

periodontitis (Ref. 2). It is not clear whether this prevention was due to reduction of supragingival plaque associated with gingivitis, or to meticulous oral hygiene, which also prevents colonization of the subgingival area by periodontal pathogens that are responsible for the onset of periodontitis. What is clear, however, is that in most instances meticulous plaque control appears to lead to reduction of gingivitis and suppression of the onset or rate of progression of periodontitis. Despite periodontal treatment, loss of periodontal attachment and loss of bone often persists. Moreover, people treated for periodontitis may suffer from recurrent gingivitis, root sensitivity, and increased susceptibility to root caries. Periodontitis appears to progress in alternating cycles of exacerbation, which are often asymptomatic and localized, followed by periods of remission. Population studies indicate that systemic conditions such as diabetes mellitus and neutrophil disorders, as well as smoking, increase the risk for developing periodontitis (Refs. 3 and 4).

Histologically, the gingiva becomes inflamed, and the sulcus is deepened to form a pocket which is lined with a pathologically altered epithelial lining, the pocket epithelium. The junctional epithelium is displaced apically. The pocket is largely filled with a subgingival microbiota that is in contact with the adjacent denuded root surface or adherent subgingival calculus deposits. The alveolar process (portion of the upper and lower jaws that forms and supports the tooth sockets) shows evidence of destruction in a "horizontal" or "vertical" pattern with concomitant loss of the connective tissue attachment to the root.

There are several variants of the disease, including adult periodontitis, early-onset periodontitis (which includes localized juvenile), periodontitis associated with systemic diseases, necrotizing ulcerative periodontitis, and refractory and recurrent periodontitis. Of these, adult periodontitis is the most common form of the disease, and it responds most predictably to scaling, root planing, and plaque control.

## 7. Oral Hygiene

The Subcommittee's definition of oral hygiene in this document represents the self-administered processes aimed at controlling microbial and other deposits in the oral cavity. Regular oral hygiene, by interfering with plaque accumulation and maturation, favors facultative (able to grow or live with or without oxygen)

over anaerobic (growing or living in the absence of oxygen) bacteria. In the process, regular oral hygiene promotes clean dentition and fresh breath, and decreases the risk of plaque-mediated inflammatory changes in the oral cavity. Today, mechanical plaque removal with assorted devices is the primary method for maintaining good oral hygiene. Chemical plaque control (e.g., antiseptic or surfactant mouthrinses) is used primarily as an adjunct to mechanical methods and may be particularly useful for the treatment of surfaces that are not readily accessible to mechanical cleansing, for postsurgical plaque control, and for oral care of handicapped persons. Antibiotics may be used as adjuncts to oral hygiene to suppress or eliminate specific segments of the bacterial population not readily accessible to mechanical cleansing.

## C. Drug/Cosmetic Status

The current statutory definitions of "drug" and "cosmetic" require some consideration when applying them to products for the reduction or prevention of plaque and gingivitis. According to the act, a "drug" includes any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," or any article "intended to affect the structure or any function of the body \* \* \* ." (See 21 U.S.C. 321(g).) According to the act, a "cosmetic" includes an article or component thereof "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance \* \* \* ." (See 21 U.S.C. 321(i).)

Some products may not clearly fall under one definition or the other. Therefore, another consideration in classifying a product is the "intended use" of the product, which is largely dependent on the claims made for the product and the accompanying labeling.<sup>1</sup> In attempting to accurately describe a product's benefits, one of the guiding principles should be to avoid misleading the public with ambiguous claims. Unfortunately, in the case of mouthrinse products, it is easy to make claims that suggest a drug-like benefit, while staying within the guidelines for cosmetic products. Much of the controversy regarding the "drug" versus "cosmetic" issue for these products revolves around the use of the word

"dental plaque" or its synonyms (plaque, bacterial deposits, etc.).

## 1. Antiplaque Products

It is the position of the ADA and the American Academy of Periodontology that the control of dental plaque is a therapeutic procedure basic to the prevention and treatment of caries and periodontal diseases, particularly the latter. The well-established association between dental plaque accumulation and gingivitis demands that effective control of gingivitis be accompanied by effective control of dental plaque. "Nonspecific" plaque control involves decreasing the entire microbial mass in a nonspecific manner, i.e., without any attempt at differentially removing or suppressing any particular bacterial species, although shifts in bacterial composition may occur. It is the primary therapy for preventing and controlling periodontal infections that may lead to periodontal inflammatory lesions.

"Specific" plaque control implies the control of specific pathogens, using strategies that will preferentially suppress certain species or categories of microorganisms. This approach generally requires the use of antimicrobial agents, typically antibiotics, with a specific antimicrobial spectrum. Ideally, the microbial composition of the dental plaque should be assessed before and after treatment to insure that the antimicrobial agents used are appropriate and that the therapy has the desired effect.

The nonspecific control of dental plaque needs to be thorough in order to achieve clinically significant therapeutic benefits. While some OTC oral health care products may be able to reduce the rate of plaque formation to a statistically significant degree, the inhibitory effect on plaque is often insufficient to be considered of therapeutic benefit. It is also highly unlikely that the marginal control of bacterial deposits has a significant relationship to most, if not all, of the cosmetic claims. Outcome variables such as taste and "feel" are more likely to be affected by flavoring agents and products that reduce surface tension than by minor variations in plaque accumulation.

The claim that a product significantly reduces dental plaque (statistically speaking) may mislead people into thinking that the reduction is therapeutically significant. Thus, people may purchase a product with the mistaken notion that a therapeutic benefit may be derived from its use, instead of seeking effective care for

<sup>1</sup>The legal opinions of this scientific panel in this area may not and do not necessarily reflect FDA's position.