

SCHOOL OF DENTISTRY

Louisiana State University

Medical Center

1100 Florida Avenue

New Orleans, LA 70119-2799

Telephone: (504) 619-8570

Department of Periodontics

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PAPS

Lillian J. Gill
Director
Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road
Rockville MD 20860

Dear Ms. Gill:

I have recently had the opportunity to read a warning letter, obtained through the FOI office, that you issued to Lares Research on July 30, 1999 regarding the use of their Nd:YAG laser for curettage (enclosed). In this letter you apparently make a distinction between laser curettage and laser sulcular debridement. If I may, I would like to ask you for clarification of your understanding of laser curettage vs. laser sulcular debridement. From the clinical perspective, these terms are synonymous, and are used as such in the clinical practice of dentistry. As you make a distinction between the two in this letter, clearing one but not the other, I presume that they are materially different in meaning to the FDA.

I would also like to mention that there exists significant concern among both clinicians and researchers that the application of pulsed Nd:YAG laser energy in the gingival sulcus presents a serious risk to the dental pulp. Here, I should emphasize that Nd:YAG laser-induced damage to the pulp may not be detectable by the standard pulpal tests we use in dentistry. This is because standard cold and electric pulp tests are relevant only when the intention is to detect hyperemic and hypersensitive pulpal tissue, not laser-damaged pulp tissue that typically has little to no inflammation and is also typically asymptomatic. In fact, histology is really the only way to determine pulpal status in the case of laser sulcular debridement. Animal models have histologically confirmed the existence of severe pulpal damage when the Nd:YAG laser is used at normal exposures near or on the surface of the tooth, similar to what occurs in laser sulcular debridement (study enclosed). If such damage were to occur in humans, it would be reasonable to expect a