



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

*m4180n*

September 14, 2000

**CERTIFIED MAIL—RETURN RECEIPT REQUESTED**

*Quarant*  
*9/14/00*  
*SBH*

Mr. Murray Collette  
Owner/President  
Oak Rubber, Inc.  
4835 Darrow Road  
Stow, OH 44224-1431

**Warning Letter No. 00-NSV-27**

Dear Mr. Collette:

**During an inspection of Oak Tennessee, Inc., 208 Industrial Boulevard, Tullahoma, Tennessee, on July 11-26, 2000, our investigator determined that this firm manufactures medical examination gloves. 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, manufacture, packing, storage or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) regulations of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulations were superseded on June 1, 1997, by the Quality System Regulation.

The inspection revealed the following deviations from 21 CFR Part 820:

1. A failure to validate the manufacturing process and the computer system used to maintain the product inventory and shipping information;
2. A failure to calibrate the leak test;
3. A failure to include labeling specifications in the device master record;
4. Your Device History Record does not document what label was used during manufacturing and failed to bear the signature of a reviewing official prior to the release of product for distribution;
5. Your Standard Operating Procedures (SOPs) are incomplete.

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 premarket submission for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices 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 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 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:JEH:man

Enclosures:

FDA 483  
21 CFR Part 820

Cc: Mr. Daniel Marshall  
Plant Manager  
Oak Tennessee, Inc.  
208 Industrial Blvd.  
Tullahoma, TN 37388-4070