



HFI-33
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

PS
d19646

Refer to: CFN 1122702

BALTIMORE DISTRICT OFFICE
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

May 8, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Charles C. Edwards, M.D., President
Scientific Spinal, Ltd.
410 Lombard Street, Suite 217
Baltimore, Maryland 21201

Dear Dr. Edwards:

A Food and Drug Administration (FDA) inspection conducted March 11 to April 7, 1998 at your Baltimore, Maryland facility determined that your firm is the manufacturer of the Edwards Modular Spinal System. This product is a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). This inspection followed a previous inspection at your Baltimore facility conducted June 13 to August 1, 1997 and an inspection of your contract manufacturer, [REDACTED], located in [REDACTED], conducted [REDACTED].

Our inspections 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 Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations, 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 The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997 by the Quality System Regulations. Since the records reviewed during the inspection were dated before and after June 1, 1997, the deficiencies noted were cross-referenced to the 1978 GMP and the CGMP requirements of the Quality System Regulations.

The deviations include the following:

1. Failure to maintain or follow procedures for, or to document adequately the receipt, review, evaluation, and investigation of complaints involving serious patient injuries which may have been the result of a device's failure to meet specifications.

Charles C. Edwards, M.D.
Page 2
May 8, 1998

2. Failure to establish and maintain a quality system that is appropriate for your device as follows:
 - A. Failure to establish and maintain purchasing controls or requirements that must be met by suppliers, as no valid contract or other documentation exists since 1994 to indicate that your contract manufacturer, [REDACTED] has been informed of requirements or evaluated to determine that they are capable of manufacturing product or performing services which would assure that product specifications are met.
 - B. Failure to maintain and document procedures for acceptance of in-process and finished devices, as no documentation exists to verify that all parts received from the contract manufacturer meet specifications.
 - C. Failure to control non-conforming product, in that products examined at your contract manufacturer and then at your facility failed to meet dimensional specifications, but were accepted for distribution.
 - D. Failure to control measurement equipment used in product acceptance and to ensure that it has been calibrated and is capable of producing valid results, in that measurement equipment used to accept at least 75 product lots from 1996 and 1997 had not been calibrated since 1995.

Additionally, CGMP violations were brought to your attention on an FDA-483, Inspectional Observations, presented to you on August 1, 1997. At that time, you told the investigator that you would correct the deficiencies in two to six weeks. During the current inspection, which occurred more than six months after this discussion, corrections had not been initiated.

You are also aware that the inspection at your contract manufacturer referenced above, found that CGMPs were not being followed to manufacture your product. A copy of the Warning Letter sent to your contract manufacturer is enclosed.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations. The specific violations noted in this letter and in the FDA-483 (enclosed) issued 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 the causes to be systems problems, you must promptly initiate permanent corrective action.

Charles C. Edwards, M.D.
Page 3
May 8, 1998

Federal agencies are advised of the issuance of all Warning Letters concerning devices so that they may consider this information when considering the award of contracts. Additionally, no pending applications for pre-market approval (PMAs) or export approval requests will be approved, and no pre-market notifications (Section 510(k)s) will be found substantially equivalent for products manufactured at the facility in which the above CGMP violations were found until such violations have been corrected.

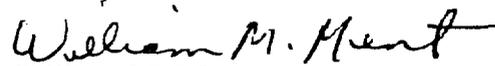
You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We acknowledge that you have submitted several responses to our investigator's observations noted on form FDA-483. We are continuing to evaluate your responses. From your correspondence and conversations with you and your representatives, Scientific Spinal is attempting to validate parts in stock and the procedures used to manufacture them retrospectively. Be aware that retrospective validation depends on accumulated historical production, testing, control, and other information. Incomplete information mitigates against conducting a successful retrospective validation. For example, your records do not include actual kiln gauge readings or start and finish times for mechanical stress relief or who performed various operations.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence and to comply with our request. 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.

Your reply should be sent to the Food and Drug Administration, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Thomas C. Knott, Compliance Officer. Mr. Knott can be reached at (410) 962-3461, extension 122.

Sincerely,


William M. Ment
Acting Director, Baltimore District

Enclosures