

containing dentifrice. The data also show that more frequent topical applications of fluoride significantly enhance anticaries protection. Supervised brushing with a fluoride dentifrice once-a-day after the noon meal resulted in 33 percent fewer cavities than unsupervised brushing. Further, subjects who brushed three times a day with a fluoride dentifrice experienced: (1) 40 percent fewer new cavities than those who brushed with a fluoride dentifrice only once-a-day, even under supervision, and (2) 60 percent fewer cavities than those whose brushing was unsupervised. The results of these three studies indicate that fewer caries occur as frequency of supervised brushing and brushing after meals is increased.

Several additional studies (Refs. 4 through 7) also indicate that brushing immediately after meals is the most favorable time to reduce the number of cariogenic bacteria from all tooth surfaces. Two review studies (Refs. 4 and 6) discussed the role nutrition plays in the etiology of dental disease. Both studies concluded that one preventative measure to effectively reduce the number of cariogenic bacteria present in the mouth is to brush thoroughly after each meal with a fluoride-containing dentifrice. Forty years ago, another study (Ref. 7) indicated that many dentists and health workers strongly recommend that toothbrushing be performed immediately after the ingestion of sugar-containing food if brushing is to be effective in reducing dental cavities. The study also included a clinical investigation evaluating the effectiveness of reducing dental cavities by brushing the teeth with one of three types of nonfluoridated dentifrices immediately after the ingestion of food. This report (Ref. 7) dealt with only one of the dentifrices, the neutral paste. Subjects in the experimental group were instructed individually to brush their teeth thoroughly within 10 minutes after each ingestion of food or sweets and, when brushing was not possible, to rinse the mouth thoroughly with water. Toothbrushes and dentifrice were supplied to all experimental subjects. Subjects in the control group were not supplied with dentifrices or brushes, but were instructed to continue their customary oral hygiene habits of brushing only on arising and before retiring, rather than after the ingestion of food. When this study was conducted in 1950, fluoridated toothpastes were not available in the marketplace; thus, the control subjects would not have used a fluoridated dentifrice as a part of their customary oral hygiene habits.

Clinical results after 1 year indicated that brushing thoroughly immediately after the ingestion of food resulted in a 63-percent reduction in caries activity in the experimental group when compared to the control group.

A more recent 1982 study (Ref. 8) reviewed the prevention control of oral diseases and recommended at least two daily brushings with a fluoride dentifrice as effective in reducing the incidence of dental cavities. The study further stated that because toothbrushing is intended to remove food debris and dental plaque from the teeth, brushing after meals and sweet snacks is commonly recommended in dental health messages to the public.

The agency agrees with the comments and with many dentists that brushing properly and thoroughly more often than once daily will promote better oral health care. Reducing cariogenic activity by brushing more often than once a day, particularly after meals, can be explained by the synergistic effect of the antienzymatic properties of fluoride (45 FR 20666 at 20672) along with the mechanical removal of food debris. The Panel recognized that three factors are necessary for caries to occur (45 FR 20666 at 20672): (1) The teeth must be susceptible to caries, (2) acid-producing bacteria of the mouth must colonize on the teeth, and (3) a substrate must be present for bacteria to proliferate and to produce acid for demineralization of the teeth. Effective anticaries protection is achieved by exposing the tooth enamel to fluoride ions and by the mechanical removal of dental plaque and food debris from tooth surfaces and gingival tissue areas. Both objectives are better accomplished by toothbrushing more often than once daily, preferably after meals. The mechanical removal of food debris from teeth and gingival areas decreases the availability of metabolized carbohydrate sources, which are required for caries development.

The agency agrees with the Panel that brushing with a fluoride-containing dentifrice at least once daily effectively renders the teeth less susceptible to dental cavities. The agency also recognizes, however, that anticaries protection could be enhanced by brushing more than once a day, preferably after each meal to remove the food particles that provide the substrate necessary for bacteria to proliferate and produce acid in the development of dental caries (Ref. 3). Therefore, the agency is revising part of the directions for all OTC fluoride dentifrices to read: "* * * brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor."

The agency disagrees with the comments suggesting that the contraindication for children under 2 years of age is unwarranted. Very young children cannot be expected to rationally interpret and consistently follow the instructions involving proper toothbrushing; nor do they have the manual dexterity to use the fluoride dentifrice product properly. Children under 2 years of age do not have control of their swallowing reflex and do not have the skills to expectorate the toothpaste properly (50 FR 39854 at 39867). Although the prevalence of dental caries is decreasing, some reports suggest the incidence of mild fluorosis (a permanent, mottled discoloration of the teeth) in young children is increasing in the United States due to the increase of fluoride in our food chain (Ref. 9). Excessive ingestion of fluoride by young children increases the risk of fluorosis during the critical time of anterior teeth development and can interfere with the successful development of other emerging teeth (Ref. 10). Toothbrushing for children under 2 years of age when teeth are first emerging may also cause minor injury to the soft tissue in the mouth. The agency recognizes that young children are most susceptible to mild fluorosis as a result of improper use and swallowing of a fluoride dentifrice product. Based on the above, the agency concludes that it is appropriate to include in the labeling of fluoride dentifrice drug products containing 1,000 ppm theoretical total fluorine the following sentence: "Children under 2 years of age: Consult a dentist or doctor." The agency is including this sentence in the directions in § 355.50(d)(1)(i) of this final monograph. The agency is also including a similar statement in the directions for dentifrices containing 1,500 ppm theoretical total fluorine for children under 6 years of age (see section I.B., comment 10 of this document).

References

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- (2) Council on Dental Therapeutics, "Evaluation of Super Stripe Toothpaste," *Journal of the American Dental Association*, 71:930-931, 1966.
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