Objective: The objective of this study was to evaluate the longitudinal effects of two experimental CPC (cetylpyridinium chloride) mouthrinses containing .075% and 0.10% CPC, respectively, on the development of gingivitis and plaque versus a placebo control. Methods: This was a double blind, 6-month, parallel group, placebo-controlled study involving 366 subjects who were balanced and randomly assigned to treatment groups. For study validation purposes, a 0.12% chlorhexidine rinse (Periex) served as the positive control. The CPC mouthrinses were formulated to pass proposed performance assays by the FDA for OTC CPC mouthrinses. At study start, subjects received a dental prophylaxis and began rinsing twice a day with 15 ml of their assigned mouthwash for 30 seconds after brushing their teeth under both supervised and unsupervised conditions. Subjects were assessed for gingivitis and gingival bleeding by the Gingival Index (GI) method and plaque by the Turesky Plaque Index (MQH) at baseline and after 3 and 6 months of product use. Oral soft tissue health was also assessed. Results: Results show that after 3 and 6 months subjects rinsing with either 0.075% or 0.100% CPC had significantly (p < 0.05, 2-tail) less gingivitis, gingival bleeding, and plaque than those on placebo. The 6 month reductions in GI, gingival bleeding, and plaque for the 0.075 and 0.10% CPC rinses versus placebo were 23%, 30%, and 27%, 19%, respectively. When evaluated by a 10-site gingival modification of the GI method, plaque by the Turesky method of Quigley and Hein Plaque (MQH) Index, and Oral Soft Tissue Health (OST) by a visual examination of the Oral Cavity. Eligible subjects had to have a minimum of 10 gradeable, uncrowned natural teeth with 4 molars, a whole mouth GI score of ≥ 0.50, and whole mouth MQH Plaque score of ≤ 3.0. A total of 366 subjects were accepted into the study. After evaluation at baseline, subjects were provided a dental prophylaxis and were randomly assigned and balanced to one of 4 rinse treatment groups: CPC placebo, 0.075% CPC, 0.10% CPC, or 0.12% chlorhexidine (CHX served as the positive control). Subjects were instructed to rinse with 15 ml of their assigned mouthrinse under both supervised (morning and unsupervised evening and weekends) conditions for 30 seconds twice daily for the next 6 months following brushing. The demographics and balance for the various treatments for subjects completing the study are shown below.

INTRODUCTION

The (OTC Plaque & Gingivitis) Subcommittee concludes that cetylpyridinium chloride (CPC) at concentrations of 0.045 to 0.1% with at least 72 to 77% chemically available CPC is safe and effective for use in mouthrinse formulations as an OTC anti-gingivitis/anti-plaque agent. “From “Advance notice of proposed rulemaking” Federal Register Vol. 68, No. 103/Thursday May 29, 2003/Proposed Rules, 32247.

PURPOSE

With this as background, the objective of this study was to evaluate the anti-gingivitis and anti-plaque efficacy of two properly formulated experimental CPC mouthrinses containing .075% and 0.10% CPC, respectively, over a 6 month period following a prophylaxis.