

**RECORD OF TELEPHONE CONVERSATION**

**Date:** November 1, 2004  
**Project Manager:** Elaine Abraham *ea 11/26/04*  
**Subject:** Dyclonine 0.5 and 1.0 %  
**Company:** Dyclo9, Inc.  
**Docket #:** 1981N-0033

FDA participants: Fred Hyman, D.D.S., M.P.H., HFD-540  
Elaine Abraham, Project Manager, HFD-560

Dyclo9 participant: Dr. Alphonse Gargiulo

Background: Dyclo9, Inc. submitted a citizen's petition for the inclusion of dyclonine 0.5 – 1.0 % in the OTC monograph for the relief of oral discomfort (CP5 dated July 9, 2004). This petition was supplemented with references and proposed claims for marketing (SUP8 dated September 5, 2004).

Discussion: The Agency requested clarification on whether Dyclo9, Inc. is interested in marketing at the OTC or the prescription strength. Dr. Gargiulo explained that the company wants to market at the prescription strength for professional claims. FDA noted that there was an approved new drug application (NDA) for dyclonine at 0.5 and 1.0%. The NDA was withdrawn, not because of safety or efficacy concerns, but because of a lack of interest in continued marketing. Since dyclonine was the subject of an approved NDA, an abbreviated new drug application (ANDA) can be submitted to market dyclonine as long as the labeling is the same as the NDA product. Of the indications submitted in the supplement to the petition, two would be allowed through the ANDA process (temporary relief of oral ulcerations or mucositis and control of the gag reflex) as these were approved claims in the NDA. The other three claims proposed (periodontal recall maintenance cleaning, scaling and root planing, and pre-anesthesia prior to local anesthetic injection) would require submission of an NDA. The Agency has required similar products to submit NDAs for these three indications, as they are new indications. It was noted that blinded, randomized, placebo-controlled clinical trials would be necessary to demonstrate effectiveness for these claims. If Dyclo9 decides to submit an ANDA or NDA, dyclonine at 0.5 and 1.0 % would be a prescription drug.

Dr. Gargiulo asked for clarification about why the *Federal Register* notice that he sent with his package included language that dyclonine HCl had been switched from prescription to OTC status. Dr. Gargiulo also needed some guidance about how to proceed with an ANDA. A response on both of these questions will be forthcoming.

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Addendum:

After the meeting, Dr. Gargiulo was given an answer to his questions via E-mail:

The first question was about the notice in the *Federal Register* of April 27, 2000 (65 FR 24704), in which it was stated that a number of drugs have been switched from prescription to OTC status, including the oral anesthetic, dyclonine HCl. After doing a search through the FDA literature, Sucrets Maximum Strength (3 mg) lozenges were found to be available by prescription only prior to May 25, 1982. At that time, the monograph went into effect and allowed that strength of dyclonine HCl to be available OTC.

To assist in filing an ANDA, the names of some contacts within the Office of Generic Drugs and the Office phone number (301-827-5845) were provided.

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

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DATE: 11/26/04

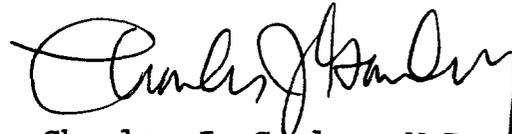
FROM: Director  
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 81-N-0033

TO: Dockets Management Branch, HFA-305

- The attached material should be placed on public display under the above referenced Docket No.
- This material should be cross-referenced to Comment No. CPS & SUP8

PDF Emailed on 11/26/04 to  
DMB

  
Charles J. Ganley, M.D.

Attachment