DRAFT
MINUTES

FOOD AND DRUG ADMINISTRATION
BUREAU OF DRUGS

Dental Drug Products Advisory Committee
Tenth Meeting

Conference Room "I"
Parklawn Building
Rockville, Maryland

January 22, 1975

Committee Members Present:

Robert B. Shire, D.D.S., Chairman
Priscilla C. Bourgault, Ph.D.
Harold A. Loe, D.D.S.
Jeanne Luck, Ph.D.
Ernest Newbrun, D.M.D., Ph.D.
Gordon H. Schrotenboer, Ph.D.
James W. Smudski, D.D.S., Ph.D.
Esther M. Wilkins, D.M.D.
Clarence C. Gilkes, D.D.S., Executive Secretary

Committee Member Absent:

Herschel Horowitz, D.D.S., M.P.H.

Consultants Present:

Basil Bibby, D.D.S.
James Carlos, D.D.S.

Guests:

Mr. Moses, Hoyt Laboratories
Mr. Robert H. Mercer, Vice President, L.D.Caulk Co.
Ms. Molly McKetterick, Reporter from "The Pink Sheet"

FDA Staff Members Participating:

Division of Surgical-Dental Drug Products:
Joseph M. Renna, D.D.S.
George W. Wade, D.D.S.
Mr. Charles Monroe
Mr. Gary Boyer
Robert O'Neill, Ph.D., Division of Biometrics

APPENDIX I

The Dental Drug Products Advisory Committee unanimously decided to make the following recommendation on fluoride supplements for publication in the FEDERAL REGISTER:

Dietary supplements of sodium fluoride or acidulated phosphate fluoride in the form of tablets, lozenges or drops, which provide an appropriate fluoride concentration, are safe and effective for the reduction of the incidence of dental caries in areas where the fluoride content of the drinking water is inadequate. Other substances such as coloring and flavoring agents may be added if they do not alter the safety and effectiveness of the product.

The following dosage schedule is recommended for areas where the fluoride concentration in the drinking water is less than 0.3 parts per million (ppm):

Under two years of age:	add 1.0 mg of fluoride to each quart of water used for drinking and preparing food or formula, or administer 0.25 mg to 0.3 mg of fluoride daily;
Between two and three years of age:	administer 0.5 mg daily;
Three years of age and older:	administer 1.0 mg of fluoride daily.

Where the fluoride level of the drinking water is 0.3 ppm to 0.7 ppm inclusively, appropriate downward adjustments to the above schedule should be made. No fluoride supplements are recommended if the fluoride content of the water exceeds 0.7 ppm.

Since there is a direct benefit from the topical action of dietary fluoride supplements, users are advised to chew and/or dissolve the supplement. All supplements should be swished around the teeth for at least one minute before swallowing.

No more than 120 mg of available fluoride should be dispensed at any one time. Each container must be labeled "Caution - Keep out of Reach of Children". The supplement must be dispensed in child proof containers.

Present data do not support claims of benefit to the offspring of pregnant women who consume dietary fluoride supplements. Therefore, these products must not be labeled, represented, or advertised to indicate such benefits. (See C.F.R. Title 21 Section 3.53 "Oral prenatal drugs containing fluorides intended for human use").

The regular use of vitamin-fluoride supplements will reduce the incidence of dental caries; however, there is no evidence that the effect of fluoride is enhanced by combination with vitamins. Therefore, there is no satisfactory rationale for the use of these combinations for reducing the incidence of dental caries.

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