



May 30, 2002

Charles Ganley, M.D., Director  
Division of Over-the-Counter Drug Products (HFD-560)  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research  
Food and Drug Administration  
9201 Corporate Boulevard, Building Two  
Rockville, MD 20850

Attention: Dockets Management Branch  
Food and Drug Administration  
12420 Parklawn Drive, Room 1-23  
Rockville, MD 20857

**Subject: Pre-meeting Materials for June 18, 2002 FDA Feedback Meeting**

**Docket No. 80N-0042**  
**“Anticaries Drug Products for Over-the-Counter Human Use;**  
**Final Monograph,” 60(194) *Federal Register* 52474-52510,**  
**October 6, 1995.**

**Docket No. 81N-0033**  
**“Over-the-Counter Dental and Oral Health Care Drug Products**  
**for Antiplaque Use; Safety and Efficacy Review,” 55(182)**  
***Federal Register* 38560-38562, September 19, 1990.**

Dear Dr. Ganley:

Thank you for the upcoming FDA feedback meeting on Tuesday, June 18, 2002.

**The purpose of the meeting is to:**

1. Review the executive summary of the Two-Week Intraoral Caries Test (ICT) Model Study and the executive summary of the Two-Week No Oral Hygiene Model Study along with the Proposed Protocol for Six-Month Gingivitis Study in order to confirm these studies will be sufficient to support approval of a Citizen's Petition to amend the Anticaries Drug Products for the Over-the-Counter Human Use Final Rule.
2. For the review and confirmation by FDA that the proposed treatment cells in the Proposed Protocol for Six-Month Gingivitis Study are acceptable to FDA.

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3. For the review and confirmation that the proposed statistical criteria in the Proposed Protocol for Six -Month Gingivitis Study is acceptable to FDA.
4. To receive comments from FDA on the proposed monograph changes.

**The following pre-meeting information is attached:**

Agenda

Executive Summary of Two-Week Intraoral Caries Test (ICT) Model (Study No. 936-9213)

Executive Summary of Two-Week No Oral Hygiene Model (Study No. 931-1151)

Proposed Protocol for Six-Month Gingivitis Study

Proposed Monograph Changes

**Meeting Participants**

Participants representing Pfizer Consumer Healthcare will include:

Michael Barnett, D.D.S, Consultant

Thierry Bilbault, Ph.D., Director, Product Development

D. Scott Harper, Ph.D., Section Director, Oral Care Technology Development

Robert Kohler, Regulatory Consultant

Lori Kumar, Ph.D., Senior Director, Clinical & Product Development-Oral Care R&D

Dawn M. Parkin, Manager, Regulatory Affairs

Mei-Miau Wu, Ph.D., Manager, Statistics

We look forward to a productive meeting and agreement of the outstanding items.

If you have any questions or would like any additional information in advance of the meeting, please contact Robert Kohler at (973) 385-5419.

Sincerely,



Robert Kohler

Regulatory Consultant

Attachments

Desk copies (12) to Elaine Abraham, Project Manager  
OTC Division-FDA

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**AGENDA**  
**FDA Feedback Meeting**  
**June 18, 2002**

**We propose the following agenda:**

**Introduction**

**Robert Kohler**

**Presentation of Results of two (2) Two-Week  
Clinical Trials**

**Lori Kumar, Ph.D.**

**Presentation of Proposed Six-Month  
Clinical Study Protocol**

**Lori Kumar, Ph.D.**

**Discussion of Proposed Monograph Changes**

**D. Scott Harper, Ph.D.**

**Discussion and Conclusion**

**All**