



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

July 3, 1997

Ref: 97-DAL-WL-34

**WARNING LETTER**

**VIA FACSIMILE AND  
FEDERAL EXPRESS**

Mr. Charles W. Federico  
President and Chief Executive Officer  
Orthofix, Inc.  
250 E. Arapaho Road  
Richardson, Texas 75081

Dear Mr. Federico:

During an inspection of your firm in March 1997, an FDA investigator determined that your firm manufactures and markets Physio-Stim device models 7313 and 7314. These products are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above referenced inspection revealed that Physio-Stim Models 7313 and 7314 are adulterated within the meaning of Section 501(f)(1)(B) of the Act, in that they are Class III devices under Section 513(f) of the Act and do not have approved applications for premarket approval (PMA) in effect as required by Section 515 (a) and Title 21 Code of Federal Regulations (CFR) Part 814.39 for use of the device in the cervical spine, and they are not exempt from this requirement under Section 520(g). The Physio-Stim is approved for the treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones, where the width of the nonunion defect is less than one-half the width of the bone to be treated. The sale and distribution of this device for cervical fusion constitute a change in indication that requires an approved PMA supplement.

We also noted that your promotional brochure, titled "The AME Spinal-Stim Limited Guarantee Program," contains the statement, "Orthofix has the only FDA approved noninvasive PEMF bone growth stimulator for spine fusions." Section 301(l) of the Act prohibits the use, on any labeling or advertising of a device, of any representation or suggestion that a device is the subject of an approved PMA. All references to FDA or to the PMA approval process should be removed from your labeling and promotional materials immediately.

Mr. Charles W. Federico, President and CEO  
July 3, 1997

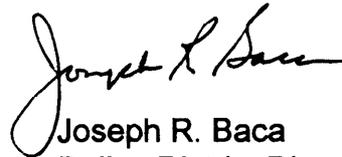
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You are responsible for investigating and determining the causes of the violations identified by the FDA.

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. This is a serious violation of the law that may result in FDA taking regulatory action without further notice. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil penalties.

Please notify this office in writing within fifteen (15) working days of the receipt this letter outlining what steps you are taking to correct the problems. Please explain how you plan to prevent this from happening again. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the correction will be completed.

Please direct your response to Gwendolyn S. Gilbreath, Compliance Officer, at the above letterhead address.

Sincerely



Joseph R. Baca  
Dallas District Director

cc: Dr. Namassivavaya Doddi  
Vice President  
Research and Development

Arthur W. Schwalm  
Chairman of the Board  
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