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The Subcommittee has thoroughly reviewed the literature and data

submissions, listened to additional testimony from interested persons, and considered all pertinent data and information submitted through December 3, 1998, in arriving at its conclusions and recommendations. The Subcommittee wishes to thank the American Dental Association's (ADA) Council on Scientific Affairs for its assistance in providing data, information, and testimony during the course of the Subcommittee's deliberations. The ADA also provided its "Guidelines for Acceptance of Chemotherapeutic Products for the Control of Supragingival Plaque and Gingivitis" to the Subcommittee for consideration in making its recommendations on the requirements for safe and effective OTC antigingivitis/antiplaque ingredients.

In accordance with the OTC drug review regulations in § 330.10, the Subcommittee reviewed OTC drug products for the reduction or prevention of dental plaque and gingivitis with respect to the following three categories:

Category I—Conditions under which OTC drugs for the reduction or

prevention of dental plaque and gingivitis are generally recognized as safe and effective and are not misbranded.

Category II—Conditions under which OTC drugs for the reduction or prevention of dental plaque and gingivitis are not generally recognized as safe and effective or are misbranded.

Category III—Conditions for which the available data are insufficient to permit final classification at this time.

I. Submission of Data and Information

Under the notices published in the **Federal Register** of September 19, 1990 (55 FR 38650), and March 8, 1991 (56 FR 9915), the following firms made submissions regarding OTC drug products that the Panel/Subcommittee determined contained active ingredients or labeling associated with claims relating to the reduction or prevention of dental plaque and gingivitis.

A. Submissions by Firms

TABLE 1.—FIRMS AND SUBMITTED PRODUCTS

Firm	Submitted Products
American Xylofin (Morgan, Lewis & Bockius) Washington, DC 20036	Xylitol All Natural Toothpaste, Xytol 32 Dental Cream.
Amer Co., Montecito, CA 93150	Insadol Toothpaste, Pyoralene Toothpaste.
Angus Chemical Co., Northbrook, IL 60062	Hexetidine solution.
Chesebrough Pond's USA Co., Greenwich, CT 06836	CloseUp Antiplaque Toothpaste, Mentadent P Toothpaste.
Church & Dwight Co., Inc., Princeton, NJ 08543	Arm & Hammer Dental Tooth Powder, Dentifrice, and Gel.
CIBA-GEIGY Corp., Greensboro, NC 27419	Irgasan DP, Irgacare MP.
Clinical Product Research, Inc., Shreveport, LA 71109	Prozyme Toothpaste, Anti-Plaquer Oral Rinse, Anti-Plaquer Toothpaste.
Colgate-Palmolive Co., Piscataway, NJ 08855	Colgate Tartar Control Toothpaste, Gelkam Oral Care Rinse, Dentaguard Toothpaste.
E. Merck, Frankfurter, Germany	Thera-Med, Cholorodont M.
E. B. Michaels Research Associates, Inc., Milford, CT 06460	Therasol Brush & Rinse Antiplaque Oral Hygiene Solution, Therasol Brush & Rinse Liquid Dentifrice Oral Irrigant.
Leaf, Inc., (Hyman, Phelps & McNamara) Washington DC 20005	Xylitol.
Lion Corp. (America), Memphis, TN 38138	Check-Up Gingival Toothpaste.
Madaus Medtech, Inc., (ACC Consulting Group, Inc.) Washington DC 20036	Parodontax Toothpaste.
Pfizer Inc, New York, NY 10017	Plax Pre-Brushing Dental Rinse.
Pierre Fabre, S.A., 81106 Castres Cedex, France	Eligydium Toothpaste, Eludil Mouthwash.
Prevention Laboratories (formerly 7-L Corp.), Harrisburg, IL 62947	Prevention Mouth Rinse.
Procter & Gamble Co., Cincinnati, OH 45242	Crest Gum Care Toothpaste.