

September 5, 2004

Lyle D. Jaffe
Division of Dockets Management
Food and Drug Administration
Room No. 1061
5630 Fishers Lane
Rockville, MD 20852

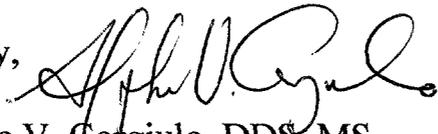
RE: Docket Number 1981M-0033/CP5, filed 07/15/04

Dear Lyle:

Per Elaine Abraham's request I am forwarding to your office materials for Ms. Abraham's examination. Materials include; 1) a written proposal for use of the oral topical anesthetic and 2) references supporting the CP. I could not download abstracts for all references, due to unavailability on PUBMED.

Thank you for your time and attention.

Cordially,



Alphonse V. Gargiulo, DDS, MS
Dyclo9, Inc.
411 Business Center Drive
Mount Prospect, Il. 60056
Email: alphygar@aol.com

1981M-0033-CP5

1981M-0033

SUP 8

Proposed Use of Dyclonine Hydrochloride

By Dyclo9, Inc,

The oral topical anesthetic rinse will be marketed for professional use. The indications for the topical anesthetic will be for:

- 1) periodontal recall maintenance cleaning
- 2) scaling and root planning
- 3) pre-anesthesia prior to local anesthetic injection
- 4) temporary relief of oral ulcerations or mucositis
- 5) control of the gag reflex

Dyclonine hydrochloride has been demonstrated to produce very effective local surface anesthesia to the oral mucosa, with onset of 1 to 2 minutes and a duration of anesthesia of 30 to 60 minutes. Generally, dyclonine hydrochloride has been characterized to show, 1) low levels of sensitization, 2) strong compatibility to other anesthetic agents, 3) a high margin of safety when absorbed and 5) a high level of stability. The topical agent is free of escharotic, caustic and astringent agents, and therefore classified as non-injurious to oral tissues.

Alphonse V. Gargiulo, DDS, MS
Dyclo9, Inc.
411 Business Center Drive, #111
Mount Prospect, IL. 60056
Email: alphygar@aol.com