



June 2, 2011

Thomas Galati
Laboratory Director
HistoScientific Research Laboratories
5930 Main Street
Mount Jackson, VA 22842

Dear Mr. Galati:

The purpose of this letter is to inform you that the Food and Drug Administration (FDA) inspection conducted at your nonclinical laboratory from April 28 to May 3, 2011 revealed no significant concerns. As a result, no response is necessary at this time.

The inspection was conducted by an investigator from FDA's Baltimore District Office and covered your activities and procedures related to the nonclinical study for GX1-6mm Focal Defect Implant entitled "GLP animal study to evaluate the safety of synthetic osteochondral plugs in the stifle joint of adult goats at 26 and 52 weeks." GX1-6mm Focal Defect Implant is a device as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

We appreciate the courtesy and cooperation extended to the FDA investigator during the inspection and subsequent closeout discussion. You may find information concerning the device Bioresearch Monitoring program at our Internet homepage. Valuable links to related information are also included at this site.

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/BioresearchMonitoring/default.htm> If you have any questions, do not hesitate to contact me at (301) 796-5633.

Sincerely yours,

Chrissy J. Cochran, PhD
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