



June 3, 2003

VIA FEDERAL EXPRESS

Mr. James D. Wade  
Chief Executive Officer/President  
Lost Mountain Tissue Bank  
3175 Cherokee Street  
Kennesaw, GA 30144

**WARNING LETTER**  
**(03-ATL-21)**

Dear Mr. Wade:

During an inspection of your firm, located in Kennesaw, GA, conducted March 24 – April 1, 2003, our investigators documented significant deviations of the regulations for human tissue intended for transplantation, as set forth in Title 21, Code of Federal Regulations (21 CFR) Part 1270, promulgated under the authority of Section 361 of the Public Health Service Act. The investigators specifically noted the following violations:

1. Failure to prepare, validate, and follow written procedures for prevention of infectious disease contamination or cross-contamination by tissue during processing [21 CFR 1270.31(d)], in that:
  - a. Your firm does not have any documentation of validation of your firm's human tissue processing procedures, including but not limited to the following: [REDACTED], centrifugation, cleaning, sterilization, [REDACTED], and packaging.
  - b. Your firm routinely reworks tissue products in order to extend the expiration date without validated written procedures for the reworking of human tissue products.

We acknowledge receipt of your letter dated April 17, 2003, submitted to this office in response to the Inspectional Observations (Form FDA 483) issued at the close of the inspection, addressing the observations and stating the corrective actions either taken or to be taken. We note that you have committed to implementing corrective actions to address the observations. In your response to this letter, we request that you detail the corrective actions you have taken and provide complete documentation to demonstrate that the promised corrective actions are being appropriately implemented.

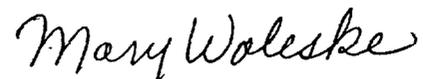
The identification of the above violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all tissue products produced and distributed by your firm are in compliance with Section 361 of the Public Health Service Act, and 21 CFR Part 1270. You are responsible for investigating and determining causes of the violations identified by the FDA. You should take prompt action to correct these violations. Failure to do so may result in additional regulatory action

without further notice. Such action may include, but is not limited to, an order for retention, recall and/or destruction.

We request that you 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 examples of any documentation showing that corrections have been achieved. If corrections cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to James C. MacLaughlin, Compliance Officer at the address noted in the letterhead.

Sincerely,



Mary H. Woleske, Director  
Atlanta District