HFI-32

10/3/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

411

Refer to: CFN 1123871

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

September 8, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jerry Englert, Chairman
Winfield Medical
7737 Kenamar Court
San Diego, California 92121

Dear Mr. Englert:

A Food and Drug Administration (FDA) inspection conducted on August 11 and 12, 1997, at your Clarksburg, West Virginia facility determined that your firm manufactures sharps containers. Sharps containers are medical devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

Our inspection revealed that this device 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, manufacturing, packing, storage, or installation, are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to follow established procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. For example, the 1.7 quart Sharps-tainer, lot 401290, was found to fail the injection molding defect specification; however, the device was released for distribution on 7/23/97. [21 CFR 820.80(d)]

2. Failure to follow established procedures to control product that does not conform to specified requirements. For example, the Product Deviation Report was not completed as required by procedure number [redacted] for the product defect noted in the QC inspection reports of the 1.7 quart Sharps-tainer, lot 401290, after the device was found to fail the injection molding defect specification. [21 CFR 820.90]

3. Failure to document the corrective and preventive action of the investigation of the cause of a device to fail to conform to specified requirements for the product defect noted in Item 2 above. [21 CFR 820.100(b)]

4. Failure to validate the injection and blow molding process to produce puncture-resistant sharps containers according to established procedures. [21 CFR 820.75]

5. Failure to thoroughly review, evaluate, and maintain written complaints pertaining to the identity, quality, durability, reliability, safety, effectiveness, or performance of your devices. For example, records of complaint investigations, 97-001002, 97-002-02, and 97-027-02 of needle punctures through the wall of the device, failed to include the raw data for the wall thickness and needle penetration test results. [21 CFR 820.198]

6. Failure to establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution, and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. For example, no area has been established and identified for the storage of incoming materials that is clearly separated from the accepted device materials area. [21 CFR 820.150]

7. Failure to follow established procedures to ensure that the device history records are maintained to demonstrate that the device is manufactured in accordance with the device master record. For example, the device master record specifies that the part number is to be printed on the device product label; however, the part number was not printed on the device product label ("CODE 185T") for the 1.7 quart Sharps-tainer, lot 401319. [21 CFR 820.184]

At the completion of the inspection, Mr. John Cordeau, Operations Manager, was given a written list of deficiencies (Form FDA-483, enclosed) which was discussed with him.

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 FDA-483 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 the causes are determined to be systems problems, you must promptly initiate permanent corrective action.

Until it has been determined that corrections are adequate, 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 pending submissions for pre-market approval (PMAs) or export approval requests will be approved, and no pre-market notifications (Section 510(k)s) will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

You should take prompt action to correct these deviations, whether identified by our investigators or your internal systems audit. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

You should notify this office in writing, within 15 working 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 make corrections to any underlying systems problems 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.

Your response should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer.

Sincerely,

Elaine Knowles Cole
Director, Baltimore District

Enclosure

cc: Mr. John Cordeau, Operations Manager
Winfield Medical
10 Columbia Blvd.
Clarksburg, West Virginia 26301