

TABLE 1.—FIRMS AND SUBMITTED PRODUCTS—Continued

Firm	Submitted Products
SmithKline Beecham Consumer Brands (Marion Merrell Dow, Inc.), Parsippany, NJ 07054	Cepacol Gold and Mint Mouthwashes, Gly-oxide Liquid.
Vipont Pharmaceuticals, Fort Collins, CO 80522	Viadent Toothpaste and Oral Rinses.
Warner-Lambert Co., Morris Plains, NJ 07950	Listerine Antiseptic Mouthwash.
WhiteHill Oral Technologies, Inc., Hazlet, NJ 07730	Omni-Med Brush-On Tooth Medication, Perio-Med Spray, Take-5 Plaque Fighter Brushless Dentifrice, Smokers Take-5 Plaque and Stain Fighter.
Witkins, Roy T., Westport, CT 06880	Perimed Oral Hygiene Rinse.

In categorizing ingredients as “active” and “inactive,” the advisory review panels relied upon their expertise and understanding of these terms. FDA has defined “active ingredient” in its current good manufacturing practice regulations in § 210.3(b)(7) (21 CFR 210.3(b)(7)) as:

[Any] component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

An “inactive ingredient” is defined in § 210.3(b)(8) as “any component other than an active ingredient.”

B. Active Ingredients Submitted For Review

Labeled Ingredients Contained in Marketed Products Submitted to the Subcommittee:

Alkyl dimethyl amine oxide
Alkyl dimethyl glycine
Aloe vera
Bromchlorophene
Carbamide peroxide
Cetylpyridinium chloride
Chlorhexidine digluconate
Dicalcium phosphate dihydrate
Eucalyptol
Hexetidine
Hydrogen peroxide
Menthol
Methyl salicylate
Peppermint oil
Polydimethylsiloxane
Poloxamer
Povidone iodine
Sage oil
Sanguinaria extract
Sodium bicarbonate
Sodium citrate
Sodium lauryl sulfate
Soluble pyrophosphate
Stannous fluoride

Stannous pyrophosphate
Thymol
Triclosan
Unsaponifiable fraction of corn oil
Xylitol
Zinc chloride
Zinc citrate
Some of these ingredients (bromchlorophene, chlorhexidine digluconate, hexetidine, soluble pyrophosphate, triclosan, unsaponifiable fraction of corn oil) were not marketed for a material time and to a material extent for antigingivitis/antiplaque use in the United States. (See 21 U.S.C. 321(p)(2).) Although the Subcommittee reviewed data to support the safety and effectiveness of these ingredients, they are not eligible for inclusion in the OTC drug review as part of this advance notice of proposed rulemaking and, therefore, are not discussed in this document. In addition, although xylitol was reviewed by the Subcommittee, the two firms that submitted data subsequently withdrew xylitol from consideration by the Subcommittee. Therefore, xylitol is not discussed.

The nomenclature used by the Subcommittee for the ingredients reviewed in this document was the currently accepted terminology stated in the 1996 edition of “USAN and the USP Dictionary of Drug Names.” Names recommended by FDA were used for any ingredients which did not have USAN names.

C. Referenced OTC Volumes

All “OTC Volumes” cited throughout this document refer to submissions made by interested persons under the call-for-data notices published in the **Federal Register** of September 19, 1990, and March 8, 1991. The information included in these volumes, except for those deletions made in accordance with the confidentiality provisions in § 330.10(a)(2), will be put on public display after June 30, 2003, in the

Dockets Management Branch (see **ADDRESSES**).

II. General Statements and Recommendations

A. Definitions

The Subcommittee adopted the following definitions as its intended meaning of terms specifically used in this document concerning OTC drug products for the reduction or prevention of dental plaque and gingivitis. The Subcommittee was aware that some degree of variation with other definitions of the same term may exist.

- **Calculus.** The hard concretions (*i.e.*, calcified plaque) that form on teeth, prostheses, and other hard surfaces. Calculus on teeth is clinically classified into supragingival calculus, which is located on surfaces not covered by the oral mucosa, and subgingival calculus, which is located apical (at the top) to the soft tissue margin of the gingiva.

- **Dental Plaque.** Organized coherent gel-like or mucoid masses consisting of microorganisms in an organic matrix derived from saliva and extracellular bacterial products such as glucans, fructans, enzymes, toxins, and acids. Plaque also contains other cells (*e.g.*, desquamated epithelial cells) and inorganic components such as calcium and phosphate. It adheres to the teeth and other surfaces of the oral cavity. It occurs at the orifice of the gingival crevices and in the periodontal pockets. Plaques may differ markedly in biochemical or microbial composition, and their localization.

- **Gingival Sulcus.** The shallow groove between the tooth and the marginal gingiva.

- **Gingivitis.** An inflammatory lesion of the gingiva that is most frequently caused by dental plaque. Gingivitis is characterized by tissue swelling and redness, loss of stippling (a normal state in which the surface of healthy gingiva is comprised of small lobes), glossy surface, and increased tissue