

**DIVISION OF OTC DRUG PRODUCTS
CENTER FOR DRUG EVALUATION AND RESEARCH**

ANNOUNCEMENT OF OTC DRUG FEEDBACK MEETING

BETWEEN: **Representatives of FDA**

and

Consumer Healthcare Products Association

Douglas Ws. Bierer, Ph.D., Vice President, Regulatory and Scientific Affairs

Del Pharmaceuticals, Inc.

Charles J. Hinkraty, President

Serap Ozelkan, Ph.D., Director, Pharmaceutical Research

Patricia Suita-Cruce, Ph.D., Vice Pres. Pharmaceuticals, Research & Development

Randy M. Sloan, Senior Vice President, Marketing

**William O. Thompson, Ph.D., Professor and Director Emeritus of Biostatistics,
Medical College of Georgia**

William E. Cooley, Ph.D., President, Cooley Consulting, Inc.

Wyeth Consumer Healthcare

Stephen A. Cooper, D.M.D., Ph.D., Sr. V.P., Global Clinical and Medical Affairs

Margaret S. Hughes, Ph.D., Associate Director, Regulatory Affairs

M. Sudam Pathirana, Ph.D., Clinical Research Scientist

Alan H. Stokes, Ph.D., D.A.B.T., Senior Manager, Regulatory Affairs

Joel Waksman, Ph.D., Assistant Vice President, Biostatistics and Data Management

TOPIC: **Proposed labeling and clinical data on benzocaine in toothache relief**

DATE: **June 28, 2004**

TIME: **1:30 p.m.**

LOCATION: **Corporate 2 – Conference Room S 400
9201 Corporate Boulevard
Rockville, Maryland**

Pursuant to the agency's policy statement published in the **FEDERAL REGISTER** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050) and February 4, 1985 (50 FR 4916), which includes provisions for agency meetings with industry or other interested persons; this feedback meeting is being announced.

All feedback meetings are open to the public and no prior reservation is necessary. For further information or to reconfirm that the meeting has not been rescheduled or canceled, call Elaine Abraham, 301-827-2222.

ATTENTION: JENNIE BUTLER

cc: Docket No. 80N-0295

DATE FORWARDED: 6/21/04

1980 N-0295

MM 130

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: June 21, 2004

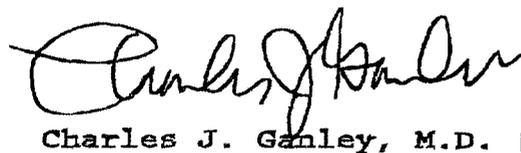
FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 80N-0295

TO: Dockets Management Branch, HFA-305

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. _____


Charles J. Ganley, M.D.

Attachment