Summary of Recommendations

The following recommendations are made to clarify the Oral Care Division of CPPW's position on the Proposed Rule:

1. We recommend that the agency specifically support an open approach to new validated technologies and test modifications as recommended by the Subcommittee, acknowledge this support in preambles of the Tentative Final Monograph (TFM) and the Final Monograph (FM) and define a guidance mechanism for helping companies validate new technologies.

2. We recommend FDA maintain the approach to final formulation testing proposed in the ANPR, which is designed to help ensure the quality of generic products containing monograph OTC ingredients, since this quality assurance regulatory model has been used successfully for anticaries products and since the methods of the *in vitro* and *ex vivo* tests appear straightforward for inter-laboratory applications.

3. We support the use of USP reference standards for final formulation testing and clinical development of antigingivitis/antiplaque products and recommend that FDA coordinate with USP to establish antigingivitis/antiplaque reference standard formulations. We note that a similar approach was successfully implemented for fluoride dentifrice formulations as part of the finalization of the anticaries monograph and has proven itself as an effective means to ensure quality by final formulation testing of monograph ingredients.

4. We conclude that, to be consistent with the existing regulations including the recently promulgated material time and extent rule, the combinations proposed by the Subcommittee should not be permitted at this time in the OTC antigingivitis/ antiplaque rulemaking as proposed "Category I GRAS/E" combinations, since there is an absence of submitted data on "significant human experience during marketing" which is a criterion of the definition of safety under the OTC Review.

5. With respect to claims, we recommend that FDA should permit the use of any or all of the three verbs (i.e., control, reduces, prevents) in proposed Section 356.65(b)(1) for antigingivitis products and in proposed Section 356.65(b)(3) for antigingivitis/antiplaque products and antiplaque claims.

6. Also with respect to claims, we recommend that FDA should permit the use of the simple phrase "controls plaque" (or "reduces plaque" or "prevents plaque" -- or any combination of the verbs with the word "plaque) on those products required to make antigingivitis claims, since the totality of the labeling of such products clearly denotes the intended use of the product as a drug, thereby leaving no question as to the nature of its antiplaque activity.