in serious violation of the Federal Food, Drug, and Cosmetic Act, (the Act).

The specific product, TPN "Y" Connector with Injection Set, manufactured by your firm exclusively for a single customer does not meet the definition of a custom device. Therefore it is misbranded within the meaning of Section 502(o) of the Act due to your failure to file a pre-market notification as required by Section 510(k) of the Act.

Furthermore, our inspection found your firm is operating in violation of the Quality System Regulation, Title 21, Code of Federal Regulation (CFR), Part 820, in that the methods used in, or the facilities or controls used for, the design, manufacturing, packing, labeling, storage, installation, and servicing of all finished devices intended for human use, are not in compliance with that regulation. The deviations from the Quality System Regulations, as listed on the FDA-483, cause your irrigation and insufflation tubing medical device products, as well as the TPN "Y" Connector Set, to be adulterated within the meaning of Section 501(h) of the Act, as follows:

1. Failure to conduct *management reviews* as required by 21 CFR 820.20(c) and as called for in your procedure Q001 "Quality System", to assure that the your firm is in compliance with the regulations.
2. Your procedure Q002, "Audits", Section 3.3.2, provides for the destruction of the audit reports when corrective action is completed. This represents a failure to document the dates and results of the quality audits as required by 21 CFR 820.22.
3. Failure to conduct quality audits required by 21 CFR 820.22, and in your procedure Q002, "Audits" to assure your firm is operating in compliance with the regulations.

4. You failed to document or perform follow-up investigations on the following complaints, as required by 21 CFR 820.198, and as called for in your procedure Q018, "Complaints".
 - a. There was no COMPLAINT EVALUATION RECORD form nor any other type of complaint record in the complaint file system for an incident documented on credit invoice 9503, found in your return goods record file, concerning leaking of product [REDACTED].
 - b. Letters dated 7/28/99 and 8/9/99 from one customer reported three complaints they had received concerning either leaking or mis-assembly of product [REDACTED]. Although an investigation and corrective action was described in your 2/14/2000 letters to the customer, there was no COMPLAINT EVALUATION RECORD form generated and no documentation of the investigation you performed.
 - c. A hand written note dated 11/21/00 documents receipt of a complaint that product [REDACTED] was breaking at the connector. There was no COMPLAINT EVALUATION RECORD form generated and no documentation of any investigation you may have performed.
5. You failed to specify how initial training of new employees would be conducted, as required by 21 CFR 820.25, in your procedure Q003, "Personnel".
6. You failed to assure adequate ongoing training of employees in their job functions and quality systems required by 21 CFR 820.25. You did not use the TRAINING DOCUMENTATION form called for in revision "B" dated 3/1/98 of procedure Q003, "Personnel", nor any other format, to document recent employee training.
7. Procedure Q004, "Design Control", fails:
 - a. To specify how to address incomplete, ambiguous or conflicting *design input* requirements as required by 21 CFR 820.30(c).
 - b. Does not specify that *design review* will include persons not having direct responsibility for the design project, as required by 21 CFR 820.30(e).
8. You failed to assure that documents required by the Quality System Regulation are approved, distributed, and changed in a controlled manner according to a written procedure, as required by 21 CFR 820.40. Your Procedure Q005, "Documentation Control", is not being followed in that the Engineering Change Order and the Engineering Change Order Log forms called for in the procedure are not being used.
9. You failed to assure that non-conforming material or product is controlled in a consistent manner, according to a written procedure, as required by 21 CFR 820.90. Your procedure Q012, "Non-Conformance Identification", is not being followed, in that quarterly Material Review Board meetings are not being held as called for in your procedure.

10. You failed to conduct quarterly complaint review meetings as called for in your Procedure Q018, "Complaints", in violation of 21 CFR 820.198(a).
11. Three instances were noted where your device history records were not completed as required by 21 CFR 820.184, in that one was missing the final records review signature, one was missing the post-sterilization inspection results, and a third was missing pre-sterilization inspection results.

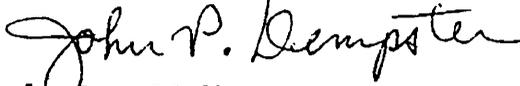
The above is not intended to be an all-inclusive list of deficiencies at Vital Concepts, Inc. It is your responsibility to assure adherence to each requirement of the Quality System Regulation. Other Federal agencies are advised of the issuance of all Warning Letters about medical devices so they may take this information into account when considering the award of contracts. Additionally, pending 510(k) or PMA applications and export approval requests may not be approved until the above violations are corrected.

We request that you take prompt action to correct these violations and to ensure that your device manufacturing operations are in full compliance with the Act and regulations promulgated thereunder. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice, such as seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of any steps you have taken, or intend to take, to bring your firm into compliance. If corrective actions cannot be completed within 15 working days, please state the reason for the delay and the time frame within which the corrections will be implemented.

Your response should be directed to Melvin O. Robinson, Compliance Officer, at the above address.

Sincerely:


for Joann M. Givens
District Director
Detroit District Office

Enclosure