

RECORD OF TELEPHONE CONVERSATION

Date: October 18, 2004
Project Manager: Elaine Abraham *E. Abraham 11/4/04*
Subject: Dyclonine 0.5 – 1.0 %
Company: Dyclo9, Inc.
Docket #: 1981N-0033

FDA participant: Elaine Abraham, Project Manager

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 ingredient is listed as Category I at a concentration of 0.05 – 0.1 % in the proposed rule for OTC oral health care drug products published September 24, 1991. FDA requested that Dyclo9 submit copies of references, if readily available, and state which claims they would like to market the product for. This information was submitted to the Division of Dockets Management as SUP8 on September 5, 2004.

Discussion: Only professional use claims were submitted in SUP8. In order to be marketed under the oral health care monograph, a product would have to be labeled and marketed for OTC oral anesthetic use. If professional claims were allowed, these claims could be used in any discussions with health-care professionals. An NDA would be required for the professional use claims that Dyclo9 is pursuing. If Dyclo9 decides instead to make OTC monograph claims in its labeling, the safety and effectiveness must be demonstrated for dyclonine since the concentration proposed is greater than the currently marketed concentration permitted by the oral health care proposed rule.