§ 355.50 Labeling of anticaries drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as: (select one or both of the following: ‘‘anticavity’’ or ‘‘fluoride’’) (select one of the following as appropriate: ‘‘dentifrice,’’ ‘‘toothpaste,’’ ‘‘tooth polish,’’ ‘‘tooth powder,’’ (optional: ‘‘dental’’) ‘‘preventive treatment gel,’’ or (optional: ‘‘treatment’’ or ‘‘dental’’) (select one of the following: ‘‘rinse,’’ ‘‘concentrated solution,’’ ‘‘rinse powder,’’ or ‘‘rinse effervescent tablets’’). The word ‘‘mouthwash’’ may be substituted for the word ‘‘rinse’’ in this statement of identity if the product also has a cosmetic use, as defined in section 201(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(i)).

(b) Indication. The labeling of the product states, under the heading ‘‘Indication,’’ the following: ‘‘Aids in the prevention of dental (select one of the following: ‘‘cavities,’’ ‘‘decay,’’ ‘‘caries (decay),’’ or ‘‘caries (cavities)’’). Other truthful and nonmisleading statements, describing only the indication for use that has been established and listed in this paragraph (b), may also be used, as provided in §330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) Warning. The labeling of the product contains the following warning under the heading ‘‘Warning’’:

(1) For all fluoride dentifrice (gel, paste, and powder) products. ‘‘Keep out of reach of children under 6 years of age. [highlighted in bold type] If more than used for brushing is accidentally swallowed, get medical help or contact a