



CONSUMER & PERSONAL PRODUCTS WORLDWIDE
Division of Johnson & Johnson Consumer Companies, Inc.

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November 25, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Oral Health Care Drug Products for Over-the-Counter Human Use;
Antigingivitis/Antiplaque Drug Products; Establishment of a
Monograph; Proposed Rules [68 F.R. 32231- 32287 (5/29/2003)]

To Whom It May concern:


These comments are submitted by the Oral Care Division of Johnson & Johnson Consumer & Personal Products Worldwide (CPPW) in response to FDA's promulgation of the Advanced Notice of Proposed Rulemaking (ANPR) on antigingivitis/antiplaque products.

The Oral Care Division of CPPW has been an active participant in industry activities surrounding the discussions of the Dental Plaque Subcommittee relating to development of the ANPR. While we support many of the joint industry task group's recommendations to the agency, there are several aspects of the Proposed Rule that CPPW wishes to emphasize and/or clarify from its own business and regulatory perspective. As noted by the joint task group in its comments on the Proposed Rule, the positions set forth by the task group are not intended to supersede separate comments that might be made by its individual members.


We offer commentary and recommendations in the following areas:

- I. Clarifying Comments Relating to Testing Methodology: Test Modifications, Test Framework for Ingredients, and USP Reference Standards
- II. Comments in Support of FDA's Position on OTC Combinations of Antigingivitis/Antiplaque Ingredients with other GRAS/E Oral Care Ingredients
- III. Clarifying Comments on Claims for Antigingivitis/Antiplaque Ingredients

Respectfully submitted by:



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cc: Robert L. Sherman (HFD-560)

Enclosure

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