



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

November 17, 2000

SENT VIA FEDERAL EXPRESS

Mr. Rayburn Waldrop, President
Brant-Wald Surgicals, Inc.
368 E. Tennessee Avenue
Oak Ridge, TN 37830

Quayle
11/20/00
JEA

WARNING LETTER NO. 01-NSV-04

Dear Mr. Waldrop:

During an inspection of your establishment located at 368 East Tennessee Avenue, Oak Ridge, Tennessee, on October 18 and 25, 2000, our investigator determined that your firm manufactures Trans-urethra-resection aprons. Under the Federal Food, Drug, and Cosmetic Act (the Act) this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body.

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 Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulation as specified in Title 21, Code of Federal Regulations, Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Device Regulations were superceded on June 1, 1997, by the Quality System Regulation.

The inspection revealed deviations from Part 820 including discrepancies relating to validation of sterilization cycles and routine dose audit testing, incomplete Standard Operating Procedures, no formal management reviews and quality assurance audits of the firm's operations, and no records of acceptance of components or evaluation of suppliers and contractors.

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 conclusion 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 system problems, you must promptly initiate permanent corrective actions.

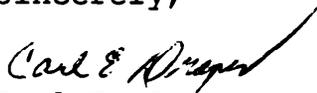
Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submission for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificate 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 these deviations may result in regulatory action being initiated by 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 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 recur. If corrective action cannot be taken 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 addressed 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/kl

Enclosure: 21 CFR Part 820