



VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-00-100

September 13, 2000

Ray E. Collier, President
Specialty Orthotics & Prosthetics, Inc.
419 W. Columbia Street
Orlando, Florida 32860

Dear Mr. Collier:

We are writing to you because on June 28, 2000, FDA Investigator Ronald T. Weber collected information that revealed serious regulatory problems involving the cranial orthosis that you manufacture and distribute. The inspection determined that you promote your pediatric cranial orthosis in the trade publication O&P Business NEWS. The cranial orthosis is a prescription device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Under the Act, this product is considered to be a medical device under section 201(h) of the Act because it is used in the cure, mitigation, treatment, prevention of disease, or to affect the structure or function of the body. During the inspection, the investigator documented violations that cause the device to be adulterated within the meaning of sections 501(f)(1)(B) and 501(h), and misbranded within the meaning of section 502(o) of the Act.

The law requires that manufacturers of medical devices conform with the requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

The inspection revealed that the cranial helmet (orthosis) is adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

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1. You have failed to exercise management responsibility to ensure that the quality system is adequate and effective as required by 21 CFR 820.20. For example, You failed to define, document, and implement management controls including a quality policy, management review, a quality plan and quality system procedures and instructions.
2. You have failed to establish and maintain procedures to effectively implement adequate corrective and preventive action as required by 21 CFR 820.100. For example, you have not established and implemented adequate procedures for identifying, reviewing, and analyzing nonconforming product or other quality problems.
3. You have neither established nor maintained written procedures or records to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR) and the requirements of the Quality System Regulation.

Sections 501(f)(1)(B) and 502(o)

Your pediatric, cranial helmet (orthosis) is adulterated under Section 501(f)(1)(B) of the Act because you do not have marketing clearance from FDA.

Your pediatric cranial helmet is misbranded under Section 502(o) of the Act because you did not register your manufacturing establishment under Section 510, the device was not included in a list required by Section 510(j), and a notice or other information respecting the device was not provided to the FDA as required by Section 510(k).

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 should know that these serious violations of the law might result in FDA taking regulatory action without further notice to you. 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 money penalties. Also other Federal agencies are informed about the warning letter we issue, such as this one, so that they may consider this information when awarding government contracts.

During the inspection, you stated in an affidavit, that you ceased distribution of the device and would do so until obtaining marketing clearance and complying with the

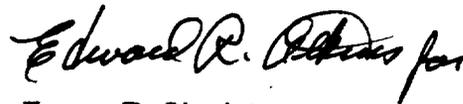
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Quality System Regulation. Please let this office know in writing within fifteen (15) working days from the date you receive this letter if these are the steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your corrections

Please direct your reply to the attention of Timothy J. Couzins, Compliance Officer, Food and Drug Administration, Florida District Office, 555 Winderley Place, Suite 200, Maitland, Florida 32751 (407) 475-4728.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance a 1-(800) 638-2041 or through the internet at <http://www.fda.gov>.

Sincerely,



Emma R. Singleton
Director, Florida District