

1212 R. CR-8 8124

12/6/99

Mr. Larry Spears
Food and Drug Administration
Office of Compliance
2094 Gaither Rd.
Rockville, MD 20850
Fax # (301) 594-4672

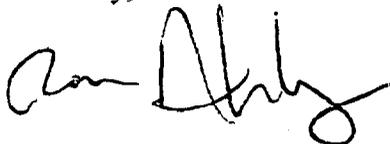
Dear Mr. Spears:

I am joining with other physicians who strongly support the FDA's efforts to increase regulation of reprocessors of single use medical devices.

I am a Gastroenterologist in Hawaii. I am concerned with the reuse of used disposable medical devices. In today's cost cutting environment, it is proper to look at all possible areas to save money. Reprocessing complex, plastic, single use devices such as biopsy forceps is simply not a safe avenue to pursue until these reprocessed devices receive FDA approval for reuse.

Reprocessors of single use devices claim to have the equipment and expertise necessary to "properly" reprocess used single use devices. They are, therefore, manufacturers in the eyes of healthcare workers and patients. In addition, reprocessing a single use device for reuse changes the device into a reusable device. Reprocessors should be regulated in the same manner as original equipment manufacturers using the existing FDA regulations for reusable devices.

Sincerely,



Ron Ah Loy M.D.

Ron Ah Loy, M.D.
Kona, Hawaii

99N4491

C 82