



DEPARTMENT OF HEALTH & HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

5/28/98  
T1793M

PHILADELPHIA DISTRICT

900 U.S. Customhouse  
2nd and Chestnut Streets  
Philadelphia, PA 19106  
Telephone: 215-597-4390

WARNING LETTER

98-PHI-21

April 30, 1998

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Dr. Abraham Lavi, President and Chief Executive Officer  
Vilex, Inc.  
811 Route 51, Building 10  
Large, PA 15025

Dear Dr. Lavi:

On February 25, 1998, Philadelphia District Investigator James M. O'Donnell conducted an inspection of your medical device manufacturing facility. The Vilex implantable cannulated bone screws you manufacture are medical devices within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act and, as such, are subject to the requirements of *Title 21 Code of Federal Regulations* (21 CFR).

The inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the FD&C Act in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with current good manufacturing practice (CGMP) regulations codified at 21 CFR Part 820 as follows:

1. Failure to establish and maintain complaint handling and Medical Device Reporting (MDR) systems.

During our previous inspection of your firm from July 23-28, 1997, Investigator O'Donnell advised you of the necessity of having a complaint handling system that will adequately document complaints and provide for their investigation as well as a determination of whether or not complaints meet the requirements for reporting under the MDR regulations codified at 21 CFR Part 803. You subsequently provided Investigator O'Donnell with a copy of a Product Complaints Form (PCF) prior to the conclusion of the July 1997 inspection. Investigator O'Donnell's current inspection reveals that your firm is not using this form. Moreover, Investigator O'Donnell evaluated [REDACTED] complaints received by your firm since July 1997 [REDACTED] and observed the following deficiencies associated with those complaints:

GEN.	SPEC.
RELEASE	
F# _____	DATE 5/14/98
Reviewed by: [Signature]	

- a) there is no documentation of specific device information, for example, the lot number(s) and size/type of device involved;
- b) there is no documentation that a determination of whether or not these events met criteria for reporting under the MDR regulations was made; and
- c) there is no documentation that an investigation was conducted into the cause of the complaints or a rationale provided regarding why an investigation is not warranted.

Further, regarding the [REDACTED] complaint from [REDACTED] you determined that, because of the date the bone screw was implanted, "[c]learly, this is not a Vilex problem." On the contrary, at the time Vilex acquired this implantable bone screw line from ISI of North America, Vilex became responsible for devices presently on the market. If you have reason to believe that devices produced prior to Vilex's acquisition of the product line are of suspect quality and do not meet the requirements of CGMP's, then you have an obligation to take appropriate corrective action with respect to devices presently in commerce. This includes a determination of the potential risks to patients who currently have these bone screws implanted in their bodies.

Also, please be advised that the MDR regulations require that you develop, maintain, and implement written MDR procedures (21 CFR § 803.17), establish and maintain an MDR event file (21 CFR § 803.18), and conduct investigations of each MDR event and evaluate the cause of the event (21 CFR § 803.50(b)(2)). A review of your complaint form revealed that it does not prompt a description of the complaint in a manner that will be likely to elicit information needed to determine whether the patient was injured and, if so, the type and extent of the injury, to assure that information needed to determine whether a death or serious injury has occurred is obtained.

2. Failure to implement the Device Master Record (DMR) and to completely follow the procedures set forth in the DMR.
3. Failure to consistently complete a Device History Record (DHR) for each batch of devices produced in accordance with procedures set forth in the DMR.

In response to FDA 483 observations made during the July 1997 inspection regarding deficiencies with the DMR and DHR, you developed and provided Investigator O'Donnell with a document entitled "Acceptance Procedure for Cannulated Screws," dated July 25, 1997. This procedure requires, in part, the completion of a Screw Acceptance Form (SAF) for each screw style provided by your contract manufacturer in response to a Vilex purchase order. During the current inspection, Investigator O'Donnell was informed that the SAF's were completed for only approximately one

Page 3  
April 30, 1998  
Dr. Abraham Lavi

week's worth of production during September 1997 and that [REDACTED] bone screws have been manufactured since that time but not documented in a DHR.

Further, our review of the Acceptance Procedure for Cannulated Screws, as implemented, finds it is deficient in the following areas:

- a) it does not include or reference the location of specifications for the various bone screw dimensions checked prior to the tip sharpening process;
- b) information regarding cutting discs is left blank; and
- c) it does not discuss the disposition of bone screws used in the final test.

In addition, we find that the SAF is deficient in that it does not provide for the documentation of the following items:

- a) bone screws rejected for discoloration, cracks, or mechanical faults;
- b) the completion of the tip sharpening process;
- c) the completion of the test to ensure bone screws are neither too narrow nor too weak, and the number of bone screws failing this test;
- d) the completion of the cleaning step;
- e) the results of the final test;
- f) the quantity of bone screws released for distribution;
- g) the primary identification label and labeling for the batch of bone screws processed; and
- h) that the steps identified in Section 9 of the Acceptance Procedure for Cannulated Screws were followed (when applicable).

4. Failure to establish procedures for finished device acceptance and release for distribution.

Investigator O'Donnell documented that the release of finished bone screws for commercial distribution is not done in accordance with established procedures that provide for, at a minimum, a determination that the bone screws were manufactured in accordance with the DMR, that all test

Page 4  
April 30, 1998  
Dr. Abraham Lavi

data were reviewed and found satisfactory, that the DHR was properly completed, and that the release is authorized by the signature of appropriate personnel and dated.

5. Failure to establish a quality system and procedures to audit the quality system.

The above-referenced deviations are examples of your firm's failure to establish a quality system to ensure that medical devices released for commercial distribution meet their specifications and comply with CGMP regulations. These deviations were also included on the FDA 483 issued at the conclusion of the July 1997 inspection, and at that time you produced a written description of a quality system and promised to implement audits within two weeks. During the current inspection, Investigator O'Donnell was advised that your firm has not conducted any audits to date.

The above is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence to each requirement of the FD&C Act and its associated regulations. The specific violations noted in this letter and in the FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

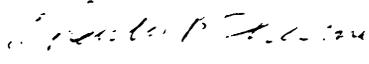
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office within fifteen (15) days of receipt of this letter of the specific steps you have taken or intend to take to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. 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

Page 5  
April 30, 1998  
Dr. Abraham Lavi

completed. Your response should be sent to Karyn M. Campbell, Compliance Officer, at the address noted on the letterhead.

Sincerely,

  
Charles B. Thorne  
Acting District Director  
Philadelphia District

cc: Robert E. Bastian, Director  
Division of Primary Care and Home Health Services  
PA Department of Health  
132 Kline Plaza, Suite A  
Harrisburg, PA 17104