

potential signs and symptoms of disease.

Therefore, the Subcommittee proposes that any reference to the control of dental plaque or its equivalents, with or without qualifications, should be interpreted as a drug claim. In addition, the Subcommittee proposes that an OTC drug product making any reference to the reduction or prevention of dental plaque also must demonstrate a clinically significant effect on gingivitis. Thus, antiplaque claims should not stand alone.

2. Tartar Products

The Subcommittee proposes that any reference to supragingival tartar (calculus) be interpreted as a cosmetic claim. The Subcommittee did not make any reference to subgingival tartar.

D. Labeling of Antigingivitis/Antiplaque Drug Products

Having reviewed the submitted labels of antigingivitis/antiplaque drug products, the Subcommittee recommends that labeling include the following:

1. Ingredients

Antigingivitis/antiplaque agents should contain only active ingredients plus such inactive ingredients as may be necessary for formulation. The label should state the name and quantity of each active ingredient in appropriate units as specified later in this document.

For various reasons, including allergic reactions, safety concerns, and personal preference, individuals may wish to avoid using certain inactive ingredients. It is impossible to make a free choice in this regard unless all the components of drug products are listed on the labels. Therefore, the Subcommittee strongly recommends that all inactive ingredients be listed on the label in descending order of quantity. However, the product should not imply or claim that its inactive ingredients have a therapeutic benefit. The Subcommittee recognizes that although full disclosure of flavoring and coloring ingredients is desirable, this may be impractical and confusing because of the large number of ingredients that may be involved. Thus, flavoring and coloring ingredients may be listed in accordance with present regulations for labeling such ingredients in cosmetic products (21 CFR 701.3).

2. Statement of Identity

The labeling must indicate the principal intended action of the active ingredient as well as the indication for

use of the product. The Subcommittee recommends that the statement of identity for active ingredients that demonstrate an antigingivitis effect should be "antigingivitis." The recommended statement of identity for active ingredients that also demonstrate an antiplaque effect should be "antigingivitis/antiplaque."

3. Indications

The indications for antigingivitis/antiplaque drug products should be simply and clearly stated, inform the user of the general pharmacological action of the product, and provide a reasonable expectation of results to be anticipated from use of the product. The indications should be specific and confined to the conditions for which the product is recommended. The labeling for any product that contains an active ingredient for which no claim is made would be misleading.

a. *For all antigingivitis products.* The Subcommittee's recommended indication for OTC drug products containing antigingivitis active ingredients is: "helps (select one of the following: 'control,' 'reduce,' or 'prevent') (select one or more of the following: 'gingivitis,' 'gingivitis, an early form of gum disease,' or 'bleeding gums')."

b. *For antigingivitis products containing stannous fluoride.* The Subcommittee's recommended indication for OTC antigingivitis drug products containing stannous fluoride is the statement in paragraph a. above and/or the following: "helps interfere with harmful effects of plaque associated with gingivitis."

c. *For all antigingivitis/antiplaque products.* The Subcommittee's recommended indication for OTC drug products containing antigingivitis/antiplaque active ingredients is: "helps (select one of the following: 'control,' 'reduce,' 'prevent,' or 'remove') plaque that leads to (select one or more of the following: 'gingivitis,' 'gingivitis, an early form of gum disease,' or 'bleeding gums')."

d. *For antigingivitis/antiplaque products containing the fixed combination of eucalyptol, menthol, methyl salicylate, and thymol.* The Subcommittee's recommended indication for OTC drug products containing the fixed combination of eucalyptol, menthol, methyl salicylate, and thymol is the statement in paragraph c. above and/or the following: "helps (select one of the following: 'control,' 'inhibit,' or 'kill') plaque bacteria that contribute to the development of (select one or more of the following: 'gingivitis,' 'gingivitis, an

early form of gum disease,' or 'bleeding gums')."

4. Directions for Use

The directions for use should be clear, direct, and provide sufficient information to permit safe and effective use of the product. The product labeling should include a clear statement of the smallest usually effective dose and, where applicable, maximum doses (or concentration if more appropriate) per time interval. If dosage varies by age, the directions should be broken down by age groups. The Subcommittee used directions from the supportive clinical trials as the basis for its recommended directions for use.

a. *For antigingivitis or antigingivitis/antiplaque dentifrice products.* The directions for use for antigingivitis or antigingivitis/antiplaque dentifrice drug products should be consistent with the directions required in the final monograph for OTC anticaries drug products in 21 CFR 355.50(d)(1).

b. *For antigingivitis/antiplaque oral rinse products.* "Adults and children 12 years of age and older: Vigorously swish 20 milliliters of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse. Children 6 years to under 12 years of age: supervise use. Children under 6 years of age: do not use."

5. Warnings

Labeling of antigingivitis and antigingivitis/antiplaque products should include warnings against unsafe use, side effects, and adverse reactions.

a. *For all antigingivitis and antigingivitis/antiplaque products.* "If more than used for brushing (rinsing) is accidentally swallowed, get medical help or contact a Poison Control Center right away. If gingivitis, bleeding, or redness persists for more than 2 weeks, see your dentist. See your dentist immediately if you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease."

b. *For antigingivitis products containing stannous fluoride.* "Keep out of the reach of children under age 6."

6. Additional Labeling Statements

For stannous fluoride dentifrice drug products. In addition to warning statements, the following statements should appear on the label of antigingivitis dentifrice drug products containing stannous fluoride: "This product may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not