



CONSUMER & PERSONAL PRODUCTS WORLDWIDE  
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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

**Re: Docket Number: 2005D-0240  
Comments on Draft Guidance for Industry: "Gingivitis: Development and  
Evaluation of Drugs for Treatment or Prevention"**

On behalf of Johnson and Johnson Consumer and Personal Products Worldwide, (CPPW), we are providing the following general and specific comments in response to the FDA's Draft Guidance "Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention", released for comment on June 28, 2005. As stated by the Agency, this guidance was developed to "to aid drug sponsors in conducting clinical trials either to submit additional information to the antigingivitis rulemaking, or to obtain approval for a new antigingivitis drug through the NDA process".

**General Comments**

Overall, we believe that the guidance appropriately defines the clinical design requirements/assessments for both treatment and prevention claims for gingivitis drug products. However CPPW would like to confirm that this guidance is solely for drug products. Hence, it does not apply to devices, or to drug/device combination products..

**Specific Comments**

CPPW believes and requests confirmation that for prevention claims subjects would have professional hygiene prior to initiation of the study. For treatment claims, no professional hygiene would be performed at the initiation of the study. Subjects should however follow through with normal scheduled visits during the course of the study.

2005D-0240

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## 1. Section V, C

### **Blinding, line 381**

CPPW recommends that the following should be inserted directly after the sentence... "In the case of a topical product, differences in packaging or discernable characteristics, such as appearance (including viscosity, color, and opacity), smell, taste, or texture, may compromise blinding."

*If double-blinded trial design is not possible, the trial design may be single-blinded with the clinical/dental examiner being blinded to the subject treatment assignment. Subjects living in the same household should be excluded from participation or if possible, assigned to the same treatment group.*

## 2. Section V, E

### **Standard of Care, line 402**

CPPW recommends that the first sentence should be revised to read... "During a chronic study (6 months or longer) *evaluating a drug product*, subjects should receive the standard of care for gingivitis."

## 3. Section VI

### **Inclusion and Exclusion Criteria, lines 449 -451.**

CPPW requests confirmation that if a product intended to be marketed OTC for patients with a lower level of gingivitis severity, it would be studied in a population with mild to moderate gingivitis.

### **Inclusion and Exclusion Criteria, lines 489 - 491**

CPPW believes that due to the possible confounding effect of pregnancy on gingivitis and safety considerations, the preference would be not to include pregnant females in the clinical study, at least until the safety of the drug has been well established.

### **Inclusion and Exclusion Criteria, line 511**

CPPW requests that the second sentence of this bullet be revised to be consistent with the American Heart Association guidelines. "This list includes"... *cardiac conditions in the high-risk or moderate-risk category for development of bacterial endocarditis requiring antibiotic prophylaxis based on the American Heart Association guidelines, such as, prosthetic heart valves, history of previous bacterial endocarditis, congenital heart disease, surgically constructed systemic pulmonary shunts, other congenital cardiac malformations, acquired valvar dysfunction (e.g. rheumatic heart disease), hypertrophic cardiomyopathy, and mitral valve prolapse with regurgitation.*

## **Summary**

CPPW appreciates the opportunity to provide input to the Agency on this important guidance. We believe this is a significant opportunity for the FDA to work together with industry stakeholders for the continued development of antigingivitis drug products

In closing, we would like to thank the Agency in advance for its thoughtful consideration of our comments/recommendations. If we can provide further assistance, please do not hesitate to contact me at 908-874-2394.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Diane D. McPherson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Diane D. McPherson  
Director, Regulatory Affairs  
Vision and Oral Health  
Consumer and Personal Products World Wide

cc:

Stephenie V. Barba, VP Regulatory Affairs  
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