



November 30, 2000

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-05-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gene P. Bernardoni, CEO
Ballert Orthopedic of Chicago
2434 W. Peterson Ave.
Chicago, IL 60659

Dear Mr. Bernardoni:

During an inspection of your establishment located at 2445 W. Peterson Ave., Chicago, IL, from May 25 to June 9, 2000, our investigator, Rachel Evans, determined that your establishment manufactures cranial helmets. Cranial helmets are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR) for medical devices, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure to establish a complete quality policy and ensure that existing quality procedures are understood, implemented, and maintained.
2. Failure to establish a management representative that:
 - a) ensures the quality system requirements are effectively established and effectively maintained;
 - b) reports on the performance of the quality system to management with executive responsibility for review.
3. Failure to establish a quality plan that establishes how the requirements for quality will be met.
4. Failure to establish procedures for implementing corrective and preventive action.
5. Failure to establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Failure to establish complaint handling procedures that ensure complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA as a Medical Device Report (MDR).

6. Failure to establish procedures that monitor and control process parameters and component and device characteristics during production of cranial helmets.
7. Failure to establish procedures that ensure Device History Records are maintained for each cranial helmet your firm manufactures.

The inspection revealed that your firm's cranial helmets are misbranded within the meaning of Section 502(t)(2) in that your firm failed to establish procedures as per 21 CFR Part 803, Medical Device Reporting (MDR). For example:

- Failure to develop, implement and maintain, written MDR procedures as required by 21 CFR 803.17.

The Act requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps 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 your firm submitted a premarket notification submission [510(k)] before your firm began offering cranial helmets for commercial distribution. This was confirmed during the inspection when the FDA investigator determined that your firm had not submitted such a premarket notification submission for these products, and was marketing and distributing cranial helmets as a finished device. Because your firm does not have marketing clearance from FDA, your distribution of these products is in violation of law. In legal terms, your product is adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. Your product is misbranded under the Act because you did not submit a 510(k) submission that shows your device is substantially equivalent to other devices that are legally marketed. Until your firm submits a 510(k) and receives notice from the Center for Devices and Radiological Health clearing the device for commercial distribution, the cranial helmet is also 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.

Note that there is no standard form for premarket notification submissions but the required information may be found in 21 CFR Part 807. The premarket submission should be sent to the following address:

Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center / HFZ-401
1390 Piccard Drive
Rockville, MD 20850

Our records indicate that your firm has not registered with the FDA and listed the devices you manufacture and distribute. The devices are also misbranded within the meaning of Section 502(o) of the Act in that they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 and were not included in a list required by Section 510(j).

Instructions on how and where to register establishments and list devices may be found in 21 CFR Part 807. You may obtain more information, including registration and listing forms, by contacting FDA's Division of Small Manufacturer's Assistance at 800-638-2041 or the Device Advice web site (<http://www.fda.gov/cdrh/devadvice/>).

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. The specific violations noted in this letter and in the Form FDA 483 issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine that your systems caused the 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. Additionally, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

We acknowledge the receipt of your firm's response, dated June 21, 2000, to our investigator's FDA-483. We do not consider your FDA-483 response to be adequate because it does not indicate when the drafted procedures, created in response to the FDA-483 observations, will be approved by responsible individuals and implemented. The procedures you submitted in your FDA-483 response lacked approval and implementation dates. Also, your response did not address your firm's registration and device listing deficiencies.

We request that you take prompt action to correct these deficiencies. Failure to promptly correct these deficiencies may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing, within 15 work days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and correct any underlying system problems that are 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 completed.

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Please send your response and any questions to Michael Lang, Compliance Officer, at 312-353-5863, ext.171.

Sincerely,

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Raymond V. Mlecko
District Director