



FEB 22 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

WARNING LETTER  
FEDERAL EXPRESS

Frederic-Edouard Koehn  
Chief Executive/CEO  
Compex S. A.  
Chemin Du Devent  
CH-1024 Ecublens, Switzerland

Dear Mr. Koehn:

We are writing to you because on November 9 – 12, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving products known as the Compex 2 device, including Muscle Stimulation, Transcutaneous Nerve Stimulation, and Iontophoresis.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps to protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance for your Compex 2 Iontophoresis device before offering the product for sale. The kind of information you need to submit in order to obtain this clearance is described in Title 21 of the Code of Federal Regulations Part 807.87 (21 CFR 807.87). We have requested that our Division of Small Manufacturers Assistance provide you with informational packets to aid you so that you may fulfill this requirement. After you have submitted this information, FDA will evaluate it and decide whether your Compex 2 Iontophoresis device may be legally marketed.

Because you do not have marketing clearance for your Compex 2 Iontophoresis device, marketing this product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows that your device is substantially equivalent to other devices that are legally marketed.

Your product is also adulterated under section 501(h) of the Act because the methods, controls or facilities used in the manufacture of your product do not comply with the

FDA Quality System Regulation (QS Reg). Our investigator made the following observations of QS Reg deficiencies:

1. Failure to investigate the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). For example, devices failed finished-device testing on August 31, 1998 (FER No. 8055) for “no charge on the battery”; “would not turn on”; “wrong serial number”; and “Error on BioA.” No failure investigation of the cause of these failures was conducted.
2. Failure to validate computer software for its intended use according to an established protocol, when computers or automated data processing systems are used as part of production or the quality system, as required by 21 CFR 820.70(i). For example, your firm failed to validate the software (TEST C2.EXE) used during finished-device testing. Devices are released for commercial distribution based on these tests.
3. Failure to conduct a quality audit to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, your firm failed to conduct a quality audit or evaluation of device production (at CFG, the contract manufacturer), and the procedures therein, even though the firm has an audit procedure and schedule.
4. Failure to verify or validate a corrective action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). For example, 119 Compex 2 devices were returned for defective Q 21 transistors; 24 of the devices were returned for “intact” or non-visual defective components; 18 of the devices were returned with “burnt” defective components; and 66 of the devices were returned with “holes” in the defective components.
5. Failure to establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services, as required by 21 CFR 820.50(b). For example, the contract manufacturer received 5, 250 Q21 (16-amp) power module transistors and 5, 267 microcontrollers (central unit computers); none of these components were sampled or tested prior to acceptance and incorporation into the device manufacturing operation. Additionally, the contract manufacturer may change manufacturing specifications and/or change suppliers, without

providing documentation to support that your firm was aware of specification changes.

6. Failure to evaluate complaints to determine whether the complaint represents an event which is required to be reported to FDA under part 803 or 804 of this chapter, Medical Device Reporting (MDR), as required by 21 CFR 820.198(a)(3). For example, your device complaint handling system failed to evaluate complaints for reportability to the FDA under MDR, and the reporting timeframes therein.
7. Failure to document oral complaints upon receipt, ), as required by 21 CFR 820.198(a)(2). For example, the device complaint handling system failed to address or document verbal complaints received from employee users of the device.

You should know that these violations of the law may result in FDA taking regulatory action without further notice to you. This action may be detention without physical examination.

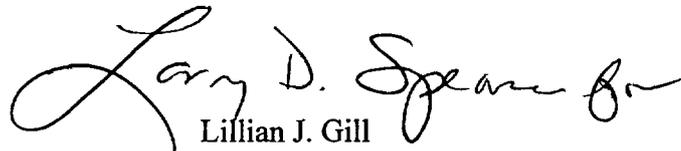
It is necessary for you to take action on this matter now. Please let this office know in writing within (15) working days from the date you received this letter the steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. If the documentation is not in English, please provide a translation to facilitate our review. Please address your response to:

Edgardo Santiago  
Food and Drug Administration  
Center for Devices and Radiological Health  
Division of Enforcement III  
Orthopedic, Physical Medicine & Anesthesiology Devices Branch  
2098 Gaither Road  
Rockville, MD 20850

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If you have any questions, please contact Carol Arras at (301) 594-4659.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian J. Gill". The signature is written in a cursive style with a large initial "L".

Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health