



Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

June 22, 1998

Ref: 98-DAL-WL-#41

WARNING LETTER

VIA FEDERAL EXPRESS

William T. Evans
President & CEO
Professional Dental Technologies, Inc. (Pro-Dentec)
633 Lawrence Street
Batesville, Arkansas 72501
d/b/a/ Professional Dental Technologies Inc. Marketing
Professional Dental Technologies Inc. Printing
Professional Dental Technologies Inc. Manufacturing
Professional Dental Technologies Inc. Therapeutics

Dear Mr. Evans:

An inspection of your drug manufacturing operation, Professional Dental Technologies, Inc. Therapeutics, at 1217 Batesville Road, Batesville, Arkansas, was conducted April 21-23, 1997, by representatives from the Dallas District Office of the Food and Drug Administration.

This inspection revealed that you are marketing "Pro-Select³ 0.12% Chlorhexidine Gluconate Irrigation Solution" for subgingival irrigation.

The article chlorhexidine gluconate 0.12% labeled for subgingival irrigation is a drug within the meaning of Section 201(g) of the Federal Food, Drug, & Cosmetic Act (the Act) which may not be introduced into interstate commerce under Section 505(a) of the Act since it is a "new" drug within the meaning of Section 201(p) of the Act and no approval of an application filed pursuant to Section 505(b) or 505(j) is in effect for such new drug. Additionally, no Notice of Claimed Investigational Exemption under Section 505(i) of the Act is on file for such new drug.

The marketing of Pro-Select³ 0.12% Chlorhexidine Gluconate Irrigation Solution without an approved new drug application (NDA) or abbreviated new drug application (ANDA) constitutes a violation of Section 505(a) of the Act.

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This product is adulterated within the meaning of Section 501(a) of the Act, because its labeling is false and misleading as it suggests the product is safe and effective for its intended use when this has not been established.

The drug is misbranded within the meaning of Section 502(f)(1) of the Act, in that its labeling fails to bear adequate directions for the use for which it is being offered and it is not exempt from this requirement under Title 21 of the Code of Federal Regulations (CFR), Part 201.115, since it is an unapproved new drug.

Additionally, the drug is misbranded under Section 502(b) of the Act in that the label does not contain the place of business of the manufacturer, including the street address, city, state, and ZIP Code as required under 21 CFR Part 201.1.

The drug is further misbranded under Section 502(o) of the Act since the drug product has not been listed as required by Section 510(j) of the Act.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that all of your establishments are in compliance with all requirements of federal law and regulations.

We request that you reply within fifteen (15) days of your receipt of this letter stating what action you will take to discontinue the marketing of this unapproved new drug. Failure to promptly correct this product may result in further regulatory action without further notice. The Act provides for seizure of illegal products or injunction against the manufacturer or distributor of illegal products (21 U.S.C. 332 and 334).

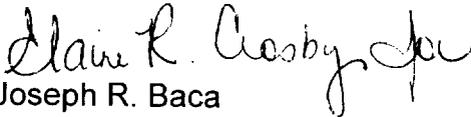
Your response to this letter should include:

- (1) An estimate of the amount of drug in inventory under your control and of the amount that remains in channels of distribution outside of your control.
- (2) Your intentions with respect to the disposition of your inventories and outstanding stocks in trade channels.
- (3) The date of discontinuance in the event that you have already discontinued marketing the drug product.

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Your response should be directed to: James R. Lahar, Compliance Officer, at the
above address.

Sincerely,


Joseph R. Baca
Director, Dallas District

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