



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

August 5, 2003

VIA FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. John J. Knight, Co-Owner
Enviropak LLC
1845 Darby Drive
Florence, AL 35630

Warning Letter No. 03-NSV-24

Dear Mr. Knight:

During an inspection of your establishment on June 25-26, 2003, our investigator determined that your establishment manufactures a Class II sterilization pouch device, which is a "device" as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated 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 (QSR) for medical devices, as specified in Title 21, *Code of Federal Regulations* (CFR), Part 820.

The inspection revealed no quality system procedures [21 CFR 820.20(e)], inadequate employee training [21 CFR 820.25(b)], no design control procedures [21 CFR 820.30(a)], no process control procedures [21 CFR 820.70(a)], no records of equipment calibration [21 CFR 820.72(b)(2)], no documentation of corrective and preventive action procedures [21 CFR 820.100(b)], inadequate device history records [21 CFR 820.184], and incomplete complaint files [21 CFR 820.198(a) and (f)].

The inspection also revealed that your Device Registration Form (FDA 2891A), mailed on June 10, 2002, lists C. David Stoddard (prior owner) as the owner and point of contact for your firm. You told our investigator during the inspection that you purchased the facility in 2001. Please update your registration information.

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 the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's Quality System.

You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA).

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 device have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct the deviations 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.

Please notify this office in writing within fifteen (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 system problems necessary to assure that similar violations will not occur.

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Carl E. Draper
Director, New Orleans District

CED:jeh

Enclosure:
21 CFR Part 820

cc: Barbara F. Knight, Co-Owner
Enviropak LLC
1845 Darby Drive
Florence, AL 35630