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#### List of Subjects in 21 CFR Part 356

Over-the-counter drugs, Antigingivitis/antiplaque drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that

21 CFR part 356 (as proposed in the **Federal Register** of May 25, 1982 (47 FR 22760), the **Federal Register** of January 27, 1988 (53 FR 2436), the **Federal Register** of September 24, 1991 (56 FR 48302), and the **Federal Register** of February 9, 1994 (59 FR 6084)) be amended as follows:

#### PART 356—ORAL HEALTH CARE DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 356 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 356.3 is amended by adding paragraphs (o) and (p) to read as follows:

##### § 356.3 Definitions.

\* \* \* \* \*

(o) *Antigingivitis drug*. A drug applied to the oral cavity to help reduce or prevent gingivitis.

(p) *Antigingivitis/antiplaque drug*. A drug applied to the oral cavity to help reduce or prevent gingivitis and dental plaque.

3. Section 356.13 is added to subpart B to read as follows:

##### § 356.13 Antigingivitis active ingredients.

The active ingredient of the product consists of stannous fluoride 0.454 percent in a compatible dentifrice base.

4. Section 356.15 is added to subpart B to read as follows:

##### § 356.15 Antigingivitis/antiplaque active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage form established for each ingredient:

(a) Cetylpyridinium chloride 0.045 to 0.1 percent in a mouthrinse with at least 72 to 77 percent available cetylpyridinium chloride.

(b) Eucalyptol 0.092 percent in a mouthrinse when combined in accordance with § 356.26(p).

(c) Menthol 0.042 percent in a mouthrinse when combined in accordance with § 356.26(p).

(d) Methyl salicylate 0.060 percent in a mouthrinse when combined in accordance with § 356.26(p).

(e) Thymol 0.064 percent in a mouthrinse when combined in accordance with § 356.26(p).

5. Section 356.24 is amended by redesignating the text as paragraph (a) and by adding paragraph (b) to read as follows:

##### § 356.24 Package-size limitations.

\* \* \* \* \*

(b) Due to the toxicity associated with fluoride active ingredients in § 355.10 of this chapter, the following package-size limitations are required for antigingivitis drug products containing stannous fluoride:

(1) *Dentifrices*. Dentifrice (toothpaste) packages shall not contain more than 276 milligrams (mg) total fluorine per package.

(2) *Exception*. Package size limitations do not apply to antigingivitis/antiplaque drug products marketed for professional office use only and labeled in accordance with § 355.60 of this chapter.

6. Section 356.26 is amended by adding paragraphs (p), (q), (r), and (s) to read as follows:

##### § 356.26 Permitted combinations of active ingredients.

\* \* \* \* \*

(p) The ingredients identified in § 356.15(b), (c), (d), and (e) may be combined in a hydroalcoholic vehicle containing 21.6 to 26.9 percent alcohol in a mouthrinse provided the product is labeled according to § 356.65.

(q) The antigingivitis/antiplaque active ingredient identified in § 356.15(a) or the combination of ingredients identified in § 356.26(p) may be combined with any single anticaries active ingredient identified in § 355.10 of this chapter.

(r) The antigingivitis active ingredient identified in § 356.13(a) or the antigingivitis/antiplaque active ingredient identified in § 356.15(a) or the combination of ingredients identified in § 356.26(p) may be combined with any single tooth desensitizer active ingredient identified in § 356.22.

(s) The antigingivitis/antiplaque active ingredient identified in § 356.15(a) or the combination of ingredients identified in § 356.26(p) may be combined with any single anticaries active ingredient identified in § 355.10 of this chapter and any single tooth desensitizer active ingredient identified in § 356.22.

7. Section 356.65 is added to subpart C to read as follows:

##### § 356.65 Labeling of antigingivitis/antiplaque 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 "antigingivitis" or "antigingivitis/antiplaque" (optional: may include dosage form, e.g., dentifrice, toothpaste, mouthrinse).

(b) *Indications*. The labeling of the product states, under the heading "Uses," one or more of the phrases