



June 27, 2002

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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 Upcoming 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.

Please note this briefing document has been amended since it was last submitted on May 30, 2002. The following changes were made:

- a) In Attachment 2, page 5: A paragraph summarizing the ‘at least as good as’ results was added.
- b) In Attachment 3: In the proposed Six-month Gingivitis Protocol, the sample size was increased and the confidentiality statement was removed.

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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.
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

Questions for Discussion

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

Michael Lynch, D.M.D., Ph.D., Director, Clinical Research-Oral Care

Dawn M. Parkin, Manager, Regulatory Affairs

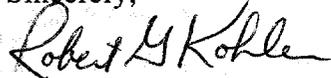
Mei-Miau Wu, Ph.D., Manager, Statistics

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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

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