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VF Works Update

Program Disapproval Lifted, "Class II Recall" Required, New Lawsuit Filed

By Editorial Staff

VF-Works and its sister company (NU-Best Franchising) are in the business of selling franchises for their video fluoroscopy (VF) equipment. The equipment is mounted in a van to give it the mobility to go to chiropractic offices to make fluoroscopy videos for patients. On July 28, 1998, the Food and Drug Administration (FDA) issued a "program disapproval letter" to VF-Works.¹ The FDA stated that VF-Works had violated certain "electronic product radiation control regulations." The FDA required VF-Works to make changes to the VF equipment before the FDA would allow the company to "introduce any of your products into commerce."

The FDA was not the only one to raise issues with VF-Works and Nu-Best. A previous article in *DC* outlined those issues, including lawsuits by franchise holders.²

Via Certified Mail
Dr. John R. Postlethwaite
President/Owner
VF-Works, Inc.
4159-A Corporate Court
Palmer Harbor, Florida 34683
RE: Objections to Recent
Correspondence to
VF-Works Franchises

Dear Dr. Postlethwaite:

It has come to our attention that certain correspondence sent by your firm to your franchisees presents somewhat less than an accurate accounting of your firm's current standing with the Agency. For example:

7/30/1999 Fax to Franchisees:

Paragraph 2 of the letter states:

"We will make the letter (ref. to CDRH rescission letter) available to you if you need to convince any of your referral doctor that this eight-month nightmare is over."

The sentence implies that the letter in its entirety will be forwarded to anyone requesting it. In reality, the letter that you are sending is not the entire letter, but a letter cleverly remanufactured by you retaining the official Agency letterhead, the introductory paragraph, the closing paragraph, and the signature block. What is missing is the lower half of page one, and all of pages two and three. Be aware that the Agency considers this action to be one of total misrepresentation of the complete intent of the letter and may misbrand your device.

The Agency makes the same observation with your paragraph three, which in part states:

"As you already know, the entire process was not one of safety, but one of record keeping. We have made every change the FDA wanted. Submitted approximately 2,500 pages of documents for their review and waited eight months before gaining their 'all clear' message."

The Agency implemented the Quality Control and Testing (QC & T) Program Disapproval action against your firm because you had not demonstrated that your firm had implemented manufacturing procedures and adequately documented those procedures to assure that your finished products complied with the required radiation performance standards necessary to certify your products. It took eight months for your firm to nominally describe the AC & T program your firm will now implement to assure that the product you manufacture will comply with the applicable performance standards.

Additionally, the Florida District office conducted a Medical Device Quality System establishment inspection of your firm and issued a Warning Letter to your firm regarding Quality System Regulations violations (previously known as GMP violations). These issues still require resolution between your firm and the Florida District office.

The issues alluded to in the previous two paragraphs include not only record keeping deficiencies, but also, more importantly, deficiencies in your manufacturing and quality control processes and procedures.

To set the record straight for all interested parties, the current status of your firm is:

1. Your firm has been granted a QC & T program disapproval rescission subject to the provisions detailed in the complete letter from the Agency dated Aug. 5, 1999 (a complete copy of this letter is attached). This means as the Aug. 5, 1999 letter states: "... the information you have submitted is essentially sufficient to demonstrate that if you implement your current Quality Control and Testing (QC & T) Program it should be adequate to assure compliance with the performance standard." This action permits you to market and manufacture your product under the new QC & T program implemented by your firm, because if so manufactured, your firm certifies the product will comply with applicable performance standards. Should the Agency find your product does not comply due to QC & T deficiencies, we will immediately reestablish the program disapproval against your firm.
2. The Agency and your firm are currently addressing issues to finalize your Corrective Action Plan (CAP) for existing product introduced into commerce. Once finalized and accepted by the Agency, you will implement your CAP as a recall action for existing equipment introduced into commerce.
3. Your firm still needs to satisfactorily address the Medical Device deficiencies delineated in the Warning Letter issued by the Florida District Office to assure that your firm is manufacturing product in accordance with Quality System Regulations.
4. Your firm will be reinspected to determine your compliance status with the provisions of the Quality System Regulations and the Electronic Product Radiation Control (EPRC) performance standards.

Be aware that a copy of this letter in its entirety will be sent to the Florida District Office and will be distributed to any and all inquiring about the status of your firm. It may be in your best interest to revise your current correspondence to franchisees to present a more balanced view of your current regulatory status with the Agency.

Sincerely yours,

Thomas M. Jakub,
Chief Diagnostic Devices Branch
Division of Enforcement I
Office of Compliance
Center for Devices and Radiological Health

Enclosure: Letter dated August 5, 1999.

Program Disapproval Lifted

As part of our review of the VF-Works situation, we filed a request for information from the FDA under the Freedom of Information Act. That was nine months ago; we just received the information in December.

Among the documents provided was a letter from the FDA to John Postlethwaite, DC, president and owner of VF-Works dated August 5, 1999. It stated:

"We have determined the information you have submitted is essentially sufficient to demonstrate that if you implement your current Quality Control and Testing (QC &T) Program it should be adequate to assure compliance with the performance standard. Based upon this assessment we hereby rescind the Quality Control and Testing Program disapproval for the Visualizer 2000."

With the program disapproval lifted, VF-Works now had FDA clearance to sell its videofluoroscopy units. But did the company sell any units during the 12 months in which the FDA's program disapproval was in effect? A review of the VF-Works website during February of 1999 revealed over 10 new franchise locations listed. The web page with the listing (<http://www.vf-works.com/locations.html>) was taken down a few months later.

A follow-up letter from the FDA to Dr. Postlethwaite (mailed just two weeks later) seems to suggest that he mailed partial copies of their program disapproval rescission letter to his franchises, presenting a "somewhat less than accurate accounting" of the situation.

"Class II Recall" Required

An additional letter from the FDA to Dr. Postlethwaite dated September 27, 1999 outlines the bases for VF-Works' "corrective action plan." The FDA required that the company notify the existing franchises of the work that was needed to be performed on the equipment to bring it into compliance:

"Please be advised that a VF-Works, Inc. representative may need to be sent to each of the customer locations (regardless of the ability or inability of the customers in performing the required field corrective actions) to actually: (I) remove the tri-field switch; (II) disconnect, pack, and send the old x-ray control panel to X-Cel X-Ray Corporation, as well as reconnect the modified x-ray control panel; (III) detach the old collimator knob stop and re-install the new collimator knob stop; and (IV) verify proper field alignment."

The letter went on to state that the FDA's Center for Devices and Radiological Health was "classifying this as a Class II recall and has assigned a recall number Z-1242-9 to this activity."

Legal Video Sues VF Works for Copyright Infringement

A lawsuit was filed in U.S. District Court, Eastern District of Texas by Legal Video Service, Inc., against VF-Works, Inc., Nu-Best Diagnostic Labs, Inc., Nu-Best Franchising, Inc., John Postlethwaite and Daniel R. Theesfeld, MD. The suit alleges that the defendants violated copyright law by "copying, distributing and publicly displaying" Legal Video's "Dummy Tells All" whiplash video. The suit alleges that Dr. Postlethwaite was given a copy of "Dummy Tells All" in January of 1998. It claims that the defendants have been "distributing and placing upon the market video tapes containing certain electronically edited portions and/or images from Plaintiff's copyrighted works." This allegedly occurred even after a "cease and desist" notice was given. The suit claims that Dr. Theesfeld "has distributed portions of Plaintiff's works in the other Defendants' (VF Works', Nu-Best's & Postlethwaite's) promotional literature, in violation of Plaintiff's copyrights, to promote his own business as well as the business of the remaining Defendants." Apparently referring to the other Nu-Best franchises, the suit also claims:

"Plaintiff is informed and believes that in addition to THREESFELD, other agents and affiliates of the remaining Defendants have engaged in similar conduct in other states; and this action is brought without prejudice to Plaintiff's right to bring infringement actions against other agents in other jurisdictions for their violations."

References

1. For a complete copy of the FDA's program disapproval letter, please go to:
<http://www.ChiroWeb.com/dynamic/documentation/disapproveletter.html>.
2. Big problems for VF-Works/Nu-Best franchising. *Dynamic Chiropractic*, March 8, 1999. Available online at <http://www.ChiroWeb.com/archives/17/06/26.html>.



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