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**WARNER  
LAMBERT**

May 15, 2000

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  
Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

**Subject: Pre-meeting Materials for June 6, 2000 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 granting the upcoming feedback meeting on Tuesday, June 6, 2000.

The purpose of the meeting is to reach final agreement on the studies to support a Citizen Petition to amend the final rule for anticaries drug products for over-the-counter human use.<sup>1</sup>

<sup>1</sup> "Anticaries Drug Products for Over-the-Counter Human Use," 21 CFR § 355.

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We thank the Agency for the previous meetings on October 8 and December 3, 1999 and the teleconference on March 20, 2000.

This pre-meeting submission presents comprehensive responses to the Agency's comments from the March 20, 2000 teleconference, as stated in the Agency's teleconference minutes. This information includes protocols for the multiple studies we plan to address all outstanding Agency comments.

We would like to advise the Agency that we have changed the test product. This change was based on consumer taste preference.

A table presenting the current and previous test products and corresponding positive controls (monograph products) is presented below for convenience in review.

	<b>Current Test Product</b>	<b>Current Monograph Product<sup>2</sup></b>	<b>Previous Test Product</b>	<b>Previous Monograph Product<sup>3</sup></b>
<b>Fluoride source</b>	0.02% sodium fluoride	0.02% sodium fluoride	Acidulated phosphate fluoride, 0.01% fluoride ion	Acidulated phosphate fluoride, 0.01% fluoride ion
<b>pH</b>	4.2	Approximately pH 7	4.2	3.5
<b>Dosing Regimen</b>	20 mL, 30 sec., BID	10 mL, 60 sec., BID	20 mL, 30 sec., BID	10 mL, 60 sec., BID

Therefore, we continue to solely request a change in pH and dosing regimen for an anticaries treatment rinse.

Agenda

We propose the following agenda for the meeting:

- Introduction
- Reply to Agency Comments and Planned Studies
- Statistical Considerations
- Conclusion and Discussion

Paul Okarma, Ph.D.  
Scott Harper, Ph.D., and  
Dominick Zero, D.D.S.  
J. Tony McGuire  
All

<sup>2</sup> 21 CFR § 355.10(a)(3)(iii) and § 355.50(d)(2)(ii).

<sup>3</sup> 21 CFR § 355.10(a)(3)(ii) and § 355.50(d)(2)(ii).

Meeting Participants

Participants representing Warner-Lambert Company at the meeting will include:

Michael Barnett, D.D.S., Senior Director, Dental Affairs/Technology Development;

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

Lori Kumar, Ph.D., Director, Research and Development, Oral Care;

J. Tony McGuire, Senior Manager, Statistics and Data Management;

Paul Okarma, Ph.D., Director, Regulatory Affairs;

Duncan Yu, Ph.D., Research Associate, Research and Development, Oral Care;

Jane Zhang, Ph.D., Scientist, Oral Technology;

Howard Rubin, Consultant; and

Dominick Zero, D.D.S., Director, Oral Health Research Institute, Indiana University School of Dentistry.

We look forward to a productive meeting leading to final agreement on the studies to support the planned Citizens Petition to amend the anticaries final rule.

If you have any questions or would like any additional information in advance of the meeting, please contact Paul Okarma, Ph.D., Director, Regulatory Affairs. His direct-dial telephone number is (973) 385-5031.

Respectfully,



Judith M. Sills, Pharm.D.  
Senior Director  
U.S. Regulatory Affairs  
and Global Product Safety

JMS:pjo

**Attachments**

Desk copies (15) to  
Ms. Linda Roberts, HFD-560

05/12/00; 2:52 PM

## Appendices

- Appendix 1** Responses To Agency Questions And Technical Summary
- Appendix 2** Clinical Protocol #936-9213: Determination of the Anticaries Efficacy of a Fluoride Mouthrinse Using an Intraoral Caries Test
- Appendix 3** Clinical Protocol #936-9201: Comparison of Two Dosing Regimens of a Fluoride Mouthrinse Using Salivary Fluoride Clearance
- Appendix 4** Research Protocol #936-9212: Determination Of The Effect Of The Listerine® Essential Oils On The Anticaries Activity Of A Fluoride Mouthrinse Using A Rat Caries Model
- Appendix 5** Clinical Protocol #931-1309: Determination of Comparative Antiplaque/ Antigingivitis Efficacy of Essential Oil-Containing Mouthrinses Using an Experimental Gingivitis Model
- Appendix 6** Research Protocol #936-9216: Bactericidal Efficacy of Essential Oil-Containing Mouthrinses Against Oral Microorganisms *in vitro*