

ITL DENTAL

3456 '01 MAY -8 10:35

May 1, 2001

US Food and Drug Administration
Dockets Management Branch (HFA-305)
12420 Parklawn Dr., Rm. 1-23
Rockville, MD 20857

Re. Docket No. 96N-0383
Export Certificates

Gentlemen:

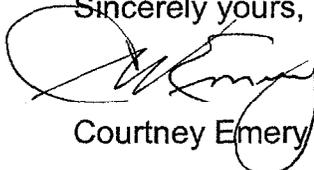
I appreciate the possibility of commenting on the newly imposed Certification Fees. This certification service provided by the FDA is appreciated. However, imposition of fees will act in restraint of trade and unfavorably effect the US balance of trade in one of the few areas where US firms have a dominant position and a positive trade balance.

Imposition of these fees will have especially negative effects on small manufacturers who are just beginning to enter the international area. The fee of \$100 does not appear large at first glance. However, many small firms, especially in the dental device area such as ourselves, often manufacture dozens of small, inexpensive devices. Sales abroad at first may be small and this fee, multiplied by the products sold will often negate any potential profits and hinder international development..

You asked for comments also on cost averaging across the centers. This certainly should be done! Profit margins on a few small devices and on a major drug may vary by many orders of magnitude. We believe some recognition of this fact was reflected in the \$100 fee proposed for devices and strongly encourage you to keep these differences in mind. We also urge you to consider the fact that any regulation has a very strong effect on the smallest entities involved. Larger firms may consider these fees another "cost of doing business." Smaller firms may find them an insurmountable obstacle to even entering the foreign market.

Your careful consideration will be appreciated.

Sincerely yours,



Courtney Emery

President

An Emery Enterprises Inc. Company

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2922 Daimler, # 101
Santa Ana, CA 92705, USA

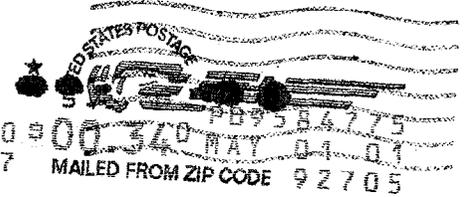
Tel: (949) 223-8950
(800) 277-0073

Fax: (949) 223-8960
E-mail: sales@itldental.com

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An Emery Enterprises Inc. Company
2922 Daimler Street, Suite 101 • Santa Ana, California 92705 • USA



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